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Nanotechnologies and Food

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Written Evidence

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Minutes of Evidence

TAKEN BEFORE THE SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY (SUB-COMMITTEE I)

TUESDAY 31 MARCH 2009

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Memorandum by the Food Standards Agency

General Comments

Nanotechnologies may offer a range of potential benefits to consumers and industry in the area of food and food contact materials, from improving the solubility and bioavailability[1] of ingredients to extending the shelf-life of food. Nanotechnology applications for the food sector have raised a number of safety, environmental, ethical, policy and regulatory issues. The main concerns stem from the lack of knowledge about the potential effects and impacts of nanomaterials on human health and the environment.

Nanotechnology has been defined by The British Standards Institute (BSI)[2] as "the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanoscale", where the nanoscale is defined as the size range from approximately 1 nm to 100 nm. For comparison, a single human hair is about 80,000 nm wide. Similarly, a nanomaterial can be defined as any material with at least one dimension in the nanoscale.[3] According to this definition, the term "nanotechnology" can encompass a wide range of products, processes and applications whose sole unifying factor is that they are linked in some way to the nanoscale. For example, the term would include:

— tiny water-filled fat droplets, which are being investigated as an ingredient for use in reduced fat products such as mayonnaise

— incorporating fat-soluble vitamins into nano-sized packages (micelles) that will dissolve in water

— the understanding and modification of the fine structure of food products such as ice cream—food technologists are looking for ways to replicate the physical properties of such foods in products with a reduced fat content

— investigation of the structure-function relationships of enzymes, which play a central role in many types of traditional food processing

— nano-particles of titanium dioxide, which are used in transparent sunscreen products (no known food applications)

— nanoparticles of silver, which are used for their antibacterial properties in a range of consumer goods and which may find applications in food containers

— carbon nanotubes—thin cylinders made of carbon atoms—which are being used as a structural component of consumer products such as tennis racquets and golf clubs (no known food applications).

[1] Bioavailability: the extent to which a substance can reach the systemic blood circulation and its availability at the site of action, when taken orally.

[2] BSI Publicly Available Specification "Vocabulary – nanoparticles" (May 2005). PAS 71:2005

[3] Note: The International Standards Organisation uses the term "nano-object" to refer to a discrete object with one or more external dimensions in the nanoscale. In this usage, the term "nanomaterial" includes material which is larger than the nanoscale but which is nanostructured—ie it is made up of smaller, nanoscale elements.

It may therefore be misleading to discuss "nanotechnology" in relation to food as if it is a single discipline, and the applications of nanoscience are more accurately described in the plural as "nanotechnologies".

The principal area of interest and concern in relation to food appears to be engineered nanomaterials, which are specifically designed and manufactured with the intention of being incorporated into food to fulfil a particular function. It is nevertheless important to note that nanomaterials are widely found in the natural world and foods will naturally contain nanoscale structures, including individual macromolecules, micelles and crystals. For example, a molecule of haemoglobin is about 5.5 nanometres in diameter, and milk contains micelles ranging from 50 to 500 nm in diameter.

Nanotechnologies can also be applied indirectly to food manufacture, for example through the development of improved surfaces for food preparation and for food transport in factories, or rapid diagnostic tests for contaminants or pathogens in food. This type of application would not directly affect the properties of the final product but could lead to improved efficiency and improved quality control. The remainder of this document focuses on the use of engineered nanomaterials in food and in food contact materials.

In order to understand better how nanotechnologies might be applied to food, the FSA recently commissioned two research projects covering food additives and ingredients, and food contact materials. Both projects were undertaken by a panel of experts from the Safety of Nanomaterials Interdisciplinary Research Centre (SnIRC), led by the Central Science Laboratory (CSL). These projects collected information on current and future applications of nanotechnologies, considered the potential implications for consumer safety and assessed of the regulatory position. In addition, the project on food contact materials included experimental work on the potential migration of nanoparticles from two types of food container. The project reports are being published on the Agency's website and are attached as Appendices 1 and 2 respectively. The findings from this research are mentioned in the relevant sections below.

A. State of the science and its current use in the food sector

Potential applications

The FSA-funded research project on food additives and ingredients identified a number of potential applications of nanotechnology in these areas including nano-sized carriers for nutrients and other food supplements, nano-sized or nano-encapsulated food additives, and nanostructured food ingredients. Practical examples included nutritional supplements, nutraceuticals and a small number of food ingredients and food additives.

The parallel project on food contact materials identified a range of potential applications including barrier layers to improve packaging properties, active antimicrobial or oxygen scavenging materials to extend shelf life, intelligent nanosensors to monitor time/temperature storage conditions and biodegradable polymer-nanomaterial composites. The researchers concluded that future applications in this area are most likely to relate to antimicrobial activity or improved barrier properties.

Current market (UK, EU and non-EU)

At least two global inventories exist and these provide some information on some of the types and numbers of nano-derived products that may be on the global market across a range of areas, including food. The Woodrow Wilson Centre's global inventory is published on the Internet,[4] as is an inventory of nanoproducts constructed by Friends of the Earth.[5] Both registers list several dozens of "food" products that have been identified However, it should be noted that Friends of the Earth's register includes materials with a particle size greater than 100 nm, which do not fit the common definition of "nanomaterial". Also, the registers are largely based on marketing information, which may or may not accurately reflect what is actually on the market.

At present, it is not possible to provide a definitive list of nanofoods and nanoscale food contact materials on the EU market, primarily because of the absence of an EU-wide register or inventory. The Food Standards Agency is currently considering various options for developing a UK-based register of nano-derived foods and food contact materials. The European Commission has stated that it will begin work on an EU inventory of nanomaterials during 2009 (see Section C).

[4] Woodrow Wilson Center (online inventory)
[5] Friends of the Earth (2008)
[6] EFSA (2009)

According to the European Food Safety Authority's (EFSA) recent opinion on nanotechnologies[7], most nanotechnology applications for food and beverages in the EU are currently at the research and development stage or near market stage and have not reached the EU market as yet. The only UK exceptions known to the Agency are

— colloidal silver in the form of food supplements (an aqueous colloidal suspension of particles of silver with an average size of 0.8 nm in purified water, also known as "silver hydrosol"). There are claims that such products may fight infections and enhance the immune system. Silver hydrosol has recently been evaluated by EFSA in the context of establishing an EU list of authorised sources of vitamins and minerals for use in food supplements. As there was insufficient information to complete the assessment, this product is unlikely to be included in the eventual list of approved mineral sources that will come into effect on 1 January 2010, in which case its continued use will not be permitted.

and

— food supplements comprising a nano-sized formulation of co-enzyme Q10 (micelles of approximately 30 nm diameter). It is claimed that co-enzyme Q10 is an antioxidant with the nano formulation apparently improving bioavailability when compared with powdered co-enzyme Q10 or oil-based formulations. The co-enzyme Q10 product was launched in 2006 and is manufactured in Germany. The German authorities have concluded that this type of formulation does not fall within the scope of the novel foods regulation (see Section C below), as the process for producing the micelles does not lead to a significant change in the properties of the active component.

The FSA-funded project on food contact materials revealed that little was available on the UK or EU markets. Most products were found on the American and Asian markets although some could be sourced by UK purchasers via the Internet.

B. Health and Safety

Risk assessment

Approaches to the risk assessment of nanomaterials have been reviewed by a number of national and International advisory committees. In the UK the Committees on Toxicity, Mutagenicity and Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COT, COM and COC) produced a joint statement on nanomaterial toxicology in 2005. The COT produced an addendum in 2007 following a review of healthcare nanoparticles.

The 2005 statement (attached at Appendix 3) provided a baseline review of the available toxicity data and outlined the risk assessment approach the Committees would use for the risk assessment of nanomaterials, including those in food and feed. They concluded that conventional toxicological assessment should be sufficient to identify toxic hazards from nanomaterials provided studies were designed based on the properties of the nanomaterial under investigation. Whilst the standard toxicological test batteries would detect possible effects from nanomaterials, there was as yet, insufficient information to exclude the possibility of effects not detectable by these methods. Although in 2007 the COT was not currently aware of such effects being reported.

The 2007 addendum to this statement (Appendix 4) concluded that biodegradable and non-biodegradable nanoparticles require a different risk assessment approach, since biodegradable particles are less likely to have toxicity intrinsic to their nanoparticulate state.

In the European Union, the Scientific Committee on Emerging and Newly Identified Health Risks (SCHENIR) has recommended strategies for the risk assessment of nanomaterials in 2006 and 2007.[8] Although there are some differences in emphasis due to the questions being addressed and the remit of SCHENIR, the strategy is consistent with that of the UK advisory committees.

In March 2009 the Scientific Committee of the European Food Safety Authority published its opinion on the risk assessment of engineered nanomaterials, specifically in relation to food and in animal feed The Scientific Committee also agreed that the general risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterization) can also be applied to the risk assessment of engineered nanomaterials in the food and feed area. The risk assessment of engineered nanomaterials has to be performed on a case-by-case basis and needs to consider the specific properties of nanomaterials in addition to those common to the equivalent non-nano forms of the same chemical substance.

There is currently limited information in several areas which leads to uncertainties in the risk assessment of nanotechnologies and their possible applications in the food and feed area. Specifically there are difficulties in characterising, detecting and measuring engineered nanomaterials in food, feed and biological matrices. This

[7] EFSA (2009)
[8] SCENHIR (2006, 2007a, 2007b)

limits the ability to assess actual exposure from possible applications and products in the food and feed area. There is limited data on oral exposure to specific nanomaterials and any consequent toxicity; the majority of the available information on toxicity of nanomaterials is from, *in vitro* studies or from, *in vivo* studies using other routes of exposure. These limitations in the database need to be reflected as qualitative and quantitative uncertainties in the risk characterization step of any risk assessment.

The risk assessment of a nanomaterial in the food and feed area requires comprehensive identification and characterisation of the material, information on whether it is likely to be ingested in nanoform, and, if ingested, whether it remains in nanoform at the point of absorption. If ingested in nanoform, then repeated-dose toxicity studies on the nanomaterial are needed together with appropriate, *in vitro* studies (eg for genotoxicity).

FSA Funded research

The FSA-funded projects, mentioned above, included an assessment of implications for consumer safety and these reports are consistent with the EFSA opinion. The researchers also highlighted several gaps in knowledge and recommended further research into the physico-chemical properties, behaviour, fate and effects of nanomaterials used in food applications,.

The project on food contact materials included tests on migration of nanoparticles from two typical materials made of nanomaterial-polymer composites (nanoclay and nanosilver). The results showed no detectable migration from the polymer composite consisting of nanoclay embedded between PET (polyethylene terephthalate) layers and a very low level of migration of silver from food containers consisting of polypropylene-nanosilver composite. In both cases, the presence of nanoparticles did not affect the migration of other (non-nano) components. The study provided some reassurance in the safety of nanotechnology-derived food contact materials but nonetheless demonstrated that migration is likely to be dependent on the type and composition of the polymer.

Research co-ordination

The Nanotechnology Research Coordination Group (NRCG) was set up in 2005 to coordinate publicly funded research into the potential risks presented by the products and applications of nanotechnologies. Defra chairs this Group and the membership includes Government Departments (including the Food Standards Agency), Regulatory Agencies and the Research Councils. NRCG has three main aims.

— to develop and oversee the implementation of a cross-Government research programme into the potential human health and environmental risks posed by free manufactured nanoparticles and nanotubes to inform regulation and underpin regulatory standards.

— to establish links in Europe and internationally to promote dialogue and to draw upon and facilitate exchange of information relevant to the Group's research objectives.

— to consider the outputs of dialogue between stakeholders, researchers and the public (as integrated with the NIDG's wider plans for stakeholder and public dialogue) with a view to enhancing and informing research decisions.

The NRCG began by identifying a programme of 19 research objectives aimed at characterising the potential risks posed by engineered nanoscale materials.[9] NRCG published progress reports in 2006 and 2007 that provide an overview of the work that has been commissioned in pursuit of these objectives.[10] Work in these areas is primarily funded by the Research Councils under their standard procedures for commissioning research. As noted above, the FSA has commissioned two reviews covering food additives and ingredients, and food contact materials.

C. Regulatory Framework

The FSA has conducted a review to identify potential gaps in regulations relating to the use of nanotechnologies in the food sector. The review was published in August 2008 (Appendix 5). The main areas covered were food ingredients, food additives and food contact materials.

No major gaps in legislation were identified by this review and, on the basis of current information; it was found that most potential uses of nanotechnologies that could affect food would require some form of approval process before being permitted for use. Manufactured nano-derived ingredients, additives and food contact materials will be captured by the general safety requirements of the EU Food Law Regulation (Regulation (EC) 178/2002), which requires that food placed on the market is not unsafe. Additionally, more

[9] Defra (2005)
[10] Defra (2006, 2007)

specific legislation exists in three major areas that cover all the likely applications leading to engineered nanomaterials being present in food:

(i) novel foods and food ingredients

The European regulation on novel foods (Regulation (EC) 258/97) applies to foods and food ingredients (other than food additives) that were not consumed in the EU prior to 15 May 1997. It establishes a mandatory pre-market approval system for all novel foods and processes and is legally binding across all 27 EU Member States. Nanoparticulate forms of a food ingredient that has a history of use will also require authorisation under the novel foods Regulation due to the difference in the production process employed, if the net result is that the nanoparticles have different properties to the existing ingredient.

In January 2008 the European Commission published a proposal to revise and update the 1997 regulation. The European Parliament has proposed that any new regulation should explicitly apply to all nanomaterials, in order to eliminate any doubt as to their status under this legislation. This proposal is still under discussion by Member States and the European Parliament

(ii) food additives

Nano-derived additives are considered within the scope of Food additives legislation. Food additives are controlled in the UK by the Sweeteners in Food Regulations 1995 (as amended), the Colours in Food Regulations 1995 (as amended), and the Miscellaneous Food Additives Regulations 1995 (as amended), with smoke flavourings being specifically controlled by the Smoke Flavourings (England) Regulations 2005. A recently agreed amendment to food additives legislation specifies that where an existing food additive is produced through nanotechnology, it should be assessed by EFSA as a new additive.

(iii) food contact materials

Migration of nanocomponents into food from, for example, packaging would be considered in the scope of Regulation (EC) 1935/2004, which provides the overall framework for the regulation of food contact materials. Provision exists for the Commission or Member States to request the EFSA to conduct an independent, expert human health risk assessment of any substance or compound used in the manufacture of a food contact material/article. Specific materials such as plastics are subject to additional measures and within these measures it is possible for a nanomaterial to be treated separately from the normal scale substance from which it is derived. It would therefore be possible for a nanocomponent to be authorised only following a risk assessment by the EFSA. The regulation of nanoscale substances in food contact plastics is currently being clarified in preparation for an updated European regulation, and the European Commission has proposed that any substance with a deliberately altered particle size should not be used, even behind a specific migration barrier, without a specific authorisation.

Animal feed

EU legislation on animal feed covers the additives (vitamins, colourants, flavourings, binders, and so on) authorised for use in animal feed; the maximum levels of various contaminants (eg arsenic, lead, dioxins); ingredients that may not be used in feed; nutritional claims that can be made for certain feeds; the names and descriptions which must be applied to various feed materials; and the information to be provided on feed labels.

The Agency is not aware of any specific applications in the pipeline with respect to the use of nanotechnology directly in animal feed. However, current procedures would allow a proper risk assessment to be performed on such products if and when they appear, including the manufacture of currently authorised additives and bioproteins by new methods.

Imported foods

Food imported from countries outside the EU can only be marketed if it meets food safety and food standards requirements that are at least equivalent to those for food produced in the UK and elsewhere in the EU. Food businesses are legally responsible for ensuring the food they import complies with these requirements, and UK enforcement authorities have powers under food safety legislation to check all imported food for compliance.

However, food products ordered from a non-EU country by members of the public in limited quantities for their personal use, for example over the Internet, may not be subject to the protection of UK food safety requirements.[11]

[11] The applicability of UK legislation will depend on issues such as where the contract between the seller and purchaser is made.

Intergovernment cooperation

At EU level, DG SANCO[12] organised a workshop in October 2008, the second Nanotechnology Safety for Success Dialogue, which provided a platform for presentations and discussions between relevant stakeholders in the nanotechnologies field, including industry, academia, NGOs, Government departments and Commission Officials. The Director General of DG SANCO subsequently identified 10 priority actions to address the key points raised during the workshop (listed in Appendix 6), grouped under the following headings: dialogue and governance, market intelligence, scientific knowledge and gap filling; and risk assessment and guidance. Several of these action points will encompass applications of nanotechnologies in the food area and will involve collaboration between EU Member States and the Commission.

The Organisation for Economic Cooperation and Development also provides a forum for international co-operation on nanomaterials through its Working Parties on Manufactured Nanomaterials and on Nanotechnology, although these are not specific to food and its current risk assessment projects are focussed on materials with no direct food connection, such as carbon nanotubes and cerium oxide.

The Swiss-based International Risk Governance Council (IRGC) recently completed a report on nanotechnology applications in food and cosmetics,[13] which included a discussion of regulatory approaches in the USA, Europe and Japan. IGRC noted that the regulatory responses to nanotechnology have been similar in each of these jurisdictions, in that existing regulations are thought to be adequate sufficient to cover nanoscaled materials in general. In each case, however, questions have been raised about the adequacy of current test methods and the ability of regulatory bodies to monitor and control measurements and risk assessments.

D. Public Engagement and Consumer Information

Public engagement

In late 2008 the Food Standards Agency commissioned an evidence review in relation to public attitudes to emerging food technologies, including nanotechnologies. The report of this review is expected to be published in March 2009. The main findings in relation to previous studies on attitudes to nanotechnologies were as follows:

— Awareness of nanotechnology is low, particularly in relation to food.

— Although general attitudes towards nanotechnologies seem fairly positive, attitudes towards its use in food are less positive. Whilst people are concerned about the risks of nanotechnology in all its forms, they seem less convinced about the potential benefits of food applications than other uses and are sceptical about why these are being developed.

— In general, use of nanotechnology in food packaging may be seen more positively than its use in food.

— Concerns about nanotechnology, *in general* include effectiveness, long-term side-effects and the ability of regulators and others to ensure safety and to ensure that developments benefit the general public.

— Other factors affecting attitudes towards nanotechnology, which are often better predictors than socio-demographics, include their scientific knowledge (eg experience of previous technological innovations), their general outlook/worldview and where they have received information from (people are more positive towards sources deemed to share a similar view point to them).

— The review uncovered no evidence of how people's views on nanotechnology affect their food behaviour or choices, mainly due to lack of food products on the market.

— The review highlighted that nanotechnology is an extremely active area of research which will be covered under FP7 (The Seventh Framework Programme (FP7) combines all research related EU initiatives, it is a key pillar of the European Research Area) but at the time of writing, awards were still pending. Research in the pipeline included looking at how consumers weigh up the risks and benefits of the technology and the psychological underpinning of differing attitudes.

[12] DG SANCO: the European Commission's Directorate General for Health and Consumers
[13] IRGC 2008

Effective engagement and public information

The evidence review identified a consensus form the existing body of work that public opinion is in the process of being formed and there was little information currently available to the public on which they can formulate their views.

Future public engagement

As the issues arising from the breadth of nanotechnologies and nanomaterials are complex, more time and resources need to be provided for the public to learn and understand the pros and cons in terms of any consumer or societal benefits and any potential risks. Developing a range of engagement activities to engage the public rather than using a "one size fits all" approach will ensure that a wider spectrum of the public are provided with an opportunity to be involved.

Any materials provided for the public need to be prepared with the public in mind ie in plain English.

Lessons learned from engagement

Effective engagement needs to developed upstream of any important decision making. The public should be involved in the framing of the discussion so that their questions are answered. As an example, the FSA commissioned research on cloned animals in 2007–2008, which took the form of reconvened workshops with the general public across the UK. This showed that the public were less concerned with how the technologies and science work, and their focus was on the 'why' and what the consequences may be. This was closely connected to the drivers behind the development and a perception that the motives were about increasing profit above other factors.

Good public engagement needs to be based on more than just scientific evidence and needs to take account of wider societal issues ie environmental, ethical, moral and economic. The worldview that consumers' hold and the channel used to provide information is as important as the content.

Some issues, like nanotechnology, are not on everyone's radar and are not part of their everyday life. To engage effectively the subject should be brought to life and the public need to see the relevance to their lives. Bringing scientists and the public together in the same room and talking on the same level can foster good relationships and can have a positive effect on the outcome.

Good public engagement will have feedback built in at the planning stage. It is good practice to let people know how their input has made a difference. This need not be more complicated than sending an email or updating websites.

Consumer information

A fundamental principle of food labelling legislation is that consumers should be provided with sufficient information to make informed choices about the foods that they eat. Information must, by law, be clear and not misleading. There is also a limit to the amount of information that can sensibly be provided on a food label.

Recognising these conflicting requirements, it is necessary when defining mandatory labelling requirements to give priority to items that are important for the safe use of the food, while ensuring that any additional labelling requirements are balanced and proportionate. Any demands for special labelling of "nanofoods" would have to be viewed against this background. At present we do not have information about whether UK consumers would value information on the use of nanotechnology in food production, and what sort of information would meet the necessary criteria of clarity and comprehension.

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SCENIHR, 2007b (Scientific Committee on Emerging and Newly Identified Health Risks), 29 November 2007, Opinion on the scientific aspects of the existing and proposed definitions relation to products of nanoscience and nanotechnologies, at http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_012.pdf

Woodrow Wilson Center, Project on Emerging Nanotechnologies: An inventory of nanotechnology-based consumer products currently on the market. Available online at: http://www.nanotechproject.org/inventories/consumer/

Appendices: [not printed]

1. Food Standards Agency research project A01057: Assessment of the potential use of nanomaterials as food additives or food ingredients in relation to consumer safety and implication for regulatory controls. (July 2007)

2. Food Standards Agency research report A03063: Assessment of current and projected applications of nanotechnology for food contact materials in relation to consumer safety and regulatory implications. (July 2008)

3. COT, 2005. UK Committees on toxicity, mutagenicity and carcinogenicity of chemicals in food, consumer products and the environment (COT, COM, COC). Joint statement on nanomaterial toxicology. http://cot.food.gov.uk/pdfs/cotstatements2005nanomats.pdf

4. COT, 2007. UK Committee on toxicity, of chemicals in food, consumer products and the environment. COT Addendum to joint statement of the Committees on toxicity, mutagenicity and carcinogenicity of nanomaterial toxicology. COT Statement 2007/01, March 2007. http://cot.food.gov.uk/pdfs/cotstatementnanomats200701.pdf

5. Report of FSA regulatory review of potential implications of nanotechnologies for regulations and risk assessment in relation to food. (August 2008). http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf

6. Letter from Robert Madelin (Director General for Health and Consumers, European Commission). Follow-up to the second Nanotechnology Safety for Success Dialogue—Top 10 actions to take by Easter 2009. (December 2008)

12 March 2009

Memorandum by Department for Innovation, Universities and Skills (DIUS)[14]

The Department for Innovation, Universities and Skills (DIUS) is pleased to submit the following evidence to assist the Committee in its inquiry into Nanotechnologies and Food.

Our response provides the information that the Committee requested from the Science and Innovation Network about nanotechnologies in food in the following countries:

- Brazil (Annex 1)
- China (Annex 2)
- France (Annex 3)
- Germany (Annex 4)
- Japan (Annex 5)
- United States of America (Annex 6)

[14] Now part of the Department for Business Innovation & Skills (BIS).

DIUS notes that the Food Standards Agency, the Research Councils UK and the Department for Environment, Food and Rural Affairs are also submitting evidence on areas for which they have responsibility.

DIUS has a wider responsibility for promoting good practice in public engagement about science and technologies. The Sciencewise-Expert Resource Centre[15] supports public dialogue projects and aims to promote best practice in Government departments. It also builds capacity for public dialogue and engagement across Government.

DIUS also provides funding for the Research Councils to support research and related post-graduate training. The Research Councils support a broad range of activities relating to nanotechnologies, which include support for research which has or may have an application in the food sector. They have also been involved in public engagement activities focusing on the social, ethical, legal and regulatory issues surrounding applications of nanotechnologies. Research Council activities and inputs into the cross-Government coordination activities are coordinated by the RCUK Nanotechnology Group. The Research Councils are submitting separate evidence to the inquiry.

In addition, DIUS chairs the Ministerial and policy coordination groups that seek to coordinate work across Government to ensure the responsible development of nanotechnologies. These groups consider the implications for nanotechnologies across a wide range of policy areas and we would like to draw the Committee's attention to key documents that explain the wider Government agenda, its coordination and how we are pursuing it in international fora.

In February 2005, the Government published its response[16] to the Royal Society and Academy of Engineering report "Nanoscience and nanotechnologies: opportunities and uncertainties".[17] The response set out the Government's agenda for nanotechnologies and invited the Council for Science and Technology to review its progress after two and five years. The Council reported on its first review in March 2007 in *Nanosciences and nanotechnologies: a review of Government's progress on its policy commitments*.[18]

Following the report by the Council for Science and Technology, the Government established a Ministerial group on nanotechnologies, chaired by the Science and Innovation Minister, to make sure that the UK continues to play a leading role in the understanding, development and regulation of nanotechnologies. The Ministerial group is informed by policy[19] and research[20] coordination groups and views expressed in the Nanotechnologies Stakeholder Forum.[21] At the request of the Ministerial group, a statement by the UK Government[22] was published in February 2008 setting out the Government's vision for nanotechnologies and outlining the range of activities being carried out.

More recently, the Ministerial group announced[23] its intention to develop a strategy for nanotechnologies that addresses both the exploitation of technologies and the management of potential risks. This will be developed in dialogue with the full spectrum of interested parties (academia, industry, non-governmental organisations and the public). DIUS is currently developing the programme of dialogue which will build on lessons learned from previous public engagement activities around nanotechnologies.[24]

Annex 1

EVIDENCE FROM BRAZIL

Background

Brazil is the world's largest producer and exporter of agricultural goods. The sector contributes more than 20 per cent of Brazilian GDP, and as such is considered to be a key area of strategic interest for the Brazilian economy. In this context, Brazil continues to invest heavily in research and development related to agri-technologies, and nano-technology has been identified as a priority. Brazilian efforts in this area are channelled through an organisation Embrapa—The Brazilian Agricultural Research Corporation.

Embrapa is an agency of the Brazilian Ministry of Agriculture, Livestock and Food Supply (MAPA) in charge of developing and extending knowledge and technology generation and transfer across a broad range of programme areas to achieve sustainable agricultural development in Brazil. Embrapa is a world-leading research organisation when it comes to tropical agriculture.

[15] http://www.sciencewise-erc.org.uk/cms/
[16] http://www.berr.gov.uk/files/file14873.pdf
[17] http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf
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[23] http://nds.coi.gov.uk/environment/fullDetail.asp?ReleaseID=391430&NewsAreaID=2&NavigatedFromDepartment=False
[24] http://www.sciencewise-erc.org.uk/cms/nanotechnology-engagement-group/

Its budget increased by R$914 million (approximately £278 million) from May 2008 to December 2010 through PAC (Growth Acceleration Programme) a Federal government initiative. This contribution was added to Embrapa's already existing budget (around half a billion GBP) and will be used for new research, facilities, the modernisation of infrastructure of labs, and for hiring new staff. The strategy released by the Brazilian government states that the investment should focus on work related to new challenges of agriculture, which are; new areas of science (genomics, nanotech, TI), challenges of production (food security, climate change, sustainable agriculture), public policies (including knowledge transfer) and institutional flexibility (international cooperation). According to the Brazilian Minister for Agriculture, Reinhold Stephanes, Embrapa is responsible for 60 per cent of the increase in field production in Brazil, which grew by 150 per cent in the last 15 years.

Brazil is also investing heavily in nanotechnology—around £70 Million were invested between 2001 and 2006 by the Ministry for Science and Technology. Nanotech also features as a key priority in the Brazilian Strategy for Science and Technology.

In this context Embrapa has decided to set up a dedicated National Centre for Nanotechnology Applied to Agri-business, which is hosted in the city of Sao Carlos (Sao Paulo state). The Centre has the specific objectives of increasing the competitiveness of Brazilian agriculture through the development of new nano-technologies. Importantly, the Centre has formed partnerships with important companies in the private sector, such as Vale Rio Doce, Braskem, the Brazilian Association of Agri-business, and Guaxupe (coffee).

Main Research Priorities and Applications

The Centre has set up a successful National Network for Nanotechnology Applied to Agri-business, which includes every major player across the private and public sectors. This national network is responsible for managing Brazil's priorities in the sector, by designing research programmes and applications in conjunction with Brazilian private companies and farmers. The Network is divided in three main programmes: 1) Development of nano-structured materials and sensors, 2) Processing techniques for membranes and films for packaging and separation processes 3) New uses for materials based on agro-industrial processes (fibres, etc.)

The following have been identified as priorities in the area of applications:

- "Ready to Eat", edible bioplastic coating. The Network's strategy notes that the US edible bioplastic coating market has increased from 19 Million USD in 2001 to 103 Million in 2006.
- Edible bioplymer coating generating a functional barrier.
- Functional packaging, with functional additives, including nutri-ceuticals (vitamins), spices, flavour, aroma.
- Nanoparticles of natural polymers (chitosan, pectin, starch), for applications in packaging, antimicrobial, strength reinforcement, controlled release.
- Palate sensors for quality control (this is an Embrapa International patent, aimed primarily at increasing the quality of Brazilian wine).
- Hidrogel for soil conditioning.
- Hidrogel for controlled release of pesticides.
- Agro-based composites (amid, fibres).
- Cellulose nanofibers from cotton, new varieties (colored cotton), sisal, and nanoparticles, including starch and chitosan.
- Improvement in mechanical properties in PVC composites.
- Recycled Polyethylene terephthalate and sugar cane bagasse fibre.

Note: Sugar cane bagasse fibres are largely produced in Brazil as a by-product from the sugar cane and bio-ethanol industries. In 2006 Brazil produced 387 Million tons of sugar cane, and 100 Million tons of sugar cane bagasse fibres.

Brazil does not seem to have any dedicated regulatory framework for nanotechnology research.

Annex 2

EVIDENCE FROM CHINA

There is no systematic reporting system in China about nanotechnology in the food sector and thus information is limited.

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

Nanotechnology within the food production chain is used in agricultural cultivation, food processing and manufacturing, animal feed, additives, supplements, and food packaging.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, in China?

The field of food nanotechnology has experienced significant growth over the last five years in China. There is no statistical data available on the level of use but it is widespread.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

It is still not clear what the next generation of nanotechnologies will look like but we would expect them to enter the market and quickly spread throughout all phases of agro-food production.

What is the current state of research and development in China regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

R&D on nanotechnologies is quite advanced and is comparable to other countries. Focus is not in the food sector directly but other sectors such as antimicrobial nano-kitchenware, food packaging, sun screen, cosmetics, textiles, etc.

What are the barriers to the development of new nano-products or processes in the food sector?

Safety issues and acceptance by the public are key barriers to the development of new nano-products or processes in the food sector. A current concern is that there is too little information available on the properties of nanoparticles and their potential impact such as how the body motabilises nanoparticles because of their varying size and high mobility. There is also no requirement for manufacturers to label nanoparticles on their products, and consumers are unlikely to be aware of such applications in foods.

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

The current regulatory framework for nanotechnologies and nanomaterials is inadequate in China though recent general legislation on food safety should help plug some gaps. Many imported food products to China are not properly inspected and domestic standards from the country of origin are not always available for review.

How effective is voluntary self-regulation at an international level? What is the take up by companies working in the food sector?

Food nanotechnology is an emerging field and good regulation is a critical issue. Self-regulation in China is difficult to measure but is likely to be focused on food safety. If the nanoparticles are shown to be safe then that could be the end of any self-regulation by a company. Take up by companies is unknown but probably widespread.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

In China, the answer is no. The current regulatory system does not require manufacturers to label whether nanoparticles are present in their product. Regulations are also not particularly extensive in relation to the development and manufacture of nanoparticles.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

China is not presently having any specific discussions about international regulation of nanotechnology in food products.

Annex 3

EVIDENCE FROM FRANCE

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

There are many potential applications and benefits of nanotechnology and nanomaterials in the food sector from food production such as cultivation (eg nano-pesticides) to food processing like the packaging of foods. In addition nanotechnologies can be used to enhance the nutritional aspects of food by means of nanoscale additives and nutrients and nanosized delivery systems for bioactive compounds. Table 1 summarises the potential applications of nanotechnology in the food production chain. These applications are expected to find their way into various products for consumer use in the coming years in France.

Table 1

APPLICATIONS OF NANOTECHNOLOGY IN THE FOOD PRODUCTION CHAIN

Chain phase	Application	Nanotechnology	Function
Agricultural production	Nanosensors	Nanospray on food commodiities	Binds and colours micro organisms
		Hand-held devices	Detection of contaminants etc.
		Incorporated in packaging materials	Detection of food deterioration
	Pesticides	Nanoemulsions, - encapsulates	Increased efficacy, water solubility and crop adherence
		Triggered release nanoencapsulates	Triggered (local) release
	Water purification/ soil cleaning	Filters with nanopores	Pathogen/containmant removal
		Nanoparticles	Removal or catalysation of oxidation of contaminants
Production and processing of food	Food production Refrigerators, storage containers, food preperation equipment	Nanoceramic devices	Large reactive surface area
		Incorporated nanosized particles, mostly silver, occasionally zinc oxide	Anti-bacterial coating of storage and food handling devices
Conservation	Food products Packaing materials	Nanosized silver sprays	Anti-bacterial action
		Incorporated sensors	Detection of food deterioration. Monitoring storage conditions
		Incorporated nanoparticles	Increasing barrier properties, strength of materials
		Incorporated active nanoparticles	Oxygen scavenging, prevention of growth of pathogens
"Functional food", consumption	Supplements	Colloidal metal nanoparticles	Claimed to enhance desirable uptake
		Delivery systems "Nanoclusters"	Protecting and (targeted) delivery of content
		Nanosized/ -clustered food/drinks (nutrients)	Claimed enhanced uptake

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials in France?

The current state of the French market is estimated to be very small. According to the experts contacted, it is likely that the nanotechnology applications will be similar to what will be found elsewhere in the Western world as a result of globalisation.

Many international food companies (eg Nestle) have subsidiaries in France. These companies are known to be interested in the applications of nanotechnology in this sector so there is a distinctive possibility of an issue on nanotechnology in food in France although it will *not* be confined only to France.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

The use of nano-materials in food packaging and food additives is expected to correspond to the two main types of applications. Use in food packaging is expected to take off over the next few years as it is likely to be more acceptable to the general public (ie little (supposedly) contamination of the food). Food additives will be the next target although it is expected that there will be resistance from consumers.

What is the current state of research and development in France regarding nanotechnologies and nanomaterials which have or may have an application within the food sector?

The French National Research Agency (ANR) supports several programs in nanoscience and nanotechnology, which may lead to new applications within the food sector. These include:

— *Pnano*, dedicated to nanoscience and nanotechnology and supporting projects of basic and applied research in nanocomponents, micro-nanosystems, nanobiotechnology, nanomaterials, instrumentation and metrology, modelling and simulation. A special section deals with the impact and risks of nanotechnology on health and the environment as well as with ethical and societal aspects.

— *Materials and Processes* focuses on research into new materials and industrial processes, improvement of their technical and economic performance and stimulation of technology transfer to industry.

— *SEST* (Health Environment and Health Work): the goal of this program is to reveal the impact, as yet unknown, of environmental factors on human health by measuring the exposure to these factors and identifying their role in the origin or the worsening of some diseases. This program deals particularly with the potential toxicity of nanoparticles.

ANR also recently launched a programme called ALIA (Spring 2008) on food and in particular food processes encouraging the use of nanotechnology.

All in all, although France is currently running a large number of R&D activities in the area of nanotechnology and nanomaterials, only a minority of projects is dealing with food.

What are the barriers to the development of new nano-products or processes in the food sector?

France will find doubt and objection from consumers to be the main barriers to the development of nano-products in the food sector. The main issue in France, at the moment, is carbon nanotube because of its similarity to asbestos—a story that was not very well handled by the French health authorities. The CEA is now the main organisation handling nano-issues in France because of its success in handling the very sensitive issue of Atomic Energy. AFSSA is also heavily involved in this area and has recently published an official communiqué on nanoparticles in water.

It is important to note, as a conclusion, that the European Commission has already put calls for research on detection and characterisation of nanoparticles in the food as part of the Framework programme and this is the first in a series of calls on risk assessment of nanoparticles in the food. So there is action at the European level on this issue which will undoubtedly affect France.

Note: This Annex was compiled with the assistance of the Institute of Medicine (IoM), Edinburgh, from information supplied by the Commissariat à l' Energie Atomique (CEA) and the AFSSA (the French Food Standards Agency).

The scientific evidence used by the French comes from (a) the reports and paper published by Dr Qasim Chaudhry of the Central Science Laboratory (York) from works in collaboration with the IOM and sponsored by the UK FSA, (b) a report by the RIKKILT and RIVM institutes in Holland, and (c) a report compiled by Friends of the Earth.

Annex 4

EVIDENCE FROM GERMANY

1. *Main potential applications and benefits of nanotechnologies and nanomaterials in the food sector*

Potential applications and benefits:

- improving the stability and durability of food;
- improving the bioavailability of important nutrients;
- better optical properties; improved flavour and consistency;
- carrier material for other substances, eg liposomes, micellas and vesicles;
- functional foods (nano-ceuticals);
- food packaging (with sensors to monitor freshness);
- pesticides (carried by nanoparticles to improve the absorption by plants); and
- food safety (eg synthetic nanoparticles which irreversibly bind microorganisms).

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

2. *Market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials in Germany?*

Current use of nanotechnology in food and dietary supplements:

- Nano green tea—use of nanotechnology to improve the bioavailability of selenium contained on tealeaves and to enhance the antioxidant effect.
- Frying oil "Canola Active Oil" with nano-phytosterole capsules (30 nm) to prevent the absorption of cholesterol and reduce the risk of cardiac diseases.
- Dietary supplements, eg nano-vitamins, nano-calcium, nano-magnesium and nano silicon (eg Neosino capsules).
- Carotenoid—nanostructured carotenoid might overcome the problems with insolubility in water and bad absorbability, improving the beneficial impact on health.

Product examples:

- Nutralease™—patent pending for the Nano-sized Self-assembled Liquid Structures (NSSL) technology. This uses nano-sized carriers to targeted compounds (such as nutraceuticals and drugs). These carriers are expanded micelles with a size of ~30 nanometers, referred to as fortifying nano-vehicles (FNVs). Further information available at http://www.nutralease.com.
- Aquanova—uses nanotechnology to produce micellas to improve the solubility of insoluble substances and to change the water/fat solubility of nutrients (eg vitamins A, C, D, E, K, ß-carotene, omega fatty acids). The patent protected NovaSOL® solutions is manufactured in ISO—and GMP certified production plants and suitable for a variety of applications in the area of food, dietary supplements, healthcare, cosmetics and pharma. They can for example easily be filled into softgels and are ready to use components for industrial processes such as preservation. AQUANOVA in 2006 received the "Excellence in Technology Award" (Frost&Sullivan) and is located in Darmstadt near Frankfurt (Germany). Further information at http://www.aquanova.de.

Use of inorganic compounds in food processing:

Use of synthetically amorphous silica (SiO_2) as food additive (E551), as auxiliary material to support the flow of powder (eg tomato powder, salt, spices), or as dispersion medium for vitamins.

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

NANO-ENHANCED DIETARY SUPPLEMENTS AVAILABLE IN GERMANY

Tabelle 4: In Deutschland erhältliche Nahrungsergänzungsmittel mit Nano-Materialien

Hersteller	Produkt	Nano-Inhaltsstoffe	Zweck
Trace Minerals Research	Co-Enzym Q10 nano liquid	"ultrakleine Flüssigkeitspartikel"	Das Q 10 gelangt direkt in Herz und Muskulatur ohne von der Leber verstoffwechselt zu werden, beworben zur Stärkung der Immunkraft und zur Überbrückung von Energiemangel
fairvital	fairvital Colloidales Silber	Nano-Silberpartikel	Antibakterielle Breitbandwirkung, beworben zur Stärkung der Immunabwehr
Vitafosan	Nano-Know-How	Nano-Zeolith und weitere Stoffe (bis 400 nm)	Verbesserte Aufnahme der Mineralien, beworben als "Aktivator für den ganzen Körper"
Vitafosan	Nano Men-Power	Nano-Zeolith plus Silizium-Sol (bis 400 nm)	Verbesserte Aufnahme der Mineralien, beworben "zur Stärkung der Mannes kraft"
Vitafosan	Aufbau for kids	Nano-Zeolith (bis 400 nm) plus Vitamine	Verbesserte Aufnahme von Mineralien und Vitamine, beworben "für eine gesunde Entwicklung"
Vitafosan	Toxi-Drain	Nano-Zeolith und weitere Stoffe (bis 400 nm)	"Saugt Gifte wie ein Schwamm in feinste Kanälchen und führt sie ab"
Healthy Generation GmbH	Nano Life by Carlo Thraenhardt	Unspezifischer Nano-Inhalt	unklar
Life Light	Nanosan Nanosilizium	Silizium-Sol	Beworben als "Spurenelement für Gesundheit, Schönheit und Jugendlichkeit"
Medica Consulting Ltd.	Energy Well Nano Mineral Silizium Pulver	Nano-Silizium	unklar
Squeezy	SQUEEZY Nano energised mineral gel	Nano-Mineralien	Hohe Bioverfügbarkeit, fördert den Muskelaufbau und die Regeneration des erschöpften Sportlers
Muscle tech	NanoVapor	"Nanomolekulare gefäßerweiternde Wirkstoffe"	"NaNO Vapor ist eine muskelaufbauende psychoaktive Erfahrung"
Muscle tech	naNOX9	"Nanoskaliges Stickstoffoxid"	"Durchflutet die Muskulatur sofort mit gefäßerweiternden Wirkstoffen"

Source: BUND (German branch of Friends of the Earth), "Aus dem Labor auf den Teller—Nutzung der Nanotechnologie im Lebensmittelsektor" (From the lab onto the plate—use of nanotechnologies in food) (see http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311_nanotechnologie_lebensmittel_studie.pdf)—See page 51–61 for overview of nano-enhanced food and beverages, food additives, dietary supplements, food packaging and kitchen-utensils available in Germany and in international markets.

NANO-FOOD ADDITIVES AND AUXILIARY MATERIALS AVAILABLE IN GERMANY

Manufacturer	*Product*	*Nanomaterial*	*Purpose*
Evonik Industries (formerly Degussa)	Aerosil, Sipernat	Nano-Siliziumdioxid	Rieselhilfe für pulverförmige Inhaltsstoffe
Rieselhilfe für pulverförmige Inhaltsstoffe	AdNano	Nano-Zinkoxid	für Mineralzubereitungen
AquaNova	NovaSOL	Nano-Mizellen	Bessere Aufnahme aktiver Inhaltsstoffe in Zellen und (Kapseln) Organe durch Einschluss in Nanokapseln
BASF	Solu E 200	Vitamin E nanosolution based on NovaSOL (see above)	Ermöglicht die Zusetzung von Vitamin E zu Getränken, ohne dass dadurch Farbe oder Geschmack NovaSOL (s.o.) beeinträchtigt werden
BASF	LycoVit	Synthetisches Lycopin Antioxidationsmittel (< 200 nm)	

Source: BUND (German branch of Friends of the Earth), "Aus dem Labor auf den Teller—Nutzung der Nanotechnologie im Lebensmittelsektor" (From the lab onto the plate—use of nanotechnologies in food) (see http://www.bund.net/fileadmin/bundnet/publikationen/nanotechnologie/20080311_nanotechnologie_lebensmittel_studie.pdf)—See page 51–61 for overview of nano-enhanced food and beverages, food additives, dietary supplements, food packaging and kitchen-utensils available in Germany and in international markets.

3. *Research and development in Germany regarding nanotechnologies and nanomaterials which have or may have an application within the food sector?*

Overview

The Federal Government launched a number of projects in 2006 to address health and environment related issues. A total of € 7.6 million (£ 5.2 million) has been allocated to these projects for a three year period. The table below sets out public-sector and industry allocations to research into the risk of nanotechnology on human health and the environment.

Project	*Duration*	*Public sector funding*	*Industry's contribution*
NanoCare	2006–08	€ 5 m	€ 2.6 m
Dialogue on Nanoparticles	2004–06	n/a	n/a
NANOTOX/INOS	2006–08	> € 1 m	n/a
NanoHealth	2006–08	n/a	n/a
TRACER	2006–08	€ 1.5 m	€ 1.5 m

Source: British Embassy Berlin—own research on various websites

The table below sets out the Federal Government overall allocations to research into the ecological, ethical, social, and military as well as consumer and health-related aspects of nanotechnology, including—the above projects.

	2002 in € m	*2003 in € m*	*2004 in € m*	*2005 in € m*	*2006 in € m*
Opportunities and risks (eg technology assessment, INOS, NanoCare)	0.257	0.460	0.460	0.040	1.582
Support measures (eg Nanotechnology Networks, Horizon Scanning)	1.840	2.189	3.048	2.929	3.780
Education, further training, social aspects	0	0.200	1.900	1.500	1.152
Total in € m (£ m)	**2.097 (1.436)**	**2.849 (1.951)**	**5.408 (3.704)**	**4.429 (3.033)**	**6.514 (4.461)**

Source: BMBF, Response to Parliamentary Question 16/2150, 31 July 2006

NanoCare

The NanoCare project (first phase in 2006–09; second phase to start in 2009), a collaborative project bringing together representatives from industry, science and the wider public. Germany's government allocated €5 million to the first phase of the project, industry contributed a further €2.6 million. The project involves 13 collaborative partners, including six companies and seven research institutes. The project involves:

— publication of data on known and unknown impact of nanomaterials on the environment and health;

— combination of industrial manufacturing and toxicity research (BASF involved as key player);

— development of standardised processes for the use of nanomaterials;

— generating knowledge into the synthesis and characterisation of nanoparticles;

— in vitro and in vivo risk assessment;

— development of standard operating procedures for the use of nanoparticles; and

— dialogue with the wider public.

While NanoCare initially focused on nanoparticles used in skin care products, the later phase of the project now also includes a wider range of aspects, including:

— research into potential exposition routes and barriers (eg pulmonary tract, gastrointestinal tract, broken skin, blood-brain-barrier, blood-plasma barrier;

— research into the link between materials properties and human toxicity;

— identification of response mechanisms; and

— development of measuring strategies and testing systems.

A follow-up call for NanoCare was launched in October 2008, the deadline for submitting further project proposals was late February 2009.

Further information: http://www.bmbf.de/pub/flyer_nanocare-projekte_en.pdf (English); NanoCare project website at http://www.nanopartikel.info; NanoCare call for proposals October 2008 http://www.bmbf.de/foerderungen/13084.php (German)

NanoNature

Additionally, the BMBF funds the NanoNature programme project, which was launched in August 2008. The projects are expected to start in the first half of 2009. NanoNature focuses on the use and impact of nanotechnology in environmental protection. Nanotechnologies that may be used in clean processes and to protect the environment include:

— water reprocessing; cleaning air and water and reprocessing polluted soil;

— recycling processes including separation of different types materials; and

— catalytic processes and materials separation in order to reduce harmful emissions into the environment.

In terms of potential impact of the use of nanotechnologies in clean processes and environmental protection, NanoNature will investigate interaction between nanomaterials structure and impact identify impact parameters, taking into account harmful substances occurring naturally:

— development of reference materials, processes and standardised testing;

— conduct research into the mobility and transformation of nanoparticles;

— carry out risk assessment using real matrices; and

— develop characterisation processes for nanoparticles in air, water and soil.

Source: Federal Ministry of Education and Research; presentation given to BfR Nanotechnology Forum, 10 November 2008; NanoNature call for proposals http://www.bmbf.de/foerderungen/12531.php (German)

NANOTOX

NANOTOX is a joint initiative by several research institutes and companies in Dresden and Leipzig (Saxony). It seeks to establish a virtual laboratory specialising in the analysis of health and environment aspects of nanotechnology. NANOTOX aim is to become a service provider for SMEs and to carry out contract research in to the potential risk of nano-scale particles. The members of NANOTOX are:

— Fraunhofer Institute for Ceramic Technologies and Systems.

— Max Bergmann Centre for Biomaterials.

— UFZ Centre for Environmental Research.

— University Clinic Dresden.

— Namos GmbH.

The members of NANOTOX launched the INOS research project in February 2006. INOS stands for "Identification and Assessment of Health and Environment Risks of Nano-scale Particles". The projects aim to conduct a comprehensive analysis of the potential adverse impact of nanoparticles on man and the environment. The Federal Research Ministry provides € 1 million towards the cost of the project. As a result of the project, a database will be established, which provides information about the health risks linked to individual types of nanoparticle. This will serve as a guide to companies on developments in this area.

Links:

— Nanotox Homepage: http://www.nanotox.de/nanotox/Willkommen.html (German)—with links to English-language websites of the Nanotox participants.

TRACER—Toxicological Assessment and Functionalisation of Carbon Nanomaterials

In March 2006 the BMBF launched TRACER, a toxicological assessment of carbon nanomaterials. The participants in this € 3 million project include four companies (including Bayer MaterialScience) and a public-sector research institute. The project aims to investigate the biocompatibility and toxicity of carbon-nanotubes and carbon nanofilaments along the whole value added chain—from manufacture, processing and blanks to prototypes. On the basis of research results, participants will make recommendations for the production and processing of carbon-nanomaterials as well as the use of relevant products.

Links:

— Information on NanoCare and Tracer projects http://www.bmbf.de/de/5915.php (German)

— Bayer MaterialScience: http://www.bayerbms.de/(English)

Bayer News Release on the NanoCare project: http://www.presse.bayer.de/baynews/baynews.nsf/id/A87EF8F221792B54C12571180034DE8F/$File/2006-0058E.pdf (English)

NanoHealth Project

The Helmholtz Association—the umbrella for Germany's 15 large science institutes—stated a project on nanotechnology-related health risks in May 2006. This aims to develop preventive strategies to minimise

health risks linked to synthetic nanoparticles and neuronal implants. The project is carried out by the Institute for Technology Assessment and Systems Analysis (ITAS) at the Helmholtz Research Centre in Karlsruhe. The key elements of the NanoHealth project are:

- Analysis and summary of current state-of-the-art in both areas, ie nanotechnology and neuronal implants.
- Development and test of an evidenced-based strategy to analyse and assess the risk of synthetic nanoparticles.
- Debate on visions and ethical issues in the context of neuronal implants.
- Discussion of key issues in 2x2 focus groups involving experts and laymen; development of action strategies.
- Presentation of the results in the form of a workshop open to the wider public.

Links:

- Homepage NanoHealth http://www.itas.fzk.de/deu/news/2006/11.htm (German)
- Homepage ITAS: http://www.itas.fzk.de/home_e.htm (English)

Further Federal Government Initiatives

The Federal Ministry of Food, Agriculture and Consumer Protection (BMELV) organises conferences on consumer protection and a foresight type study (based on the Delphi method of expert forecasts) into nanomaterials in consumer goods. The BMELV will also conduct a survey into nanomaterials in food.

BMELV Food Safety Strategies (in English)—Reference to nanotechnology on page 35 http://www.bmelv.de/cln_045/nn_1299748/SharedDocs/downloads/__EN/01-Brochures/FoodSafety,templateId=raw,property=publicationFile.pdf/FoodSafety.pdf

The Federal Environment Ministry (BMU) has been responsible for driving the NanoDialogue initiative—an interdisciplinary dialogue involving all stakeholders including government, industry, research, NGOs, industry associations and the wider public. The Federal Environment Agency (UBA) within the remit of the BMU will conduct nanotechnology life cycle analysis and studies into toxicokinetic.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

BMU NanoDialogue and NanoCommission English-language website: http://www.bmu.de/english/nanotechnology/nanodialog/doc/37402.php

A number of German government agencies—including the Federal Institute of Risk Assessment (BfR), the Federal Institute for Occupational Medicine and Health (BAuA) and the Federal Environment Agency (UBA) with input from others—have proposed a programme of risk-related research into nanotechnology. This has not yet led to the establishment of dedicated research funding in addition to NanoCare and other risk-related nanotechnology research projects (eg into CNTs).

English translation of the draft research strategy into nanotechnology environment and health risks: http://www.baua.de/nn_7554/sid_61037A3BB139D43BBCE4BA5848D183C8/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/draft-research-strategy.pdf; further information:

- Federal Environment Agency (UBA) http://www.uba.de
- Federal Institute of Risk Assessment (BfR) http://www.bfr.bund.de
- Federal Institute for Occupational Medicine and Health (BAuA) http://www.baua.de

4. *Barriers to the development of new nano-products or processes in the food sector?*

Poor public acceptance of nanotechnology in food

BfR study illustrates that only 20 per cent of respondents consulted would buy nanotechnology-enhanced food products. Public acceptance is much better in the area of surface treatment/cleaning (86 per cent would buy such nano-based products), clothes (75 per cent) and skin care (36 per cent). In terms of risk perception, the majority of respondents consider inhalation of nanoparticles the greatest risk (78 per cent). Almost 12 per cent consider oral intake as the biggest risk associated with nanotechnologies.

Source: Federal Institute of Risk Assessment (BfR) representative opinion poll conducted in May 2008; Full report available at http://www.bfr.bund.de/cm/238/wahrnehmung_der_nanotechnologie_in_der_bevoelkerung.pdf

Issues with general safety of nanoparticles

Different toxicity of nutrients/bioactive substances due to enhanced bioavailability or different distribution within the human body; further research necessary on the impact on physiological substances/matabolites transport in organisms; investigation needed into whether nano-carriers affect epithelial tissue and intestinal function; further research needs to be carried out into the bioavailability of nanoparticles following oral exposition.

Source: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008

Potential risks associated with synthetically amorphous silica (SiO_2)

There is some in-vitro evidence of impact on cell nuclei, ie accumulation of 40–70 nm nanoparticles in nuclei; negative impact on replication and transcription (but manufacturers doubt that in nano-particles are present). New gel-based production processes for SiO_2 may require new safety assessment. This BfR assessment has been endorsed by the Risk Assessment Working Group of Germany's NanoCommission.

Open questions about the risk of nanoparticles in food

The physical and chemical properties of industrial nanoparticles as potential food additives need to be investigated, especially whether the nanoparticles bind with other food components or whether they move freely through the gastrointestinal tract. Further questions to be investigated are whether nanoparticles as food additives affect the gastrointestinal function or the gastrointestinal microflora. The risks through indirect contamination and migration from packages need to be investigated as well as the status of nano-particle enhanced food compared with novel food.

Methodology for risk assessment

The BfR recommends that methodologies be developed for a risk assessment of nanoparticles in food, including definitions and distinction between synthetic vs. natural nanoparticles; free vs. matrix-bound nanoparticles. Further generation of toxicological data, especially after oral exposition, is needed.

Sources: Federal Institute of Risk Assessment; presentation given to the Nanotechnology Forum, Berlin, 10 November 2008; Bericht und Empfehlungen der NanoKommission der deutschen Bundesregierung 2008 (in German only)—

http://www.bmu.de/gesundheit_und_umwelt/nanotechnologie/nanodialog/doc/42655.php

Annex 5

EVIDENCE FROM JAPAN

State of the Science and its Current use in the Food Sector

In Japan, nanotech is applied mostly to food products, including supplements, food additives and flavours, and not much to food packaging or food production processes. The size of the Japanese market is still small—approximately 1 billion yen (GBP14 million) as of 2005, according to the National Agriculture and Food Research Organisation, citing statistics by the Ministry of Economy, Trade and Industry (METI). It was a tenth or less the size of the market of cosmetics containing nano-materials.

But the nanotech-containing food market is likely to exceed the nanotech-containing cosmetics market in the near future. It is expected to grow 20 billion yen (GBP148 million) in 2010, 150 billion yen (GBP1.1 billion) in 2020 and 250 billion yen (GBP1.85 billion) in 2030.

According to a symposium in January 2008,[25] Japan is far ahead in the development of surface chemistry of emulsifying agents, followed by North America and the EU. Japan is also in the top position of solid fermentation, solid culture technologies and brewing technologies. These technologies are mainly aimed at improving the absorption of nutrition in the body, although some researchers are hoping to increase the use of nanotechnologies to raise Japan's self-sufficiency ratio for food, which stood at 40 per cent in 2007, the lowest among developed countries.

[25] "Food Nanotechnology committee—application of nanotechnology and materials technologies to the food industry." (Excerpts of a symposium organised by Centre for Research and Development Strategy, the Japan Science and Technology Agency held on 30 January 2008 in Japan.)—Japanese only.

In the symposium, a researcher at Japanese food company Kagome said that food companies are keen on research into food structures; ie research into gel structures in such products as cheese, gelatin and puddings. However, R&D to improve the texture and taste of food products is yet insufficient. Therefore, many companies expect to establish technologies to measure and evaluate fine structures in foods effectively.

Ministries have launched various research projects on nano-foods, but they are still at the early stage. For example in 2007, the Ministry of Agriculture, Forestry and Fisheries (MAFF) launched a project called "Development of nanoscale processing or evaluation technologies for food materials". Researchers in the projects set a goal to reduce the size of solid particles of 100 micron in diameters (such as rice, grains, soybeans) to 100 nanometres, and create 10 emulsion particles of 10 nanometres, in five years. They are also working to develop technologies to create and evaluate particules and assess the safety of these products. To this end, the project has 22 sub-projects with participation from four quasi-independent research institutions, six universities one company and two regional governments.

Health and Safety & Regulatory Framework

The National Agriculture and Food Research Organisation said that there are few regulatory frameworks to control the application of nanotechnologies in the food sector in Japan. They also said there are probably no rules for imported food products containing nanotechnologies and nanomaterials. So basically Japan is allowed to use particles of even less than 100 nanometres in diameters for food products.

The main reason of few regulations is that there are little data which can convince the risk of nano-foods against people's health. Still, since 2004 the government has been garnering various opinions about safety through committees. The main ministries are METI, MAFF, the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). An MHLW committee issued a report in late 2008, and recommended the government to work hard to collect information to create possible regulations as well as to educate the public.

The National Agriculture and Food Research Organisation said Japan may take a step forward this year, after WHO and EFSA held conferences on safety issues.

Inter-governmental co-operation has been going well among these key ministries (MHLW, METI, MEXT, MAFF) in terms of participation in committees etc. But major responsibilities are divided by each ministry: MAFF for overall food issues, MHLW for safety issues, and METI and MEXT for overall nanotechnology.

In the future, the National Agriculture and Food Research Organisation believes that Japan should make a rule to conduct safety tests when large particles, which are currently widely used in foods, are re-engineered as nano-particles because these structures may change and endanger people's health.

Public Engagement

In the autumn of 2008, Hokkaido University held a small conference to discuss nano-food and its safety with consumers. The National Agriculture and Food Research Organisation was represented at the conference and believed the general public had a positive impression about nano-foods. Meanwhile, in the symposium in January 2008, a journalist of Nikkei Biotechnology Japan said that nano-foods and food nanotechnologies have yet to be a topic among consumers, and there are few consumer movements against nano-food and safety issues. Japanese consumers tend to show strong resistance against GM foods, so nanotech for food applications may trigger similar safety concerns once people get to know more about it. Accurate and proper dissemination of scientific information is therefore necessary in Japan.

GBP1 = 135 yen

Annex 6

EVIDENCE FROM THE UNITED STATES OF AMERICA

State of the Science and use of Nanotechnology in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

— Use of nanotechnologies in food products or in food production is considered to fall in one of two categories—nano-inside vs. nano-outside. Nano-inside indicates use of nanotechnology as food additives, and nano-outside indicates the use of nanotechnology in the production of food packaging.

— Applications and benefits in food products—In food additives, improvements could be made in food shelf life, texture, flavor, or nutrient composition. Some additives can also be used to detect food pathogens, or used as food quality indicators.

— Applications and benefits in food production process—In food packaging—nanotechnologies in this area are considered to be of use to increase product shelf life, provide indication of spoilage (though nanosensors), or generally increase product quality (eg by inhibiting gas flow across packaging materials.)

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

— Current State of the Market—According to Lux Research, sales of products containing nanotechnology (in general) generated $30 billion of sales in 2005. In the food industry, some experts predict that nanotechnology will be incorporated into $20 billion worth of consumer products by 2010 (Helmut Kaiser Consultancy). Five out of the 10 world's largest food companies are pursuing research in exploring use of nano in their food products or packaging. According to the Woodrow Wilson Project on emerging nanotechnologies consumer products list there are around products in the food and beverage field—around 10 per cent of the total products in their database. www.nanotechproject.org/inventories/consumer/analysis_draft/

— Examples of current items on the market are: Canola oil that contains nanomaterials which block cholesterol from entering the bloodstream (Canola Active Oil by Shemen Industries). Another is a chocolate "slim" shake which is supposedly tastier and more nutritious due to the properties of nanoparticles designed to carry nutrition more efficiently into cells (Nanoceuticals Slim Shake Chocolate by RBC Life Sciences). There are beer bottles on the market from Hite Brewery Beers (Honeywell) whose bottles are created using nanoparticles which block the transmission of oxygen into the beer, thus keeping it fresher for longer periods of time. Nanotea is another product, which claims to use nanoparticles to increase absorption of selenium in the body from the tea, which purportedly boosts selenium's natural activity in the body by 10x (Shenzen Become Industry & Trade Co, Ltd).

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

— According to Kuzma and VerHage's Nanotechology Report (http://www.nanotechproject.org/publications/archive/nanotechnology_in_agriculture_food), industry observers indicate that there are literally hundreds of new food and food packaging products under development which could be on the market in as little as two years.

— According to the report above, there are several examples of next generation nanomaterials which could be used in future food products. Some nanoparticles are being designed to block substances in food (like the canola oil example), but could also include blocking food allergens. Other nanomaterials are being developed to be given to livestock, in order to detect and neutralize animal pathogens before they reach consumers (Clemson is designing a nanoparticle to neutralize the poultry pathogen campylobacter). There are additional nanoparticles being developed in order to deliver nutrients to human cells that either had previously low or no absorption. In the area of food packaging, nanosensors would be embedded in food packages designed to alert consumers that a product has spoiled, and is no longer safe to eat.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

— R&D in U.S.—A project by Dr. Jennifer Kuzma and Peter VerHage (detailed in the report above) included the creation of a database of all available food-related nanotechnology applications and products that are likely to appear on the market in the coming years. It compiles information about food nanotechnologies that are still in the developmental stage, but includes only those from companies or labs that have agreed to release the information. Most of these are being made/developed within the United States. The website for the database is: www.nanotechproject.org.

— Beyond this database, which the creators admitted only "scratches the surface" of food related nanotechnology products, there are many products under development which are being kept secret, mostly by industries, due to varying concerns regarding public opinion, regulation, or duplication.

What are the barriers to the development of new nano-products or processes in the food sector?

— Currently, there are few methodologies or guidelines in the industry sector on how to asses potential risks from certain nanomaterials/particles, which can complicate risk assessment in the food sector. Future regulation spurred by these perceived risks could limit or inhibit use of nanotechnology in food products, especially if all nanomaterials are required to go through the review phase (see below), and not be eligible to be considered as a material Generally Recognized As Safe (GRAS) if the parent material had that classification.

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

— The legislation regulating nanotechnology in food is currently the Food Additives Amendment of 1958, which has been subsequently renewed and added to. The regulatory agency in charge of this is the Food and Drug Administration (FDA). This law states that any new substance added to food must undergo formal pre-market review and approval by the FDA through a food additive petition process which results in a regulation which specifies the conditions by which the additive can be safely used in food. http://www.fda.gov/nanotechnology/regulation.html

— However, circumventing the approval process occurs because some nanoparticles are just drastically reduced sizes of familiar Generally Recognised as Safe (GRAS) substances. This could allow a manufacturer to assert that the new particle has a "reasonable" certainty that a particular additive will have no harm, if the parent material is considered safe. However, the reduced size actually changes the particles physical properties, which could necessitate a case-by-case scientific evaluation of all nanoparticles, which could inhibit or slow innovation of new particles if all nanoparticles/ materials must go through a new extensive regulatory process.

— A new bill that just passed in the House, which has yet to be introduced in the Senate, will attempt to further coordinate nanotechnology information. H.R. 554 mandates that the Nanoscale Science, Engineering, and Technology Subcommittee of the National Science and Technology Council (NSTC) develop and maintain a publically accessible database of projects falling under the various existing categories. This database will be "official", and is not related to the nanotech project database referred to in the fourth question. This bill still needs to be approved by the Senate prior to becoming law.

— Additional papers on this subject can be found on proposals for nanotechnology regulation on the website for the Woodrow Wilson Center for Emerging Technology—http://www.wilsoncenter.org/ index.cfm?topic_id = 166192&fuseaction = topics.home

How are imported food products regulated?

— Currently, all imported food products containing nanomaterials are subject to the same levels of regulation that U.S. products undergo. However, the House has just introduced a bill, called the "Food and Drug Globalization Act of 2009", sponsored by Representative John Dingell (D-MI) which would greatly increase U.S. oversight on imported food products. This Act focuses on all food and drug imports, but will affect those including nanotechnology as well. This Act will require that ALL foreign food manufacturers to be certified as meeting all U.S. food safety requirements (including nanotechnology safety requirements) by third parties accredited by the FDA. All testing would need to be done by facilities certified by the FDA, and the results provided to the FDA. Uncertified facilities and their uncertified products would be banned from being imported in the U.S.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

— The FDA could be unaware of nanomaterials used in a product if the company does not report it. Also, some small particles can be derived from existing substances and still be above the 100nm size range required to be considered a nanoparticle, and therefore not technically qualify as "nanotechnology" and thus would not require reporting.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

— The 1958 Act which governs food additives has done a comprehensive, albeit limited, job of providing regulation for nanomaterials so far. The current regulations are not seen as adequate for the future, according to the testimony of Dr. Michael R. Taylor of the George Washington University of Public Health at a public meeting discussing nanotechnology materials in FDA regulated products. http://www.nanotechproject.org/publications/archive/statement_michael_taylor_at_fda/

— Others like him have expressed their concerns that the current regulatory system will prove to be inadequate to deal with the predicted high number of new food and food packaging nanotechnologies that will be forthcoming. Many experts believe that more regulations need to be put in place, and that the FDA is also not currently adequately funded to review the potentially large number of new products coming under review, or even to handle more in-depth checking of current nanotechnology used in the food sector. A listing of additional papers on this subject can be found on the Woodrow Wilson's Project on Emerging Technologies website—http://www.nanotechproject.org/publications/page4/

— The FDA itself claims that through coordination with other agencies, future regulation of nanotechnology should not pose a problem. The FDA regulation policy for nanotechnology can be found at the following link: http://www.fda.gov/nanotechnology/regulation.html

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

— Currently, there does not appear to be any inter-governmental co-operation on regulations and standards for nanotechnology in the food and food packaging sector. Many critics of the FDA system of regulation in the U.S. have cited the regulatory system in Europe as being equally as good, but faster. Recent trends indicate that regulations are becoming more globalized, which could prove useful for the development of future regulations for nanotechnology.

March 2009

Memorandum by Department for Environment, Food and Rural Affairs (DEFRA)

1. This memorandum sets out Defra's written response to the inquiry that the Committee is undertaking into nanotechnologies and food.

2. We understand the inquiry specifically excludes the potential impacts of nanomaterials in waste streams and the environment, instead focussing on food products and consumers.

3. In this context Defra would like to make the Committee aware of the role of nanotechnology in pesticides and highlight some related research on the potential environmental benefits of nanotechnology use in agriculture.

Pesticides

4. Of the authorised pesticide products currently on the market, nearly all utilise nanotechnology in some way if they contain a surfactant eg an emulsifying agent or dispersant.

5. However, rather than being a novel nanoscale process this is actually an established method of pesticide production, with these surfactants (which are necessarily at the nanoscale) acting to stabilise the product.

6. There are currently 1,468 products approved for use in the UK that utilise surfactants. All agricultural pesticides used throughout Europe are considered under an EU review programme to ensure that the safety of all pesticides is evaluated to modern standards. This is implemented in the UK through the Plant Protection Products Regulations 1995 as amended.

7. We are aware of research being undertaken into developing "smart nanoscale pesticides" aimed at slower release (so reducing the amount of pesticide needed). However, we understand this remains at the R&D phase and we are not yet clear whether these would actually be considered as being at the nanoscale ie <100nm.

OTHER RELATED RESEARCH—"ENVIRONMENTALLY BENEFICIAL NANOTECHNOLOGIES"

8. Defra published a report in May 2007 entitled "Environmentally beneficial nanotechnologies: barriers and opportunities", which can be viewed at:

http://www.defra.gov.uk/environment/nanotech/policy/index.htm

9. In this report the possible benefits of nanoscale environmental sensors in agriculture were highlighted, as these could allow more precise nutrient management. However, this was in the context of reducing greenhouse gas emissions and was not explored in detail in the report.

March 2009

Examination of Witnesses

Witnesses: DR ANDREW WADGE, Chief Scientist, Food Standards Agency, DR STEPHEN AXFORD, Head of Science and Society, Department for Innovation Universities and Skills (now part of Department for Business Innovation and skills) and MR JOHN ROBERTS, Head of Chemicals and Nanotechnologies, Department for Environment, Food and Rural Affairs, examined.

Q1 ***Chairman:*** Good morning, I should like to welcome our first three witnesses; this is the first public hearing of the Select Committee's inquiry into nanotechnologies and food and I should like to thank you very much for coming to join us to kick off our inquiry. I should inform you that the proceedings are being webcast, so your *sotto voce* comments will be picked up and broadcast to the nation. I should also draw attention to the information note which is available to members of the public. This sets out the interests which have been declared by members of the Select Committee, so I will not be asking members to repeat their interests whilst they are asking questions because you have those written down. Before we start on our questioning I should like to invite the three witnesses to introduce themselves and also, if they have any opening statement they would like to make at this stage, to make a statement please. Perhaps we could start with Dr Axford.

Dr Axford: Stephen Axford from the Department for Innovation, Universities and Skills where I am responsible for Science and Society. That comes with a specific interest relevant to today of the public engagement, public dialogue and attitude of the public towards the science.

Dr Wadge: I am Andrew Wadge. I am the Director of Food Safety and Chief Scientist at the Food Standards Agency, so considerable interest obviously in the topic today.

Mr Roberts: I am John Roberts from the Department for Environment, Food and Rural Affairs. I head the division which deals with chemicals and nanotechnologies.

Q2 ***Chairman:*** Are there any general comments that the three of you would like to make before we move to the questions? Do you have any prepared opening statement you would like to make or are you happy just to go to the questions?

Dr Wadge: I am happy to go straight to the questions.

Q3 ***Chairman:*** I will kick off with a very general question which is to ask you how the Government see the opportunities and challenges for nanotechnologies in the food sector. We are obviously just starting this inquiry but we have heard various comments about the very large potential for nanotechnologies in the food sector, which is of course why we are carrying out this inquiry at this point. I should be interested to hear your views on both the opportunities and the challenges.

Dr Wadge: The words "potential" and "challenge" are very much pertinent here in that a lot of the applications are very much at a potential stage; they are still in the laboratory. There is a lot of talk about what might be in the future in terms of applications, perhaps in food contact materials or in relation to specific ingredients. Those are potential applications which may bring benefits for food manufacturers and possibly for the consumers as well. In terms of challenges, our number one challenge, certainly from the Food Standards Agency perspective and Government perspective more generally, will be to ensure consumer safety. It is assessing the safety and looking at whether the risk assessment paradigms are appropriate, looking at the regulatory framework, whether the current regulatory framework is appropriate and also another challenge is around consumer and public engagement and understanding of nanotechnologies. We have obviously learned from previous experience where technologies have developed without some appreciation and understanding amongst the public that whilst on one level they may confer certain benefits, if the public are not convinced or are mistrustful of those benefits, then they will not be interested in purchasing the products. In general there is tremendous potential there but it is very much at the potential stage; uncertainties exist in terms of what that might mean and real challenges centre around assessing safety and public acceptance.

Q4 ***Chairman:*** I do not know whether the other witnesses wish to add anything at this point. You say that the development is still at the laboratory stage and we will come back to that later on in the session to try to understand where we are. Are you talking about the UK or are you talking about globally when you refer to the product still being at the research and development stage rather than in the market?
Dr Wadge: In general, a lot of the potential is still in the laboratory stage. There are products on the market globally and there are two products that we are aware of that are currently on the market in the UK; rather niche products, I have to say, that are both food supplements. It is very much the case that we are looking at potential applications in the UK rather than products on the market but we are aware that in other parts of the world there is perhaps a greater range of products on the market.

Q5 ***Chairman:*** What areas do you think the applications are likely to be in and are the Government doing something to encourage development of those applications?
Dr Wadge: I will leave colleagues to talk about the extent to which we are encouraging the innovation of new technologies. The main areas in relation to food are food contact materials and the opportunities that are present for nanomaterials to provide greater impermeability. I see prevention of permeability, antimicrobial applications, perhaps intelligent packaging and sensors and also, in terms of food ingredients, greater solubility of fatty materials in an aqueous media, ingredients and contact materials as the most likely. That is the intelligence that we have got from our conversations and discussions with the food industry.

Q6 ***Chairman:*** What about initiatives? Maybe DIUS can give us a view on initiatives for encouraging nanotechnology development.
Dr Axford: Yes. We would have to look to the structures we have in place such as the Technology Strategy Board, Knowledge Transfer Networks and so forth which are ways of getting the science out of the laboratory and into those businesses which can find ways of developing innovative products and developing the commercial opportunities.

Q7 ***Chairman:*** Can you say anything more specific about that?
Dr Axford: I do not know a huge amount of the detail of some of those specifics around particular technologies, certainly not specifically in relation to food. I would have to look to colleagues who were closer to the food sector.

Chairman: Perhaps that is something you could send us a note on to follow that up, just to look more specifically at what is being done to encourage R&D and translation in relation to food.

Q8 ***Lord Crickhowell:*** We had a seminar the other day with a wide representative group of advisers and I asked the same question then. We are told today, as we were told then, that there are only two known products, supplements and so on, in this country; we are going to cover questions about European legislation later. However, the fact is that we live in a global world and therefore I am rather sceptical about the view that because products are not known to be here, that are known to be in use in other parts of the world, they will not be here and it seems that if they are not now, they very soon will be, either in large quantities or brought in in various ways. Could you enlarge a little on this slight disregard for what is happening globally elsewhere? We heard, for example, of one manufacturing company based in the United States and what it was doing in the way of research and so on. Clearly there is a great deal going on in other parts of the world. How are we setting about really seriously identifying the global impact, which must be a UK impact as well?
Dr Wadge: I certainly would not want to give the impression that we are complacent about what is happening around the world. That is partly why we have commissioned two projects and we have provided you with reports on them in terms of what the current state of the market is. We have not been solely looking within the UK; we have been looking more broadly. You are absolutely right; if products are being developed in other parts of the world then we have a global food supply. Obviously within Europe we have European food legislation which requires that any food which is imported into the UK or any other part of the EU needs to meet at least the level of food safety requirements within the EU. That provides some reassurance but that is why we need to look at specifically improving methods of assessing the hazard characterisation and identification, exposure assessment, better understanding about what happens when nanomaterials are ingested, how they are distributed through tissues in the body and the toxicity of these materials. Those will be important areas for research that go along side by side with the development of the products. It is important as well that we tailor the research to meet the specific nature and properties of the nanomaterials which are being developed.

Q9 ***Lord Haskel:*** Dr Wadge spoke about the challenges of safety and public engagement. It seems to me that one of the challenges would be, from the point of view of the man in the street, the fact that these materials are so small. Are we able to detect

them so that we know whether they are present or not? Is the state of the science of detecting them sufficiently advanced as well?
Dr Wadge: Yes, it is a significant challenge and it is one which we will need to address over the years. At the moment I do not think we can be clear about the distribution of nanomaterials within the body, whether we can detect them in tissues and therefore to carry out a full and complete risk assessment you would need that type of information.

Q10 ***Lord Haskel:*** Can we detect them in food?
Dr Wadge: It depends what we are talking about. Part of the challenge here is that we are talking about nanotechnologies, a whole range of different technologies from micelles to hard particles to biodegradable particles. Certainly, with products which are going to be approved and put on the market, that is something which we will look at very closely to make sure that there are appropriate testing methods and means of assessing the exposure and the safety of those products.

Q11 ***Baroness O'Neill of Bengarve:*** This is a very general question. How do the Government coordinate their work on nanotechnologies? How do they strategise? How do they prioritise funding through research and innovation? I should say that in the next question we will come to some more specific points about the Nanotechnology Research Coordination Group, so we know that exists. Generally how do the Government coordinate?
Dr Axford: Taking an overview of that, you mentioned the Research Coordination Group and that is down a level below the strategic. There is a ministerial group on nanotechnologies, currently chaired by Lord Drayson, including representatives speaking for the ministers who speak for health and safety; I think that is Work and Pensions. Other members of the high level ministerial group are Huw Irranca-Davies from the Department for Environment, Food and Rural Affairs, Dawn Primarolo from Health, Lord McKenzie of Luton, responsible for health and safety and Ian Pearson from Business, Enterprise and Regulatory Reform [now known as Business Innovation and Skills]. That sets Government's direction on nanotechnologies overall; obviously not exclusively with relation to food but across the piece. Below that there is also effectively a policy group called the Nanotechnology Issues Dialogue Group. That allows the Government to coordinate activity at a policy level, that is between all interested parties, between Government and other stakeholders. Then there are other bodies such as the Nanotechnology Research Coordination Group which looks at how the publicly funded research, say in research councils and elsewhere, is covered and looked after. Then there is a number of other groups as well which inform those various bodies such as the Stakeholder Forum which is open to the public, which allows wider views to be input to the system.

Q12 ***Baroness O'Neill of Bengarve:*** That lists the bodies, which is extremely helpful. When we come to the actions which are taken, for example in December 2006 the DTI—of which I take it DIUS is the successor body here—published a review of the framework of current regulations covering nanomaterials. How are the Government responding to that review? Who is coordinating the response specifically?
Dr Axford: In relation to how it responds on the nanotechnology regulations, that is Defra.
Mr Roberts: The BRASS report reviewed the regulations which were applicable to nanotechnology and demonstrated in fact that there is a very wide range of potential regulations. Many of them in fact derive from European regimes; many of the regulatory regimes are determined by European legislation. We are currently pulling together responses from departments because a wide range of different departments have responsibility for the particular regimes and we are asking them to make sure that they continue to have regard to nanotechnology issues as they develop those regimes. The European Commission has also published its own review of the European regulation; that was done towards the end of last year. They also are monitoring and keeping an eye on how those various regimes need to respond.

Q13 ***Baroness O'Neill of Bengarve:*** In their evidence to us DIUS talked about the development of a national strategy for nanotechnologies. What progress is there at this point on that strategy and who is responsible for coordination?
Dr Axford: Agreement to the strategy will be taken by the ministerial group. They are next meeting towards the end of April, when they will agree the way ahead for the next steps of the strategy, potentially including a consultative process through the summer into the autumn. That is where that is at the moment.

Q14 ***Baroness O'Neill of Bengarve:*** So there is a draft strategy at this point.
Dr Axford: I do not believe there is a draft strategy.

Q15 ***Baroness O'Neill of Bengarve:*** The workings for one?
Dr Axford: It is certainly work in progress with, no doubt, an awful lot of evidence and information already collated. It has to capture the work of many other parties who are also similarly developing what you might call strategies both on the research end but also the Technology Strategy Board also has its own

development of a strategy for nanotechnologies. Government have to somehow capture all of these in their overarching strategy.

Q16 ***Baroness O'Neill of Bengarve:*** It is now nearly five years since the Royal Society and Royal Academy of Engineering report on nanotechnologies was published. Is this not quite a slow pace at which to be developing a strategy?
Dr Axford: I do not know the answer to that question. I would imagine that it is an incredibly complex area and as others have already alluded to, there are huge issues around knowing who should be accountable, who should be responsible, where the regulatory regimes reside and I imagine it is finding one's way through the forest which is slowing it down.

Q17 ***Lord O'Neill of Clackmannan:*** What was the purpose of the 2006 review which followed the Royal Society and Royal Academy study? DTI published a review of the framework of current regulations and nanomaterials; that was in 2006, three years ago. It does seem an unconscionably long period. Who is responsible? Which department was responsible for leading on this?
Mr Roberts: May I just answer that slightly differently by saying that the government approach is based on two things? First of all we need to get the science in place because the science has to underpin the way that the regulatory system develops. Then we need to keep an eye on the regulatory system. To the extent that it needs to be changed, we need to make the changes. The BRASS report showed that in a lot of areas the regulation is in principle capable of dealing with nanotechnology, provided that one understands the risks and the hazards that nanotechnology may present. It is a question of developing the science and developing the regulation step by step to keep the two together. Would it be helpful if I talked a little bit about how the research agenda has been carried forward since the Royal Society report, because I think that may help?

Q18 ***Chairman:*** Yes.
Mr Roberts: Following the Royal Society report the Nanotechnology Research Coordination Group identified 19 research priorities which were set out. There are five taskforces under that coordination group which take forward particular aspects. Those are to do with measurement and detection and characterisation of nanomaterials, fate and behaviour in the environment, human toxicology, co-toxicology and social engagement. It has taken a while to get momentum on the research, but it is true to say that the research is now accelerating. Over the period 2005–08 the Government spent about £10 million on research in these areas and I suspect the pace has picking up since. I can refer to a number of particular initiatives but not an overall figure. I just make the point that some of the research we are doing for underpinning regulation is actually also relevant to innovation. For example, characterising and detecting nanomaterials is important for regulation, but it also forms the basis for the industry to take forward, so some of the research covers more than two areas. In terms of research, last year we commissioned an independent review of the progress we have made on those 19 research objectives, a very comprehensive piece of research which was done by a team of academics and it will be published very shortly; it is going through peer review and final preparation for publication. That was encouraging in the sense that they found a lot of evidence that progress is being made on all the research objectives but it also indicated that on none of the research objectives have we yet completed the task. We do not yet know the answer fully on any of the research objectives. What we are going to do with that research is to use it to revisit the 19 research objectives to identify the gaps and the next directions so that we can take forward the next phase of research. If I may, the other two points I would make about research are first of all that we need to do this internationally. As Lord Crickhowell was saying, the issue is global; there is a lot of experience in other countries and we can get much better results if we coordinate our research programmes. That is being done through OECD, which has a similar structure of task forces, and we are sharing out research tasks among us to cover the field. The other observation is that the most productive research tends to come from collaborative projects involving different institutions and different disciplines. We are seeing much stronger results coming through from that, although it does take a little bit longer to get the research proposals put together and in place. In my own area, two quite exciting issues are the environmental nanoscience initiative, the second phase; the first phase was worth about £850,000, the second phase will be worth about £4.5 million and almost half that money is coming from the US because we have a partnership with the US EPA, so we will get the benefits of collaboration there. OECD has set out an ambitious programme to look at 14 of the most commonly produced nanoparticles. We are taking forward analysis of two of them; as it happens they are not food products but cerium oxide and zinc oxide. We have just launched a £3.5 million programme to characterise those two nanomaterials. Other countries will be doing others which are on the list. When that work is done we will know about those particular substances in much more detail but we will also have a much better knowledge of how to do the assessment of nanomaterials, how to do the characterisation, the measurement and the assessment of health and safety implications.

Q19 ***Lord Methuen:*** We have talked quite a lot about the national Research Coordination Group but in 2007 the Council for Science and Technology expressed concern over the progress of funding for health and safety research. You indicated that quite a lot of progress has been made in addressing these concerns. Would you comment on that?
Mr Roberts: Those were the points I have been covering to some extent. The EMERGNANO report has looked at something like 650 projects which have been financed globally over the last three or four years. It has demonstrated that there has been progress on all of our research objectives but there is still progress to be made on all of them.

Q20 ***Lord Methuen:*** The CST stated that the primary reason for this lack of research was the Government's over-reliance on responsive funding to deliver the necessary research. What has been done to overcome that problem or would you not agree with that?
Mr Roberts: The question of funding is an important one and the route we have chosen to go down is using the existing mechanisms and existing programmes and seeking to coordinate them, for example relying on the budgets of my department to look at environmental issues, the Medical Research Council and the DoH to look at toxicological issues, the Food Standards Agency to look at food issues. This has the strength that the research is embedded in those departments' programmes and those are the departments who will need to use the research for their regulatory processes but it does not mean that we have a single centrally directed budget to drive forward the research.
Dr Axford: In terms of research councils, there is a major cross-council programme on nanotechnology and even within that, on the issues, for example, of toxicology, the Medical Research Council has specifically had a call to look at that area, to look at the implications of nanotechnology on health to the tune of about £3 million.

Q21 ***Lord Methuen:*** What is being done to look at the long-term effects of possible toxicity due to nanomaterials?
Dr Axford: I would imagine that will be part of the research undertaken.

Q22 ***Lord Methuen:*** But you are not aware of what is going on at the moment.
Dr Axford: No, not the detail of what has actually been funded under that programme.

Q23 ***Chairman:*** What sort of response has there been to the MRC's call?
Dr Axford: It is fully taken up. It is a direct programme but it is obviously there to be responded to.[25]

Q24 ***Chairman:*** Mr Roberts, in your helpful summary of the OECD assessment of risk associated with 14 nanomaterials, as I understood it the 14 did not include any potential food applications. Do you think it should?
Mr Roberts: I think it is right that it does not contain many that are connected with food, although possibly the nanoclays may be used in bottles and therefore may have some link with food. They were chosen on the basis that they are ones which are in production now and therefore where there is potentially exposure to the environment or to human beings from those. It is those where we have some evidence available in order to make the assessments. It was a programme designed to capitalise on what we already have and the challenges we face today rather than a more prospective programme looking at potential applications in future.

Q25 ***Chairman:*** We have heard that, for example, the nanosilver particles are used in food contact materials like chopping boards or refrigerators. Is nanosilver included in the list of 14?
Mr Roberts: It is. Nanosilver was identified by the Royal Commission as one that was potentially something we should be concerned about. Defra has asked our Advisory Committee on Hazardous Substances to have a look at the issues around nanosilver and they are due to give us preliminary advice, although it will require some further work.

Q26 ***Earl of Selborne:*** On silver, when you mentioned earlier that there were two known food products with nanoparticles, was silver one of them?
Dr Wadge: Yes, in relation to a supplement.

Q27 ***Earl of Selborne:*** Yet the European Food Safety Authority has said that there is not enough evidence to suggest that this is cumulatively safe. How is it then that this has got through the system already?
Dr Wadge: Yes, that is one which will fall within the system; at the moment it is outside the system, it is quite a niche product and has been around for a long time. Under the new controls on supplements, that will fall out of the permitted list from January next year, 2010, because the safety data has not been provided to support that.

Q28 ***Earl of Selborne:*** That means that the material which is already available will be withdrawn.

[25] "To date the MRC has made five awards totalling approximately £3 million from response (not directed) mode funding. There is an open call and the submission of further proposals is being encouraged. Details are included in the additional written evidence provided by DIUS".

Dr Wadge: Yes.

Q29 ***Lord Crickhowell:*** May I ask a general question and then follow up with a specific one which has already been touched on? Mr Roberts, you have been giving very helpful and impressive evidence, if I may say so. We were a bit surprised that Defra's response to our enquiries was a one-page note on pesticides. We wondered what Defra were up to. Clearly Defra are more heavily involved than that indicated. You have been doing your best to cover a lot of ground in response to specific questions. Surely what we are going to need from you is a pretty detailed report from Defra about all this work you are clearly engaged in and about which we have not yet been informed except by you this morning. May I ask that you follow up your evidence—I hope the Chairman agrees to my request—with a really detailed account from Defra of what you are doing, covering all these points you have been talking about and adding any more that you would like to include. May I then put my specific question which follows two which have already been asked by Lord Methuen and the Earl of Selborne in a way and that is on long-term toxicology? Certainly the medical evidence that we received in an interesting seminar we had indicated that we do not really know a great deal yet about long-term effects. We know a good deal about the way the gut absorbs and the effectiveness of the gut in dealing with all the normal things, including some of the natural nanoparticles which it has been dealing with for millennia, but we do not know the long-term effects yet and we do not know therefore how these nanoparticles move on into the other parts of the body, the brain particularly and so on. Is one of these 19 research projects really homing in on the need for this long-term assessment of nanoparticles on the human body? If not, what is going to be done about it?

Dr Wadge: While John is looking through the particular 19 projects, I should like to comment on that, if I may? One of the real challenges for us is around the toxicological assessment and the risk assessment. We have received advice from our independent Committee on Toxicity and also the independent panel which advises the European Food Safety Authority that whilst the current risk assessment paradigm is appropriate there are considerable gaps in our understanding along the way around exposure and distribution and toxicity. I think that there will need to be a considerable amount of research in this area and I know that the MRC are picking up some of that. However, it raises bigger, wider questions about whether we have the appropriate capacity of toxicologists within the UK and that is something we need to look at. I am sure that at an OECD level, consideration will be given to develop harmonised risk assessment processes for nanomaterials. OECD currently agree the toxicological assessments for long-term effects of contaminants and other chemicals and it will be OECD which agrees those risk assessment methods for the very specific thing you mentioned around long-term toxicity. You are absolutely right that this is an area which will need a lot more research.

Q30 ***Chairman:*** Before we move on to the next question, perhaps we could home in on the particular issue of toxicology in the gut which Lord Crickhowell mentioned. We have gained the impression that, at least in this country, there is rather limited expertise in that area which is crucial of course to understanding potential risks associated with food. I just wondered, either from the Food Standards Agency or from DIUS, how many grants have been issued for research in relation to toxicology of nanoparticles in the gut which would be a central issue in understanding and filling the gaps.

Dr Wadge: We have just put a call out for our first project on the toxicokinetics of nanoparticles and that will be a collaborative project. We are very much at the early stages here. The research we have commissioned so far has been to carry out reviews: reviews of what products are available; reviews of the regulatory framework; reviews of public engagement and public attitudes to nanotechnology. We are very much at the early stages and a lot more needs to be done. I am not familiar with what MRC are doing.

Dr Axford: I am not familiar with the absolute detail of what the specific projects are. We could come back to you with information on that.

Chairman: Please do.

Q31 ***Lord O'Neill of Clackmannan:*** Much play has been made of the OECD and EU. Where are our partners in these organisations in relation to research and in relation to the seemingly endless process of reviews that you have been telling us about this morning? Are we missing out on other people's research or are we further ahead? At the moment we do not really know how we are comparing against, let us say, the French or the Germans or the Italians or the Swiss. I am not asking for a league table but we need to know how you are behaving or how you are performing by comparison with people alongside whom you are supposed to be working in these international organisations.

Mr Roberts: If I may say on nanotechnology generally rather than on food, my impression is that the amount being spent on EHS, environment, health and safety issues is broadly similar in three markets, Japan, Europe and the US? They are broadly of similar orders of magnitude both in terms of investment in innovation and investment in health and safety research. We can see whether there are more detailed figures and if the information I have

given is not absolutely right, I will try to provide something in more detail.
Chairman: It would be helpful if we could have some figures on that.

Q32 ***Lord Haskel:*** Like other members of the Committee I am quite impressed with all the work that you are doing on getting the science in place and getting the research done. Meanwhile this industry has to be regulated. It seems to me that the first thing you do when you regulate is to define what it is that you are regulating. I wonder whether you could tell us how you are going to define nanotechnologies and nanomaterials in this context of regulation.
Dr Wadge: There are very many definitions out there at the moment and we provide the BSI definition in our evidence to you. I know that the European Commission is also looking at definitions currently in relation to cosmetics but what they have agreed there will also no doubt be broadened out at some point in relation to food. From our perspective it is not so much the exact precise cut-off point in terms of size, it is far more around the properties which will have a bearing on the risk assessment; whether it is biodegradable or not, whether it is persistent and so forth, those are the key points. It is important that there is some agreed definition and that is something which is being worked up at a European level because that is where European food law is agreed.

Q33 ***Lord Haskel:*** Is this work on agreeing a definition within Europe proceeding through the European Parliament Committee on the Environment?
Mr Roberts: May I make two observations? First of all, I am not sure it is clear that we have to have a common definition of nanotechnology across all regulatory regimes. Clearly we need consistency; we also need to deal with the circumstances of each regime. A lot of regimes will say that products have to be safe and they have to be safe irrespective of whether they contain nanotechnology or not. If they contain nanotechnology then of course there has to be an assessment of the nanotechnology component but you do not have to define nanotechnology in legislative terms in order to achieve that. In terms of chemicals and nanotechnologies generally, the EU Scientific Committee on Emerging and Newly Identified Health Risks has proposed some definitions. I can provide a copy of these but for nanomaterials it simply says any form of material that is composed of discrete functional parts, many of which have one or more dimensions of the order of 100 nanometres or less.

Q34 ***Lord Haskel:*** So it is size.
Mr Roberts: It is size as the starting point for consideration of risk.

Q35 ***Chairman:*** Does that make sense toxicologically?
Dr Wadge: I think it does as a useful starting point. If I may broaden out to the regulatory framework in relation to food, we have looked at that and asked the very specific question as to whether nanomaterials, nanotechnology, nanoparticles will fall under the current regulation or could somehow squeeze through the current regulatory framework. We received some reassurance on that point from that review. Under general food law there is a requirement on food businesses to make sure that any food which is put on the market is not unsafe. That provides a general level of safety. Then there are some specific pieces of legislation relating to novel foods, food additives and food contact materials. The food additives regulations have recently been amended so that where an existing food additive is produced through nanotechnology it would have to be assessed by EFSA for its safety, so it would have to go through some independent assessment. Similar proposals are currently underway and we are supporting those for the novel foods and food ingredients regulations, also for food contact materials. There is a sense that the existing regulation, once it has been strengthened to capture the specific requirements around altered particle sizes and changed composition and properties of nanomaterials, that they would be captured under the regulations.

Q36 ***Lord Haskel:*** What definitive view then are you giving to the food industry if they come to ask you whether to label something as a nanomaterial or not?
Dr Wadge: Labelling is a separate issue. The first point is whether it would be permitted and we would provide advice, as we do generally and we are in discussion regularly with the food industry about products, about whether they fall within certain requirements of novel food legislation and so forth. If we felt that it was a novel property or a new size that was being produced, then our advice would be that it would need to be submitted for pre-market approval under the novel food regulations or food additive regulations.

Q37 ***Lord Crickhowell:*** What measures are currently in place to allow the Government to monitor the use of nanotechnologies in the food sector?
Dr Wadge: That is something that is being considered at the moment. Obviously if we are starting from a point where there is not very much on the market in the UK we need to look at what our role might and should be in relation to monitoring the use of that technology. There are proposals for the European Commission to produce a European register of nanotechnologies in relation to food and we also have the option of producing something within the UK. Our current thinking is that it would make sense

to work alongside the Commission to make sure we are familiar with what they are doing and to see whether we then need to add a further register within the UK. In terms of really understanding what is happening in the market, a register clearly could be very useful. However, our experience has been that as useful for us certainly is the regular dialogue that we have with all parts of the food industry about the technologies that they are developing, the products they are developing and how they fit within the regulatory framework. I have to say that a register might have some benefit in terms of actually dispelling some of the myths which are currently around that somehow nanotechnologies are being widely used in food currently on the market in the UK because those are some of the suggestions I have read in some articles. So a register might be helpful in terms of dispelling myths in that way and setting straight what products really are being used and not being used.

Q38 ***Lord Crickhowell:*** At one point in your answer I thought I was going to sum up as "There are no measures currently proposed" but you actually then said "We have our usual ongoing discussions with the food industry and they are really the existing measures". However, in your evidence you did say that you were seriously considering a register. If you did have it, how do you think it would work?
Dr Wadge: It is still very early stages and we are still thinking that through and we want to see what the proposals are from the Commission. I have to say that it is not something we have done in any other field and we need to think through the benefits of that. We do not, for example, have a register of GM technologies that are used, a register of other different types of technologies which are used in food. We would need to think carefully about what the benefit of putting that effort in to a specific area such as nanotechnology might be and that is something we are considering.

Q39 ***Lord Crickhowell:*** Defra has a voluntary reporting scheme. How successful do think that has been?
Mr Roberts: It has not been terribly successful. It has only generated a dozen or so responses in the first two years. We are examining how we can make that more successful. There is a challenge here between industry's desire for confidentiality of new developments and our interest in knowing what they are doing.

Q40 ***Lord Crickhowell:*** You made exactly the point I was going to put to you. Is there not a real problem here because with the best will in the world I am sure many of the best companies are doing some very serious research and very responsible research and we have had an account of one company doing just that. But one is extremely sceptical about their willingness to reveal what they are doing, if it is going to make a difference to them in the competitive market if they suddenly have a smoother ice cream or dressing using much less fat or whatever they are seeking to achieve and want to show that it is of benefit to the customer and not just for themselves, which is the big lesson learned from the GM disaster. So you have quite a problem, have you not, in getting real material out of companies about the research they are doing?
Dr Wadge: There is a genuine tension there is there not? However, we do have regular dialogue, for example we talk with beverage manufacturers around possible use of micelles to put colours in and so forth so there are technical developments which they are happy to discuss with us but they would not necessarily want to discuss more widely because of commercial pressures. The fundamental safeguard here is that these companies know and are very familiar with the need to make sure that their products fall within the requirements of general food safety and even wider than that the general requirements of the public acceptability. There will be a real caution amongst these companies about learning the lessons from the GM experience in terms of simply thinking that because they have some new bit of technical kit, somehow this will be broadly welcomed by the public at large. They are very, very cautious on that point.

Q41 ***Chairman:*** In the evidence that DIUS submitted it mentions that in Germany it appears from the table that there are 17 products on the market which use nanotechnologies. Presumably *de facto* those are also on the market in Britain because Europe operates as a single market? What kind of approval process have they been through?
Dr Wadge: I am not sure. They would be permitted under EU law but I am not sure whether they would be on sale in the UK. I am not sure what 17 products are being referred to there. I can refer to one specific product, which is the co-enzyme Q10, where we had quite detailed conversations with our counterparts in Germany around whether that particular product should fall within the novel food requirements and they were quite clear that the micelles which were being used were not changing the nature of the properties of the coenzyme Q10 so it did not need to go through that additional safety assessment. In a way that shows the ability of regulatory bodies such as ourselves to communicate, as we do regularly with counterparts across Europe, so that where there are products on sale in one Member State we will talk and discuss as to why those products are on sale and whether they should or should not need to go through further assessments.

Q42 ***Lord O'Neill of Clackmannan:*** In the case of the Federal Republic there are two quite substantial supermarket chains, German owned and German directed. Has nobody thought of looking at their range of products and sending anybody to do that? This is quite a sizeable part of the supermarket market share in the UK. I would have thought that major players like that might well have been taking advantage of nanotechnology on some of their products.
Dr Wadge: You referred earlier on to the reviews that we are doing and two of the reviews were looking at the use of nanomaterials, food contact materials and food ingredients more generally and that showed very little is currently in use in the UK market, but we fully expect that to change and that is why we are so concerned about getting the regulatory framework and the risk assessment frameworks right in anticipation of that change.

Q43 ***Baroness O'Neill of Bengarve:*** Do you have a sense of the timeframe? How urgent is it? It is rather a different story, requiring the withdrawal of a large number of products which have been on the shelves and would have had bad effects on public confidence in the technology and preventing them getting on the shelves until the assessment has been done. How much time do you think you have to get this regulatory framework in place?
Dr Wadge: The particular silver product that we talked about earlier is an anomaly in the sense that it is a product which has been around for some time, it is a rather niche product, as a food supplement it will fall from the permitted list and no longer be permitted. What I was trying to explain earlier is that the regulatory framework is such that any nanoparticle that is either changing the size or the nature of the property of the material will need to go through additional safety checks so that we will not be in a situation where we have lots and lots of products out there on the market which then have to be withdrawn.

Q44 ***Baroness O'Neill of Bengarve:*** The "we" there is European, is it?
Dr Wadge: Yes.

Q45 ***Baroness O'Neill of Bengarve:*** So there is an expectation that a number of these products on the market in Germany will quietly be withdrawn because they will need to go through additional checks before they come back on the shelves.
Dr Wadge: I would be very happy to look into that and provide some additional information because I am not familiar with the particular products that you are talking about. I would rather not comment without being familiar with what they are.

Q46 ***Chairman:*** Perhaps you could follow that up. They were listed in an annex to the DIUS submission in a table produced by the German Federal Risk Assessment Institute.
Dr Wadge: Yes; okay.

Q47 ***Earl of Selborne:*** I should like to take us back to the European regulatory framework and in answer to Lord Haskel's question Dr Wadge helpfully referred to the review which the FSA had conducted on the European regulatory framework. I think you referred to the general safety requirements of the EU food law regulation which would be the same whether the food was nano-engineered or not. You referred to novel food and food ingredients and noted that this is in course of revision. The regulation for food additives has already been added. Then there is provision under packaging regulations which presumably are relevant, animal feed and the like. Would you like to comment on whether you are satisfied that the amendments either in progress or already in place put the regulatory framework in a fit-for-purpose state?
Dr Wadge: I think that they do. I think that they do provide the necessary regulatory framework. Where the challenges and difficulties will lie will be far more around the precise nature of the risk assessment and the toxicological testing rather than the regulatory framework. It is there that more work is needed. I feel reasonably confident around the regulatory framework that products would need to go through additional safety testing. Once a product has been developed then the nature of that safety testing will be adapted on a case by case basis according to the properties of the particular material that is being looked at and that is one of the very specific bits of advice that we have received from the independent toxicological experts.

Q48 ***Earl of Selborne:*** You refer to the problem about the adequacy of current test methods. In your evidence you refer to the International Risk Governance Council's report which says that whether you are looking at Japan, America, European Union, all seem to be approaching this in roughly the same way but you point out that questions have been raised about the adequacy of current test methods and the ability of regulatory bodies to monitor and control measurements and risk assessments. In other words, the technology does not appear to be there to give the sort of assessments which are clearly going to be needed. You have identified the problem. How do you see this being resolved?
Dr Wadge: It is an area where we clearly have a part to play and we have just put the call out for our first particular project looking at toxicokinetics which will really address one specific part of that. The MRC is starting to fund projects and there is an international

programme which is being coordinated through OECD of risk assessment work. If I were a budding young toxicologist then that is an area I would be getting into because I think there will be considerable research funding in that area over the next ten to 15 years and that is what is required.

Q49 ***Earl of Selborne:*** We have already talked about colloidal silver which has been around for a long time. We are now realising that the EFSA is not likely to list it as an approved supplement. At what moment does the precautionary principle rear its head? Do we just wait until the final review is listed and presumably there will be other such products coming forward which eventually will be withdrawn but meanwhile they could or could not be cumulatively toxic. Why do we not take the precautionary principle seriously?
Dr Wadge: The precautionary principle is what is going to lead to the colloidal silver being withdrawn because the company has not produced the safety data to support the sale of that particular product. The regulatory framework that is set out requires a pre-market assessment of safety that would be approved by independent experts on scientific committees. That is a precautionary basis; it is one where the onus is on the manufacturer, the food business, to demonstrate safety before it is put on the market.

Q50 ***Earl of Selborne:*** It just seems surprising, as you can already anticipate that in a year or so this will be withdrawn, that you do not enact the principle sooner rather than later. Precaution usually means you take it sooner rather than later, rather than just allow the process to continue.
Dr Wadge: The area of food supplements is quite a specific area apart and the UK in particular compared to other Member States has a long history of quite large consumption of a range of food supplements which are perhaps not consumed in other parts of Europe and there are current measures under way to bring the sale of those products under greater control and assessment of safety. This particular product and a number of other supplements have been on the market for a while and manufacturers now have to provide the safety data to support their continued use. These are not nanotechnology supplements in general but it is just the nature of that area of legislation in relation to supplements. In relation to food more generally, we have been able to demonstrate that there is not currently a range of nanotechnology materials on the UK market and that food businesses would need to go through a pre-market assessment of safety that would be considered by independent experts.

Q51 ***Earl of Selborne:*** On the revision of the novel foods regulation, a 1997 regulation which is to be updated, the European Parliament has proposed that any new regulation should explicitly apply to all nanomaterials. I gather that is under discussion by Member States and the European Parliament. What is our position on this?
Dr Wadge: We support the additional controls and requirements to assess safety of nanomaterials which would have a different size or a different property compared with the existing foods that are on the market. The whole way the novel foods regulation works is that it makes a comparison and sets a date back in 1997 where, if a food has been in continued use for a period of time within Europe then it is not considered to be novel. What this change in the legislation is ensuring is that a change in the size or the properties due to nanotechnology would make that a novel product and would require further assessment before it is used.

Q52 ***Chairman:*** Presumably that is going to involve a definition of nanotechnology. You said earlier on that the definition is a bit woolly. So when we talk about a new product being defined as a novel product, I assume there will have to be a precise definition.
Dr Wadge: Yes.

Q53 ***Chairman:*** As a related question, you talked about this product involving a co-enzyme which was deemed not to be a novel product even though it had nanotechnology in it. How does that square? Is that the current situation which will change in future and will not be able to slip under the radar screen in future?
Dr Wadge: In the end the debate was around the properties of that particular material and although it was produced by nanotechnology, under the current novel food regulations the properties were not considered different, therefore it was not considered novel. If the regulations are changed to include anything produced by nanotechnology methods, then perhaps it may come under that requirement in future.

Q54 ***Baroness O'Neill of Bengarve:*** You have been telling us about the likely shape that the European regulation will have. Will that put the European regulation on a different track from the Japanese or US regulation? We have been there before in other areas and it does create difficulties.
Dr Wadge: There are very specific differences of approach and we have seen that clearly in relation to GM between North America and Europe. In a sense that reflects the different political and social environments that the regulations are derived from. Probably what is most important from a scientific

point of view is that we have international agreement on the risk assessment procedures and that is where the OECD work has a really important part to play. There will always be an opportunity for a much wider socio-political layer which is then put on top of the science in terms of the types of controls which are required in one part of the world compared with another part of the world. That is just the nature of the differences between different parts of the world.

Q55 ***Lord O'Neill of Clackmannan:*** In your evidence in relation to project A03063 you give a helpful description of the proposed changes to the food packaging regulations. What is the attitude of the Government to this? You are rather coy. I realise this is just a résumé of the regulations but what is the Government's attitude to that? How do you envisage implementing this on labels which are small enough to be acceptable to the packaging requirements?
Dr Wadge: There are two questions there. One is: what are the changes required to make sure that nanomaterials are properly assessed and need to be assessed before they are permitted for use such as nanoclays for example. Then the second question is the question of labelling. At the moment labelling is something which in broad terms is required where consumers need information that is meaningful to them. The priority has always been around information on safety and nutritional composition. For genetically modified materials there is a requirement for safety assessment and also labelling. Given that we are at such an early stage in nanotechnology we have not had that debate yet around what the nature of the labelling might be and how useful it would be for consumers to have the word "nano" put on one part of the label. That is certainly something where we would be engaging with consumers to find what type of information they would find useful. Once we get to a position where there are very specific products which are much closer to coming onto the market, of course we are in a position there where there are competing demands of clarity and useful information and a very small space on particular products to provide information around safety and use-by dates and nutritional composition, some environmental factors and possibly also information about the nanotechnology as well. It is something we are going to need to engage in and that is something we have done in the past. We will engage with consumers quite broadly with deliberative research to find out what sort of information they need and what is actually useful. There is no point putting "nano" on a label if it does not actually mean anything to anybody.

Q56 ***Lord O'Neill of Clackmannan:*** One of the problems we have had so far is the debate about nutritional information and whether it should be something which is imposed or be the right of the manufacturer or provider of the food to put down with their own particular spin. I find I am an avid reader of breakfast cereal nutritional values and if there are more than two cereals on the table I get totally bewildered. I understand the problem and I wish you well in your endeavours.
Dr Wadge: Thank you.

Q57 ***Lord Haskel:*** We have had a fair bit of discussion about the draft report on Regulatory Aspects of Nanomaterials by the European Parliament and indeed I think you told us you are conducting a review about this. Can you tell us whether you think that this is going to be a basis for having the same risk assessment procedures throughout Europe? Are you working with your counterparts in Europe on this? What is your general view about this draft report?
Mr Roberts: On many products we have European-wide systems. If you look at chemicals generally, for example, we have just introduced a major new regulation, which is European-wide, to identify the risks around chemicals generally. If I may, I will explain how I think that relates to nano which is why I think some of the comments the European Parliament rapporteur has been making are perhaps misfounded. REACH regulates substances other than those which are regulated by other regimes such as the food regime, the pesticide regime or the pharmaceuticals regime. Nanoparticles are substances so they therefore fall within the scope of the general European regulation. The question that we need to work through is how we should apply that regime in the circumstances of nanomaterials. The first question you have to ask is whether a nanomaterial is the same substance as a larger material or not. We are quite clear across Europe, both the Commission and the Member States, that if someone is producing a nanomaterial then the risk assessments they have to do under REACH would have to deal with the risks which might be associated with the nanomaterial. There are still big issues which we have to deal with because the testing regime associated with chemicals was designed for chemicals rather than nanotechnology. It may pick up many of the risks but it may not pick up all of the risks and therefore we do need to review how the tests are done to see whether there are new risks or new tests which need to be added to the suite to make sure we do capture the risks. We may also need to deal with some of the issues such as the fact that for registration under REACH there is a threshold of one tonne before a manufacturer has to go to Europe. For most chemicals that is fine; for

nanomaterials a tonne may be rather a lot. It does not necessarily mean that nanomaterials are exempt, because if a manufacturer produces, for example, bulk titanium oxide and nano titanium dioxide, then they have to register the whole of their production, so the nanomaterial would be included. The principles which underlie general regulation of chemicals, similarly pharmaceuticals or pesticides, that you have to provide information, that you have to provide information through the supply chain so they can be used safely and the regulator has the opportunity to restrict the manufacturing use if there are proven risks, apply to both bulk materials and nanomaterials in the same way. The way I would see the regulatory regime going forward is amendment of some of the detail to make sure the tests are sufficiently comprehensive and any criteria in terms of thresholds and so on may need to be adapted to reflect nano. However, the principles that we use for regulation of chemicals, of foods, of pesticides should apply to nano in the same way they apply to the products generally.

Q58 ***Lord Haskel:*** That is very helpful. Do you think that will be adopted throughout Europe? REACH is a European system so we are working on this together and whatever rules we come up with will apply throughout the market; it will be part of REACH.
Mr Roberts: It will be part of the REACH system.

Q59 ***Chairman:*** Just to be clear, in this report to which Lord Haskel is referring from the Committee on the Environment, Public Health and Food Safety, the European Parliament says in paragraph E " . . . in the context of REACH, it has so far not even been possible to agree on guidance on the identification of nanomaterials, leaving important decisions in the context of registration to economic operators". I am assuming translated into English that means that nanomaterials could slip through the net under REACH. Are you saying that is wrong, that this committee are wrong?
Mr Roberts: It is more subtle than that. Some guidance was published by the European Commission after agreement with Member States a couple of weeks ago about how far we have got in terms of the application of REACH to nanomaterial. I can happily provide a copy of that, if that would be helpful; that analyses the issue in rather more detail. What it says is that if the nanomaterial is a new substance, if, for example, it is a fullerene, then it is clearly a substance on its own and REACH would apply to that substance. If it is the same as a bulk form, then it is probably the same substance as the bulk form but the chemical assessments and the safety data sheets would have to reflect any particular risks that arise in the nanomaterial and in terms of classification and labelling, the hazard symbols which are put on products, if the nanoform has different risks, then it might merit a different hazard symbol to the same chemical in bulk form. The draft report from the rapporteur is an over-simplification of a rather more complex situation.

Q60 ***Chairman:*** This report is pretty hard hitting in general and I wondered whether you think that the European Parliament committee is kind of over-egging it when they say, for example, the committee "Considers it highly misleading for the Commission to state, in the absence of any nanospecific provisions in Community law, that current legislation covers in principle the relevant risks relating to nanomaterials". That seems almost directly contradictory to what Dr Wadge has said a few moments ago and I could quote from other paragraphs. This is much more critical of the European regime than you appear to have been. Could you enlighten us as to whether the committee has got it wrong or whether you have got it wrong?
Mr Roberts: If I may make one procedural point, this is a proposal from the rapporteur; it has not yet been endorsed by the committee. My understanding is that the committee is considering it today and then the European Parliament will vote on it in the next week or so. My view is that some of the statements in the report are absolutely right and some of the statements in the draft are wrong. The one you have just indicated is one I would not agree with.
Dr Wadge: John put that extremely well. I have nothing further to add to that.

Q61 ***Lord Crickhowell:*** I happen to chair another committee's examination of REACH's report on food so I pricked up my ears when you started talking about REACH. I think it is probable that if there need to be changes they will take quite a time. My experience of these things is that they take a long time to change right across Europe because everyone wants a say and the industries want a say. How long do you think it will take to sort out the regulatory changes to make them sensible?
Mr Roberts: I have a lot of sympathy with that point. It is going to take four or five years for the European system to work through the issues and then for the legislative process to be completed. From the UK Government's point of view we have been urging the Commission to make fast progress on these issues. My Secretary of State did write to the Commissioner last year stressing the importance of addressing nano issues comprehensively and urgently.

Q62 ***Lord Methuen:*** Can we go back to pesticides? Often these pesticides use surfactants at the nanoscale but they do not currently use engineered nanoparticles although there are products, "smart nanoscale pesticides" in development. Does Defra have a policy in place to deal with such products once they leave the research and development phase and enter the marketplace? I also include in this things like fertilisers which presumably will use the same things and things which are used by animal feedstuffs.
Mr Roberts: I can answer that question in respect of pesticides although I am afraid I do not have the information with me today on fertilisers and feedstuffs so I would need to respond to that separately if I may. There is a European regime in place which deals with the authorisation of pesticides which operates at two levels. The active ingredient has to be agreed at the European level as having passed the tests included in the relevant annex. Secondly, individual products are approved for use in the UK and the Pesticide Safety Directorate does that on behalf of my department. The advice I have had from them is that they would regard a pesticide containing a nanomaterial as a new product requiring a specific authorisation. So if a company changed the formulation of a pesticide to include, for example, an encapsulated active ingredient instead of one in solution, then that would require a new approval and a safety case would have to be made for the use of that product before it was authorised.

Q63 ***Lord Methuen:*** You will obviously risk assess these products. Is there sufficient information to understand fully their impact on the food chain and the environment? This goes for the other products which I mentioned.
Mr Roberts: That question is hypothetical to an extent until we get a case because it would depend on the nature of the case. We would do the normal test that we would do and we would look at all the scientific evidence that is available. It is a system of positive approval, so they have to make the case that it is safe rather than that it can be used in the absence of any evidence to the contrary. They would have to make a case and the Advisory Committee on Pesticides would give us the scientific view about the case that had been made.

Q64 ***Lord Methuen:*** You would get the equivalent for fertilisers presumably.
Mr Roberts: I am afraid I am not familiar with the authorisation procedure for fertilisers so I would need to take advice.

Q65 ***Lord Methuen:*** There must be something similar in place.
Mr Roberts: The regime on pesticides is clearly tougher because pesticides are necessarily toxic to something. There is therefore a system of positive approval. Fertilisers generally are more benign substances so I am not sure they are tested to quite the same rigorous extent as pesticides but I will need to take advice on that and come back to you.

Q66 ***Chairman:*** May I follow up a little bit on Lord Methuen's question? You said that the risk assessment would be done by the Advisory Committee on Pesticides.
Mr Roberts: They would review the evidence submitted by industry.

Q67 ***Chairman:*** Does that Committee have on it anybody who is an expert in nanotechnology?
Mr Roberts: I will need to look at the list. To be honest, I doubt it, but it is clearly an issue we would need to look at. The issues we would need to understand would be environment and fate, how the nanomaterial moves through the environment, followed by toxicology and eco-toxicology from exposure of humans or animals or plants or eco-systems as a result of that application. If we did not have that expertise, then we would need to look elsewhere for it. We have it, for example, on the Advisory Committee on Hazardous Substances and if necessary we would make a link between the Advisory Committee on Pesticides and the Advisory Committee on Hazardous Substances.
Dr Wadge: There are eco-toxicologist and toxicologists on the Advisory Committee on Pesticides but as I understand it the point you are making is whether they have specific expertise in the toxicology of nanoparticles, I doubt that. It would not preclude the opportunity to bring that expertise in to those particular committees.

Q68 ***Chairman:*** May I also ask the same question, whilst we are engaged in conversation, about the Advisory Committee on Novel Foods and Processes? If a nanofood product were to come through for approval with the UK competent authority, is there expertise in this area on that Committee?
Dr Wadge: No is the answer. Is there access to toxicological advice? The answer is yes. There is quite a lot of history of seeking advice from the Committee on Toxicity and I have included in the evidence some of the reviews which the committees have done on nanotechnology so far and the recommendations that they are making around the risk assessments. If there were very specific points on nanotechnology that required additional expertise, we would refer that to the Committee on Toxicity and they would take advice as necessary.

Q69 ***Baroness Neuberger:*** You have already mentioned the issue of public engagement and this being a key area. What future plans do the Government have to engage with the public, or conduct research on public perceptions on the use of nanotechnologies in the food sector? We would like to know who is going to carry it out and how it is going to be coordinated across Government.

Dr Axford: I could give a general view. Recently, in January of this year, there was a renewed ministerial commitment on nanotechnology overall. They gave seven key commitments overall but one of those was to develop the programme of dialogue around nanotechnology involving all key players. That includes, for example, academia, industry, non-governmental organisations and of course, critically, the public. That is part and parcel of the strategy to which I alluded earlier being put forward by the ministerial committee. We therefore, through a number of mechanisms, for example DIUS are responsible for a programme of activity called the Sciencewise Programme, which is all about getting better evidence of what the public thinks or finding a way of engaging the public in a constructive way on key issues. That is a process which can be applied on nanotechnology. There have already been two major goes at talking to the public about nanotechnology within the last two or three years. When it comes to the specifics of what is actually done on food that would have to be something Andrew would be able to talk about and what would be done in relation to food. I do not know what level of detail you would like to know about the general way that Government go about some of their work in other areas.

Q70 ***Baroness Neuberger:*** It is not particularly so much about how the Government work. We know a little bit about the general public understanding of science-type work. It is really perhaps some of the methodologies you are going to use for this actual engagement. For instance, there is very good evidence that with quite complex areas of nanotechnology, in the food sector would be a good example, things like citizens' juries may be very useful. It would be very interesting to know, given that this is part of the strategy, what Government are intending to do.

Dr Axford: Certainly on nanotechnology as a whole and even more so on food in particular it is a little bit early to say exactly which techniques we would use. Given what we have heard this morning about the problems almost of definition, we need to know what we need to achieve through any engagement process. Are we worried about the toxicological impacts? Are we looking at the commercial benefits? Until we know where nanotechnology is exploited in the commercial sector, it is very hard to know what to talk to the public about. It is very hard to engage them at the fundamental science level where a lot of it still is. We heard earlier that a number of these technologies are still often in the lab.

Dr Wadge: The Food Standards Agency absolutely stands ready to engage in public debate and, taking the lead from Lord Krebs who was our first chairman who really set a very high standard of public engagement on science, that is something we are very keen to follow. We do have a number of mechanisms in place. Perhaps I can talk about what we did on cloned animals a couple of years ago as an example of the type of engagement that we might do in relation to emerging technologies more generally. We commissioned work in 2007–08 which took the form of reconvened workshops. We brought members of the general public together, we had a range of experts from all different parts of the debate, talking about their work and we reconvened the group after they had gone away to think about it and they had an opportunity to ask questions.[26] It worked very well in terms of eliciting a rather broad consensus as to what the general public's concerns were. They were less concerned, interestingly, with how the technology and the science worked and their focus was much more on the why and the consequences and the benefits from the technology. That is perhaps not surprising, given what we learned from the GM debate which got very polarised. What we would want to do through citizens' juries, and we have a number of citizens' forums available which we regularly use and debate a range of issues that are topical for us, is to make sure that we are not simply finding out what the people on the extremes of public opinion think but actually what the general public feel once they have had a chance to be really informed about a technology. We do have the methodology available and we stand ready to engage in that debate.

Q71 ***Baroness Neuberger:*** You have already raised the GM issue and obviously some of that was extremely uncomfortable in many ways. Presumably one of the things you are saying therefore is that the engagement with the public will happen relatively early in order to avoid that kind of extreme view. I am not sure whether you are saying that.

Dr Wadge: If we do not, then it seems to me then that we have failed to learn one of the key lessons. It is important that there is an engagement and recognition of the role of everybody, not just Government but food businesses a well, to engage and talk about the types of technology and make sure that there is a general understanding and acceptance of technology.

[26] "This answer is not entirely correct. The Participants were in fact presented with information about the technology by the research company and not by a range of outside experts".

Q72 ***Baroness O'Neill of Bengarve:*** This is a question which also bears on public engagement but it really arises out of the DIUS submission which very usefully brought together evidence from a number of different countries. Brazil is quite startling and of course lies outwith the three big groups that we have discussed and one meets ready-to-eat edible bioplastic coating and pallet sensors for quality control apparently aimed at increasing the quality of Brazilian wine. Then there is a statement that Brazil does not seem to have any dedicated regulatory framework for nanotechnology research. There is a big player with a lot of research and there is free trade and it is quite complex to keep out products which do not meet certain standards. Do either DIUS or Defra or the Food Standards Agency have a reaction to the Brazilian evidence?
Mr Roberts: I am not familiar with the Brazilian situation but I can talk about the attempts at regulation of nanotechnology on the global level, if that would be helpful.

Q73 ***Baroness O'Neill of Bengarve:*** That would be.
Mr Roberts: If I may take one step back and look at chemicals, broadly speaking there are very few global rules restricting chemicals. The only ones which are restricted at the global level are 12 persistent organic pollutants which include substances like DDT and PCBs. Attempts for a broader regulatory framework for chemicals generally have not been possible to agree politically until recently. A big attempt to have a strategic approach to international chemicals management in order to deliver the WSSD, the World Summit on Sustainable Development objectives on chemicals had to be on a voluntary approach because some countries, not least the United States, opposed global regulation. The global community has attempted to regulate chemicals such as mercury for the last decade and in fact we had a breakthrough last month and there is now agreement to have international regulation of mercury emissions and that reflected a change in the approach of the United States and countries such as China and India were quite reluctant but in the end came along. In terms of nanotechnologies, we will be discussing that at the SAICM, the Strategic Approach for International Chemical Management meeting, which takes place in Geneva in May, where it has been identified as an emerging issue. We will be raising awareness there. It would be wrong to say there is scope for international global regulation of nanotechnology in the immediate term. We are trying to raise awareness of the issues in countries, not only those producing nanotechnologies but those which may also import products containing nanotechnologies and therefore have to deal with waste streams that may require specialist handling; at least raise awareness, spread the science and begin to get cooperative action going.

Q74 ***Baroness Neuberger:*** May I move on to the question of labelling and consumer information? Again this is mainly for the FSA. You said in one of your additional reports that there is a need for consultation on declaring the use of nanoparticle ingredients or additives in food products but in your main evidence you say that you do not have information on whether UK consumers would value information on the use of nanotechnologies in food and what sort of information would meet the necessary criteria. What are the Government doing to obtain the information about what the public feels about that?
Dr Wadge: We need to address that through the deliberative research with consumer forums, once we are a bit closer to products being on the market. At the moment it is a little bit difficult to do it in a vacuum in a way. Consumers need to know what specific products we are talking about that are now about to come onto the market and how that might benefit them or benefit others. Certainly that is how we would carry out that research, through our citizens' forums, to really gauge a sense of what information they would find useful and whether particular types of labelling would actually be helpful to them. At this stage, it is still a little bit too early to say.

Q75 ***Baroness Neuberger:*** I completely take the argument about it being early and therefore very hypothetical, but I just wonder whether there is not an argument for at least beginning that discussion, simply to make it clear that there will be transparency in this area.
Dr Wadge: Certainly we will be starting the process of talking about nanotechnologies with our citizens' forums in the autumn this year. I can ensure, given this conversation, that the question of labelling and information is included in those sorts of discussions.

Q76 ***Lord Methuen:*** Mine is an unrelated question. Mr Roberts mentioned these 19 tasks of priority research projects and five taskforces and he also mentioned 14 nanomaterials which were under investigation. It would be useful if we had details of what those were.
Mr Roberts: Certainly.

Q77 ***Earl of Selborne:*** I want to go back to the process of public dialogue, public engagement. I think everyone recognises and admits that the GM debate was a bit of a disaster quite frankly, because of the polarisation to which you referred. What are the lessons learned from the GM debate, even if they are only negative ones, as to how this debate should be structured?

Dr Wadge: That is a very big question, is it not? I am not sure that necessarily everything from the GM debate translates and transfers to this particular issue. Having said that, there clearly are some very important lessons and the first is to engage with the public at an early stage to ensure that a range of debate and dialogue takes place around the types of technologies which are being used or might be used in producing food and what the implications are for consumers of those different types of technology. Early engagement and bringing together scientists and the general public and groups such as the Food Standards Agency can play a facilitative role in encouraging that sort of debate to raise awareness to begin with of the sorts of issues and then specifically to tease out some of the very specific questions around acceptability and requirements for information and labelling and so forth.

Q78 ***Lord O'Neill of Clackmannan:*** Perhaps I should declare an interest as Chairman of the Nuclear Industries Association. A consultation was conducted by DTI which subsequently fell in the courts and they had to undergo the same process in a rather modified fashion to secure acceptability. Really what I just want to say is that the GM consultation was not the classic example we would want to follow but there are other failures as well. There is the potential pitfall of the litigious opponents and some of the people who are already on the fringes of the debate, having a higher bar of standards, wanting to pull more things into nanotechnology than perhaps the current definitions will allow. These are the kinds of people who might well be standing in the wings with lawyers ready to require judicial review. I merely make this additional cautionary point that the unfortunate experience of GM is as nothing compared to some of the subsequent failures of the Government's consultative processes which were expensive both in time and money to correct.
Dr Wadge: Yes.

Q79 ***Lord Crickhowell:*** As we approach the end of the session, I am extremely grateful that I have a very much clearer idea of what the Food Standards Agency and Defra are about and what is going on. The big gap I have at the end of this session is in understanding what the Government are really doing to close the big gaps we have in scientific knowledge. I have a big gap in my impression of what drive is being put, what money is being put behind the research programmes, behind what the universities are doing. I just do not have an impression that there is as much effort going in to really stimulating the research that is needed as I think there should be.
Dr Axford: We can respond to that in a broad sense. Looking at nanotechnology overall, setting aside the food specific for the moment, across the research councils there is something like £50 million across all programmes generally in the area of nanotechnology and a further £50 million in the specific cross-council programme on nanotechnology projects. There is actually a lot of investment going on in the broad area of nanotechnology.
Lord Crickhowell: May I ask then—I really do have a black hole here—what is actually going on here? I am afraid you have not given me any clear picture at all in your answers to questions; even that last answer does not. We really do need a pretty detailed report from your department as to what they are doing, what the programmes are, what money is being spent where and what you hope to achieve by it.
Chairman: Particularly in the area of risk assessment which is what concerns us rather than, say, development of new TV screens or something like that. If you could help us with a bit more detailed information on that area.

Q80 ***Baroness Neuberger:*** I have just been left with a sense of unease on the public engagement side. It is partly in your response to the Earl of Selborne when talking about the lessons learned from GM. One of the things you have been saying is that it is a bit too early. At the same time your response on GM is that we should have got in there earlier. I do not feel very comfortable that thinking has been developed very carefully. I have always taken the view personally that it is better to get in earlier. All the evidence about public engagement in other areas, say in the health services, shows that to be the case. I know you say this is starting in the autumn. Is there not some argument, given that we are doing this inquiry now, for ratcheting up at least the advance warnings of what you are going to be doing in the autumn?
Mr Roberts: Of course, we did do some work on social engagement in the period 2004 to 2006–07, which was the first wave, which included citizens' juries and a number of engagement exercises. A number of other people have also done them, such as *Which* who ran a jury last year and we have access to those results. The second phase of work which has been described will build on the first phase of work which was done three years ago.

Q81 ***Baroness Neuberger:*** I understand that. I still think there is a time issue.
Dr Wadge: It is useful to clarify what I meant around that in the sense that I do not think it is too early to start the engagement; far from it. We need to learn the lessons and start the engagement. I meant in relation to specific products and the types of information that people might require in relation to that.
Baroness Neuberger: I accept that.

Q82 ***Lord Haskel:*** On this question of research and all the work you are doing, does that fall in at all with the money which the Government are putting into resuscitating the economy? Is that part of that?
Dr Axford: The money we have talked about so far is money which was allocated in the last spending review, to the research councils for example. Not any new money, no new stimulus potentially.

Q83 ***Lord Haskel:*** It is not going to be part of stimulating the economy.
Dr Axford: We do not have any idea about that.

Q84 ***Chairman:*** We shall learn after the Budget. Do you have any other comments you wish to add? I should like to thank you very much for giving us nearly two hours of very interesting conversation but there may be things that you would like to add at this point.
Dr Wadge: No, nothing. Thank you for the opportunity.
Dr Axford: No thank you.

Q85 ***Chairman:*** There will be a transcript of these proceedings which will be sent to you for corrections so you will have a chance to make sure the written record accurately represents what you have said. We have asked you for some written material and the Committee Clerk, Antony Willott, will follow that up. Equally, if you have any points you think of that you would like to submit to us in writing, we should very much welcome that. Finally, I should like to ask, if you were advising us on recommendations we should produce at the end of our deliberations, whether you have any particular thoughts.
Dr Wadge: Other than a large increase in the budget of the Food Standards Agency . . . I think you have touched on an area of concern in relation to risk assessment and the capacity we have in relation to toxicological expertise and that is a concern that I have more broadly than simply around nanotechnology and I am involved in discussions with other chief scientists around that particular point. It is something that this very specific issue of nanotechnology does raise from my perspective.
Chairman: Thank you. Would others like to add anything? Thank you very much indeed.

Supplementary memorandum by the Food Standards Agency

At the evidence session on 31 March, the Food Standards Agency was invited to provide additional information in relation to a list of products reported to be available on the market in Germany. Our comments on this list are given below.

In addition, we would like to provide supplementary information in relation to products from non-EU countries (exemplified by Brazil, as raised during the meeting on 31 March), and on the FSA-funded review of public attitudes that was published after our earlier evidence was submitted.

(a) *Products on the German market*

On investigation, it seems that not all of these products are currently on sale and in many cases the presence of nanoparticles has not been confirmed.

The information provided from the UK contact in Germany (Annex 4 to the written evidence from DIUS) referred to two sources, a presentation by a member of the Federal Institute for Risk Assessment (BfR) and a list of products reported by BUND, the German equivalent of Friends of the Earth, to be available on the German market.

The first presentation was given at a forum "Consumer Protection—Nanotechnology" that was held at the BfR in November 2008. We have confirmed with the German authorities that the examples in this presentation were given as illustrations of potential future applications, rather than examples of "nano-products" that were already available on the German market. In the case of the nanoscale micelles manufactured by the company Aquanova, this technology has been investigated by the German authorities, who concluded that the coenzyme Q10 product did not fall within the definition of "novel food" as since the metabolism of the coenzyme Q10 in this formulation was not different from common products already on the market.

The BUND lists were based on a global inventory published earlier in 2008 by Friends of the Earth (FoE) in Australia. In addition to the products in the original FoE inventory, BUND reported that a number of additional products available in Germany, largely via internet sites, were being marketed as containing nanoparticles. In drawing up these lists, a size threshold 300nm was applied (where particle size information was available). The lists include products which are poorly described in the marketing information, and which may or may not contain nanoparticles.

The list also includes a number of brands of food supplements containing nanoparticles of silver, also known as colloidal silver. This is a long-established substance and, as explained in our original evidence (page 4), it is found also on the UK market.

In the case of food additive silicon dioxide (silica, E551), the German industry has confirmed that this substance has a long history of use and the specification currently used is the same that has already been assessed and authorised for many years. Although nanoparticles occur during the manufacturing process, these immediately aggregate and agglomerate into much larger units and the dimensions of the silica particles used in foodstuffs are typically in the range 2-12μm.

The presence of nanoparticles in other products on the list, whether below 300nm or 100nm, has not been confirmed.

We would certainly agree with the point made in the FoE and BUND reports, that the extent to which substances are absorbed into the body is likely to differ when they are presented in small particles compared with larger particles. This is true whether the particles are in the nanoscale or of some larger dimension. Indeed, the effect of different formulations, including different particles sizes, on the bioavailability of active substances has been a major area of investigation in the pharmaceutical industry for many years. Similar investigations are also carried out by the supplements industry. We would reiterate that it is the responsibility of food businesses to ensure that the products they market are safe, and this includes considering the effect of changes to manufacturing processes and reformulation of existing ingredients, even where such changes do not trigger a formal regulatory review.

(b) *Products on the Brazilian market*

At the evidence session on 31 March, the Committee was concerned about the implications of product development in countries like Brazil and whether such products could automatically gain entry to the EU market.

We would like to emphasise that UK and EU regulations apply equally to imported products as to domestic production. World Trade Organisation rules are designed to prevent unfair barriers to international trade but it is not the case that a product that is legally marketed in one WTO member state must be accepted in other WTO member states. Countries are free to establish their own safety requirements, provided that these do not discriminate against imports.

The UK contact in Brazil has confirmed that their report (Annex 1 to the evidence submitted by DIUS) refers to the absence of regulatory controls in relation to research and not to the marketing of food. In other words, there are no laws or directives preventing Brazilian scientists from conducting research in nanotechnology applied to food. The same situation applies in the UK. Brazil does however have a solid regulatory framework that applies to the commercialisation of new products, especially in the area of food, and there are standard food safety + health and safety laws which are applicable for all new products, including products obtained using nanotechnologies.

(c) *Evidence review of public attitudes to emerging food technologies*

In September 2008 the Food Standards Agency commissioned a review of existing studies on public attitudes to a range of new technologies in relation to food, including nanotechnologies. This report was published on 26 March 2009 and a copy is attached [not printed] for the Committee's information. The main findings in relation to nanotechnologies and food were summarised on page 7 of our earlier evidence.

21 April 2009

Supplementary memorandum by Department for Innovation, Universities and Skills (DIUS)

This response provides the further information that the Committee asked BIS to provide at the evidence session on 31 March 2009.

Nanotechnologies cut across traditional scientific disciplines and could lead to a very diverse range of potential applications and potential risks, therefore research usually involves inter-disciplinary working and responsibility for risk management is shared across a number of Government departments and agencies.

In February 2008, the Government published a detailed statement that described the range of activities carried out by Government departments and agencies and the Research Councils, and the reasons for those activities. It also described the mechanisms that are in place to coordinate those activities. We have provided copies of the statement to the Committee. While it does not specifically address nanotechnologies in specific sectors such

as food, we hope that it will give the Committee an overview of how the various activities and responsibilities are linked.

The direction of the Government agenda for nanotechnologies was set out in 2005 in response to the report by the Royal Society and Royal Academy of Engineering "Nanoscience and nanotechnologies: opportunities and uncertainties". The Council for Science and Technology review in 2007 found that good progress was being made in certain areas, although there was scope for improvement in others. Subsequently, the Ministerial group on nanotechnologies was established to give a greater profile to the Government's work in this area. The statement was the result of the first meeting of the group. At its most recent meeting the group agreed on the need for an informed debate about the future direction of the development of nanotechnologies, and agreed that a strategy should be developed in dialogue with stakeholders.

On the specific information that DIUS offered to provide to the Committee–

Work taking place to encourage research and development and translation in relation to nanotechnologies in the food sector. (This would include projects such as knowledge transfer networks which are not aimed specifically at the food sector but would impact upon it.)

The Government funds a number of activities to translate the knowledge and ideas generated by fundamental research into new products and services in areas where there are market opportunities through the Technology Strategy Board. It does this in a number of ways, for example Innovation Platforms, Knowledge Transfer Networks, Knowledge Transfer Partnerships and initiatives such as the Small Business Research Initiative.

The joint evidence submitted to the Committee by the Nanotechnology Knowledge Transfer Network and Leatherhead Food International noted that they have formed a Food Focus Group to promote awareness of the potential for nanotechnologies for the food industry.

One of the 24 Micro and Nanotechnology open access centres funded by the Technology Strategy Board, Eminate, focuses its work on state of the art solutions to the food and pharmaceutical industries with the aim of applying in-house process technologies to develop customer products in the areas of advanced coatings, materials and powders, food technology, drug delivery, measurement and scale up through to pilot productions. This is a five year project and the total grant is £3.5 million of which £3 million has been drawn down to date.

Although not specifically addressing food, the Technology Strategy Board is currently preparing strategies for nanoscale technologies and biosciences. For nanoscale technologies there is a focus on linking the pervasive nature of nanoscale technologies to societal challenges of living with environmental change, living with a growing/ageing population, and living in an intelligent connected world. For Biosciences, the focus will be on food technology and food safety.

The Research Councils are not specifically encouraging research in relation to nanotechnologies in the food sector although, as described in their evidence to the Committee, they are funding a large amount of fundamental research in areas that may be of relevance to the development of new technologies and products and to the improved understanding of potential risks.

Details of projects being funded by the Government into the toxicology of nanoparticles in the gut.

The Medical Research Council issued a "highlight notice" in March 2007 to encourage applications in nanotoxicology with the aim to inform policy development. The notice has proved successful in stimulating a significant increase of applications to the Research Boards. Since launch five awards were made at a total level of approximately £3 million. This research aims to better understand the uptake of nanoparticles into cells and the functional consequences including oxidative stress, inflammatory response, cell death and genotoxicity. By linking this information to the physical and chemical characteristics of nanoparticles, predictive models for nanoparticle toxicity can be developed that will help risk assessment. There is currently no agreement on which characteristics should be studied to evaluate the toxicity of nanoparticles and many of the funded studies aim to address this issue. A lot of this work is currently focused on the lung, although some of the principles may be transferable to other organs systems. Building on the current funding and the recommendations in the recent report from the Royal Commission on Environmental Pollution, the Medical Research Council has further refined the highlight notice to encourage in particular studies which investigate the effects of engineered nanoparticles *in vivo*.

More detail on the awarded studies is below:

1) Mechanisms of bioreactivity of engineered nanoparticles with pulmonary gas exchange barrier (Imperial College)—£600k/3yrs
Investigates the toxicity of common nano-particles, such as carbon nanotubes, silver and titanium oxide, when taken up by lung cells. The toxic effects will be related to the physical and chemical properties of the nanoparticles to establish patterns that will allow to predict the health effects engineered nanoparticles.

2) Understanding the genotoxic potential of ultra-fine superparamagnetic iron oxide nanoparticles (University of Wales, Swansea)—£450/3yrs
Studies the genotoxic properties of iron oxide nanoparticles with the aim to develop high-trough-put screening tests for genotoxic effects; Aims to understand dose-response relationships, to inform future in vivo studies and predictive approaches.

3) Defining the biologically effective dose for pro-inflammatory effects of nanoparticles in lung target cells (University of Edinburgh)—£500k/3yrs
Investigates the inflammatory response in lungs following the exposure to commonly used industrial nanoparticles. The potential of these nanoparticles to cause oxidative stress and inflammation will be examined at the cellular level and in animal models to establish and validate better models for predictive testing.

4) Biological consequences of exposure to prosthetic nanoparticles (University of Leeds)—£500k/3yrs
Hip replacements generate nano-sized metal wear particles that are released into the body. The project studies the genotoxic and immunotoxic consequences in animal models over a period of 10 months.

5) Pathway analysis in characterising toxicological properties of nanoparticles (Imperial College)—£550k/3yrs
Uses novel technologies (proteomics, functional genomics) to identify key pathways that are responsible for toxic effects. The aim is to apply these for routine screening purposes in the future.

In addition to these projects the Medical Research Council supports research exploring the potential of dietary nanoparticles for therapeutic use at the MRC Collaborative Centre for Human Nutrition Research in Cambridge. This programme investigates the uptake of dietary nanoparticles in the gut, the toxicity of these particles and their effect on diseases of the digestive tract. Dr Jonathan Powell, the Principal Investigator, has given evidence to the Committee.

The toxicity of wear particles released from hip replacements and the dietary nanoparticles for therapeutic use are studied in the medium to longer term.

Although the focus of research at the National Nanotoxicology Inhalation Research Centre (funded by the Health Protection Agency) is on inhalation, research into the absorption of nanoparticles across the skin is planned and the possibility of studies into gut absorption is being considered. In addition, the Food Standards Agency has recently published a research requirement in the area of the toxicokinetics of nanoparticles, which includes their behaviour in the gut.

Details of how the Government is trying to close the gaps in scientific knowledge required for risk assessment: what programmes are being supported, what money is being spent, and how the Government is measuring progress.

Through the Nanotechnologies Research Coordination Group (NRCG), Defra coordinates the activities of Government departments, their agencies and the Research Councils. The NRCG has published two research reports that provide much of this information and copies of the reports can be found at http://www.defra.gov.uk/environment/nanotech/research/index.htm. A Defra-commissioned report "Emergnano" was published on 15 April 2009 and details how much progress has been made between 2004 and 2008 on NRCG's health, safety and environmental research objectives (http://www.defra.gov.uk/environment/nanotech/research/reports/index.htm#emergano). On the basis of the report, the NRCG will update its research requirements and publish the new requirements.

The Emergnano report looks at global research in this area and identifies gaps that still remain. Globally there is insufficient evidence to be able to say that any of the health, safety and environmental research objectives have been completed. Thus full risk assessments for any nanomaterial are not possible at present.

The OECD and EU are also very active in the area of risk assessment. Defra leads an OECD steering group that is dedicated to identifying best risk assessment methods in the absence of complete data.

DIUS does not retain funds centrally (these are managed by delivery partners) and hence does not directly fund work on risk assessment. However, DIUS does provide support in the following areas

— Progress in the ability to measure and characterise nanoscale materials is essential for both the development and the risk assessment of nanotechnologies. DIUS supports the National

Measurement Programmes across a number of different areas, with a significant sum being spent on nanometrology.

— DIUS provides funding for the fundamental research supported by the Research Councils, who have provided a separate submission to the Committee.

— DIUS funds the Technology Strategy Board. In addition to its support for innovation, the Board part-funds SAFENANO, a free information service run by the Institute of Occupational Medicine to provide companies with a multi-disciplinary range of solutions to ensure that they can offer employees a safe and healthy working environment and products that are safe for consumers.

March 2009

Supplementary memorandum by Department for Environment, Food and Rural Affairs

1. This memorandum sets out Defra's additional written evidence to the inquiry being undertaken by the Committee into nanotechnologies and food, as requested in the letter from the Clerk to the Science and Technology Sub-Committee I of 15 April.

2. Defra officials have spoken with the Clerk of the Committee to clarify the information requested and understand the information below reflects those discussions.

3. The Communication from the European Commission to the European Parliament, the Council and the European Economic and Social Committee on the "Regulatory Aspects of Nanomaterials" accompanies this Memorandum, but as a separate document. [not printed]

I) Details of Recent and Current EHS Research Projects Funded by Defra

Project Title	*Description*
Environmental Nanoscience Initiative programme (Phase 2)	ENI-2 aims to develop an interdisciplinary research programme between the UK and USA to develop models that will support our understanding of environmental exposure, bioavailability, fate and risks of nanomaterials. It is intended that the research will cover a wide range of disciplines including detection and risk analysis. This second phase builds successfully on the first which concentrated on developing UK capacity in nanotechnology research. ENI-2 will utilise synergies and a wider skills base to enhance the value and impact of the programme outputs and ensure a truly multi-disciplinary approach to nanotechnology research. Work is ongoing to finalise the contract with a planned letting date later this year.
An outline scoping study by the Institute of Occupational Medicine to determine whether high aspect ratio nanoparticles (HARN) should raise the same concerns as do asbestos fibres	Concerns about the potential health effects of high aspect ratio nanoparticles (HARN) are based primarily on toxicology studies of industrial fibres including asbestos. The objectives of this study are: i) to undertake a scoping study to review the existing literature on industrial fibres and HARN to determine whether they should raise the same concerns as do asbestos fibres and ii) to set out a research strategy to determine whether health concerns about HARN are well–founded.
A study by the Institute of Occupational Medicine to identify physicochemical factors controlling the capacity of nanoparticles to penetrate cells of the respiratory epithelium, especially those of first contact on inhalation of the particles.	The Cell Pen project investigated the mechanisms of particle movement across the respiratory epithelium to try to establish the resulting possible toxic effects in and beyond the lung. The project advised on i) Identifying which features of nano-particles/tubes/fibres are important in particle-cell interactions, considering the potential role of nanoparticle (NP) chemistry, structure, mass, numbers, shape, surface area, surface charge and surface functionalisation; ii) Suggested how they may be modified to enhance or reduce their capacity to enter cells; and iii) Suggested how interactions between NPs and cultured human cells might be studied.

Project Title	*Description*
EMERGNANO: a review by the Institute of Occupational Medicine of completed and near-completed environment, health & safety research on nanomaterials & nanotechnology	This report was commissioned by Defra as a way of taking stock of the research work on nanotechnologies since the 2004 Royal Society and Royal Academy of Engineering report.[27] The EMERGNANO report has assessed global research undertaken since then and mapped the knowledge gained against the UK NRCG's 19 research objectives. The report identifies where research gaps remain.
Identification of physiochemical factors controlling the capacity of nano-particles to penetrate cells of the respiratory epithelium—A study by Imperial College Consultants Ltd	For some susceptible individuals inhaling high levels of air pollution containing nano-sized particles, may lead them to develop heart and lung problems. This suggests that breathing in very small, nanosized engineered particles might also cause heart and lung problems. This work aims to discover how inhaled engineered nanoparticles reach the delicate air sacs of the lung, and how they interact with the cell barriers that protect us. The research uses human epithelial cells to look at whether the nanoparticles interact with and/or are internalised by the cells, what properties of the particles might make them reactive and what cellular processes are involved.
Research into the likelihood and possible pathways of human exposure via inhalation arising throughout the lifecycle of a selection of commercially available articles containing carbon nanotubes—Central Science Laboratory	This study follows recent research findings from the University of Edinburgh which demonstrated that some types of carbon nanotubes (CNTs) may present health hazards similar to those of asbestos. This further study will collate all available information in regard to potential hazards of CNTs, possible route(s) of exposure, and will use the available data and modelling approaches to estimate the extent of human inhalation exposure to CNTs throughout the lifecycle of some selected CNT products. The information generated will help identify the critical stages within the lifecycle of selected CNT products that may pose risk to human health or the environment.
An evaluation of the UK skills base for toxicologists and ecotoxicologists—Plymouth University	There are concerns about the capacity of the scientific community to respond to current and emerging demands for toxicological and ecotoxicological assessments and whether there are enough scientists working at the bench (toxicologists, chemists, biologists) and experts involved in regulation and policy to support this activity. The aim of this project is to identify the current status of the scientific community, areas of expertise, and identify the gaps in skills, knowledge or recruitment. The analysis will identify whether there are gaps in provision, and areas where investment may be needed in future training and/or recruitment.
Imperial College study to indentify physiochemical factors controlling the capacity of nanoparticles to penetrate cells of the respiratory epithelium, especially those of first contact on inhalation of the particles	An important area of research is to evaluate the mechanisms of action of engineered nanomaterials and one key aspect of the reactivity of nanosubstances is their interaction with cells and membranes. This work aims to determine (a) which combination of factors influence nanoparticle uptake and/or translocation by human alveolar epithelium; (b) the fate/cellular location of internalized nanoparticles and whether particle uptake is active or passive; and (c) whether nanoparticles influence the functional integrity of the alveolar epithelial barrier.
PROSPEcT: UK contribution to the OECD Nanomaterials sponsorship programme	The *PROSPEcT* LINK project is the UK's contribution to the OECD sponsorship programme and aims to undertake a detailed characterisation of two nanomaterials of commercial relevance to the UK—cerium oxide and zinc oxide. The data generated, and test methodologies employed will go a long way towards the ecotoxicological hazard assessment for these nanomaterials. In addition the data generated will be used to help establish QSARs (Quantitative Structure Activity Relationships) for predictive safety evaluations of novel nanomaterials.

[27] 2004 Royal Society and Royal Academy of Engineering Report "Nanoscience and nanotechnologies: opportunities and uncertainties"

Project Title	*Description*
An examination of the nature and application among the nanotechnologies industries of corporate social responsibility in the context of safeguarding the environment and human health—Cardiff University (BRASS)	This research project will attempt to ascertain how much dependence is currently being placed on corporate social responsibility and how effective CSR, as currently employed by the UK nanotechnologies industries and researchers, is in limiting the exposure to public health and environmental risks. The project will also attempt to identify exemplar models of CSR and ascertain where failure by industry stakeholders to adopt a responsible approach is resulting in potential risks to public health and the environment.

II) Comparison Figures on Amounts Spent by the UK, European Union and United States of America, on Nanotechnologies Environmental Health and Safety Research

The recent Defra commissioned EMERGNANO project identified the following levels of expenditure by the UK, EU and USA over the period 2004–08:

	Number of studies	*Amount spent (2004–08)*
UK	44	£3.3m
EU*	114	£63.1m
USA	165	£37m

* includes the UK figure, plus work from Switzerland.

III) Note on Regulations and Authorisation Procedures Governing Fertilisers

There are three tiers of regulatory controls which ensure that all fertilisers for sale in the UK are safe for use. These are set out in two areas of primary fertiliser legislation, namely fertilisers which may be freely sold anywhere in the European Union (EC Fertiliser Regulation 2003/2003), and other fertilisers (The Fertilisers Regulations 1991). The third tier covers Health & Safety regulations which apply to all products manufactured or used in the UK. All manufactured fertilisers (including those containing nanomaterials) are required to comply with all of these regulations and legislation. We are not aware of any current plans for manufactured nanomaterials to be included in fertilisers by manufacturers.

The EC Fertiliser Regulation 2003/2003 defines the composition and definition of all fertilisers, which have been approved as EC Designated fertilisers. All EC Designated fertilisers can be traded freely within the EU. Every importer and manufacturer must ensure any fertiliser intended for sale in the EU complies with this Regulation.

The Fertilisers Regulations 1991 (as amended) specify the labelling and packaging of the product and place a responsibility on the manufacturer to declare the nutrient content of the product. The Regulations include a series of Schedules listing type designations of fertilisers.

Additional controls exist for Ammonium Nitrate (AN) fertilisers and these are set out under the "Ammonium Nitrate Materials (High Nitrogen Content) Safety Regulations 2003". They require that all imports into Great Britain of relevant Ammonium Nitrate material from outside the EU are to be notified to Defra.

Details of the Task Forces and Research Objectives under the Nanotechnology Research Co-Ordination Group (NRCG)

Task Force	Research Objectives (by most relevant Task Force)
1. Metrology, characterisation and standardisation	*RO 2 To identify the most suitable metrics and associated methods for the measurement and characterisation of nanoparticles.* *RO 3 To develop standardised, well-characterised reference nanoparticles.* *RO 4 To understand the properties of nanoparticles in the context of their ignition and explosion potential, and assess/develop methods for evaluating this.* *RO 9 Optimisation, development and application of technologies that enable the measurement of exposure to nanoparticles in soil and water.*

Task Force	Research Objectives (by most relevant Task Force)
2. Exposure, sources, pathways and technologies	*RO 5 Further identification of sources of nanoparticles.* *RO 6 Optimisation and development of technologies that enable the measurement of occupational and environmental exposure to nanoparticles via air.* *RO 7 Understanding the fate and behaviour of nanoparticles in air.* *RO 8 Development of exposure control devices.* *RO 10 Research to understand the environmental fate, behaviour and interaction of nanoparticles in soils and water.*
3. Human health hazard and risk assessment	*RO 11 Research to establish a clear understanding of the adsorption of nanoparticles via the lung, skin and gut and their distribution in the body (ie toxicokinetics), identifying potential target organs/tissues for toxicity assessment.* *RO 12 Research to establish a clear understanding of inter and intra-cellular transport and localisation of nanoparticles and their cellular toxicity.* *RO 13 To establish a clear understanding of whether oxidative stress, inflammatory effects and genotoxicity apply to nanoparticles.* *RO 14 Research to establish a clear understanding of the deposition, distribution, toxicity, pathogenicity and translocation potential and pathways for nanoparticles in the airways and lung and their potential impacts on the cardiovascular system and brain.* *RO 15 Given the current use of nanoparticles in consumer products there is a need to further our understanding of dermal uptake, penetration and toxicity in the skin.* *RO 16 To develop testing strategies for human health hazard assessment and assess how fit for purpose current test methods are as applied to nanoparticles.*
4. Environmental hazard and risk assessment	*RO 17 Research to establish the uptake, toxicity and effects of nanoparticles on groundwater and soil microorganisms, animals and plants, especially in the context of remediation.* *RO 18 Research to establish the mechanisms of toxicity, toxicokinetics and in vivo effects of nanoparticles to key ecological groups (including invertebrates, vertebrates (eg fish) and plants). A key aspect of such work should be the facilitating of knowledge transfer from human toxicological studies to inform ecotoxicology.* *RO 19 Define endpoints to be measured in ecotoxicological studies and assess how fit for purpose current standard tests for persistence, bioaccumulation and toxicity are when considering nanoparticles. This should lead to the defining of a suite of standard PBT protocols for use in environmental hazard assessment.*
5. Social and ethical dimensions of nanotechnologies	*RO 1 To understand the social and ethical implications of nanotechnologies through a programme of public dialogue and social research.*

IV) Details of the Fourteen OECD Sponsorship Nanomaterials

The materials for the sponsorship programme were selected as a representative set of either commercially available, or soon to be available nano materials.

The table[28] below shows the materials and which countries have agreed to work on them.

Sponsorship material	*Lead sponsor*[1]	*Co-sponsor*[2]	*Contributors*[3]
Cerium oxide	UK, USA, BIAC	Australia, Netherlands	Germany, Switzerland, EC
Zinc oxide	UK, BIAC	USA, BIAC	Australia, Canada
Fullerenes (C_{60})	Japan, USA		Denmark, China
SWCNTs	Japan, USA		Canada, France, Germany, EC, China, BIAC
MWCNTs	Japan, USA	Korea, BIAC	Canada, Germany, France, EC, China, BIAC
Silver nanoparticles	Korea, USA	Australia, Canada, Germany, Nordic Council of Ministers	France, EC, China
Iron nanoparticles	China,	BIAC	Canada, USA, Nordic Council of Ministers
Carbon black			Denmark, Germany, USA
Titanium dioxide	France, Germany	Austria, Canada, Korea, Spain, USA, BIAC	Denmark, China
Aluminium oxide			Germany, USA
Silicon dioxide	France, EC	Belgium, Korea, BIAC	Denmark
Polystyrene			Korea
Dendrimers		Spain	USA
Nanoclays			Denmark, USA

Where:

1 = Lead sponsor assumes responsibility for conducting or co-ordinating all of the testing determined to be appropriate and feasible to address the endpoints for Phase 1 of a listed nanomaterial. A Joint lead may be developed depending on the degree of participation committed toward addressing endpoints.

2 = Co-sponsor conducts some of the testing determined to be appropriate and feasible to address the endpoints of Phase 1 for a specific listed nanomaterial.

3 = A contributor provides test data, reference or testing materials or other relevant information to the lead and co-sponsors.

March 2009

[28] The most recent table as provided by the OECD Working Party on Nanomaterials, December 2008.

TUESDAY 21 APRIL 2009

Present	Crickhowell, L.	Methuen, L.
	Cunningham of Felling, L.	Neuberger, B.
	Haskel, L.	O'Neill of Bengarve, B.
	Krebs, L. (Chairman)	O'Neill of Clackmannan, L.
	May of Oxford, L.	Selborne, E.

Memorandum by Leatherhead Food International

BACKGROUND

Leatherhead Food International (LFI) is proudly independent and has been providing solutions and services to the food and drink industry since 1919.

LFI is renowned for its comprehensive Global Food Regulation services, applied Food Safety Research, Nutrition and Food Innovation expertise. These technical areas are complemented by a wide range of Knowledge services including publications, training, consultancy, market research, conferences, and online databases.

LFI clients use our services and solutions to ensure their businesses, from dynamic start-ups and SMEs through to the largest multinationals, can meet the challenges of today's ever changing market place. The client list includes the major global companies in the food industry as well as ingredient suppliers, manufacturers, retailers and foodservice businesses.

As part of the need to provide cutting edge information and research, LFI has started a working group called NanoWatch. This group is composed of food and drink companies who wish to understand the potential benefits and concerns of new technologies. In addition, in collaboration with the nanotechnology Knowledge Transfer Network (NanoKTN) LFI has formed a food focus group. This group will enable the industry to have a voice on research funding, regulation and other developments that could impact on the industry.

STATE OF THE SCIENCE AND ITS CURRENT USE IN THE FOOD SECTOR

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

Currently the main applications and benefits for nanotechnologies and nanomaterials in the food sector are in packaging and in the addition of nutraceuticals or vitamins to foods. Examples for the packaging sector include the addition of antimicrobial coatings to packaging matrices to reduce bacterial contamination/growth and the addition of specific additives to the packaging matrices to improve resistance to oxygen permeability and preserve freshness of the product. With respect to the addition of nutraceuticals to foods, examples include nano-/microencapsulation (the formation of very small capsules around the nutraceutical) to preserve them from oxidation. Furthermore, research is published indicating that nanoscale nutraceuticals have increased effectiveness because of their small sizes and increased surface areas.

Nanomaterials are being used to coat surfaces of buildings, windows, electronics, appliances (such as washing machines and refrigerators), personal clothing etc, In the main, the use of these has not transferred to the food industry, however the potential benefits are great. For example, it is likely that as well as preventing bacterial contamination on food surfaces in food preparation areas, the use of inert non-sticky nano-materials on machinery could also be used to prevent fouling of food processing machinery. This would reduce the frequency of cleaning the machinery and not only result in greater efficiency of the process and energy usage but also reduce the amount of detergent needed for cleaning.

The potential applications are extensive. Some examples are:

— Development of smart sensors. These could be used in packaging to alert the retailer or customer when the contents are not safe to eat.

— Development of smart sensors for food analysis. Very rapid detection of the presence of food poisoning bacteria or viruses would be extremely beneficial. Additionally many products are analysed for nutritional content, and these are done by traditional laboratory analyses. Smart lab-on-a-chip

or lab-on-a-foil sets are being developed which could increase the speed and accuracy of analysis and cut the cost.

— Development of smart filters that could selectively remove allergenic ingredients from foods while they are being manufactured. This would be very beneficial for removing trace amounts of peanut or similar allergenic material.

— Development of technologies that allow the formation of nanoscale emulsions. The properties of these are not known but could include higher stability of the emulsions, reducing or eliminating the need for the addition of emulsifiers. This would contribute greatly to "cleaner-label" foods by reducing additives. In addition, complex multiple emulsions could be made which would allow a fat reduction in foods whilst keeping the popular creamy sensory mouthfeel that consumers like.

— Manipulation of the size and structure of ingredients to increase their functional properties. Examples of this include making smaller crystals of salt that would have a higher salty taste allowing a salt reduction in foods which would be a healthy benefit for the consumer. Other examples could include an increase in thickening or gelling ability of the hydrocolloids/thickening agents, or in emulsifying ability of hydrocolloids/emulsifiers, reducing the need for several chemical additives to stabilise a food product

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

Cientifica predicted that the value of the nanotechnology applications in the food industry would rise from $410 million in 2006 to £5.8 billion in 2012. Currently, the technology and applications are mainly in the packaging and food contact materials sectors, but potentially the whole of the food & drink industry and market would benefit from the very diverse materials and technologies being developed.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

In the area of nanotechnologies, ultra high mixing technologies are likely to be implemented in the next few years. In food products these are likely to be applied to emulsions in the first instance and then to other ingredients and products. In the area of nanomaterials, coatings such as the glass-like nano coatings will be applied to food preparation surfaces to minimise bacterial contamination, to interior surfaces of fridges, microwaves, cookers and also to food contact machinery in manufacturing processes. They will probably reduce the amount of "downtime" due to cleaning needed and therefore reduce water wastage, energy costs and level of detergents used. It is likely that application of these will grow rapidly in the next five years. In addition, self-assembly technology to create functional nanomaterials will be of significant interest for the food and drink industry.

Beyond this there will be developments in the chemical and microbiological analyses based on nanotechnology and nano materials that will make for faster and better detection of contaminants. There will also be applications in structuring of food products to make healthier ingredients and products.

As the pharmaceutical industry is very active in nanotechnology applications; an overview and transfer of the technologies adopted for the production of pharmaceutical products across to the food industry would be essential.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

There is very little research and development in the UK regarding nanotechnology within the food and drink industry. In spite of enormous interest from the food & drink industry in the potential, very little is known about what is out there, what is feasible, what is safe and how it might be applied. The industry needs independently-reviewed knowledge and expertise that can be transferred to food product development, along with a scientific approach to be able to see the potentials. To achieve this, Leatherhead Food International has formed a NanoWatch Working Group to inform members of the group on new developments and also to carry out small proof-of-principle trials. In addition, Leatherhead is in collaboration with the Nanotechnology Knowledge Transfer Network (nanoKTN), having formed a Food Focus Group to promote awareness of the

potential for these emerging technologies and materials for the food industry and to encourage the industry to make their voice heard.

The main developments are being carried out outside the UK in countries (such as USA, Japan, India) that see the potential benefits to the industry and are being actively encouraged to develop further.

What are the barriers to the development of new nano-products or processes in the food sector?

- Possible confusion over nanotechnologies and nanomaterials.
- Legislation on safety/novel foods that would impose unviable costs and delays to development.
- Lack of knowledge on developments in the non-food areas and in transference of such knowledge to the food & drink industry.
- Lack of funding for research into the potential benefits for the food & drink industry and Consumer.
- Lack of funding for research into the safety/toxicology of nanomaterials in food & drink industry
- Fear of consumer backlash driven by the media spotlight on "Franckenfoods"—this in turn is driven by a lack of consumer understanding on how foods are manufactured, why they are made the way they are, and what the industry is trying to achieve.
- Lack of funds for education of the public in relation to nanotechnology in foods

Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?

The scientific understanding is very limited and confused by various experiments that do not apply to foods; an example is the direct treatment of cells or animals with selected nano particles especially those unlikely to be used in the food industry applications. Specific research within the specific food & drink model systems is essential.

Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?

There needs to be a clear distinction between nano particles naturally and currently present in foods (this will include ones made during manufacture), and those that are not normally expected such as the persistent materials. The development and use of nanotechnologies that restructure accepted current ingredients also is unlikely to need safety or toxicology testing.

There needs to be more funding in certain areas but this should go hand in hand with the development of the technology in foods.

Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

In some cases current frameworks are thought to be sufficient. However further research within specific food & drink model systems is required for assessment of the risk of exposure to materials not normally used in food and drinks.

Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?

It is unnecessary to treat naturally present nano materials or particles in the same way as certain manufactured materials. It is important to recognise that natural ingredients in foods are already subjected to processes that create nanoparticles. These have been eaten and considered as safe for a long time. A common sense approach is needed and the realisation that elimination of total risk is not possible.

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

It has been acknowledged by the Food Standards Agency in its regulatory review report on potential implications of nanotechnologies for regulations and risk assessment in relation to food[1] (August 2008) that the existing European/UK legislative framework is broadly adequate to cover potential risks of nanotechnology-based products.

Under general food law, "unsafe food" (as defined in Article 14, Regulation (EC) 178/2002 on general food law) cannot be placed on the market.

Additionally, new food ingredients and agents used in food and feed manufacture and processing marketed in the European Union (EU) must be subject to a pre-market safety assessment. These include:

— novel foods and novel food processes,

— food additives,

— flavourings, and

— food packaging materials.

It is anticipated that the engineered nanomaterials in food will fall into one of these categories and would therefore require a pre-market approval before being placed on the European/UK market.

These procedures involve the submission of dossier to the Commission or an EU Member States by the company asking for approval of the placing on the EU market of its new food ingredient or agent. Compositional, production and safety data must be provided in this dossier, as required by the Commission.

Any imported nanomaterials engineered using nanotechnologies will have to comply wit EU law and be subject to the EU approval procedures mentioned above.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

According to EU/UK food law, it is the responsibility of a food manufacturer to ensure that its food products are safe for human consumption and have been submitted to the relevant EU approval procedures, when these apply.

In terms of voluntary reporting on the use of nanotechnologies, in the UK, Defra has set up a voluntary reporting scheme. After a two year trial, they have received a very low response from the Industry and this may reflect the very limited use of nanotechnologies by the UK/EU food industry.

According to UK government officials from the Food Standards Agency, the food industry claims not to use nanomaterials.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

Yes, as aforementioned, the current European/UK legislative framework is adequate to cover potential risks of nanotechnology-based products. Moreover, although nanotechnologies is not specifically mentioned in current food-related legislative texts, the new regulation on food additives published in December 2008 and the proposal for a new novel food regulation which may be adopted by 2010 both refer to nanotechnologies for their pre-market approval requirements.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

The European Commission has set up an international co-operation program in order to develop a common strategy on nanotechnologies with specific countries or regions around the world.[2] The Commission intends to develop with Member States, international organisations, European agencies, industry and other stakeholders, terminology, guidelines, models and standards for risk assessment throughout the whole life-cycle of nanosciences and nanotechnologies products. It also aims at looking at current risk assessment and management procedures to verify if they are adapted for ensuring a high level of consumer/environment protection.

[1] See at: http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf
[2] See at: http://cordis.europa.eu/nanotechnology/home.html

In terms of regulatory systems in other parts of the world, the EU regulatory framework can be compared to the ones in the USA and Japan.

In the USA, like in the EU, there are currently no special regulations for the application or utilisation of nanotechnology in foods. The US Food and Drug Administration (FDA) states that it regulates "products, not technologies," and anticipates that many products of nanotechnology will fall under the jurisdiction of multiple centers within FDA and will therefore be regulated by the Office of Combination Products. As in the EU, any new materials sold in the USA, regardless of the technology used to create them, must be subject to the standard battery of safety tests. Therefore, like in the EU, any new nanomaterials will undergo a pre-market safety assessment. The difference with the EU is that some US States have decided to enact laws on nanotechnologies that are more stringent than federal laws. For example, Bekerley, CA adopted a municipal ordinance on nanotechnology in December 2006 to impose reporting obligation on facilities that manufacture or use manufactured nanoparticles. Cambridge MA, city council recently declined to adopt an ordinance regulating nanomaterials, but agreed to take numerous steps, including developing an inventory of commercial, industrial and research facilities in the city that manufacturer, process, handle or store engineered nanoscale materials.

In Japan, no provisions are laid down specifically on nanotechnology in their current legislation. They have like in the EC, legislative requirements on ensuring that that food sold on their market in safe for human consumption and this would apply to nanomaterials. The Japanese government is not currently intending to set up committees or workshops to discuss nanotechnologies and food safety. Although a network is being developed for European researchers in Japan (ERA-Link/Japan), via the Commission international co-operation program on naotechnologies. In 2002, the Japanese government emphasised in its Biotechnology Strategy guidelines that nanotechnology along with biotechnology and IT can be used as a tool to achieve developments in medical science, food safety, agriculture and the environment.

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

From studies on consumer acceptance, there appears to be a lack of knowledge of nanotechnology generally, but those who do know something about it are more prepared to accept it if they see a benefit to themselves or society.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

It is not known how effective they have been. A survey is currently being undertaken by BRASS at Cardiff University on the importance of company responsibility in considering safety issue in research. It is unlikely that the food industry will engage with this to any extent. A series of educational days would be useful for the public

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

The lack of any obvious benefit to the consumer leads to a refusal to accept GM foods. The benefits from nanotechnology need to be understood and clearly communicated to the public

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

The information could involve lengthy technical data in order to avoid over simplification. Yes the consumer should know but not necessarily on the label. Regulations on the information need to be considered together with education on the technology

Additional Comments

It is of concern that any specific legislation will increase consumer concerns on nanotechnology and demonise it. The food industry is careful to ensure that foods are safely produced and current legislation requires ingredients, foods and food packaging to be safe for the public. In the main, nanotechnology is a new tool for the industry to produce safe foods but with added benefits.

March 2009

Memorandum by the Institute of Food Research

Summary

The UK has played a leading role in the understanding of the functionality of foods at the molecular level. The major barrier to the use of knowledge to rationally manipulate natural nanostructures in foods to design novel "functional" foods is the technological challenges of producing acceptable commercial products, clearing them as novel foods and substantiating health claims for such products. For manufactured nanoparticles based on materials that are metabolised within the body, there is a need to establish whether the nanostructures adversely affect metabolism and to demonstrate benefits from improved bioavailability. In the case of products that could lead to deliberate or incidental ingestion of non-metabolisable nanoparticles there are major barriers concerned with lack of knowledge on release, uptake, retention within the body and potential toxicity, which make assessment of risk and safety difficult at present. It is important that the initial products that emerge have tangible benefits.

If food-approved materials are to be adequately labelled then there may need to be a basis for discriminating between the native material and the nanoform. Current regulations within the UK and EU would be adequate for controlling future nanoproducts related to food or food contact materials produced or sold within the UK or EU. However, without agreed standards worldwide, regulation of imported products, either at a national or personal level may become increasingly difficult.

Nanotechnology will impact the whole food chain and there needs to be coordination between government bodies and funding agencies on research.

State of the Science and its Current Use in the Food Sector

1. Nanotechnology offers potential solutions to excessive food waste through improved protection against food spoilage and improved shelf-life on storage; improved microbial safety of food products through anti-microbial packaging and food contact materials; improved authenticity and security through smart packaging and radio frequency identification technology; the development of novel functional foods with enhanced nutritional value; the design of foods to combat problems such as obesity and associated long-term chronic disease, to promote good health and protect against disease—with the potential to tailor such systems to personal needs (genetic pre-dispositions) and lifestyle.

2. If nanoscience of foods is understood to mean an understanding of the functionality of foods at the molecular level then the UK has played a leading role in this area particularly through work at the Unilever Research Laboratories, the University of Leeds, the University of Nottingham and IFR. The use of nanoscience tools such as probe microscopy has enhanced this understanding. The current need to design foods to combat obesity and associated diseases is building on this knowledge to rationally manipulate naturally occurring nanomaterials and nanostructures in foods to tackle these problems. To our knowledge there are no food-approved food products in the UK which contain added nanoparticles. Such products are available world-wide and appear to be mainly targeted to additives that improve the nutritional properties of foods (nanoceuticals) or applications designed to enhance food safety through use of anti-microbial coatings (usually nanosilver) on packaging, containers, surfaces or devices such as refrigerators, utensils etc. Some of the anti-microbial products may be available within the UK.

3. We believe that functional foods designed to improve the bioavailability of nutrients could be on the market almost immediately, subject to regulatory approval and public acceptance. The "next generation", foods designed to combat problems such as obesity could be available within five years and in the longer term there are opportunities to design foods to provide targeted protection against chronic disease and to promote good health through into old age.

4. The UK has played a leading role world-wide in developing a nanoscience understanding of food structure and materials which can underpin the development and design of novel foods. There are relevant studies on the uptake and toxicology of nanoparticles that can be of relevance to the food sector. However, there is restricted research on the ingestion of nanoparticles within a food matrix which will influence uptake and retention within the body. Although there is funding for research on the release of nanoparticles from surfaces into the environment and the consequences of their anti-microbial action, there is less opportunity to fund research on the consequences of release and uptake within foods and effects on natural human microbial flora.

5. The major barrier to the use of knowledge to rationally manipulate natural nanostructures in foods to design novel "functional" foods is the technological challenges of producing acceptable commercial products, clearing them as novel foods and substantiating health claims for such products. Additional barriers to the

use of foods or food contact materials containing manufactured nanoparticles would depend on the nature of the nanoparticles concerned. For nanoparticles based on materials that are metabolised within the body there would be a need to establish whether the nanostructures adversely affects metabolism and to demonstrate benefits from improved bioavailability. In the case of products that could lead to deliberate or incidental ingestion of non-metabolisable nanoparticles there are major barriers concerned with lack of knowledge on release, uptake, retention within the body and potential toxicity, which make assessment of risk and safety difficult at present. Such products would be perceived as "nanofoods" and public perception with respect to benefits and risks could be a barrier to their use and development.

Health and Safety

6. Scientific knowledge related to the rational manipulation of naturally occurring nanostructures, or the use of metabolisable nanocarriers for encapsulation, is sufficiently advanced to assess the risks and safety of novel foods based on such technology. There is a gap in knowledge on the ingestion of non-metabolisable nanoparticles from complex food matrices and the consequences of such ingestion on uptake, storage and the long-term potential risks due to such accumulation within the body. There is a need for specialised, directed research on the interplay between food matrices and nanoparticles, both in terms of the release and uptake of the nanoparticles themselves, and also of the consequences of the adsorption of biologically-active materials released from food, such as peptides, oligosaccharides, etc, and their subsequent uptake and transport within the body. Generic information on the role and mechanisms of the action of nanoparticles as anti-microbials for aerobic microorganisms may not be of relevance to the behaviour of the anaerobic populations of microorganisms within the gut.

7. We believe that the distinction between environmental and food-related issues mean that there is a disproportionate level of funding in the environmental area. Nanotechnology will impact the whole food chain and there needs to be coordination between government bodies and funding agencies on research. For example the use of nanotechnology in the delivery of pesticides, insecticides, fertilisers and nutrients requires information on both their inhalation, and on ingestion through contamination of foods, in order to evaluate their safety and application. It is a food as well as an environmental issue and the research should be coordinated, although funded through different sources. Similarly the release of nanoparticles from packages or containers is a food issue related to uptake and acceptable daily intake values, particularly for edible coatings, but also an environmental issue related to disposal of coated raw materials and packaging, particularly for biodisposable packaging. Such research needs to be coordinated and may be very important in ultimately influencing consumer reactions to nanotechnology and food.

8. We believe that current risk assessment frameworks within the food sector are adequate: it is a lack of knowledge in some areas rather than a lack of adequate procedures.

9. We believe that the naturally occurring nanoparticles in foods such as proteins, carbohydrates or fats are safe because they have undergone stringent testing and assessment appropriate to the materials. Some plant proteins are NOT inherently safe—materials such as ricin and certain allergens are potentially very dangerous, but adequate procedures are in place for risk assessment and clearance of novel foods. For nanoceuticals based on metabolisable materials there may be additional risks associated with enhanced bioavailability and overconsumption, rather than optimum consumption of nutrients or additives, and also potential consequences of changes in the sites of metabolism and nature of the metabolic products. For non-metabolisable nanoparticles the risks are currently indeterminate because of the lack of adequate information on uptake, storage and long-term potential toxicity.

Regulatory Framework

10. The current regulatory framework is basically fit for purpose, certainly with regard to the safety of foods, based on the onus within European law on producers to ensure that food and food contact materials are safe. Hence they are liable to ensure adequate clearance of foods or food contact materials based on nanotechnology through the appropriate regulatory bodies. However, there are concerns which may influence public perception regarding regulations on the labelling of foods and food contact materials. If food-approved materials are to be adequately labelled then there may need to be a basis for discriminating between the native material and the nanoform, possibly through modified E numbers, where there are differences in safety aspects and ADIs for the two materials. Currently there would appear to be no requirement to label food contact materials as containing nanoparticles. This may have an adverse affect on consumers who may feel that they are being denied information and choice even where the concerns are largely with disposal rather than the safety of the product in a food context. A major problem with imported materials is that "Nano®" is used as brand name and has no meaning in terms of the health and safety claims for the product. In addition the use of the term Nano is voluntary and products containing nanomaterials may not be labelled. This makes

assessment of products at a personal and national level difficult particularly because the countries of origin for the products may have very different criteria for assessment. It would be better if there was universal agreement on standards and a branding that signified quality and safety.

11. Although there are published codes of practice it is difficult to assess how well they are followed. A general observation might be that voluntary self-regulation is often open to abuse. In this case one bad product could easily lead to a strong public backlash against nanotechnology in food, particularly if consumers felt they were being misled, deceived or exploited.

12. Current regulations within the UK and EU would be adequate for controlling future nanoproducts related to food or food contact materials produced or sold within the UK or EU. However, without agreed standards worldwide it is possible that regulation of imported products, either at a national or personal level may become increasingly difficult. For example, in terms of imports there could be potential problems with novel applications such as edible coatings on fruits and vegetables: if such coatings containing nanoparticles were made and used on imported materials to reduce microbial spoilage then it is difficult to see how this could be detected or regulated.

13. IFR's understanding is that there is inter-Government co-operation within the EU and exchange of information between certain Governments. The lack of agreed standards is a major problem with potential imports and for individual consumers purchasing materials through the internet. The main lesson to be learned from the different regulatory systems world-wide is the need for such systems to be timely and correct, thus not stifling commercial development of products, but equally not inflaming public disquiet or mistrust about nanotechnology.

Public Engagement and Consumer Information

14. Purely from involvement with workshops and meetings concerned with nanotechnology and food, IFR's impression is that there is a general awareness of nanotechnology and an awareness of its potential use in food. A general question asked seems to be "are nanotechnology applications in food safe?" The difficulty is that such a generic question is difficult to answer because the risks and safety aspects depend on the product or application and need to be assessed for individual cases. The answer that there are procedures in place to ensure the safety of the use of nanotechnology in the food area in the UK is not entirely convincing because there does appear to be an underlying mistrust of the Government and industry in issues of this type.

15. Having taken part in public engagement activity we believe that Government, certain industries and stakeholders have made good efforts to engage and inform the public about nanotechnology and food. However, the coverage in the media, with notable exceptions, is often negative, less balanced or informative, but probably reaches a wider audience. Wider publicity could be given to the general problems that face the food and agricultural industries which could be tackled using nanotechnology.

16. The most interesting lessons that can be learned from other technologies are from what happened in the initial debate on the use of GM technology. The public wishes to have the right to choose based on information on benefits and risks. It is important that the initial products that emerge have tangible benefits, and are not trivial or seen to have shallow commercial benefits for a restricted group of multinationals.

17. The ability to exercise choice is very important to the public and raises the issue of labelling. Many applications of nanoscience or nanotechnology in food need not be labelled or called nanofoods. However, there are some areas where labelling could be important. Where approved food ingredients or additives have been reduced in size to alter and improve their function, and there are differences in the safety data and recommended intake levels, then there is a need to discriminate between the two forms in the use of labelling. Use of conventional E numbers or named materials may not be sufficient on labels if safety data and ADIs are different for the two forms. The use of nanoparticles in foods or food contact materials which are not metabolised in the body should require labelling to allow consumers to exercise choice in the purchase and use of these materials. Even if the food contact products are shown not to contaminate foods and the foods to be safe on ingestion then consumers may have concerns relating to the disposal of waste material such as packaging and the consequent environmental effects.

Other Aspects

18. Although touched upon in some of the answers to some of the above questions we believe that there are wider issues that affect the use of nanotechnology related to food and that these issues are also important to the public perception of the use of nanotechnology in the food sector.

19. Nanotechnology will impact across the whole food chain. "Smart" farms and "smart" delivery systems offer routes to improving agricultural yields, responding to local climatic variations and reducing the use of pesticides, insecticides and fertilisers. Selective and targeted use of chemicals, through sensing environmental

variations locally, or sensing chemical signals related to pests, or plant wound responses, offer routes to reduced use of chemicals in farming. Some of the advantages of nanoencapsulation and delivery could be offset by problems related to contamination of crops, soils and streams, or problems associated with the detection of contaminants on food materials, possible new routes of uptake, distribution and bioaccumulation within the body, and the subsequent long-term effects of such accumulation Thus it is not just the advantages to agricultural production weighed against environmental factors that need to be considered but also the downstream effects in the food sector. Given that funding is these areas is often through different agencies there is a need to ensure adequate and co-ordinated funding covering all aspects.

20. Another aspect that will impact on the food sector, but not directly related to food or food contact materials, is the use of GPS and RFI technologies in the tracking of food and food materials from source through transport and storage to shops and distribution centres. Coupled with smart packaging this could improve authentication of foods, inhibit or allow more rapid identification of food contamination or adulteration, and reduce waste.

21. At the far end of the chain there is the ultimate disposal of waste material. This raises questions about the fate of packaging and food contact material containing manufactured nanoparticles, particularly if such technology is used in conjunction with biodisposable packaging. The containment of anti-microbial nanoparticles within matrices may answer the questions raised about accidental release of these particles into foods. However, the question remains as to the fate of these nanoparticles on disposal of these food contact materials and the consequences for the environment. The contamination of rivers or streams could ultimately lead to the re-introduction of these materials back into the food chain but in a different, perhaps more easily ingested form. Again, different agencies deal with the funding of research and with the regulation of food and environmental issues. Different agencies can be reactive or proactive in their approaches and this can lead to disproportionate levels of funding, gaps in knowledge and different approaches to regulation. There needs to be a way of co-ordinating activities to ensure that regulation and decisions on the use of nanotechnologies in food and agriculture are based on knowledge of the long-term effects of these products. IFR hopes that the Ministerial Group on Nanotechnologies (led by the Minister of State, DIUS) will provide a catalyst for action.

22. In terms of public opinion, portrayal of the wider benefits of nanotechnology in both food and agriculture, and the demonstration of a co-ordinated approach to assessing risks across the whole food chain, would counter some of the negative media rhetoric directed to applications directly related to food.

11 March 2009

Examination of Witnesses

Witnesses: Ms Kathy Groves, Leatherhead Food International, Dr Vic Morris, Institute of Food Research, Dr Paul Butler, Packaging Materials and Technologies Limited, and Dr Frans Kampers, Wageningen, BioNT, examined.

Q86 ***Chairman:*** I would like to welcome our four witnesses. Thank you very much for coming to join us for this second public hearing in our inquiry into nanotechnologies and food. We are very grateful to you for sparing the time to come and answer some questions and hopefully enlighten us on this important and interesting topic. I should inform you that proceedings of this hearing are webcast, so are available to the public. I should also draw attention to the information note which is available to those members of the public who are here in the audience and that note sets out the declared interests of members of this Select Committee so we do not need to repeat those during the questioning. When we start in just a second I would like to invite the four witnesses to introduce themselves for the record, but also if you wish to make any form of opening statement describing your views about the issues then you are very welcome to do so, otherwise we will move straight on to the questions. Perhaps I could ask Kathy Groves to kick off and introduce herself and then move along the row.

Ms Groves: Good morning. I am Kathy Groves. I am the principal microscopist at Leatherhead Food International.

Professor Morris: I am Vic Morris. I work at the Institute of Food Research in Norwich, which is a BBSRC institute, and I am interested in nanoscience techniques to look at food structure.

Dr Butler: I am Paul Butler. I run a consultancy company advising packaging converters and retailers on the latest advances in packaging materials and technologies, including nanotechnology.

Dr Kampers: My name is Frans Kampers. First of all I would like to thank you for inviting me to this prestigious committee. I am from the Netherlands, from Wageningen UR. One half is the university and the other half is a contract research organisation. I co-ordinate the bionanotechnology research at Wageningen, so I head a virtual institute called BioNT within Wageningen UR, and our main focus is on the applications of nanotechnology in food. Various groups within Wageningen UR work on food, applications in food, sensors, processing

improvement and things like that. That is my interest in this.

Q87 ***Chairman:*** Thank you very much. Would any of you like to make any further statement before we start? Let us move straight on to the questioning. I would like to kick off with a very general question to all of you. We are obviously interested both in the potential of nanotechnology in the food industry in the future and also on the regulatory side of that whether there is any need for additional regulations and what the uncertainties are in risk assessment. I wonder if we could start off by seeking your views on what you think the potential benefits of nanotechnologies and nanomaterials are to the food industry and, of course, to consumers of food?
Professor Morris: There are four areas I would think of. One is the reduction of waste in the food chain; safer foods, particularly anti-microbial effects; healthier foods, you can design food structures to try and prevent and slow the progression of diseases and you can also design foods to combat things like obesity and build effects into foods that would control hormonal responses that control the amount people eat; and there are new commercial opportunities, particularly with small firms, in the nano area.
Ms Groves: That sums up a lot of them. An added one is the advantages of nanomaterials in the food processing and manufacturing side, either anti-microbial surfaces or anti-stick surfaces that would stop machinery clogging up and reduce the downtime for cleaning.
Dr Butler: My background is packaging so I will just address the food packaging side of things. In food packaging, one of the major problems we have in all the developing countries is food waste. This is consumer food waste from the home. I think nanotechnology could help in terms of producing packaging that is more communicative and informative to the consumer. For example, a consumer would have a much better idea of whether the food was safe to eat or had to be discarded. At the moment we have some very ineffectual date coding systems on food and a lot of food is thrown away that is perfectly healthy and still suitable to eat. Nanotechnology as an enabling technology could help with what is known as smarter packaging or intelligent packaging.
Dr Kampers: I would like to place the question into the larger perspective of challenges for mankind basically. We have a growing world population and increasingly people want to have more protein in their diet but we know at the moment that is impossible to produce in the way that we produce it now. Since meat is a nanostructured material that has a structural hierarchy from the nano level up, you can understand that if you want to have replacements for meat in a more sustainable production way then we will need to look at how we recreate the structural hierarchy from the nano level up, so you start with nanotechnology in these areas. Another big challenge for mankind is keeping the health system economically viable. The curative healthcare system that we have nowadays will not be sustainable in the long run because it is too costly. We believe that with a paradigm shift towards preventive healthcare we can both help individuals remain healthy and also keep the system within economic boundaries. Food is a very important component of that preventive healthcare system paradigm. We believe that nanotechnology can add to that system. Mind you, if everybody ate 200 grams of vegetables a day and two pieces of fruit a day in a varied diet nobody would need any technology to stay healthy. We very rarely do that, so the food industry is looking at technologies to help individuals get the nutrients that they need to stay healthy and in that way we hope to reduce some of the costs of the healthcare system. These are basically large challenges to mankind in which we believe nanotechnology can play a role as an enabling technology.

Q88 ***Chairman:*** Thank you for those helpful responses. In the work we have done so far and the literature we have read we understand that nanotechnology may mean different things to different people, so we deliberately entitled our inquiry "nanotechnologies" rather than "nanotechnology". I wonder whether any of you would like to comment on distinctions that you might see amongst different nanotechnologies that could be usefully drawn in terms of the food sector and what the functional indications of those differences might be.
Professor Morris: I think an area where there is a big difference is in talking about nanotechnology we are talking about natural structures and materials which are manufactured which are not broken down in the body and that is an area where possibly the risk benefit analysis is harder to assess because of a lack of knowledge in those areas.

Q89 ***Chairman:*** So natural versus persistence?
Professor Morris: Particularly in manufactured materials that are not broken down in the body and so are likely to persist in the body and we do not know the consequences of that. I think that is an area that attracts too much public concern, particularly because there seems to be a reluctance to label materials or you have labelling over the Internet which is not regulated and there seems to be a reluctance in the UK to want to label packaging or these non-metabolisable materials put into food and people might feel, therefore, they have not got a choice in assessing the

risks themselves either in what they buy on the Internet or what they might buy in the UK.

Dr Butler: My own view on nanotechnology is that obviously it is everyone's favourite prefix—we have got the Nano iPod and everything like that—so it has become a bit of marketing hype. My own view is that nanotechnology only gets really interesting—and I know you do not want to get sucked into what size is nanotechnology and what size is not—when you have property changes which you do not normally have. I grew up with my Periodic Table of 92 elements and I was quite happy with all their physical properties. Nanotechnology gets very interesting when you get down to the 20–50 nanometre size and all kinds of unusual properties are now generated by these so-called bulk materials. It is like a material scientist who is given a whole new palette of materials, strange elements with unusual properties. I did metallurgy at university and with something like silver, silver melts at 960°C and it does until it gets tiny, tiny, tiny and then you can melt it with a hairdryer. These are dramatic changes in properties that could have huge effects in terms of aerospace and medicine. Packaging and agri-food just happens to be one of the many applications of nanotechnology, but to me true nano is when the quantum effects kick in and you get these dramatic changes and the material just does not behave like it ought to behave and then you can do some really, really interesting things with it.

Dr Kampers: It is really from what perspective you look at nanotechnology. If you look from the opportunities perspective then you look at the quantum effects that allow you to create new functionality that we have not been able to create before. The various applications in all sorts of application areas benefit from these new properties and arise from quantum mechanics basically and from the fact that you have a lot of surface versus volume ratio. If you look at it from the benefit side, we have all sorts of different applications for nanotechnology in food which ranges from sensors that have very little to do with the food itself and packaging materials that come into contact with food, but also applications that go into the food that are intended to be eaten. There are very many sorts of nanotechnology in the application area of food. If you look from the perspective of risk and risk assessment then you have to look at what classes of nanotechnology could pose risks and toxicologists agree that the persistent nanoparticles, especially those that are non-biologically degradable, in-organic, the inorganic metal oxides and metals, are the particles that pose most risk. There we start to look at what sorts of properties determine that risk and that is an area we know very little of yet, especially if you ingest the particles. This is an area that still needs to be assessed, but it is only a very, very small part of all the applications of nanotechnology in food. For me, it is a pity that everybody focuses on that specific area. I know risk is something that concerns us all but, on the other hand, the benefits may be tremendous and outweigh the risks to a very large extent.

Q90 ***Lord Cunningham of Felling:*** I just wondered whether very briefly each of you could say what you think the public reaction would be to manufactured nanoparticles in food, given that, for example, there is still something of a debate going on about putting fluoride ions in the drinking water even though the evidence in terms of dental health is pretty overwhelming. What do you think would be the prospect of persuading people that it is in all our interests to have nanoparticles in the food chain?

Dr Kampers: Are you referring to inorganic nanoparticles, the persistent nanoparticles?

Q91 ***Lord Cunningham of Felling:*** Any kind. I said manufactured nanoparticles.

Dr Kampers: The most important area of application in food probably is not nanoparticles but in delivery systems. These are larger systems so they usually are not seen as nanoparticles. They are nanotechnology because the nanotechnology is in the wall of the particle, but it is not a nanoparticle per se since it is much larger than 100 nanometres, although you would like to include that as well. I think you have to explain to the general public what the benefit for the individual consumer is, like there is a product that delivers oil to the small intestine and it makes sure that the oil does not come free in the stomach, in the mouth or anything, it is delivered to the small intestine, and the idea is it triggers the small intestine to give a signal to your brain that you are saturated basically and is a way of convincing your body that you have eaten enough. This is a product that when you use it is supposed to make sure that you stop eating sooner than you would have done if you had not had this product. Obviously the product falls apart in your gastrointestinal tract so there is nothing left of the nanotechnology except molecules, of course, but these are all harmless molecules, they are food grade molecules. If you have story like that—

Q92 ***Lord Cunningham of Felling:*** Excuse me, I think fluoride ions are pretty harmless too myself but that has not persuaded the public to universally accept it. The question is not really about the efficacy or otherwise of the technology in scientific or nutritional terms, it is the public acceptance.

Ms Groves: Your answer would be in how you asked the question. It depends on how you ask the question. If you say, "How do you feel about the food industry putting nanoparticles in your food" then I think you would probably get a big response saying, "I'm not keen on that at all", but if you say, "The food industry are structuring food on a nano scale" then you might

get a different answer. If you put choice of benefit from healthier food against less healthier food then that would weight their response. The public do not really know how food is manufactured and then put on the shelves in the shops. There is a lack of information on actually how it is currently manufactured.

Q93 ***Lord Cunningham of Felling:*** I am struck by what you have just said on what was happening with the genetically modified tomato sauce, which was a best seller until people discovered that it was genetically modified and then they stopped buying it.
Professor Morris: I think the most important thing is people aim to exercise choice. We might think it is unreasonable they do not want to eat those sorts of foods but they ought to have the choice as to whether they do or not, and they ought to be able to access the benefits and risks in an understandable form so they can make their own assessment. I think if they have that choice, whether it means labelling or information in some way, their perception would be much better and they would not feel it is something that is being forced on to them.

Q94 ***Lord May of Oxford:*** If I understood your example right, and I may not have, it was an example where you put in something that is completely harmless and safe which, however, in effect modified behaviour in a way that was advantageous, and all I can say, like Lord Cunningham having had experience of the genetically modified fuss and so on, is just wait until Greenpeace hears that you are going to put nanoparticles in food that modify behaviour, there will be some term like "Frankenstein food" that comes with that.
Dr Kampers: It is inevitable that some of the NGOs will come on to this area. However, I believe that communication about the application, benefits and potential risks of these technologies is essential and it is also important, as my colleague said, that the consumer has the choice so they can choose whether or not they would like to have the benefits versus the risks or perceived risks of such a product. It is important not to do that in obscurity.
Chairman: I think the choice point has an echo in the response of the public to fluoride because although people object to fluoridation of water almost everybody buys toothpaste with fluoride.

Q95 ***Lord Haskel:*** I wonder if we could move on to another aspect, which is the politics of nanotechnology in food. You have told us about the way in which nanoparticles enhance food safety, reduce waste, is healthier and more sustainable. In view of the fact that there are so many benefits, are there any Government initiatives in place to encourage nanotechnology development that contributes to these objectives and towards achieving these objectives? Are governments doing anything to help you?
Professor Morris: Certainly the Research Councils are. There are research programmes on nanotechnology in most of the Research Councils and there are programmes on things like health into old age in the BBSRC which fits that agenda. Certainly in terms of basic research there are programmes available to fund that. I am not sure about the other Government agencies, such as the FSA or environmental agencies.

Q96 ***Lord Haskel:*** Is there any co-ordination between the Government and the industry? I notice that there is a technology transfer network.
Ms Groves: There is, and there are nanotechnology centres dotted about the country. There is one we have been working with that has been set up with Government funding through the Technology Strategy Board and the Knowledge Transfer Network for Nanotechnology is obviously set in place to enable technologies from difference research areas to be translated into food or other areas.

Q97 ***Lord Haskel:*** Obviously your company supports that. Do you find it effective? Does it work?
Ms Groves: It is very limited in resources, I would say. There are not enough resources for that sort of knowledge transfer.

Q98 ***Lord Haskel:*** Where do the resources come from?
Ms Groves: They come from the funding for research and development and that has short pockets.

Q99 ***Lord Haskel:*** It is not the commercial companies?
Ms Groves: The commercial companies will put money into research and they do collaborate together on pre-competitive research funding. In fact, they are doing that on a small scale.

Q100 ***Chairman:*** I wonder if Dr Kampers would like to add any comment about the situation in the Netherlands or other European countries.
Dr Kampers: Obviously I cannot say very much about the situation here in the UK, but in the Netherlands we have just completed a proposal for the next generation of nanotechnology programming, science programming and one of the ten themes that we have identified is food. The proposal is to spend about €40 million over five years on applications of nanotechnology in food in the Netherlands. In the Seventh Framework Programme, both in the nanotechnology theme and in the food theme, there are calls that address nanotechnology applications in food.

Dr Butler: The Institute for Nanotechnology in the UK is one of the partners for this European project which is funded for four years from April 2008. There are 16 partners from ten European countries. Part of that is to share information about health and safety, about regulatory aspects of nanotechnology. Again, they are looking at all the major sectors, which includes agri-food.
Dr Kampers: Can I add one point. You also asked about the involvement of the industry. In the proposal in the Netherlands, 50 per cent[3] of all the money comes from industry. It is aimed at collaboration between government institutes, science institutes and the industry.

Q101 ***Lord O'Neill of Clackmannan:*** On this point about funding, to what extent could you draw an analogy, say, with the biotech industries? Admittedly, there it is linked with pharmaceuticals and specific research programmes for the development of particular drugs, but that has been very successful in attracting venture capital and that kind of money. Would it be right to say that the state of nanotechnology at the moment is that it is insufficiently advanced to attract the attention of specific investors rather than people who have, as it were, food industry interests, the like of which you were alluding to both in your introduction and your example?
Dr Butler: It is quite early. Nanotechnology is such a broad platform that at this stage where you are discovering what it is and what it can do you are probably not going to get the VCs involved until you have got a specific application in a specific sector, and that is beginning to happen, but at the moment we are still exploring the many, many potential applications of nanotechnology. That would be my take on it.
Ms Groves: Yes, it is very broad and that complicates it to some extent. Also, it is at a very early stage in terms of the food industry and I think it is fair to say there is a nervousness in the food industry about how the consumer views what they are doing if they launch into nanotechnology, yet they want to see what is available and what could be beneficial so they are courting it.
Dr Kampers: In the Netherlands we see two ways in which the results of the research get to market. The first is existing companies adopting results from the research and putting them into products or processes and improving them. The second way, that is probably the most important and effective, is spin-outs, small companies, new companies, start-ups generated by the knowledge institutes and the knowledge infrastructure. So PhD students start up their own business, they attract a little venture capital but basically rely on funding from the market side. There is a little bit of venture capital involved there but most of the funding is through other funding programmes that are available and things like that, subsidies.

Q102 ***Lord May of Oxford:*** You have already given us some examples of potential applications of nanotechnologies and nanomaterials, but I wonder if you could say a bit more about the applications of these technologies that UK companies or, more generally, companies in other countries are currently working on and what applications we are likely to see on the market maybe next year, in five years or ten years?
Dr Kampers: You have got everything about sensing and diagnostics. These are low-hanging fruits, as we call them, where small companies are working to improve sensing devices, sensors basically that can detect volatiles or bacteria, fungi, things like that, to improve food quality. Another application area is improving processes like the emulsification processes, sieves and things like that, these kinds of areas. In the application area where you add technology, nanostructured materials to foods, nanoparticles, there are very few applications of persistent nanoparticles in food at the moment, but these delivery systems are something that attract a lot of attention and are not very far from the market as we speak. Then you have got packaging materials that improve the shelf life especially of fresh products but also inform the consumer about the quality of the food inside the package with sensors and also systems that change colour when the quality of the product deteriorates or the ripeness changes. These are applications that are already available in the US. There are systems that you can buy at the moment for these applications. They are fairly close to market.
Dr Butler: From a food packaging point of view, to give one specific application which will involve using nanotechnology to create a self-adjusting use-by date. We need to move away from date coding to more visual displays on a package to inform the consumer whether the food is still good enough to eat or not. That will involve a display, a printed battery, some very, very simple electronics which will be printed on flexible trace paper or plastic and the enabling technology to do that will be nanotechnology, for example inkjet printing using nanoparticles to lay down circuits on flexible films to then put on top of food packaging, but of course the nanoparticles that you inkjet print will be part of the manufacturing process and once they are consolidated and have been cured they will no longer be nanoparticles, they have done their job, they have created a structure so will present no problems at all to the consumer. I think it is important we understand that sometimes in nanotechnology you

[3] This figure is actually 25 per cent. 50 per cent of the total funding comes from the participants (including universities, industry and research institutes) and of this, half is contributed by industrial participants.

might start off in the manufacturing process with a nanoparticle with perhaps some concerns over its health and safety and what it might do, but at the end of the day you might produce a product where, yes, you would use nanotechnology but that product is now completely benign.
Professor Morris: There is another example of that. Frans mentioned the idea of marketing nano-encapsulating oils and delivering them further down the small intestine to generate a hormonal response. Using nanoscience you can actually look at how you design the structures in the emulsion and you can manipulate those structures to have the same effect so you can slow down the rate of hydrolysis of the fats so they are hydrolysed further down the small intestine and you can visualise how to do that and then you can use normal processing techniques to generate those structures by using nanoscience to understand how to use conventional processing to generate a new product that has got new properties. I think they are the sorts of products that could come on the market in perhaps five to ten years.

Q103 ***Lord May of Oxford:*** Let me put it another way. We had a study from something called Cientifica and it seems concordant with other studies. First of all it makes the projection that by 2015 it is going to be a trillion dollar industry, and then it looks at 2007 and it says excluding semiconductor applications it is nearly all the applications in chemistry, less than one per cent in the food sector, and its projection for 2012 is that maybe the share of the food sector by 2012 of all nanotechnological research might be as much as two per cent. My question is what are the main drivers of R&D in the food sector? Are there research drivers that are driven by the food industry or does the food industry, insofar as it is a player, primarily rely on adopting and applying new technologies that have been developed in other sectors? I find it a little bit disconcerting to think that the main driver of applications for nanotechnology in food is going to be chemicals. I do realise food is chemistry but, again, it plays into the hands of the NGOs who are worried.
Ms Groves: Those are really probing questions and the others will have a view on them. There is no doubt that one of the main drivers, and there are drivers for the food industry and their R&D, is in healthier foods. Consumers are very keen, and I am keen to carry on eating fatty, nice tasting foods but I want to be healthy as well, so people do want that. Healthier foods is a big driver. Cleaner labels or removal of E numbers and trying to simplify manufactured products is a big driver. In order to do that you have to understand what those ingredients do and then you have to understand how maybe changing the process of the food will allow you to remove some of those ingredients by using nanostructures of those natural ingredients in food. Those are just two drivers but I am sure there are many others.
Dr Butler: No. I think there are many, many ways to skin a cat and there are many ways to get lighter packaging and more recyclable packaging. I think we have got the nanoclays, which have been floated as a way of getting better barrier properties on transferred plastics, which has been hyped up a little bit. I know of no commercial examples. They have certainly tried PT plastic beer bottles, for example

Q104 ***Lord May of Oxford:*** Are there any applications?
Dr Butler: I do not know of any at all, in packaging. I know lots of people working on it.
Dr Kampers: Apparently, in the US, you can buy beer in PT bottles, thanks to the nanoclay and nanocomposite applications. I know that one of the brewers in the Netherlands is looking at that application but it is not on the market. Can I also add one more application area or driver for the industry? The industry, also, apart from the health aspects of food, looks very much at the safety of foods. Food has never been as safe as it is now in industrialised countries and it is a tremendous effort for the food industry to enhance that even more, and that is why they are very anxious to look at all sorts of measuring devices, diagnostic devices, that can maintain that or improve even on that aspect, and they are looking for devices that can give them an answer quicker with less qualified personnel and closer to the production line. Basically, that is what they are looking for, also, in nanotechnology—if nanotechnology can deliver on devices like that.
Professor Morris: I think there is an example of sectoral use of nanotechnology, in terms of future chips, and so on, in GPS and radio frequency identification of food, and tracking them from source right through to the shop or the consumer, so you can actually check the conditions under which they are stored and transported, and you can check whether that route has been interrupted. So if the food was adulterated you could very quickly find out where it happened and track it down. So there is that aspect of nanotechnology which applies to the agri-food sector which is readily acceptable at the moment by the public.

Q105 ***Lord Crickhowell:*** The question I want to address is: what are the main challenges to the use of nanotechnologies and nanomaterials in the food sector? We have in front of us, as it happens today, a submission from the Leatherhead Food International & Nanotechnology Knowledge Transfer Network. Basically, what this submission says is that they see enormous potential and considerable scope for growth but that we know almost nothing about the whole subject. They say:

"There is very little research and development in the UK regarding nanotechnology within the food and drink industry . . . very little is known about what is out there, what is feasible, what is safe and how it might be applied", and they refer to the lack of research or the forthcoming research. We have heard in earlier evidence that we really do not know yet very much about the long-term effects on the gut of certain manufactured nanoproducts. So over the millennia, nature has been absorbing nanoparticles into the gut and modifying it but we do not know very much about it. So I suppose my question is: is the lack of knowledge and the lack of much research yet the biggest obstacle? What are the obstacles? What is the main challenge, if it is not that?
Ms Groves: In looking at that question that was sent to me, I put "scientific challenges". As a scientist that, perhaps, would be a natural answer for me to give. There are some huge scientific problems in both structuring at that nano-level in complex foods (and nearly all manufactured foods are pretty complex) but, also, measuring them. It is a challenge just to know where fat, sugar and protein are in a lot of foods, let alone what size and scale they are. Obviously, there are challenges in terms of consumer acceptance of the food industry manufacturing foods at a nano-scale with nanoparticles. I think it is important to, again, stress the distinction between nanoparticles which are not normally consumed in large quantities, like titanium dioxide or silica or silver or any of the metals, and the foods which are usually consumed—fats, proteins and carbohydrates. I think it is important to distinguish between those.

Q106 ***Lord Crickhowell:*** As I understood it, you referred, I think, to really changing the process of manufacturing but not really using nanoparticles in the gut, except you have learnt how to change the process. We did have a description, I think, at one of our seminars, of the way in which you might reduce the fat content in food by, basically, attaching the food from much smaller—I am not sure what the word is—segments, but it did seem to me that we are into an area of confusion, which I am not sure I understand, about what is a manufactured nanoparticle and what is simply a change in the manufacturing process. Is this an area that we really know enough about and understand enough about?
Ms Groves: No. I think it is very difficult because early on, I think, one of the first questions was a distinction between manufactured and natural. Actually, a lot of manufactured particles are natural particles; they are natural foods which have been manufactured into structures within a food product. So, yes, there will be changes to food processing which may well need to involve nanotechnologies in order to change the structure of the ingredients in the food that we put in. That is one aspect of the nanotechnology of foods, and it is the distinction as to whether they are manufactured nanoparticles of water being boiled, which I think, in the seminar is one of the low-fat examples. So if you have water in oil and water, emulsion, in a salad dressing, are those water droplets manufactured nanoparticles or are they natural but they have been processed to be very small? That is going to be something that needs to be decided in order for legislation purposes and regulation.

Q107 ***Lord Crickhowell:*** If there is a need for more research, again we heard in evidence at our last session the difficulty about manufacturers' intellectual property rights; even if they are not worried so much about intellectual property rights they are, perhaps, reluctant to exchange too much information about technological developments which may have huge commercial advantages. Is that an obstacle that you see as a real one to real progress—the very natural lack of willingness to communicate too much between companies about their research programmes?
Professor Morris: I think it comes down to a matter of choice. If those products are introduced without any way that the consumer can tell that it involves nanotechnology, they might be concerned. I think then there could be a problem. However, if those were labelled in some way, so that people can choose whether they use them or not, I think it would not be so much of a problem.

Q108 ***Lord Crickhowell:*** You keep coming back to labelling as a solution.
Professor Morris: It is a possible solution.

Q109 ***Lord Crickhowell:*** One of the problems is that we have got far too much labelling, in many ways, and people now find almost all labelling confusing. Surely it is a step too soon to talk about labelling if we cannot actually know quite what the threats are, what is right and what is wrong and we have not got the basis of scientific research on which to label. Are you not jumping a bit far ahead?
Professor Morris: I am not saying labelling has to be the way to do it; I am saying that the consumer needs to have some choice as to whether they opt to buy a particular food or not, and they need some way of knowing whether the processing of that food is something that might concern them. We might think it is unreasonable they should be concerned, but they still feel they have a choice as to whether they buy it or not

Q110 ***Lord Crickhowell:*** My final question on research, if this is an obstacle, is that we found it rather difficult in our last session to get really reliable and complete information about the amount of

government research and finance for the research in this field, and we hope we are going to get a rather more complete paper from the department concerned in the future. Would any of you like to comment on the adequacy of the government's research programmes in this field in this country, in Europe or elsewhere?
Dr Kampers: "In the field"—you mean?

Q111 ***Lord Crickhowell:*** If it is so important that we know more about the science of nanotechnology, if it is going to be possible to assess the safety of these products, ought there not be a more concerted scientific programme, and what are governments doing, or should governments be doing, to see that that happens?
Dr Kampers: In my personal view, building trust with the consumer is very basic; it is a pre-requisite for the acceptance of the technology. "Building trust" means that we understand the risks, so risk assessment is important. We know that the risk is predominantly located at the inorganic nanoparticles, but still we feel that we have to do more research into the risk assessment, both hazard assessment and the exposure assessment of nanoparticles. There it is tremendously complex because if we talk REACH, basically, that is governed by the chemistry; for bulk or small particles it is the same. Nanotechnology has added a whole new dimension to that problem because size matters now. There is another dimension that nanotechnology has added because we also can control the geometry of the particles, so we can make rod-like particles and we can link spherical particles. So there is another dimension added to the complexity. There are even other dimensions because we can functionalise particles so that they behave totally different from the particles that we started off with. So the complexity to look at these kinds of issues is tremendous, and we lack the data to get to a level where we have generic knowledge of where the risks really are in this multidimensional space. That is something that, in my view, needs to be addressed internationally; it is too complex for one country to do. We have to co-operate to find out where the hot spots are and where the relative safe zones are in this area, and that is something that we have not succeeded yet. But it predominantly focuses on nanoparticles. So the application of nanotechnology in sensors and surfaces is totally different; it is something that focuses on these particles.
Professor Morris: I think there is an emphasis on manufactured nanoparticles, and I think it really should be on materials that are not broken down in the body. I think that is the distinction that alters the risk involved in these technologies.

Q112 ***Lord Haskel:*** Of course, the research that you are speaking about is very, very important, but is there any research going on to look at what are the concerns of the public? What are the concerns of the consumer? Obviously, the two go together.
Dr Butler: Yes. If any of us buy a packet of crisps, or potato chips, inside is a metallised plastic film. That film is nanodimensional[4], but it is not declared anywhere on the label and it has been around for donkeys years. It depends how you define "nanotechnology" but actually if you wanted to define it that way, as aluminium metallised film, which is used extensively, people are totally relaxed about it, are they not?
Professor Morris: Certainly *Which?* have carried out workshops to look at public concern on nanotechnology, and the nanotechnology institutes, particularly Cambridge, have actually hired social scientists to try and answer public questions and have public forums where people can ask the sorts of questions they are concerned about and get scientific answers.

Q113 ***Lord Haskel:*** So you think the public will just be quite passive—
Professor Morris: I do not expect them to be quite passive about it.
Dr Kampers: As a matter of fact, Wageningen UR is doing research on the mechanisms that govern the processes within groups in society to accept this kind of technology in food. So we are doing research to get some generic knowledge on how these processes are conducted and what influences these processes and how communications, for instance labelling, could help make society accept these kinds of new technologies in application areas of food. We are doing research ourselves in that area.
Professor Morris: The worst thing that can happen is that people are told: "This is a product that involved nanotechnology; it is perfectly safe, you should accept it", and not be allowed to assess the risk themselves. I think people feel that whatever the risk they may choose not to accept it, even if it is a very, very small risk. They want that choice, and as long as they have that choice I think they are more likely to accept it.

Q114 ***Lord May of Oxford:*** At the risk of seeming unduly obsessed with risk and public attitude, I would remind you that, at least in the UK, when nanotechnology first appeared on the scene there was concern voiced in various quarters, not least by Prince Charles, and Michael Crichton's book, and I think we managed to handle that pretty well, by putting together a committee that consulted and met with many of the concerned people and sketched some of the credible worries, and so on, and possible

[4] It is nanosized in one direction only, as are nanoclays.

regulatory things to do. So that we have not had any fuss about it because we have learnt, at least, some of the lessons of GM foods. However, I am not myself at all convinced that that will persist once you have the particularly sensitive issue of putting what some people would feel are worrying things into food. I am a little surprised that none of you share this worry.
Professor Morris: I think the worry is about what is available on the internet which is not regulated. One of the things that would be useful is if the first products that come from large, multinationals have really demonstrable good health benefits, or good benefits to people. With GM, the benefits did not seem to outweigh the risks that people were concerned about. At the moment, some of the products you can buy over the internet seem fairly trivial and the benefits in using those seem almost non-existent.

Q115 ***Lord May of Oxford:*** My own personal view is that the answer to this is to have products that people want to buy, so that they can see a benefit and they can weigh that against the risk. What happened with GM is that the first wave of products was not offering benefits of a manifest kind to the consumer. I would hope that in the food industry the first wave of products would be for things that offer clear benefits to the consumer rather than to the food business. I wonder whether you share that. Do you have any thoughts about what to do about that?
Professor Morris: I agree with that. Certainly in terms of healthier foods and foods that provide protection, I think those are things that people can see a real benefit for. The trouble is that to do that science, it is not concerned about risk it is simply about doing the science to understand how to manipulate these things using conventional processes. I think that is just taking time and while that is happening lots of trivial products are appearing on the internet, and I think that is the problem.
Dr Kampers: One of the problems, as was addressed earlier, also, is that the industry is very, very reluctant to communicate that they are using nanotechnology in food. It is not that they are not willing to share the knowledge with their competitors; it is because they are very much afraid of the reaction of the consumer to the product.

Q116 ***Lord May of Oxford:*** That is surely a mistake?
Dr Kampers: Yes, sure, but I cannot help it. We try to communicate—
Ms Groves: Who is going to put their head above the barrier first? Which company is going to risk going to the wall?
Dr Kampers: The effect is that nobody tells anybody that nanotechnology is used, so the benefits of the product are not associated with the nanotechnology used; the benefits are claimed to the product. So the wider public cannot distinguish between benefits that are generated by this new technology and will not learn to appreciate the technology in this way. So that is one of the reasons why labelling might have a beneficial effect on this.
Ms Groves: Coming back to your question on research funding, generally, in the years that I have been in science, research funding has gone from quite generous funding in the food industry to being very specific, and anything which was near-market or was in any way commercial would not be funded by government. Maybe there is now a point for discussion where you could actually say there should be some government funding, linked with food industry funding, to make open research into the sorts of nanotechnologies in food product development.

Q117 ***Baroness O'Neill of Bengarve:*** Is there any research going on into this question of identifying those nanoparticles (inorganic nanoparticles, I understand) which might be the area of risk, and, also, conversely, identifying where the areas of relatively low-risk are? Is that research something that is being done behind closed doors and in a non-co-ordinated way?
Dr Kampers: There is a project by the OECD at the moment going on where they look at different kinds of nanoparticles, and this is the first initiative to co-ordinate this kind of research. What I am always saying is very many people, research institutes, are doing research on the toxicology of more sexy particles, like carbon nanotubes and things like that, and there are few people looking at the toxicity of particles that are less applicable or less sexy. There is really a need for more co-ordination in this area. There is research going on looking at what kind of properties will influence the risk of particles. For instance, I know of research in the US where they look at particles that are used in the bloodstream for medical purposes and where there are four parameters that are seen as crucial in determining whether the particle is in a hot zone or in a relatively safe zone. So there is research going on and we are making progress but, as I said, it is a very complicated issue and then there are many aspects to that. So we really need to do more in this area.

Q118 ***Earl of Selborne:*** I would like to follow up the line of thought that you have been developing as to what extent UK public funding of research in this area might contribute to this international need. I think Dr Kampers reminded us that this is too big for one country, that we lack data and that there is an urgent need to get this data on risk assessment and hazard assessment, particularly to head off any public concern which may well be coming at us. First of all, my question is: are we pulling our weight

already? Leatherhead say, in their evidence, that we are under-funded in this area, and we have heard from Holland that you have, in Holland, a €40 million programme with 50 per cent funded by—
Dr Kampers: It is only the food part of the programme. There is also a risk theme, so there is also €20 million going into risk research.

Q119 ***Earl of Selborne:*** That is over and above the €40 million?
Dr Kampers: That is on top of that. Food is one of the 10 themes and risk is also one of the 10 themes in that programme.

Q120 ***Earl of Selborne:*** Perhaps I could ask our witnesses from the UK as to where we fit into the scheme of things at the European level. Are we able to pull our weight? Are we contributing to these, clearly, European level programmes that you have identified as needing to be undertaken?
Ms Groves: In terms of gut health, there is considerable funding. In terms of real products and foods there is very little.

Q121 ***Earl of Selborne:*** So are you making a plea that the government funding (research council funding in the main, we are talking about and departmental funding) should be directed to this area of hazard assessment, risk assessment and determination of what happens to these nanoproducts in the human body?
Ms Groves: I think you have to, again, make the distinction between persistent, non-digestible products, particles, and other normal foods—normal manufactured foods—which may well be enclosed or packaged or made with nanotechnologies, in terms of research into toxicity.
Professor Morris: I think the difficulty is that those particles are very unlikely to be added directly into food. So it is a big problem in understanding what would happen to those particles if they got into the body, particularly in the food matrix, and how they would interact with things like gut bacteria. There is a lot of information in the environmental field on how they affect bacteria, but when you are talking about aerobic and anaerobic conditions they are very different. You need a lot of understanding of the risk associated with those particles, and their applications in the food industry are going to be very small. They are very expensive and there is very little reason why you would want to introduce them.
Dr Butler: I think it is going to be in health and medicine that there is going to be a major application of nanoparticles, and that is, of course, going to bring this whole issue about interaction with the body into sharp focus. I agree with colleagues that the food side is going to be relatively small, and I still go back to what I originally said, that in many instances nanotechnology is an enabling technology, and nanoparticles are used to create something—to devise a system—and that something that you have created is totally benign because the properties of the nanoparticles are now no longer what they were at the beginning. That is what we do not really understand: when you have got this brand new functionality and brand new properties, what does it mean to various sectors? It is security, it is information technology, it is energy and it is construction, including food, but there are many, many sectors and application areas where using nanotechnology to make things is going to be terrifically important.

Q122 ***Earl of Selborne:*** Would you give your thoughts as to what role the United Kingdom's research communities should be playing in addressing these issues?
Dr Butler: I think printed electronics, to me, which underpins many of these industrial sectors, is terrifically important. In other words, the ability to print a two-dimensional, flexible, electronic display, or battery-powered sensor, whatever it might be—it could be an e-book, or an e-newspaper that constantly updates, for example, when you are on the tube or it could be a smart package on a food—that uses nanotechnology as an enabling technology for printed electronic displays, sensors or batteries, all printed at high speed, roll-to-roll printing. That is an area that the UK is a little active in but, in my view, needs to be more active. So it is using nanotechnology but the result is printed electronics, and then the applications are in a number of fields, which include things like alternative energy, for example—solar. If you can print solar cells then you will get much more dramatic properties using nanoparticles. Having printed the solar cell it is now completely safe and benign.

Q123 ***Earl of Selborne:*** Where within the European Union would you expect the most progress in this area to be made?
Dr Kampers: May I comment on your first question first? Obviously, we made a different choice. We are doing research and we would like to know about the kinetics and the dynamics of nanoparticles in the gastrointestinal tract, because we see that worldwide there is very little attention to these persistent nanoparticles in the gastrointestinal tract and the oral route. There is a lot on inhalation toxicology, also the skin is researched for certain particles, but there is very little known about the oral route. We have decided, within the Netherlands, that since we are looking at applications of nanotechnologies in food it is also our obligation to know what might be the risks of these applications. Also, we do not want to wait until somebody, somewhere in the world,

starts with an application of some kind of nanoparticles in a food product and it comes on somewhere in the market or it can be bought on the internet; we would like to know what kind of risks are associated with these kinds of applications of nanotechnology. Although, at the moment, there is very little of these applications known, there are very few persistent nanoparticles in food products at the moment. But we cannot rule out that there might be, in the future, somebody who wants to put nanoparticles in food. In the Far East we already know that there are companies that, for instance, add nanoplatinum to food products because they think it is beneficial. As I said, in the Netherlands we would like to know what kind of risks are associated with these kinds of applications, from a generic point of view, so that we can distinguish between things that have low risk and things that have high risk, so that we can focus in the first instance on these high risk applications.

Q124 ***Chairman:*** Can I come back and seek a bit of clarification, because we have had two written submissions? On the one hand, the Institute of Food Research, from which Professor Morris hails says: "The UK has played a leading role world-wide in developing a nanoscience understanding of food structure and materials . . . ", and the Leatherhead, from which Kathy Groves hails, says: "There is very little research and development within the UK regarding nanotechnology within the food and drink industry." Those two statements seem to me to be, at one level, almost contradictory. I wondered which one is correct, or are they different slants on the same position?
Professor Morris: I assume they are, possibly, different slants. When we are talking about what has been done in the UK we are talking about the understanding of actual food structure itself, the food matrix, its functionality and how to process it. We are one of the world leaders in that respect.

Q125 ***Chairman:*** Are you saying that, as so often happens in the UK, the basic research is being done but the translation of research into products and benefits is being done elsewhere?
Professor Morris: I think that probably needs qualifying. I think it is being done in major companies like ICI and Unilever, but they do not talk about it, at the moment. It is a fear of public perception of nanotechnology. Who is going to be the first person to bring these products on to the market?

Q126 ***Chairman:*** As Lord May has said, it does not make any sense to do it and keep it a secret because eventually you are going to have to divulge that it is going on.
Professor Morris: I think there is a real concern within companies that people find out they are using what somebody might call nanotechnology when, in fact, they are using nanoscience; they are trying to understand the foods and through that understanding they will produce products using conventional technologies, and then they can talk about those products and sell the benefits without the associated risk. They are not really nanoproducts; they are conventionally processed products but they are done in a rational way.

Q127 ***Lord Methuen:*** What mechanisms are in place for companies, academia and the Government to share information on new developments in this field? Is this limited by IPR considerations?
Ms Groves: Well, there is the NanoKTN centre set up by the Government and the Technology Strategy Board, and Leatherhead does play a role in linking universities to industry. I do not think there are many structures in place designed to do that.

Q128 ***Lord Methuen:*** How much involvement is there with academia?
Ms Groves: A limited amount, but only limited by the amount of time you have in your life and the number of resources or people that can liaise between industry and academia. Sometimes industry will go to universities directly, but there is a need, I think, for an interpreter between universities and industry, to be honest, because fundamental research on food is a long way off what will happen in the manufacturing process. So there are companies like Leatherhead which are good at being able to make that connection between the two.
Professor Morris: I think there is an effort to try and correlate all the safety data and the toxicity data; the FSA and the Central Science Laboratory are trying to build up databases, and that sort of information is freely available.

Q129 ***Lord Methuen:*** Would it be true to say that this is not a subject which tends to interest universities—it is not sexy enough?
Professor Morris: Which—the food or complexity?

Q130 ***Lord Methuen:*** This type of research into food. It seems to be more into industry rather than academia.
Dr Kampers: Not in the Netherlands.
Ms Groves: I think in the UK it is.
Professor Morris: There have been very good universities in the past—the University of Leeds, the University of Nottingham, and Unilever Research, Colworth where there was almost a university kind of atmosphere, which were doing very fundamental research and published it, on food structure and how to manipulate it, at that sort of scale. There has been

academic research on manipulating the nanostructures in food, and it is published and is available.

Q131 ***Chairman:*** You talk about it in the past tense.
Professor Morris: It is still being done. I think, in the past, it was simply trying to understand the food structure in terms of understanding the functionality of foods—how you can make foods last longer or more attractive to eat. Now it is more about what happens to that food when you digest it, how it is broken down by the body and how you can manipulate those structures to control that breakdown. It comes back to this idea about controlling fat; if you can make a full-fat product but you can slow down the breakdown of the fat, then you can actually make people think that they have eaten enough, so the next time they eat the food they will eat less of it. You can try in a rational way now, from past understanding, to try and do those sorts of processes. Certainly, in the lab, on an in-vitro scale it works. You can change food structure and control lipolysis and you can do it at a sufficient rate to actually expect to create hormonal change.

Q132 ***Chairman:*** Is any research done in-vivo or is it all in-vitro?
Professor Morris: It is starting to be done. We have contacts across Europe, particularly in countries like Finland, where we are starting to do human trials on those types of food. That work is starting to occur but it is quite difficult because translating the science on interfaces on to emulsions—what happens to emulsions when you process it on a large scale and then eat it—is quite difficult. That is why it takes a long time to translate it into practice.

Q133 ***Baroness O'Neill of Bengarve:*** You have spoken about the universities doing research that is published and open, and you have also spoken about the companies doing research that is, I take it, not published and not open. That is a pretty unstable situation, in some ways, if it is to end up as consumer products. What would you see as a useful thing that this Committee could recommend that would move things forward in terms of co-ordination? An alternative thought: if you were making a pitch to the Technology Strategy Board to put more resource into the development of research on the use of nanotechnologies in food, what would you say to them?
Ms Groves: I think there is a need for a pre-competitive area of research which is publicly funded with full, open information to the public that the industry are willing to participate in. It has got to be close enough to their drivers and to their products for them to realise the benefit and the need for doing it. Also, it has got to be far enough away, if you like, so they can take their IP, their whole ownership of the final development. Ultimately, I am not sure if you are asking should we control the food industry far more in terms of what they produce.
Baroness O'Neill of Bengarve: I was thinking of empowering rather than controlling.
Lord O'Neill of Clackmannan: Commercial research is done not for philanthropic or blue skies reasons, it is done for profit, and it is trying to reconcile these two, what appear to be, conflicting objectives. If the Unilevers of this world can get an edge over their competitors they are not going to share it in the interests of humanity, in general, because they have shareholders who have a higher priority.

Q134 ***Baroness Neuberger:*** Are we not hearing, also, that there is a rather different attitude in Holland, from what we are seeing in the UK? Clearly, the companies keep their secrets, as it were, close to their chest, but there is a greater emphasis on doing more general research, if I understood you rightly, Dr Kampers.
Dr Kampers: Yes. Also, in the Netherlands, it is true that, for economic reasons, of course, you keep results confidential, at a certain point in time. It is a continuum from pre-competitive research towards application-driven research, and somewhere we meet each other and we are trying to find ways of exchanging the results in such a way that we are bridging the knowledge gap—which is not typical to the UK; it is there everywhere. So methods of bridging the knowledge gap are very important, so results are applied in the industry and the economics start to work and we start making money with these results. Because if we do not make money we do not earn the money to do the research for the next generation of applications, of course. We are looking at things like, as I explained, these other research initiatives in Holland where we participate with the industry to make sure that results in academia are used by the industry, because they also have invested in these research projects. Also, we look at things like setting up joint research centres where academia use the infrastructure but, also, industry can use the infrastructure, so that people meet up and start discussing the possibilities of results while the research is being done. These are ways of trying to bridge this knowledge gap, but it is also there in the Netherlands, I have to admit.
Ms Groves: In the Netherlands, my feeling is, there is a better set up for linking universities to industry. Going back to your point, yes, the industry is there to make a profit but it is then part of the economy, so it is important that we have successful industries. The universities are there to conduct fundamental research but, also, to teach, and there is a need for industry to link up with the universities far more closely, but I do not think you can do that easily

directly because they are operating to completely different goals and at completely different levels. Maybe one recommendation will be to have some sort of set-up where you have an intermediary which can understand how the industry works but, also, can understand the fundamental science that the universities produce, and merge the two together.

Q135 ***Lord Haskel:*** There is, of course, a third element to this, and that is the regulator.
Ms Groves: I thought you were going to say "the consumer" then.

Q136 ***Lord Haskel:*** Presumably, with so much uncertainty around, and you have been telling us about the uncertainty, what do you say to the regulator? How much information do you give to the regulator about the work that companies are doing?
Dr Kampers: As much as possible. I think the role of the regulator is very crucial in building trust with the consumer. Regulatory bodies represent an objective body to the consumer and they are generally regarded as looking after the interests of the consumer. Having regulation in place implies that somebody, objectively, has assessed the risks of such products, and that means that the consumer is more likely to trust the claims and, also, the low risk of such products. I would say having good regulation is crucial to the acceptance of these technologies in food, and therefore it is my vision that both academia and industry should give as much information as possible to these regulatory bodies in order to have the right regulation in place at the right time.
Professor Morris: I think, also, when they are regulated it should not just be on the risks and: "Is this a safe product?" but what are the actual benefits of a product, what are the health claims and are they viable claims?

Q137 ***Chairman:*** One of the points we have heard in a previous session is the question of whether or not foods incorporating nanotechnologies would require regulation under the Novel Food regulations or whether they would pass into public consumption under more general, food safety regulations. I think that we were not quite clear about the situation with regard to different nanotechnologies. I do not know whether any of you have a view about that.
Ms Groves: I think part of the difficulty with regulation is that you get into semantic arguments about definitions rather than trying to look and see whether something is actually safe or how you might label it. So maybe there needs to be a change to the nature of regulation, certainly for something as complicated as nanotechnologies where you have to look at a far wider spectrum of technologies and applications.

Q138 ***Chairman:*** That is not the view of the regulators themselves; the Food Standards Agency told us that the current framework is adequate.
Ms Groves: I think it is adequate in terms of health and of safety, but if you want to move on to regulate nanotechnologies, it needs to be more than just definitions.
Professor Morris: I think it may also need to co-ordinate the different parts of the regulation. If you are talking about food packaging, there may be concerns about whether a material can leak into a food and perhaps be certain that that will not happen, so it is safe in terms of its use in the food aspects, but what happens to that material when it is thrown away? That is an environmental issue, but it may be a factor that is very important in whether people want to use that sort of packaging. I think you need to tie that use up over the lifetime of the product. It could happen that with use of nanotechnology across the agri-food chain, if you are thinking about nanotechnology applications in spraying pesticides, you may see the benefits to the agricultural industry but there is also the possibility of contamination or detection of the material in food.

Q139 ***Baroness Neuberger:*** Moving on, and the large question first: is there a difference between using manufactured nanoparticles and using natural ingredients that have been modified at the nano scale?
Professor Morris: I think it comes down to the question of material that is not broken down in the body.

Q140 ***Baroness Neuberger:*** So with the persistent ones there is a difference?
Professor Morris: I think so.

Q141 ***Baroness Neuberger:*** The difference being mainly a difference in risk or a potential difference in risk? Or a potential difference in hazard, maybe.
Professor Morris: I think it is a potential problem in risk because you simply do not know how these materials will be accumulated, where they will be accumulated and what the consequences will be. I do not think you can extrapolate that knowledge from the size of particle.

Q142 ***Baroness Neuberger:*** Should we be making a distinction for regulatory purposes between these two types of nanoparticle?
Professor Morris: I think so, yes.
Ms Groves: I think so.
Professor Morris: If you are talking about labelling, the only concern is I think the label ought to be for materials that persist in the body and are not broken down.

Q143 ***Baroness Neuberger:*** Yes, this yoghurt with nanoplatinum, which is not on the market in the EU, I understand—has that been through any trials and is that labelled?
Professor Morris: I have no idea.

Q144 ***Baroness Neuberger:*** Could we import it? Do you think that the manufactured nanoparticles will turn out to have a lot of applications in foods or will their usefulness be quite limited?
Dr Kampers: The usefulness will be limited. In my view there is very little sense in putting expensive nanomaterials in a food that the body does not do anything with. So its use is very limited, but there are examples where there is improvement on the flowing characteristics of certain food products, and, also, as a carrier for vitamins.

Q145 ***Baroness Neuberger:*** So there would be applications in the food sector, and particularly the packaging applications or the clean surface applications, but much less in foods themselves?
Professor Morris: I think for the persistent ones, I would imagine, there would be very little use at all, but you can make nanoparticles that are broken down in the body which act as carriers.

Q146 ***Baroness Neuberger:*** Do you think that a single regulatory system should be used for health and safety purposes, or is that asking too much?
Professor Morris: I would like to see any regulation of particles emphasising the health benefits as well as considering the risk. At the moment, the trouble is you have a brand name, on the internet and it says: "Nanosilver—wonderful, marvellous", but if you actually had some sort of brand where you used those particles which said: "This does give you health benefits but there is no perceptible risk that you can detect", I think that would be an advantage. If there was some sort of voluntary labelling of where people use nanotechnology, that might be an advantage, but I can see the objections to its use.

Q147 ***Chairman:*** Can I ask a bit more about your view on the regulatory process? You drew this distinction between persistent nanoparticles and things that are not persistent in the body. Earlier on, we heard from Dr Butler that the key point was whether or not the properties of a material change as it approaches the nano scale (he gave a graphic example of the properties of silver, which is a nice example). I just wondered, within the regulatory system, do you think that the regulation should look at the total exposure to all kinds of nanoparticles over a period of time? The temptation would be to look at each food type or each application independently and give approval to something on an independent risk assessment for that particular product, but as far as the consumer is concerned, he or she may be eating 10, 20 or 50 different products as we roll forward in time, each of which has been separately approved but their exposure is as a result of an interaction and accumulation of all these different products. What is your view about how that should be tackled in the regulatory system?
Professor Morris: I think there are two aspects. One is, again, particles that are not broken down, but, again, I would have thought that is something that is going to be fairly rare in the food industry. Certainly if you are using nanocarriers then what you are trying to do is to enhance the delivery of something, and ideally what you would want to do is optimise it and, hence, you have lots of products that are enhancing the delivery of something and you could end up having too much of it, and that would be as bad as having too little. So by having lots and lots of products that, say, enhance the delivery of vitamins, you could actually have a problem due to an over-consumption of those materials. Again, it may come back to not so much labelling but a recommendation that this gives you a certain percentage of your daily intake of that product, and at least then people are aware that if they take more of that there could be problems.

Q148 ***Chairman:*** That is placing quite a lot of expectation on the consumer to keep track of how much they are getting from different products.
Professor Morris: I think the problem is that if you do enhance delivery then you have to think about the consequences. Particularly if it is an orange juice, say, and you are enhancing the delivery of a vitamin, people might want to drink the same amount of the orange juice when they probably ought to drink a tenth. They have no way of knowing what their delivery is or what the optimum level of intake is. People do accept now labelling that says: "This product will give you one-tenth of your expected amount of that compound in a day". I think that would be acceptable.
Dr Kampers: In my view it is a product development issue. It is not typical to nanotechnology because nanotechnology is used as a technology to enhance the delivery. But I think when you develop a product that delivers more of a specific nutrient then you have to realise that this accumulation of different products can take place. So, in my view, it is the responsibility of the company that developed this product, to make sure that there are safeguards that people do not get too much of a nutrient in some way. So it is a product development issue more than a nanotechnology issue, in my view.

Q149 ***Baroness Neuberger:*** You have already said, to some extent, that we get into terrible definitional problems with this, but would you be able to have a go at defining nanotechnologies and nanomaterials

in the context of the food sector specifically? I realise that Ms Groves, particularly, has already raised your eyebrows about this. I know it is hard.
Ms Groves: It is very difficult. My instinctive reply is to say that nanotechnologies are technologies which allow you to manufacture or structure particles at a nano scale—so less than 100 nanometres. Nanoparticles and nanomaterials could very well be large structures made up of nanoparticles. It is very, very difficult (and a lot of nanotechnologies are still very much emerging; they are still at the developing stage) to define them, other than by saying they produce nanoparticles. Then I do know that there are products, not in the food area, which use nanotechnology to create nano-sized particles less than 100 nanometres which then become larger particles (in a sense, that is what you have in the packaging) and, therefore, are not a risk in terms of their size. So you do get into: do you label those as a nanotechnology when, in fact, they are completely locked into a much larger structure? I am sorry, that is a scientist's answer.

Q150 ***Baroness Neuberger:*** I think that is one of our difficulties in looking at some of that. You have all made it very clear that you think we should, in a sense, worry more about things that remain in some sense in the body and are not broken down rather than whether something is a manufactured nanoparticle or something that is a natural ingredient. Going back to the regulatory theme, how would you distinguish that? How would you state that in terms of a regulatory environment?
Professor Morris: You mean: how do you define—

Q151 ***Baroness Neuberger:*** Yes.
Professor Morris: I think with persistent particles it is fairly easy to define what are nanoparticles; it is when its properties change—for example, when titanium changes its transparency. So there I think you can say these are particles where they have been reduced in size and their properties have changed; they are being put into food packaging or they could be put into food because they give new properties.

Q152 ***Baroness Neuberger:*** You think there it is really easy?
Professor Morris: Yes. I think when you are talking about manipulating structures in food that are naturally there it is nanoscience, but the actual technology may be a conventional technology, which you understand.
Dr Kampers: If you boil an egg you will change the nanostructure of the egg. How much change can you allow to call it nanotechnology? It is a very difficult issue. On the other hand, it is not difficult because the ISO definition of nanotechnology and the OECD definition of nanotechnology are fairly good definitions; it is just that they are virtually useless from a regulatory point of view, and that is the issue. So the difficulty is in finding a definition that can stand up in a court of law, that provides you with sound criteria to classify whether something is nanotechnology or not. In my view, one of the solutions could be that you look not at the size but at the new functionality which has been created by exploiting nanoproperties. Then you could say that "this is a nanomaterial". If there is new functionality created by man, by using nanotechnology or nanostructured materials, then you have a nanomaterial.

Q153 ***Baroness Neuberger:*** Would you argue that that should be applied across all sectors or was that purely, would you say, in the food industry?
Dr Kampers: No, it should be applied to all sectors.
Professor Morris: I think there is an example of a natural nanoparticle where people have taken enzymes, which you can think of as natural particles, and modified their functionality. Then they would have to go to conventional trials if they were used in food. The difference there is the methodology and the procedures are well established to test whether those materials are safe, whereas with an engineered persistent material the methods are not there to assess it.

Q154 ***Chairman:*** Before we draw to a close (and I would like to give you a chance to make any other points you would like to make), I want to go back to an earlier question which Lord May asked about the timeline, because we are hearing, at the moment, some fairly mixed messages about what is available now, what is likely to be available in two to five years' time, and beyond. Recognising that it is always difficult to predict what is going to happen, particularly when it is in the future, what I have understood is that at the moment, as we speak, there are applications of nanotechnology in the broad sense in the food industry. We have heard about the nanoclay films that are used in beer bottles, for example, and we have heard about the metallised film in potato crisp packets that involve nanotechnology, and we were told in a seminar about fridges that are on the market with nanosilver linings, and I know from one of the submissions we had from a government department that there are 17 products on the market in Germany in which nanotechnology is used to encapsulate food products. These are mainly in the food supplements industry. So there are things going on now, and obviously with the internet there are things that you could buy in this country whether or not they are manufactured in this country. So that is my understanding of where we are now, and I would like to ask whether that is your understanding of where we are now. Perhaps you could be a bit more

explicit about where you think we will be, say, in three to five years' time. Will we be in about the same place or will things have changed dramatically, in your judgment?

Professor Morris: I think in five to ten years' time there is a real prospect that nanoscience understanding of foods will have generated a range of new foods that have health benefits or protection against disease, improving lifestyle into old age. I think that is a real possibility. They will be prepared by conventional technology through an understanding of how to do it.

Dr Kampers: I sometimes compare nanotechnology in general—not in food—to electricity; we are at the stage now that we know how to make a light bulb, a resistor and a coil, but we are in no way at the level that we can build a radio or a computer. The technology is very generic and that makes it very, very difficult to extrapolate into the future. However, if we look at what is happening now in food, I agree, within five to ten years' time we will see improvements in food safety, monitoring, we will see improvements in the sustainability of certain processes that are important to the food industry, we will see better packaging materials and increased shelf life, especially for fresh products, and we will see products that deliver specific nutrients to individuals. What we see in the further future is that we have to link up to the needs of the body—basically, the biochemistry of the body—and then deliver the right nutrients, and that is something that is much further on and is a very complex issue but, also, will require nanotechnology to deliver that part of the delivery end.

Dr Butler: In packaging, as Dr Kampers has just mentioned, I think we will have much more communicative packaging that will allow consumers to manage their food inventory better so that there will be less food waste, for example; there should be less examples of sicknesses from food-borne bacteria because there will be things like freshness indicators on packaging, ripeness indicators on packaging—ripeness indicators on fruit, for example, because we all know sometimes it is extremely difficult to tell whether a pear or a melon is ripe or an avocado is ripe. So I think there will be advances of that kind, and convenience and functionality, that will be underpinned by nanotechnology.

Ms Groves: I think your assessment of the state of it at the moment is right. Packaging was the first area that really developed nanotechnology for foods, and I think that will carry on. What Paul says is correct, too; I think we will be able to accurately judge whether packaged food really has gone past its safe use-by date or whether you can actually use it, or say: "That date has gone" and it goes into the tip. In the short term I think there will be developments and understanding of what happens in the gut which will lead to healthier foods, and there will probably be more food supplements out there on the internet available for people. I think, probably, the next step-change will be taking the properties of packaging surfaces into the manufacturing and food preparation area, to make efficiencies and waste savings there and, also, make safer areas. Long term, I think, the idea of looking at manufacturing processes and how you structure foods to make them healthier or safer, because we are looking at nanotechnology, will develop better, more stable products.

Chairman: Thank you very much. Are there any additional comments that any of you would like to make before we close the session?

Lord May of Oxford: I cannot resist remarking that there was an obese character called Herman Kahn 50 years ago who coined the word "futurology", and I think, also, the phrase "mutually assured destruction". He prepared a list of the 50 great challenges confronting humanity, and in the top ten was a pill to control appetite; somewhere around 28 was worries about population growth, and I am reassured to see that maybe we are, at least, in that direction and moving.

Chairman: On that cheerful note, I draw the session to a close and thank our four witnesses for their help in exploring the issues that we have put to you today. Thank you very much for answering our questions. Copies of the transcript will be sent to you for correction before it is finalised, and of course if there are any points which you would like to follow up by writing to us we always very much welcome any additional comments in writing which will help us in our deliberations later on. Written material is published alongside the transcript, so you can add to our work in that way. Thank you all very much indeed.

TUESDAY 28 APRIL 2009

Present	Crickhowell, L.	Methuen, L.
	Cunningham of Felling, L.	Mitchell, L.
	Haskel, L.	O'Neill of Bengarve, B.
	Krebs, L. (Chairman)	O'Neill of Clackmannan, L.
	May of Oxford, L.	Selborne, E.

Memorandum by the Food and Drink Federation

1. General Introduction and FDF Position

1.1 The Food and Drink Federation (FDF) is the leading representative of the food and drink manufacturing industry in the UK. A brief summary of the industry and organisations we represent is attached as an Annex.

1.2 FDF has been studying nanotechnology and the implications for our industry sector for several years. We support the use of nanotechnology as a general enabling technology with widespread industrial applications. We believe there is a need for adequate safety assessment in all applications of nanotechnologies, where their application gives rise to changes in existing products or processes, such that a new assessment of any risks to human health or the environment may be required. We believe that it is possible to adapt the existing regulatory system to deal with new scientific evidence on engineered nanoparticles as necessary.

1.3 According to our knowledge to date, FDF is of the view that direct applications of nanotechnologies in food appear limited, though there is interest at ingredient level, particularly in delivery systems, and interest in potential indirect applications in, for example, packaging, processing applications and food safety. We know of no food products or processes currently on the market in the UK which use nanotechnologies within the working definition which is generally applied.[1] To the best of our knowledge, interest in nanotechnologies within our membership is still at the research stage, though we understand that some applications are near market and beginning to enter the European market, such as packaging materials containing silver nanoparticles.

1.4 The food and drink manufacturing industry is very sensitive to the need for consumer acceptability of its products and is innately conservative in the application of new technologies to food. That said, our industry strives to innovate and improve products to meet consumer demand and expectations and is under pressure to reformulate to meet the needs of a changing population in a rapidly changing global environment. It is therefore important that we are able to make the best use of all the tools available to meet the challenges of innovation and competitiveness against a background of limited resources and the pressures of a global economy.

1.5 FDF has sought involvement in dialogue at all levels to enhance our knowledge and understanding of nanotechnologies and to inform our membership, where they are not directly or actively engaged in R & D in this area, and act on their behalf in national and European fora. As such we are represented on a task force established by our European Confederation, CIAA; on the BSI NTI/1 Committee; Leatherhead Food International's Nanotechnology Forum; we are affiliate members of the Nanotechnology Industries Association; and are involved in public dialogue through CIAA and the Responsible Nano Forum.

[1] In the absence of international agreement on a definition, we use the generally adopted measure of 1-100nm in any one dimension to describe nanoparticles. The recently published SCENIHR report ((Scientific Committee on Emerging and Newly Identified Health Risks), Risk assessment of products of nanotechnologies, 19 January 2009) describes and characterises nanomaterials, and the Czech Presidency has suggested a definition for inclusion in the proposal to amend the novel foods Regulation as follows: *"'nanomaterial' means any intentionally engineered material that has one or more dimensions of the order of 100 nm or less or is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic to the nanoscale. Properties that are characteristic to the nanoscale include: (i) those related to the large specific surface area of the materials considered and/or* (ii) *specific physico-chemical properties"*

2. State of the Science and its Current use in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

2.1 Areas of interest include direct application in food, eg nano-encapsulation of flavourings and other ingredients; packaging applications, eg nano-coatings and barriers, "intelligent" packaging which will indicate the safety status of the enclosed food, improved printing inks; cleaning applications and equipment in processing facilities; diagnostics and process technologies, such as novel filtration and other separation technologies such as nano-sieves. The ability to understand and manipulate particles at the nanoscale is also opening up potential applications to improve foods in a conventional way through enhanced application of food technology. Such applications offer a number of benefits. For example, nano-encapsulation offers the ability to deliver smaller quantities of ingredients in a way that maintains flavour and texture properties of the food whilst reducing the content of ingredients that consumers are encouraged to eat less, such as salt and fats. Ingredients such as flavourings and micronutrients could also be protected until ready for release into the food, thus maintaining the quality of the ingredient for longer shelf life. Packaging could provide a quick and easy indication of whether or not the food inside is still microbiologically safe, for example by changing colour, or extend shelf-life through better oxygen barriers. The application of special coatings could enhance the use of modified atmosphere packaging through better control of the gases and moisture which affect the product, reducing spoilage and waste. Silver is a natural antimicrobial, and at the nanoscale is already in use in refrigerators and food containers in some countries, and has applications in food packaging.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

2.2 We know of no food products currently on the market produced by companies within our membership that either contain, are packaged in, or have used nanotechnologies in their production. We are aware of a small number of products on the market in the UK and elsewhere in the EU which are, or claim to be, "nano", such as a beer bottle which uses clay nanoparticles as a gas barrier; a food supplement using a nano-encapsulated ingredient; various food ingredients such as the minerals calcium, magnesium and silicon dioxide which claim to be of the nanoscale for improved absorption. These are understood to be in use mainly in the sports, health food and supplements sectors. There are also developments in oil-in-water and water-in-oil emulsions through the use of micelles, which can encapsulate ingredients such as omega-3 fish oils and deliver them in products without the fishy taste to provide a health benefit. Such applications are already understood to be in use in some parts of the world. EFSA has recently undertaken risk assessments on certain nanomaterials, for example Titanium nitride, in nanoparticle form, for use as a nano-coating in PET bottles, was recently assessed by EFSA as being of no toxicological concern.[2] We assume from such applications to EFSA for safety opinions that there are proposals to market the products in Europe.

2.3 We do not consider as nanotechnology applications the natural occurrence of nanoparticles such as in protein, fat or sugar molecules, or their presence through conventional processing techniques, such as milling, homogenising and emulsifying. Nor would we consider the ability to understand and manipulate particles at the nanoscale to fall within the definition of nanotechnology applications, unless particle size has been deliberately engineered to behave differently to its conventional counterpart. There are, however, grey areas in interpretation in the absence of an agreed definition and characterisation of nanomaterials.

2.4 At processing stage, nanosensors could lead to improved quality control and testing along the production and supply chain, indicating any breaks in optimum refrigeration, for example. Higher up the chain, sensors could be used at agricultural stages to monitor pest control and regulate the use of fertilisers and pesticides, minimising inputs according to conditions.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

2.5 FDF is not aware of applications beyond the general areas mentioned above, though we would not rule out the possibility of exciting developments which we cannot yet foresee. There may be developments at research level which could be of potential future interest to the food industry. As with any new technology, developments are proceeding apace and many research applications are subject to commercial confidentiality.

[2] EFSA Scientific opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) on 21st list of substances for food contact materials. *The EFSA Journal (2008) 888–890, 1–14.*

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

2.6 FDF and its members are closely connected to the research community and academia but as a membership organisation, we are not directly involved in research activities. Some of our members are linked to science-based organisations involved in research. We believe the UK to be at the cutting edge of R & D in nanotechnologies in general, though applications in food, food production and food packaging are currently limited by comparison with applications in other industry sectors.

What are the barriers to the development of new nano-products or processes in the food sector?

2.7 Consumer acceptability is clearly a pre-requisite for any application of nanotechnology in or around food. Consumers tend to be distrustful of new technologies applied to food and drink manufacture, especially if they find the technology difficult to understand or react to alarmist media coverage. What might be considered of benefit in other consumer goods such as electronic equipment or mobile telephones, or in pharmaceuticals and medical applications, may not be appreciated in food. Whilst FDF and many of its members and counterparts elsewhere in Europe are actively engaging in stakeholder dialogues, there is a clear distrust of the industry and in some quarters what appears to be deliberate scaremongering. There is also a degree of "hype" that makes it difficult to distinguish between genuine and new applications of nanotechnologies and marketing efforts to make a product more interesting by advertising it as "nano". For this reason we are advocating transparency throughout the supply chain so that food and drink manufacturers are adequately informed by their upstream ingredients and packaging suppliers about any applications of nanotechnologies in the products they purchase.

2.8 The other major hurdles are regulatory procedures and the immense costs of bringing new products to market, which might be regarded as prohibitive to all but the largest producers. In addition to R & D costs, the time and resource needed to develop a submission for regulatory approval are significant. Timings are also lengthy in the EU and can add significantly to the timescale of bringing a new product to market by comparison with other areas of the world such as the USA or Australia. Recently adopted legislation on food additives and flavourings may improve timescales, and current negotiations on a recast novel foods Regulation may centralise and accelerate approval procedures, but we have yet to see this in practice.

3. Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?

3.1 The recently published SCENIHR Report[3] and EFSA opinion[4] set out the areas of uncertainty regarding toxicology and potential new risks associated with articles at the nanoscale. EFSA's opinion, the draft on which we commented via CIAA, our European Confederation, considers current toxicity-testing approaches used for conventional materials to be suitable as a starting point for risk assessment for engineered nanomaterials (ENMs). This provides helpful guidance to industry. With new regulatory texts already setting out requirements for assessment of new particle sizes, industry needs clear terms of reference and guidance on the expectations from approval packages if innovative products are to be brought to the European market. EFSA also notes the absence of reliable and cost-effective methods of measurement and detection of ENMs in food and feed and recommends action to develop such methods to assess exposure in both humans and animals, and to generate information on the toxicity of different ENMs. We would add that such methods are essential to industry to verify products and to comply with regulatory requirements.

3.2 FDF is also conscious of health and safety aspects of handling nanoparticles by our own workforce and we are actively monitoring developments in risk assessment in this area, thus acting as responsible employers. We applaud the work being undertaken by the Institute of Occupational Medicine, which we believe to be a leader in the field.

[3] SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks), Risk assessment of products of nanotechnologies, 19 January 2009.

[4] EFSA Scientific Opinion on a request from the European Commission on the Potential Risks Arising from Nanoscience and nanotechnologies on Food and Feed Safety. *The EFSA journal (2009) 958* , 1–39.

Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?

3.3 We believe the research associations, Campden BRI and Leatherhead Food International, are best placed to comment, though please see also our comments in paragraph 3.2 above. The EU has made a considerable research investment, some €3.5 billion, into nanotechnologies, including the health and safety aspects of their use, under the FP7 programme. The nanotechnology Knowledge Transfer Network (KTN) and International Life Sciences Institute (ILSI) are active in this area. We would also refer the Committee to the response of the BSI's nanotechnology NTI/1 Committee concerning the need for funding of work on international standards and metrology, which are basic tools for the practical application of nanotechnologies, as is an internationally agreed definition.

Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

3.4 FDF believes the SCENIHR and EFSA reports cited above have clearly set out the requirements in this area. We acknowledge that there remain some unknowns and further research is needed.

Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?

3.5 FDF draws a clear distinction between naturally occurring nanoparticles and the presence of nanoparticles in food from certain conventional processes, and nanoparticles or nanomaterials that have been deliberately engineered to confer different properties. The latter should be treated differently for regulatory purposes where they confer novel properties and therefore might pose different risks. FDF's view is that food processing technologies like emulsifying and homogenisation as well as processes based on colloidal properties with particle sizes in the nanoscale range should be differentiated from the term nanotechnology unless deliberately engineered nanoparticles are involved.

4. Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

4.1 EU food regulation is already very comprehensive. We consider the existing legislative framework to be adequate or adaptable in all areas where nanotechnologies may be applied in food or food processing. Regulatory gaps are being filled as specific regulatory texts come up for review (eg food additives, enzymes and flavourings, novel foods, food contact materials). FDF responded to this effect to the Food Standards Agency's (FSA) regulatory review in 2006. The European Commission noted in its Communication on Regulatory Aspects of Nanomaterials[5] that "Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation." (Section 2, paragraph 4.) We concur with this position.

4.2 Imports to the EU are subject to the same legislation as products produced within the EU. We cannot, however, comment on the effectiveness or otherwise of implementation and enforcement of the law on imported products, particularly those traded via the internet.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

4.3 We believe the food and drink manufacturing industry behaves responsibly and would seek regulatory approval for any product or process which was significantly changed through the application of nanotechnologies such that it differed from the conventional product or process. We would question whether self-regulation is even applicable: the European General Food Law, Regulation 178/2002, in any case places an obligation on food business operators to ensure that any food product placed on the market is safe.

[5] Communication from the commission to the European Parliament, the Council and the European Economic and Social Committee, COM(2008) 366 final, Brussels, 17.6.2008

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

4.4 We believe the regulatory framework will be able to adapt to meet any new requirements in view of the general way in which the Regulations are cast. Any change in material specification, eg for food additives, would require a re-evaluation of the substance. The EU regulatory structure relies strongly on positive approval, therefore new products and processes would not come to market unless the control mechanisms were in place. We believe that the products of nanotechnologies, used directly in food, already fall within the scope of the existing EU Novel Foods Regulation, and that recast regulation of food contact materials will also cover packaging applications.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

4.5 Dialogue is ongoing at several levels: EU institutions, EU and international standards bodies, trans-Atlantic co-operation, OECD. There is also a project on EU/US regulatory convergence.

5. Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

5.1 We assume awareness in the general population to be low, except where interest is taken in developments that have already come to market, such as in the area of sunscreens. The term "nano" has taken on a general meaning of "very small" and is widely used in the marketing of many newer and smaller consumer goods, such as mobile telephones and electronic devices. We have engaged with Which? in their public dialogue and are actively involved with the Responsible Nano Forum, which is promoting public engagement. Through our European Confederation, CIAA, we are involved in a stakeholder dialogue at EU level.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

5.2 Industry is involved in initiatives as above. This is a relatively new area of public engagement, as developments are largely still at research phase. Previous experience with new technologies is that consumers tend not to take an interest until products are on or near the market, or awareness is raised through high profile campaigns or media coverage, often in a negative way. We are not aware of any specific Government initiative to engage the public in dialogue. Which? and other NGOs such as Friends of the Earth have been at the forefront.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

5.3 Whatever attempts are made to engage the public, interest tends to be limited to those either with specific issues or concerns or a strong opinion or viewpoint, whether or not based on factual information, or those with a high level of interest in new technologies. Only when products actually come to market or media headlines raise awareness in either a positive or negative way have we seen mass interest in the application of new technologies in food. Our experience is that most consumers do not care, as long as the product looks and tastes good and the price is right.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

5.4 Yes, provided this is done in a factual, objective and balanced way. In view of the many potential applications of nanotechnologies in fields other than food and feed, information should be application-specific. General references to "nanofoods" would be uninformative and unhelpful in terms of informing consumers about the use of nanotechnologies in food, food packaging and food production.

The Committee would also be interested to hear about any other issues not already covered by this call for evidence that are relevant to the scope of the inquiry.

5.5 FDF sees nanotechnologies as useful enabling technologies that could enhance food production to provide processing and consumer benefits. It would be regrettable if such scientific advances were closed off because of irrational fears about the use of new technologies or a failure to provide convincing evidence of their safety in use. FDF would like to see rapid developments in addressing the uncertainties outlined in EFSA's report so that industry can progress research into innovative products and processes with confidence in assessment procedures and regulatory outcomes. For our part, we are engaging in co-operative dialogue

and, through CIAA, engaging with the Commission's Safety for Success initiative. Through stakeholder dialogues we are seeking to ensure transparency and exchange of information with interested parties. We welcome the Committee's very timely Inquiry and look forward to constructive outcomes.

Annex

THE UK FOOD AND DRINK MANUFACTURING INDUSTRY

The Food and Drink Federation (FDF) represents the food and drink manufacturing industry, the largest manufacturing sector in the UK, employing over 500,000 people. The industry has an annual turnover of £70 billion accounting for 15 per cent of the total manufacturing sector. Exports amount to almost £10 billion of which 64 per cent goes to EU members. The Industry buys two-thirds of all UK's agricultural produce.

The following Associations are members of the Food and Drink Federation:

ABIM	Association of Bakery Ingredient Manufacturers
ACFM	Association of Cereal Food Manufacturers
BCA	British Coffee Association
BOBMA	British Oats and Barley Millers Association
BSIA	British Starch Industry Association
CIMA	Cereal Ingredient Manufacturers' Association
EMMA	European Malt Product Manufacturers' Association
FA	Food Association
FOB	Federation of Bakers
FPA	Food Processors' Association
GPA	General Products Association
MSA	Margarine and Spreads Association
SB	Sugar Bureau
SMA	Salt Manufacturers' Association
SNACMA	Snack, Nut and Crisp Manufacturers' Association
SPA	Soya Protein Association
SSA	Seasoning and Spice Association
UKAMBY	UK Association of Manufacturers of Bakers' Yeast
UKHIA	UK Herbal Infusions Association
UKTC	UK Tea Council

Within FDF there are the following sectoral organisations:

BCCC	Biscuit, Cake, Chocolate and Confectionery Group
FF	Frozen Food Group
MG	Meat Group
ORG	Organic Food and Drink Manufacturers' Group
SG	Seafood Group
VEG	Vegetarian and Meat Free Industry Group
YOG	Yoghurt and Chilled Dessert Group

13 March 2009

Memorandum by British Retail Consortium

1.0 Introduction

1.1 The British Retail Consortium (BRC) is the main trade association for retailers, and our members are responsible for approximately 80 per cent of all grocery sales in the UK

1.2 Retailers take a keen interest in all issues affecting food production and packaging. Whilst retailers sell a large number of own brand products in their stores, they are not manufacturers in their own right. For this reason our submission focuses on issues of retail and consumer acceptance, rather than the detailed science around nanotechnology.

1.3 Retailers have strict policies in place to ensure the products they sell are safe and legal. We believe there could be benefits in nanotechnology for consumers; however, as the application of the science is new we support a robust regulatory and safety assessment framework. We want to work with stakeholders to ensure

there is a good understanding of the benefits, risks and regulatory gaps around nanotechnology to avoid it being rejected due to lack of understanding.

1.4 We have responded to those questions in the request most relevant to our sector.

2.0 State of the Science and its Current use in the Food Sector

2.1 *What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?*

2.2 We believe the benefits could be in improving the composition and packaging of existing foods. In terms of food, the main application we foresee is the ability to improve the efficiency of an ingredient in terms of reducing its usage but retaining its quality. For example, manipulating salt crystals at a nano level could have a huge impact in reducing salt consumption but retaining the taste customers expect. Re-formulation on this basis, to improve the nutritional composition of a product without compromising the taste could play its part in improving the nutritional value of processed foods. In terms of packaging, there could be benefits through lengthening the shelf life of food, reducing the amount of packaging and improving its potential for recycling.

2.3 *What is the current state of the market for, and the use of, food products, and food production processes involving nanotechnologies, either abroad or in the UK?*

2.4 This depends to a certain extent as to the definition of a nano food process as we understand this could extend to products such as traditional cheeses. In our opinion the definition of nano food should take account of whether it is engineered or naturally occurring, whether it is soluble, its size and change in properties. This raises the issue of whether manipulating existing ingredients such as salt at a nano level is something that would be counted as new technology or simply the better application of a known product. There could be a market for these types of products as consumers may see it as re-formulation but retaining the taste they want. In terms of more innovative, new products developed from scratch, our market is conservative and consumers will weigh up the benefit to them.

2.5 *What are the barriers to the development of new nano-products or processes in the food sector?*

2.6 All retailers are led by consumer demand, which means consumers need to see tangible benefits, which could cover a number of factors including nutrition, sustainable development or innovation. As consumer knowledge is currently low they would need to recognise such benefits over existing products and for this to be sufficient to overcome concerns they might have. We know, from the GM debate that consumers could not see a benefit in GM food for them and became concerned about the perceived health and environmental risks due to the messages they received at the time. This demonstrates the need for Government to explain to consumers the benefits, give clear direction on risk and also the key role the media have in reporting new and emerging science in a factual and balanced way.

3.0 Health and Safety

3.1 *Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?*

3.2 We believe there does need to be a distinction in terms of food safety between completely new food ingredients which are produced from scratch and existing ingredients which are engineered at a nano size that retains their properties but enables them to be used more efficiently. We also believe risk assessment needs to account for where nanotechnology is used, drawing a distinction between packaging and food. We responded to the FSA consultation in 2008 on novel foods to suggest more detail was required on the definition of novel foods and if that covered nanotechnology. We are clear, however, that we support a robust and transparent regulatory framework.

4.0 Regulatory Framework

4.1 *Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?*

4.2 We believe this would be improved by clarifying the definitions in the novel food regulations to make it clearer if it applied to nanotechnology.

4.3 *How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?*

4.4 In general terms self-regulation works well in the UK food sector, for example, the industry has made good progress on nutrition, removing artificial transfats and colours, reformulating products to reduce the amount of salt and saturated fat, and supporting public health campaigns to encourage customers to eat healthily.

5.0 Public Engagement and Consumer Information

5.1 *What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?*

5.2 Our belief is there is a very low awareness of nanotechnology generally amongst consumers. In some non-food products there is an understanding that nanotechnology is used positively, improving quality, for example miniaturising components in electronic equipment. Our members have confirmed from that their customer care lines do not receive queries about nanotechnology and our belief is that customers do not believe it is currently used in food. In terms of the public perception, there is a positive approach to some of the non food applications but we are cautious about their perception of its use in food. Consumer demand for GM has never recovered from the damaging media reaction in the late 1990's and we believe they remain cautious about other products that use new technology.

5.3 *How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?*

5.4 To date engagement with the public has been limited. We would be happy to contribute to a Government led engagement which aims to raise awareness and discuss the issues in a pragmatic fashion. The Government needs to be at the heart of discussions to ensure these are based on science and fact and not dominated by speculation and individual opinions.

5.5 *What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?*

5.6 We need to bear in mind the lessons that should be learnt when GM food was trialled in the 1990's. We must ensure that an authority, FSA in our opinion, is available to provide the facts from a consumer perspective. FSA action should include proactive engagement with stakeholder groups, including consumers and the media, to ensure current issues are understood and uncertainties answered. Ultimately the introduction of nanotechnology to food products will only succeed if consumers can see a benefit for themselves, something that was never clearly demonstrated with GM food.

5.7 *Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?*

5.8 The key issue is whether consumers understand the use of nanotechnology and the issues around them, which will rely on education. Information is only effective where it helps consumers make an informed choice. Without the knowledge to make informed decisions there is a danger that labelling will mislead consumers.

12 March 2009

Memorandum by Dr George Kellie, KellieSolutions Ltd

HOUSE OF LORDS PRESENTATION

Background

Dr George Kellie is chairman of KellieSolutions™, a leading UK marketing and technology company. Dr Kellie's businesses have been in existence for nearly 20 years and have a strong reputation and expertise in plastics, packaging, and sustainability strategies. KellieSolutions™ has been focused on the detailed analysis and evaluation of advanced new technologies in packaging, paper and plastics films on a world-wide basis. This has included shelf life extension solutions.

In the field of sustainable materials, KellieSolutions™ has also been particularly active, working on advanced materials in packaging, film, sheet and fibre form. Dr Kellie is actively involved in generating new sustainable solutions across a broad range of applications for major international clients.

In recent months George Kellie has published a series of articles on practical business actions in the recession and as a contribution to the recovery is offering a free consultancy service to struggling UK businesses.

Nanotechnology and its Place in the Packaging Market

From a KellieSolutions perspective, nanotechnology fits in to a group of processes and techniques designed to meet a complex range of requirements. These range from extended shelf life through to easy to recycle, etc. In general, we view nanotechnology in a much broader category of micromaterial addition. Whether these are actually in nanometres or just in very low addition levels largely does not matter. What does matter is the ability to create products which can meet a complex series of challenges.

Trends and Opportunities in Advanced Packaging Materials

Summary. Packaging developments in the coming years need to focus on an interlocking series of objectives. These include aspirations such as lightweight, easy to recycle, low CO_2/greenhouse gas impact and, of course, low cost. Overriding all of this is product safety.

At the heart of this work is the need to extend packed food shelf life and dramatically reduce food waste. These are beneficial outcomes that apply to society in general and not just to the commercial enterprises involved in the industry. However in order to gain mass market acceptance these new packaging formats have to be cost effective and safe. Three of the major trends are in techniques for extending shelf life, time/temperature Indicators, and nanotechnology. These threads are interdependent.

Shelf Life Extenders. In the area of advanced technology for extending shelf life, we can already see the development of materials which offer shelf life improvement through atmospheric modification. These can be modified atmosphere (MAP) packs (these are very well known) and more recently the use of moisture, oxygen, ethylene, and CO_2 sachet-type absorbers. All of those play a part in extending shelf life depending on the food degradation/barrier requirements.

Time Temperature Indicators (TTIs) and related devices are also interesting. KellieSolutions have done a considerable amount of work with a number of these products. While they attract consumer interest, at this time their costs are often prohibitively high and at times it is difficult to easily verify whether they really provide more information than the simple "use-by" date. A much more important area where TTIs can have impact is to look at monitoring and management of the Chill Chain. The Chill Chain process is one of the key controllers of the quality of food that arrives in the store. The more we know about the Chill Chain, the more we know the history of how packs have been stored and distributed. By measuring and monitoring pack history we reduce food degradation risks and improve process efficiency. This is the area where we believe there are greatest gains to be made. In addition, the cost of TTIs becomes insignificant when they are monitoring a transit pack or pallet with multiple packs compared to the cost when they are applied to individual packs.

Nanotechnology

Nanotechnology involves advanced materials dimensioned at or near atomic scale. A nanometer is one billionth of a meter. At this nano level the characteristics and performance of materials can radically change often providing unique properties and benefits previously impossible to achieve. In our work we talk more about "micro" and "miniature" rather than nano. These micro additives are still materials used at low levels but not strictly nano. For example this allows us to create new generation vacuum micro-deposited materials for clear barrier films. The opportunities are exciting. In the future nanocomposites may be able to modify packaging films to increase gas barrier, enhance strength, and improve temperature resistance. Not surprisingly nanotechnology has not yet achieved its much-hyped potential which has run well ahead of reality. Also before nanotechnology can be fully adapted to direct food-contact packaging applications, the technology must be evaluated in safety regulatory systems.

Some examples of nanopackaging materials include:

— Nano composites. These can create high barrier layer in films and bottles with minimal extra weight. These can help to create barrier packs with long shelf life under ambient storage conditions.

— Electrically conductive inks. Potentially these can be used to print radio-frequency identification (RFID) tags and other on-pack electronics.

— Nanoclays. These are being incorporated into plastic nanocomposites. Once again gas/moisture barrier is the main focus.

— Zinc oxide nanoparticles. Such materials are aimed at providing antimicrobial performance.

By using a nano level or just micro level deposition, we can open up a whole new set of markets and opportunities.

Ultra Clean Materials. A related area is the micro evaluation of surface properties. This is not about deposition, rather the reverse. The aim of these techniques is to produce ultra pure and ultra clean films. Measuring "clean" and "pure" is difficult and requires using different techniques including liquid particle scanning and Time-of-Flight Secondary Ion Mass Spectrometry (TOF-SIMS). This work opens up new opportunities by focussing on packs that have a minimal impact on the products contained within them. In simple terms.. "less is more".

One of the most promising innovations in smart packaging is the use of nanotechnology to develop antimicrobial packaging. KellieSolutions has recently patented advanced processes to micro-deposit anti-bacterial additives.

Safety

This is a live issue which is being followed by several bodies. The Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organization (WHO) are starting to look at the issues. In June 2009 they will hold a joint meeting to examine potential food safety risks from nanoparticles.

KellieSolutions™ Ltd

April 2009

Examination of Witnesses

Witnesses: Dr Mike Knowles, The Coca-Cola Company, Mr Andrew Opie, British Retail Consortium, and Dr George Kellie, Microflex Technologies Limited, examined.

Q155 ***Chairman:*** I would like to welcome our three witnesses this morning, as well as the members of the public who are sitting behind them, to this third public hearing in the inquiry into nanotechnologies and food. I should inform witnesses and members of the audience that the proceedings are being webcast as usual and that an information note is available for members of the public which sets out the declared interests of the members of this Select Committee. Before we start on our questions I would like to invite the three witnesses to introduces themselves and if you have any comments that you would like to make as a prelude please feel free to do so, and you will have another opportunity at the end to make any additional comments if you wish. Dr Kellie, would you like to go first?

Dr Kellie: Thank you, my Lord Chairman. My name is George Kellie. I am Chairman of a very small specialist company called Kellie Solutions. You will see the name Microflex Technologies, that is one of our businesses. We have been around for about 20 years. Our core work is technology-based with a certain marketing involvement. By sector, packaging is about half of what we do in terms of technology. Other related areas are in things like hygiene. Our customer base is very varied. It goes from, at one end, the supermarkets and food companies to, at the other end, basic packaging material companies. Finally, just to say we invest in our own technology as well as work we do with customers and we have developed a significant number of patents and other developments.

Q156 ***Chairman:*** Thank you. Dr Knowles?

Dr Knowles: My Lord Chairman, I am Mike Knowles. I am here representing the UK Food and Drink Federation and also the European Confederation of Food Industries. I also work as Vice-President for Global Scientific and Regulatory Affairs for The Coca-Cola Company. I would like to make a short statement if I may. We are very pleased to be here to give evidence to this Committee. I am sure you have already heard there is a shared enthusiasm within the food industry to explore the potential benefits and applications of nanotechnologies in food production, processing and packaging. The publicity given to the application of nanotechnologies in food suggests there are many current applications on the market, but this is contrary to our understanding and knowledge of the situation. We believe there is a need for a full safety evaluation before any product from a nanotechnology should be commercialised. We are bound by the current legal frameworks within the European Union and, of course, we exercise due diligence to ensure our members comply with that European framework. We are working actively to prepare the ground for potential applications through transparency and engagement with

appropriate organisations, including the Food Standards Agency and European institutions. We believe it is extremely important to build trust throughout the supply chain and, of course, with the final consumer. Thank you.

Q157 ***Chairman:*** Thank you. Mr Opie?
Mr Opie: My name is Andrew Opie. I am the Food Policy Director at the British Retail Consortium. We are the trade association that represents retailers who account for approximately 80 per cent of grocery sales in the UK. We welcome the chance to give oral evidence today. The timing of the Committee's inquiry is very apt because we are just starting to get to the stage where customers are getting curious about nano in food, but what we would welcome is more discussion around the demystifying of some of the terms that have been bandied around nano so consumers can understand more both about the benefits and potential issues around nanotechnology as well.

Q158 ***Chairman:*** Thank you all very much. Perhaps I could kick off with a general question. Dr Knowles, we have heard that the food manufacturers as represented by the FDF are enthusiastic to explore the potential benefits of nanotechnologies and nanomaterials. I also note in Dr Kellie's written evidence he says: "Not surprisingly, nanotechnology has not yet achieved its much hyped potential which has run well ahead of reality". I wonder if, between you, you could give us a feeling for where you think that these potential benefits lie that you are keen to explore.
Dr Knowles: My Lord Chairman, I think the advances in packaging are the ones which are most advanced in terms of real applications and, in fact, the European Food Safety Authority has reviewed two of these recently and given its endorsement to their use but that, of course, is subject to the Commission and the Council giving their final approval. There are the potential benefits for barriers to protect against oxygen ingress or gas escaping through the walls of plastic materials, antibacterials, which you know are on the market already in the UK in plastic containers, nanosilver, and also, looking a little further forward, sensors in the packaging which may detect deterioration in quality or even the presence of pathogenic micro organisms. In terms of the direct addition to food there are many, and I know you have received a host of examples of the potential direct applications, for example the nano-encapsulation of vitamins, nutrients, some additives and what we call functional ingredients to protect them during manufacturing and storage of the food, but also to enhance their functionality in the body. It is somewhat analogous to the medical application where you can improve targeted delivery of some ingredients through protection by the application of certain nano-encapsulation processes. In addition, the carriage, if you like, of certain functional ingredients to their target organs within the body, as in medicines, we believe can be enhanced in the future by appropriate nano-coatings or nano-carriers. I know there are already examples on the market of certain supplements which are nano-encapsulated to enhance their properties in this way. There are benefits in cleaning operations; surfaces can be coated with various nano-coatings. Some call it the Lotus effect as in the Lotus leaf where the water falls off in discrete droplets rather than getting into the leaf. This would reduce the use of water for cleaning and has benefits in terms of protecting against contamination by films being built up on food processing machinery surfaces. Of course, in filtration, nano-sieves, there are applications that are quite advanced in the purification of water through nanofiltration. We have ultra-filtration now and we have nanofiltration coming along which we have been looking at as a company, as a member of the International Water Association, for developing countries. It is a very effective way of cleaning water. Those are just a few of them, my Lord.

Q159 ***Chairman:*** Thank you very much indeed. I do not know whether Dr Kellie or Mr Opie would like to add anything to that.
Dr Kellie: First of all to say that what we have just heard fits in very much with some of what I have put in my own paper. When I look at the work that we are engaged in, which is very much packaging, we do not get involved in food directly, we see the opportunities that nano offers as being very exciting because they also interlock with another major theme that we are involved in which is in terms of sustainability and packaging waste. I do not want to divert the Committee into another whole subject, but packaging waste is an equally critical area. The ability to take, for example, plastic films much used in packaging and make them thinner, make them lighter and yet retain their strength, and therefore by doing that significantly reduce the weight of material that we use in packaging, and almost all the UK's major retailers are signed up to packaging weight reduction, is of great benefit because ultimately as we make these materials thinner, and you can recognise it from your own experience, it becomes harder to deal with the strength properties. The second thing is barrier. We have talked a bit about barrier. Barrier is the critical element in terms of shelf-life, and I am sure you are all very well aware of that. We look at barrier in terms of moisture, in terms of oxygen, and in terms of CO_2. It depends what you are packaging in terms of what you want to exclude from the pack. This is incredibly important for two reasons. One, it goes without saying that every step that we can take that reduces

food waste in a global sense is a positive move for us to make. The second thing is it offers us the potential to pack products and retain their shelf-life under ambient conditions. In other words, we do not have to expend energy to retain the product under frozen or chilled conditions. There are some terrific gains if nano can deliver but there is a lot of work to be done. There are great gains that we think are enormously beneficial.

Mr Opie: The only thing I would add to that is we do see there is quite a big role for nanotechnology potentially to answer some of the public policy issues we are facing. We have already spoken quite a lot about food waste packaging and those sorts of issues at the moment where retailers and manufacturers are under pressure, quite rightly, from Government and from their consumers to deliver on these issues. The other area that we are quite interested in is some of the areas around reformulation of food. Can we deliver the same benefits to consumers in terms of taste and texture, for example, but cutting out some of the issues such as some saturated fats in products. What we have found in some areas of reformulation is that it is difficult always to take consumers with you if they do not get the same taste or texture from the food that they would usually expect to see in the food they are routinely buying and, therefore, some of the measures to cut some of the worst nutrients out of our diet would be improved if we could deliver the same taste, texture and product to consumers but help them by taking some of the saturated fat out of the product, for example. We see there could be potential in this in terms of taking customers with us in an easier way to meet some of the targets in nutrition and health.

Q160 ***Lord Haskel:*** I wonder whether you could help us on the matter of definition. I think at the very beginning we ought to decide what it is that we are talking about. We wondered how you would define "nanotechnologies" and "nanomaterials" in the context of the food sector.

Dr Knowles: My Lord Chairman, if I can start. This is a difficult question that we have been discussing for many months. I am going to refer to greater authorities than I in terms of developing definitions. The International Standards Organisation—ISO—has a definition of "nanotechnologies" and I will read this: "Understanding and control of matter and processes at the nanoscale typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size dependent phenomena usually enables novel applications". Then it defines a "nanometre" where one nanometre is 1,000 millionth of a metre. For "nanomaterials", we in the food industry are looking at the emerging definitions from the Scientific Committee on Emerging and Newly-Identified Health Risks—SCENIHR—in Europe who have discussed this themselves and the definition that they propose, that we think is reasonable, is as follows: "Nanomaterial means any intentionally engineered material that has one or more dimensions of the order of 100 nanometres or less or is composed of discrete functional parts either internally or at the surface, many of which have one or more dimensions of the order of 100 nanometres or less, including structures, agglomerates or aggregates which may have a size above the order of 100 nanometres but retain the properties that are characteristic to the nanoscale. Properties that are characteristic to the nanoscale include those related to the large specific surface areas of the materials considered and special physico-chemical properties." The importance for us is to link both the size and the novel properties that the materials have. It is not size alone which determines whether a material is nano. That is how we currently think of nanomaterials and nanotechnologies.

Dr Kellie: I would like to endorse that and say that we, being practical people, are about producing practical solutions, we are not theoreticians, we are not writing academic papers, we are trying to produce real results. For us, the definition matters far less than the important issue which is we are dealing with materials which at a very small level or micro level or, ultimately, nano level have got exceptional properties. That is the key. The key for us is that these materials in extremely small quantities turn out to have properties which are amazing. For example, we could put a nanoclay into a plastic nanocomposite and suddenly obtain significantly greater strength properties. It is the exceptional properties rather than the pure definition of nanotechnologies that matters i.e. the materials do not have to be 100 nanometres or less. It is the exceptional properties that we are concerned with because we want results, quite frankly.

Mr Opie: I am not going to disagree with the definitions here. The one thing I would say is the thing we discussed at the start; definitions is one issue in terms of the regulatory framework, which I am sure is one issue we will look at later, but there is also the general consumer's understanding about what is meant by nano. I talk about that for both potential benefits and risks. For example, on the non-food side we have seen a lot of interest in the use of nano—iPods, sunscreens, those sorts of issues—where consumers have embraced nano. Whether they have an understanding of what is meant by "nano", there is a risk in some ways that products could be sold as nano on the basis that they give something extra when they might not and whether they understand what is going on. Do they understand, for example, that there are already nanomaterials out there in food at the moment, for example in cheeses and various other products? For us, the definition is obviously

important in terms of the regulatory framework but a bigger issue for us is a consumer's understanding of what is meant by nano so when they go into a store they know what to expect.

Q161 ***Lord Haskel:*** I think you are right. I assume the public would be concerned about the nanoparticles that persist in the body. I wonder whether you think that different types of nanomaterials should be treated differently for regulatory purposes? What you have given us is a definition of particles which are intentionally manufactured, but do you think we need a definition for regulatory purposes of nanoparticles which are specifically for the food industry which persist in the body?
Dr Knowles: That is a difficult question to answer because at the moment we do not have any information about nanoparticles that persist in the body or persist anywhere. What we are doing to address part of your question is we are defining engineered nanomaterials and separating them from naturally occurring nanomaterials, such as Mr Opie just alluded to. Of course, we are exposed to nanomaterials all the time through the food supply. When we metabolise proteins, carbohydrates, lipids, they are metabolised at a nanoscale in-vivo, so the body is well-used to handling, if you like, natural nanomaterials. Ricotta cheese is the example that is frequently quoted as having been around an awfully long time and has micelles and nanoparticles in it, nano-emulsions, if you like, it is not nanoparticles. I am sure your concerns are related to the nanosilvers, nanogold and nanozinc oxides, the inorganic nanoparticles, and personally at the moment I do not see any direct applications of those in food. In supplements that is a different matter, and I do not represent the supplements industry. I am not ducking the question. I do feel there are toxicological questions being asked about those materials. I know that the Public Health Institute in Bilthoven in the Netherlands is looking at the pharmacokinetics of nanogold and nanosilvers as part of their study into the toxicology and fate of those materials. I do not see the persistent, if they are persistent, materials as being something that applies to the food industry per se but may apply to some of the supplements that are currently on the market in other countries. I should add, they are not being manufactured in Europe to my knowledge. I hope that helps.

Q162 ***Lord Mitchell:*** Continuing on the subject of practicalities, Dr Kellie, you mentioned it first of all but I want to talk in terms of applications and what applications of nanotechnologies and nanomaterials in the food sector are UK companies and overseas companies currently working on. When you have answered that I want to ask about what is going to be happening in the future, so you can think about that too.
Dr Kellie: First of all, I think clearly there are a number of significant development programmes going on in nano at the moment in different areas. I have alluded to a number of the ones I am particularly familiar with in terms of lightweight barrier materials, but there are others which interact with those which are nano in the packaging sense but maybe not in the direct sense. For example, one of the areas we see as having a sizeable impact in time is the ability to produce printed electronics. You might say what has that got to do with packaging, but it has got a lot to do with packaging. The most direct application is printing so-called RFIDs, that is the tags, so-called smart tag idea, so that we can print the electronics on to the pack. That is (a) cost-effective and (b) by printing electronics we can carry a vast amount of interrogatable date about the content of the pack. Much more than a bar-code, an RFID allows us to carry data first of all about the life of the pack and, secondly, if necessary, about the application of the pack. We see that as particularly important. A secondary stage beyond that that people are looking at is something we talked about earlier, which is being able to actually monitor the status of the pack. If we print electronics, for example, that would measure the temperature the pack has been under through the Chill Chain, which we regard as a very important piece of data to be able to manage, it tells us more about the lifecycle that the pack has endured. The range of nano-derived applications is wide. The number that is coming to market is still relatively small at the moment. The amount of work and effort that is going on to develop these concepts is pretty substantial.

Q163 ***Lord Mitchell:*** This tagging you are talking in terms of, I can understand how it is beneficial to the manufacturers but how does it help the consumer?
Dr Kellie: It benefits the consumer in a number of ways. First of all, the more data that we know about the pack, and the products we contain in the pack, the better. It is more than just when to replenish the stock in the warehouse, which I accept is one piece of information, or to tell the retailer how many he has sold in any one week, which is commercially valuable, it can carry a lot more data than that. As I explained, for example, it can carry data about the lifecycle of the product. As these electronics become more complex, just to take the example of its progress through the Chill Chain, printing electronics allows us to know how long it has been in the Chill Chain and what the temperature conditions are. Temperature conditions are absolutely critical. It is critical for chilled products that they remain in this magic temperature band of 2–4° which is the typical temperature range. If for any reason it goes outside

that, potentially food can go off. That benefits the consumer absolutely directly because the more we know about the pack and the more we reduce the risk of exposure to food that has gone off for any reason the better for the consumer. That data will definitely benefit the consumer if we can apply it in that way.

Q164 ***Lord Mitchell:*** I know in your marketplace at the moment forecasting what is going to happen in a month's time is probably difficult, but how do you see developments in the next five or ten years? Where do you expect them to come from?
Dr Kellie: First of all, over the next five years I expect it to be an explosive period of development. If I look at the amount of research that is going on, the number of specific applications that you can see that are in early stage development at this point, that is significant. The amount of finance that is going behind that is also significant. The $64 million question is what is going to come first and fastest. I have outlined some of the areas that we think are going to come first and fastest, in other words lighter/thinner materials is one that is going to come relatively quickly. Barrier is going to come at some pace as well. The controlling factor probably will be more about the regulatory issue, which is what you as a Committee are addressing, and that is critically important because if we do not put safety first it does not matter how wonderful our technology is, safety has to be paramount throughout the process. In my opinion, that will be the controlling factor. The developments that are going to come most rapidly will be those that ensure the nanomaterial is buried within the layers of the product and the pack rather than directly in food contact. Once we get into direct food contact the regulatory demands and the safety demands, rightly, are higher. My anticipation is over the next three years, far less the next five years, you are going to see a significant number of developments coming to market and coming forward as well for regulatory testing.

Q165 ***Chairman:*** Thank you. Would you like to add anything to that?
Dr Knowles: If I move to the direct applications, of which there are very few at the moment in terms of development, and what individual companies are doing then I guess you would have to ask them. It is a very competitive market in the food industry, as you know, and if the major companies are working this area, and some are of course, in the direct applications, as Mr Opie mentioned one of the technologies which is quite near to market now is the changing of the texture of the foods, the new mixers, special types of food machinery. I am not a food technologist but they are capable of producing nano-emulsions to change the texture, reduce the use of certain macro-ingredients, such as saturated fats or other fats, and retain the organoleptic properties. In addition, there are extensions of that application to change the way in which the materials are metabolised. It may increase satiety by using some nano-emulsified materials. More along the lines I mentioned earlier is the nano-encapsulation of certain nutrients to improve the bioavailability as well as protect them against oxidation or other degradation processes, and that is quite an exciting area. It is paralleling the developments in medicine where, knowing what the target organs are, one can improve the specificity by appropriate manipulation with nano-encapsulation. Again, there are opportunities there for maybe delaying digestion and improving satiety, which we are all looking for. We are all competing for the same diet. Certainly nowadays we are told to reduce the amount that we are consuming, so we are all competing for a smaller market, so to speak, and we are looking for ways in which we can improve the health properties of foods. Nanotechnology does offer opportunities there. I only know of one major project that is going on in the US with the Food and Drug Administration, the Institute of Food Technology and the International Life Sciences Institute, of which I happen to be the President globally, and the Grocery Manufacturers Association. The European food industry is involved peripherally in that. They are looking at all of the potential applications, doing a major review of the literature, which is the first phase, and then looking at potential applications at different periods of time. Then they will look at all of the toxicological data, which is the next phase, and draw from that the published papers which will put in context what they think will be the sequence of applications of nanotechnology following appropriate safety evaluation. I am sure we are going to discuss safety evaluation later. It is all predicated on appropriate safety evaluation before we can use any direct applications.

Q166 ***Chairman:*** When is that review due to be completed?
Dr Knowles: The first phase certainly by the end of the summer, maybe September/October, and then we will move on to the later phases. We are also looking at the development of what is called the Woodrow Wilson project on nanopackaging last year, as an example for an exercise on hypothetical additions to hypothetical foods. There will be a series of case studies looking at how they would be evaluated by the regulators both in terms of the chemistry and the technology as well as the toxicology. It is not a good time to go asking for a lot of money from our bosses in the food industry—it is never a good time to do that but this is a particularly bad time, as you are well aware—but we are asking for funds to try to get this series of case studies up and running to give, as the

packaging study did, some real examples that we can use not only in terms of educating the public as to the benefits of nanotechnology, which is extremely important, but identifying any gaps that we need to identify for a safety evaluation.

Q167 ***Lord Methuen:*** I think we all know that trace elements, such as beryllium, copper and selenium, are also necessary in our diet. Does nanotechnology offer the capability of controlling the levels of this or is this already handled by current technology?
Dr Knowles: My Lord Chairman, the addition of selenium and other trace minerals is handled by current technology. We do not usually add selenium to food as such, it has a very small safety threshold between what is required nutritionally and what is unsafe only by a factor of three, so certainly in the major companies it is not an element that we add. There are issues around different parts of the world where local selenium levels are high so we do not want to exacerbate those issues. I am not sure if there are nanoparticulate selenium compounds or nano-encapsulated compounds in the supplements industry which are being marketed. Nano zinc oxide, nanosilver, nanogold, nano selenium, nano copper, many minerals are being looked at from a supplements point of view. I do not know anything about the beneficial properties of those materials but they are available.

Q168 ***Lord Methuen:*** With regard to research and development, where does the UK stand? Are we at the cutting edge or are other countries ahead of us?
Dr Kellie: My Lord Chairman, first of all I am aware of one or two developments in the UK. For example, Hallam University is doing a programme under the SustainPack Development Programme which is about adding or using nanotechnologies in packaging. I talk most of the time as if all the packaging developments were plastic, and, while it is easier to add nano to plastic materials, paper and paperboard are a very significant part of the packaging regime and, indeed, attractive materials to the public. The problem normally with paper and board-based packaging is that it does not carry very good barrier properties, you have to coat it or do something to it, so the potential to use nanotechnology there is being explored and, as I say, I am aware Hallam has an active programme in that area. Outside that I am not so well aware. I suspect, but I do not know for definite, that there is more taking place outside the UK than inside the UK at the moment.

Q169 ***Lord Methuen:*** We have information that Japan and Brazil, for instance, are doing quite a lot in this area.
Dr Kellie: Again, my Lord Chairman, this is exactly the type of technology which Japanese packaging companies are exceptionally good at. If you look at their history they have been extremely good at developing lightweight advanced barrier packaging and this is a natural fit to what they have done, so what you tell me would not be a surprise.
Dr Knowles: May I add something which may be helpful. The European Union claims to be the biggest supporter of nanotechnology research in the world, certainly it has allocated several hundred million this year in the Framework 7 programmes for nanotechnology and last year it committed, I think, €1.4 billion to this and overall €3 billion has been committed to nanotech research. The UK is part of that. I must say, I see far more activity in Holland as a single country in nanotechnology than anywhere else. I live in Brussels so I am not too far from the centres around Wageningen University, the TNO, NIZO, which is another research association there, doing a huge amount of work. At a meeting I was at in the States last year the Dutch Government had a stand itself rather paralleling Silicon Valley for electronics to their 50 kilometre valley—not quite a valley in Holland—their stretch of the countryside where all these organisations are situated. They are very well supported both nationally by their own research funds as well as being very good at obtaining the EU funds for this work. There is a project on safety in nanomaterials being formulated, again led by the Dutch, but it does include universities in the UK and ILSI, International Life Sciences Institute. There are projects which the EU has funded, I believe, in the UK on the applications of nanotechnologies. In terms of the health research, and maybe we will come to this later, in Ken Donaldson's laboratory at the University of Edinburgh, the UK has one of the leading laboratories in the health-related effects of inhalation of nanoparticulate matter, particularly from diesels and also the rigid engineered nanomaterials, such as carbon nano-tubes. That is a world class organisation. The Institute of Occupational Medicine, also in Edinburgh, is doing a great job in now pulling together all of the research that is ongoing on health-related aspects of nanotechnology. That is a world class centre. In terms of the health side we are doing very well; on the application side, perhaps not as well as some of the others.

Q170 ***Lord Crickhowell:*** On that last point, we have got a paper in front of us from the Department for Innovation, Universities and Skills trying to set out what is going on. What seems to be clear is that there is much more going on about the lung and inhalation than there is about the gut at the present time. All the evidence we have received so far

suggests that there is very little yet about the long-term effects on the gut and there is quite a lot going on about inhalation. There are quite a lot of suggestions, of course, that nature has been coping very well with nanoparticles for a very long time, but clearly if there is going to be a regulatory framework there does need to be substantial research into the toxic effects, if any, of the long-term consequences of absorption. Would it not be rather important for the industry, even if the Government has not yet directed its funding much in this direction, to ensure that it takes place and surely it is in the interests of the industry to develop research work in this field. We have heard all about the benefits. We do not want to discover rather too late in the day that there are rather nasty consequences because nothing could be more disastrous for the industry than for the thing to blow up in its face.

Dr Knowles: My Lord Chairman, on your last point we cannot put them on the market until there has been a safety evaluation under the legal regimes for the food industry in Europe. You are absolutely right, most research has been, and continues to be, on inhalation, partly because there are concerns about the impact of particulate matter in the environment and partly because of worker safety. The chemical industry, who is the primary supplier of nanomaterials, and the food industry does not make nanomaterials, it works with its suppliers and they are the chemical industry, the big chemical companies, they are concerned about the manufacture of these materials for whatever purposes, food or primarily for other applications. Their major exposure is through inhalation and that is why I think most of the work is there. Plus, it is easier from an analytical point of view to work with particles which are airborne. There is a dearth of analytical methods which would allow us to measure those same particles in a food matrix or any biological matrix. Until we have that methodology development and, again, the Central Science Laboratory and the University of York have produced an extremely good overview of the difficulties of the analytical challenges in nanoparticulate analyses in biological matrices, it is very difficult to put the toxicology in place because you do not know how to measure what you are giving to animals, if you are using animals. That is one of the reasons why there is so little research in the area of ingestion. I do agree 100 per cent with you that it has to be funded by both the industry and the Government, and the industry is funding that. I mentioned the International Life Sciences Institute and that is an organisation that is global, supported by the food industry, the chemical industry and the pharma industry, through over 400 companies. We are paying collectively for the research they are doing, but they are not doing the basic research, they are trying to develop through consensus meetings the areas of research others should have been funding. The member companies in the chemical or pharma area would then be expected to do the appropriate toxicological research on their materials. Where we are lacking guidance, and the European Food Safety Authority has issued its opinion on what types of tests should be undertaken to identify hazards, is the type of test that one would carry out to identify hazards from a material which is derived from a nanotechnology in a food because once it is in the food, then because they are reactive materials the food itself, I am sure, is going to coat the surface of these materials and then how do you measure what is being absorbed. In the classical drug context, the absorption, distribution, metabolism and excretion of materials needs to be measured and until we have the tools to measure them it is very difficult to do that toxicology, which is why I believe it will be some years before the food industry will be looking at direct applications. I am sure we do make less than we ought to be making in terms of contributions to the basic science from the toxicological point of view from the industry in total, but I do not know, because I am not in the chemical industry, what work they are actually funding themselves or doing themselves in fact.

Q171 ***Lord Crickhowell:*** You have talked about the desirability and necessity for proper hazard assessment but the departmental paper I was quoting from says: "Globally there is insufficient evidence to be able to say that any of the health, safety and environmental research objectives have been completed, thus full risk assessments of any nanomaterial are not possible at present". In a sense, I think that summarises what you have just been saying, that it is going to take a very long time, which suggests that probably it will not be possible for a number of the areas that may be desirable to be really entered into the market until that research has been done. Is that right?

Dr Knowles: As a generalisation I think that is right. There are potential applications where one is using, for example, natural materials to nano-encapsulate some materials and there it is rather easier to do the appropriate toxicology and look at the normal digestion processes to see whether, in fact, they are completely digested within the gut and absorbed in the normal way or, if they are absorbed in a nanoparticulate form, are they metabolised rapidly once they are in the systemic system via the conventional processes. There are areas where there has been more progress in safety evaluation than others, but it is a difficult, challenging and exciting area.

Q172 ***Lord May of Oxford:*** That is all very interesting, but going back to the essence of this question, which was is the UK in the lead, in the middle of the pack or a laggard in applications, I understood the answer to be broadly it is a laggard. That was what I heard you say. I would ask why do you think this is? Is it simply the familiar phenomenon which is a rather peculiar thing whereby the current Government is very keen to get people from the world of business to tell universities which are among the best in Europe how to run themselves, whereas business itself is notable for being rather poor in picking up things that are done here or elsewhere? What would you say in response to that? Did I not hear the reason to the original question correctly? If I did, why is it so?

Dr Knowles: I would not use the term "laggard". I think it is investing perhaps less than other countries because the basic industries which are generating those materials are not in the UK. The heavy chemicals, which is the BASFs, et cetera, of this world are not in the UK and they are the major producers of the materials and are close to the centres where the research is being undertaken in Holland and Germany and so on. The Commission is also seen as the primary source of funding in this area and what we really need because of the enormity of the challenges is a co-ordinated research approach. The European Union has a system called CORDIS which is trying to do that, trying to fund work across the appropriate centres in the European Union to address all of the questions, which are many, related to nanotechnologies. I think the UK on the health side and inhalation, as we have mentioned, is certainly in the vanguard. In the applications, I am not sure how much work is being funded by industry here. As I have said, it is far greater in the manufacturing companies. It is related to where the actual development work is taking place rather than where the centres of expertise may be, and I am sure there are opportunities in the UK which are not being exploited in that area. I should say, my Lord Chairman, that I have lived outside the UK for almost 18 years now, I have lived in Brussels all that time, so I tend to be more familiar with what is going on in continental Europe rather than now in the UK research establishments.

Dr Kellie: Maybe I can add to this without turning it into a table-thumping exercise. First of all, the comment that we are a laggard might be too harsh, but we are certainly not in the vanguard, that is absolutely clear. Why are we not in the vanguard, because we have allowed our manufacturing industries to decline and you are seeing simply the basic decline of UK manufacturing as a proportion of GDP. I have given that lecture for the last ten years and every time I do the proportion of GDP that is manufacturing goes down. I am an absolute advocate that the future of this country, particularly coming out of the recession, will be led by manufacturing companies. Let me add a more positive spin to that. There are some super small and medium-sized companies in this country that are picking up that challenge. I do not just talk about my own company, I am aware of a number of small to medium-sized businesses that recognise by picking up these technologies they can gain new markets and significant opportunities, there just are not enough of them about. There are some great relatively small, relatively young companies which are on the way, we just need a lot more of them quite frankly.

Q173 ***Lord Cunningham of Felling:*** Is it the case that you think the regulatory, research or other obstacles and challenges that you face are going to be overcome quickly or do you see some real obstacles which will slow down the eventual implementation of the use and sale of food or packaging with nanomaterial content?

Dr Knowles: The European regulatory system is very comprehensive, as it should be, in terms of the control of the use of these materials. As we have discussed, until the safety evaluation procedures are developed, agreed and accepted by all interested parties, all stakeholders, that is going to be a barrier to the introduction of nanomaterials in food. In packaging it is a little easier because if you have barrier properties between the nanomaterial and the food and can demonstrate by analysis there is no migration into the food, from the public health point of view that application is easier and is already taking place. There is, of course, the environmental impact which is being looked at; what the effect is of these materials in the environment when the packaging is discarded. That is another series of research topics which are being undertaken right now. As far as the regulatory barriers in other countries, the US's is similar to ours, and by "ours" I mean the European Union's. It requires case-by-case evaluation of the introduction of any nanotechnology derived material into the food supply, but it has a process for doing it rather quicker and has stated publicly that it operates on a case-by-case basis. In Japan, again, it is a much quicker process for getting materials onto the market. These are single country regulatory entities, of course, and as you will know it is easier with a single country regulatory entity than trying to discuss with 27. There is an opportunity for industries in those countries to get their materials evaluated and onto the market quicker than in Europe, which is not to say that there is not a great deal of activity within the European Union regulatory system to improve the speed—there is. What we are seeing now is the introduction of what is called the comitology procedure to expedite approvals, through the Member States voting within standing committee

rather than going to the European Parliament for a number of co-decision procedures which extend the debates. To summarise, as soon as we have an appropriate safety evaluation system the current regulatory process will allow a more rapid introduction of materials than we have in the current discussions, but it will never be as rapid as the US and Japan simply because of the process.

Q174 ***Lord Cunningham of Felling:*** I think what you are really saying is the speed or the momentum which develops for packaging, wrapping, bottling, will be significantly different from the momentum for nanomaterials being added to the food chain?
Dr Knowles: Yes.

Q175 ***Lord Cunningham of Felling:*** Can I ask you one other question in this regard. Where do you put public opinion in your ranking of barriers and obstacles to be overcome?
Dr Knowles: This is a question that has been asked many times before and what we in the European Food Industries Confederation, and of course the FDF is a major participant in that, are doing with regard to public opinion is holding public meetings with all of the interested stakeholders. We started these in mid-September last year where we invited the NGOs, Friends of the Earth, Greenpeace and any other NGO that had an interest in this area, the suppliers, the Commission officials, the Consumers' Association of Europe, about 50 people to a meeting which was chaired by the European food industries to discuss their issues. We had a series of presentations from officials and from industry. We repeated that at the end of March this year and we have made a commitment to continue to have these public meetings for as long as is necessary to gain the confidence of the consumer and other stakeholders as well. The NGOs are an important factor in whether these are a success. We have learned our lesson from GM and we are committed to hold these meetings alongside similar meetings, in which we participate, that the Commission holds. They have had two what they call Safety for Success meetings with all public stakeholders, academics and industry on the application of nanotechnology. The very name—Safety for Success—tells you what are the real barriers to the implementation of nanomaterials. We are 100 per cent committed. I do not know if you have seen this, but this is from the Food Safety Authority of Ireland and is an extremely good little booklet derived from a large report they produced for the public on the benefits and explains the functionality of nanomaterials in food. We support that and we support any type of leaflet or other form of education for the public about nanotechnology. We are not in a position to have direct public contact, but through the consumer associations we expect this to cascade out and we will continue to do this as long as is necessary.

Q176 ***Baroness O'Neill of Bengarve:*** Are you concerned that a mishap in those jurisdictions which you have described as having more rapid approval systems might boomerang on the pace at which public confidence could be built in the European jurisdictions?
Dr Knowles: As far as the US is concerned, and we are working very closely and the Commission works very closely with the FDA, they are implementing the same rigid safety procedures that Europe implements as well. Japan, whilst it talks a lot about the use of nanotechnology there, I do not think actually has anything on the market so it will also undertake appropriate safety evaluations in the same way. Globally, through our various international organisations that we belong to as the food industry, and the pharma industry though less so because they have their own organisation, likewise the chemical industry, we are ensuring that all the risks associated with production of nanomaterials, worker safety, as well as the public health risks from the application of those materials are understood and discussed in public fora globally, so we want to bring in the others. China is also interested in nanotechnology and we are operating through the International Life Sciences Institute with China as well. We have 14 branches outside the US. Europe is the biggest one actually. We are working together to ensure that does not happen. It would certainly have dire consequences for the technologies if it did.
Mr Opie: Can I just answer the previous question about public opinion that Lord Cunningham raised?

Q177 ***Chairman:*** Yes, please do.
Mr Opie: Obviously for us that is the key issue. Consumer acceptance of any product is going to be the key thing. We are not scientists ourselves, you will note I am the only one who is not a doctor on the panel, we are retailers, and we need to take consumers with us with any products we put on the shelves otherwise we would not stay in business. For us, it is very important that consumers first of all understand the benefits for them, and that was one of the issues with GM, I do not think consumers ever really understood what the benefits were for them in GM. There may be some clearly defined benefits here. For example, we know people are looking at maybe being able to take salt down a nanosize so we use less salt in the product but give people the same taste. We know when we have reformulated previously with salts and sauces, crisps and things like that, it is a difficult thing to achieve to take consumers with you but it is something they would see a benefit in for themselves in reducing their salt consumption. The benefits need to be explained to consumers. We also need to

demystify some of the issues around nano as well so they understand both the benefits and risks to them and all of those benefits and risks are put in proportion in a way that they can understand. I think of an example the Food Standards Agency did. A couple of years ago it did a survey on the levels of benzene in fizzy drinks, for example, but in the press release they put out they put it in proportion by talking to consumers about the exposure to benzene from walking down a busy street, for example. That resonated with consumers because that was something they understood. We talk about nano and lots of the safety issues and things like that, but I think consumers are a long way from that and we need to find a way where we can explain to them the benefits, the risks, the safety assessments and the regulatory frameworks in a way that they can understand so where there are benefits for them, and benefits maybe in their diet or lifestyle, they can accept that and can make a clear choice when coming into our stores about whether they buy that product or not.

Q178 ***Earl of Selborne:*** I would like to go back to the comparison of the regulatory framework between the European Union and other members of the OECD, particularly Japan and the United States. As I understand it, and perhaps Dr Knowles will correct me if I have him wrong, he said that fundamentally Japan and the United States are working to the same rigid safety procedures as the European Union. Here in the European Union we are waiting for resolution as to what would be appropriate safety evaluation systems. Japan and the United States seem to be getting on with it. There seems to be less barrier to innovation than here in the European Union. How do I reconcile these two observations that we are both working to the same standards and yet Japan and the United States are getting on with it?
Dr Knowles: They are. We are getting on with it too. They do not have products on the market either. They have systems which are inherently quicker because they are single country regulatory systems, but, because they are still waiting for the appropriate safety evaluation procedures as far as direct application to food is concerned, they do not have any products on the market in those countries either. They are still applying whatever science they have and, if anyone has made any submissions to them, they are being refused. I am not aware in those countries of any nanomaterial directly added to food. Packaging is a different matter and we have already had two applications approved through the EFSA system in Europe, so we are at the same level, if you like, as the current state of science, the current knowledge level which is equivalent globally. We are trying to ensure that it remains equivalent globally. As we increase our knowledge, we can apply that through the regulatory system for approvals of nanomaterials. They will be quicker because they are single country approval systems and in Europe it is just an inherently slower process.

Q179 ***Earl of Selborne:*** That is the nature of the problem, is it, that the timescale of the European Union is more bureaucratic or takes longer, or is it more thorough because it is adopting harsher scientific criteria?
Dr Knowles: I do not think it is adopting harsher scientific criteria than the others. I think it is just slower bureaucratically.

Q180 ***Chairman:*** Could I just clarify one thing, Dr Knowles. You say there are no man-modified nanoparticles used in food. I am just looking at a submission we have had from the MRC, which refers to silicates, luminosilicates and titanium dioxide. It says that exposure has been for decades as food additives mainly. Is there some disagreement between the MRC and yourselves?
Dr Knowles: I hope not. I think what they are referring to is that those materials have a distribution curve of particle sizes, as you will know. At the bottom end of the distribution curve, there will be some particles which fall within the nano size. Certainly titanium dioxide and silicates are being made now more towards the nano scale than they used to be, but they are not being used directly in food. Titanium dioxide is being used in sunscreens. There have been discussions in Brussels about those from the German Bureau of Risk Assessment as to whether they should be re-evaluated. Where they are being specifically engineered to have a much higher proportion of nanomaterials present, it needs to be evaluated as to whether that means they have different properties to the macro and micro scale.

Q181 ***Chairman:*** Are the silicates in use at the moment?
Dr Knowles: The silicates are used as free-flow agents. They help flow. I do not know in respect of food as to whether they are being used in increased nano proportions. As far as I understand—and we discussed this at the end of last year in the Safety for Success meeting—there is very little, if any, of this material used in Europe, the silicates material, for direct food addition. Silicates are produced in situ for packaging for a barrier material, but again I do not think that has final approval from the European Union, although the European Food Safety Authority has approved that. It is coated inside bottles in situ for improved barrier properties.

Q182 ***Baroness O'Neill of Bengarve:*** The Food Standards Agency is currently considering developing a register of nano-derived foods and food

contact materials. Do you think this would be useful? How would it work and, if it could work, should it be voluntary or mandatory?
Dr Kellie: It must be right that in a development area like this, where we all admit that it is an exciting product area, we also clearly realise that we do not know all the answers for the direct food contact applications, nor indeed the long-term effect. The more data that is collected and managed the better. I come back to a previous question on the public opinion issue. For me, nanotechnology opens some great opportunities, but we have to carry the public confidence to get all the benefits we are going to get. If we do not do that now, we will regret it and end up with a situation which will act ultimately against the public interest. The more we can monitor and manage what is coming onto the market, it seems to me a better system. Whether it should be voluntary or regulatory, I will leave to others, but I think it is important to do this.

Q183 ***Baroness O'Neill of Bengarve:*** Do you think it should be done by the Food Standards Agency or by another body?
Dr Kellie: They are the natural party here in the UK to do that.
Dr Knowles: I believe Defra tried to operate, and still does operate, a voluntary register which was not wholly successful. Given the discussion we have had, it is not surprising that many materials were not submitted as being nanomaterials because they are still very much in development. Assuming that those involved know what they are supposed to do in terms of making an application or a notification to the register for a very early development, which may come to nothing, at which point do you have to notify whichever agency is responsible? The French also, by the way, are thinking along the same lines. Therefore, it is difficult to say at this moment in time how it would be developed and indeed how it would be policed. We cannot put products on the market until they have been through a full safety evaluation. As soon as they have been through that, they are public knowledge anyway, so I am wondering what the value of a register would be. I am not opposed to it, I am just still at the stage of contemplating how one would develop such a register and what its value would be to the public. If it does have public benefits when products are approved, I think that is fine.

Q184 ***Baroness O'Neill of Bengarve:*** You think it is either premature or redundant really?
Dr Knowles: I think at this moment in time it is premature. It may be of course that the Commission itself will develop such a register after these materials are approved.
Mr Opie: We would query what the purpose of the register is if all the products have been through the regulatory framework, the products are safe for the market and they are on the market. Why would we then need a subsequent register on top of that? Any retailer will give information to any consumer who wants to know about the products it sells, so that is openly available. They can approach the retailer directly and lots of people do. We are not sure, if the food that is being put on the market satisfies all the regulations and is safe for the market, what the purpose of this would be. The second point raised is what are we defining as nanoproducts here. Are we talking about ricotta cheese or the traditional materials, some of the milled products, for example, which would be down to a nano size? Until we see the further definitions of what we are describing as nano-engineered food, I think it is difficult for us to say exactly what would be on there, but we remain to be convinced that there is a purpose in having something above and beyond what is already available through the regulatory framework.

Q185 ***Chairman:*** What we have understood, both from this conversation today and from previous witnesses, is that there are a number of products which, for one reason or another, do not go through any specific regulation beyond the general requirement set for food. You picked up the cheese example. One benefit of having a register would be to explain to people that they are already eating a lot of food that contains nanoparticles. They may be natural, they may be man-made as to the silicates that we referred to a few minutes ago, but they are out there. It does not mean to say that they are unsafe, but they have not been through a specific novel food regulatory or food additive regulatory process. Would there not be benefit in explaining to the public more transparently what was happening?
Mr Opie: I would absolutely support the issue around communication and education of consumers and using things like cheeses and various traditional products, milled products, to explain the process. The problem with registers is that they can quickly turn into blacklists, in effect. There is another way to communicate that to the public without necessarily needing to use a register. We would absolutely support the FSA using things like traditional cheeses in a way to demonstrate to the public that the products they have been consuming already they may well see as nanoproducts, but we are yet to be convinced about the value of a register of itself, not that it could not be used in communication and education.
Dr Knowles: The very same point was made to me by the Director General of the Health and Consumer Protection Directorate in the Commission. We talked about production not of a register but of this kind of material to explain from traditional cheese

manufacturing, as an example, through to the more modern developments in terms of making nanoemulsions and nano-encapsulated materials which are natural, if I can use that word, to help educate the public as to what these materials actually are. A list is not going to help educate the public. There should be some continuum from the very traditional food-processing which has produced nanomaterials, such as some of the cheese-making processes, through to the more modern food-processing techniques which are still manipulating conventional, traditional food materials. Then we move on to what we call the engineered nanomaterials.

Q186 ***Lord Cunningham of Felling:*** If the industry or maybe the Food Standards Agency were to produce a list of traditional food production processes and techniques which resulted in saying to the public all of these things which have gone on for centuries—wine-making, brewing and cheese-making—all result in products which contain nanoparticles, is this part of the education process?
Dr Knowles: Yes, that is what I was alluding to. I think it may be helpful. I cannot speak for the Food Standards Agency of course, but I think that is certainly one tool in the education of the public which should not be overlooked.
Dr Kellie: I heartily endorse this. This is an area where education done early is going to be very valuable. What we do not want, in my opinion, is to see a new technology which has in a broad sense great advantages suddenly derailed because we have run into a period of, let us say, misdirected publicity. We should put what we are doing in context. We should explain what we are doing. That is the right thing to do, in my opinion, and putting it in context is the right way to do it.

Q187 ***Lord May of Oxford:*** My question builds on the discussion we have been having and the remarks Mr Opie and Dr Kellie have made about the need to bring people with you as you do this, which involves, on the one hand, having products that are clear and, on the other hand, being upfront about what is going on. We had evidence earlier from somebody who, when asked the question, "What are you doing to inform people about nanoparticles in products?" said, "We hope they do not notice." That occasioned a certain number of raised eyebrows. The FDF have said that they are advocating transparency throughout their supply chain. Are they doing this? How do they do it? Do the current regulations facilitate this sort of transparency in what is coming into the food you then process?
Dr Knowles: It is being done by the FDF and by every Member State's equivalent of the FDF from an initiative in the Confederation of European Food Industries in Brussels. We have drafted and sent it out to all members—and there are over a quarter of a million food producers in the European union, a dozen rather large companies cascading down to the single, family organisations—to ensure all understand what the regulatory regime is that controls the use of nanomaterials should they get approached, as they are of course, by salesmen from the various producer companies. They are aware of what questions to ask, either verbally or in writing. They are given this template of questions including the law, such as the novel food regulations, additives, flavours and packaging regulations that control the use of these materials in food, given as an annex to this document. We are making sure that the whole supply chain is aware. We are working with the Chemical Industries Association of Europe. They have just set up a new nano forum of their own which the food industry will be a member of to ensure we have continuity of information from the producer through to the user and then hence to the public. As far as we are concerned, it does not stop with us, it carries on to the public, but we have to have the information from our suppliers.

Q188 ***Lord May of Oxford:*** I take it that was a yes from you?
Dr Knowles: Yes.

Q189 ***Lord May of Oxford:*** If somebody started using nanomaterials in their products in a novel and deliberate way, either in food or in packaging, you are confident that you would know about it?
Mr Opie: Speaking for our members as major retailers, they would all have approved lists of both suppliers and ingredient suppliers that they would use in their specifications for their own-brand products. They would pick this up definitely and will have an ongoing dialogue as well with suppliers. It is not as if either a major or a minor supplier is going to come with a product directly to a retailer without them doing due diligence on that product before they then specify for something that they ultimately sell under their own brand in their stores.

Q190 ***Lord May of Oxford:*** Looking back up the supply chain, suppose fertilisers or pesticides using nanotechnologies came onto the market. Would you be aware if your suppliers were using them? Insofar as you want to be reassured, would you have any concerns about things like that if the products themselves, the pesticides or the fertilisers, had been approved by government?
Dr Knowles: If the products had been approved, we would be aware because our suppliers would be required to divulge to us and the bigger companies the specifications of their materials. That would apply to any supplier. We are making every effort we can to make sure that these smaller companies are aware of their responsibilities, hence we have given them this

template for questions that they should be asking of their suppliers.

Q191 ***Lord May of Oxford:*** You are at peace about this. Are your colleagues also?
Dr Kellie: In packaging terms, I am confident that there is pretty open declaration. There has to be open declaration of developments. In almost all the developments I work on, the composition of the materials is openly declared and we would not have it otherwise.

Q192 ***Chairman:*** How about from the retail sector?
Mr Opie: Yes.

Q193 ***Chairman:*** Can I challenge that? From my experience of the Food Standards Agency, I have some questions about the reliability of knowledge about the supply chain. If the system were as robust as you indicate, how do you end up with these major issues of contamination that spread throughout the food chain—for example the famous case of Sudan 1? As I understand it, the way you check is that you ask your immediate supplier one up in the supply chain, "Can you authenticate this product and that it is what it says on the tin?" If they say yes, that is your validation. They do exactly the same, but of course it is like Chinese whispers. If you are only asking the one person next to you, the message can get degraded as it goes through the supply chain. In the case of Sudan 1, it ended up that there was a producer somewhere in the Far East who was contaminating the chilli pepper. The importer accepted the certification that it was not contaminated and all of the users accepted the certification from the importer. I am not at all confident that the system is as robust as you suggest. How do you respond to that?
Dr Knowles: You are quite right. No system is 100 per cent perfect. You picked out Sudan 1, an example that went through without being caught. This happens. There is no such thing as a 100 per cent guarantee that we will not miss something. In terms of nanotechnologies, these are highly sophisticated, way beyond the competence of the kind of suppliers that are dealing with those materials. They will be very expensive materials as well, so the likelihood of that happening in this situation is remote.

Q194 ***Lord May of Oxford:*** I do not see that as an answer to the question about pesticides or fertilisers, frankly.
Dr Knowles: If we are buying materials, we ask all the way through as a company, right through to buying a flavour from a flavour house; we ask for the full composition of individual flavour chemicals which are in there. Not every company does that, but we do. Most major companies do the same. The concerns are the small companies, which is why we are spending time educating them, but again on nanotechnology they are very expensive techniques. The packaging is extremely expensive compared to conventional and the use of these materials is not going to be such that the small companies are likely to pick it up, at least for some considerable time. It requires a lot of expertise which only the major companies will have.
Mr Opie: Sudan 1 has certainly improved vigilance along the chain, if nothing else since then. That situation has definitely improved since then. There will always be a problem with adulteration of product, for example, whether that is deliberate or inadvertent, as we saw with GM rice a couple of years ago when we had problems with imports of GM rice, but what it does show is that, once the chain knows there is a problem, it can act incredibly quickly by taking the products out of the chain. Irish pork dioxins, for example, were a problem before Christmas. The chain right up to the retailer, as soon as it knew it had a problem, reacted extremely quickly to that and took all potential problem products out of the chain. Whilst there may be a problem with adulteration on odd occasions, when that is identified, action is quickly taken to prevent that reaching the consumer.

Q195 ***Lord Haskel:*** If we can continue this discussion about engaging the public, you told us that you spend a lot of time on presentations to the public, demystifying the regulations, communication and education. Presumably, this is done because of the experience with GM food. You want to avoid the experience of that. Have you done any work to try and find out what it is that the public is concerned about, or are you assuming that the public's concerns are similar to those about GM food? Because, if you want to reassure them just informing them is not enough, you need to deal with their concerns. Do you know what their concerns are?
Dr Knowles: The UK Consumers' Association *Which?* has conducted that type of study. They have asked consumer focus groups about nanotechnologies and different applications and presented that last February at a meeting that we attended. It is clear that they have different concerns depending on different applications and, when it comes to food of course, they have the greatest concerns. Studies have been done also by academic organisations between European countries and the US, published in *The Public Understanding of Science* last year. There is an interesting difference where the majority in the US think that nanotechnology is a positive contribution to the economy and something to be welcomed, whereas it is the reverse in Europe where more people do not want to have something which they perceive as potentially risky and where they cannot see any benefit. It comes back to

explaining the relative benefits of the different applications to the consumer. We are working with consumers in Europe and we leave it to the European Consumers' Association to invite whoever they like from their organisations, from whichever country. The discussions have been very interesting to date. In the UK, we have the Responsible Nano Forum and the FDF is a member of that organisation. It includes the consumer group *Which*? too and we discuss their concerns and listen to what their concerns are. You are absolutely right, that, until one knows what their specific concerns are, one cannot address them. We are operating this dialogue at every level where we think it is needed and at every level they tell us it is needed. We are responding to their requests and we want to ensure we do not lose what we see as this potentially very valuable technology in the way that we "lost" GM in Europe.

Mr Opie: I guess for retailers they have all of that and also that they have the benefit of direct contact daily with their customers, so they know exactly what customers think about products and a whole range of issues which they can capture through their own surveys and through enquiries to their customer care line. Interestingly in GM, they do not tend to get many enquiries until there is a potential issue either in terms of contamination or in the media. Then they get a spike of enquiries and it will drop away again because most consumers assume that British retailers do not sell GM and, therefore, when they go into a store, they are quite happy with what is on the shelves. In a similar way, we have spoken to some of our members who sell non-food nanoproducts like sunscreen, for example, and it has been very interesting to hear from them that they have had very few enquiries from consumers about the use of those products. In fact, the enquiries have been all around the beneficial properties of things like sunscreen, the fact that you do not have to put quite so much of the product on your face, as much as queries about the product itself. I guess retailers are lucky in a way. They can draw on the research done by people like the FSA, *Which?* and others but also they have direct feedback from their own consumers and they will take that into account before they put any product on the shelves.

Q196 ***Lord Haskel:*** Do you think the Government has any role in this?

Mr Opie: I spoke earlier about the role of the FSA, for example, as the independent authority on food, of the benefits as well as the risks in proportion to other foods and other issues that we encounter from the public. Going back to the early days when we used to have problems with avian flu, for example, the FSA did an excellent Q and A on the issues about avian flu and what it means for you in terms of possible transmission and all these issues. All the retailers referred their customers to the FSA line and found it incredibly helpful. It was very well written, very clear and it satisfied what customers needed to know because it was written in a language they could understand and allayed their fears. What we saw quite quickly after that was a real drop-off in terms of problems with poultry sales.

Q197 ***Lord Haskel:*** You see the FSA as the Government?

Mr Opie: Yes, for this purpose because the Government has had problems sometimes around the presentation of food safety, the creation of Defra from MAFF, those sorts of issues, therefore, we do support the FSA and what it does. We feel it has a lot of trust amongst consumers. By being able to refer consumers to an independent authority, that helps to reinforce the messages that retailers can give.

Lord Cunningham of Felling: The whole point of the FSA was that it was not the Government.

Q198 ***Lord Mitchell:*** Clearly, the whole GM saga was a public relations and communications disaster. If there were another GM equivalent which developed today and was about to be launched, do you feel that your industry is much better placed to be able to handle the potential objections of the public?

Dr Kellie: What you have seen from all the conversations to date is the fact that we are proactive. I speak of my end of the technical chain. We believe that the whole issue of consumer confidence has to stand right towards the top of the agenda. We have to be proactive. What the GM issue taught us, if nothing else, was that in bringing new technologies to the market, if we do not bring the consumer with us, it is all a waste of time. There is a massive amount of more advanced thinking. These subjects are discussed very early on.

Dr Knowles: I think we are much better equipped. I worked through the GM saga as an industry member of a group that really did not understand communication with the public. The food industry did, but it was not the food industry that was running that; it was the producers. Now that lesson has been learnt by all the supply chain and I think, as an example with nanotechnology, we are engaging with the public even before these materials are starting to get off the laboratory benches.

Q199 ***Lord O'Neill of Clackmannan:*** You say that you have learnt the lesson of GM food. What you did was to pack your bag and run away. That was the lesson that you learned. If you cannot win an argument the first time, you do not try and win it the second. I would ask of the retailers: is your role to lead or is it to follow? If it is to follow, it sometimes can be inconvenient. If I go into a supermarket wanting to buy vegetables, my choice is heavily skewed towards organic food, about

the value of which I remain to be convinced. As a Scotsman, I do not find much attraction in terms of the price differential. I am encouraged by one aspect of the recession, and that is that the sales of organic food are declining. You do not have a good record in this area of standing up for science and having a go. You say, "It is not our problem. It is the producers'," but you screw the producers in so many other ways when you want to get the prices down from wholesale organisations. I am not convinced of the intellectual strength of the retailers' case.

Mr Opie: We are led by consumers. If consumers do not want it and do not want to pay for it, there is no point in a retailer putting it on the shelves. It is interesting that you raise organics. Organics are still a very small proportion of the products that a retailer sells, but they have grown over the years because consumer demand has driven them and, therefore, retailers have kept pace with demand and put more organics on the shelves. The problem with GM is that consumers could not see a benefit for them so they rejected the product. The one thing we have not talked about today, when we talk about public opinion, for example, is where consumers are getting all of their food messages from. We have talked a lot about industry and government but we have not talked about the role of the media, for example, where a lot of consumers will get their messages from. It is not always about science, sometimes it is about perception. Therefore, if we come back to the role the FSA or the Government can play, it is in briefing some of the key informers and also journalists as well as ourselves, consumer groups, to get the messages through all the avenues to people. The basic point is retailers are good if they meet consumer demand. The ones that do not meet consumer demand go out of business because we are a very competitive industry and, therefore, we have to meet what consumers want. That is why we are very careful about any products that we put on the shelves.

Dr Kellie: There are some still fighting GM in packaging because GM has an enormous opportunity in packaging. We are actively involved in bioplastics made from potentially GM-derived materials because they offer enormous, real, positive benefits in, for example, compostable packaging which is a great opportunity and indeed possible alternatives to your plastic cups here on this table. Those are still being actively pursued.

Lord May of Oxford: Resonating with what Lord O'Neill just said, Lord Cunningham and I were both at the centre of the storm of GM. That was not a spontaneous event that arose from the general public, it was a carefully orchestrated campaign by a very effective NGO. The first time they tried it did not work. The second time it was spectacularly successful, and of course the lack of conspicuous beneficial products to motivate people to engage is the key. The reason they disappeared is that the retailers just decided they did not want to bother. Nanotechnology has had an attempt to do this, if you remember, which was indeed headed off at the pass by an inquiry that involved the NGOs. I would not be too complacent, even with perfect oversight, information and good products, if one of the NGOs decides that this is a good campaign that should be waged, maybe really fighting an anti-globalisation campaign under this banner. That was more a statement than a question. The air of feeling that it is all okay and we are on top of it, I think, is well steered clear of.

Q200 ***Baroness O'Neill of Bengarve:*** It sounds, I suppose, very appropriate for the retail sector to say that we are following what our customers want, but every time you put out a new product—not a new product involving high-tech but just a new and different biscuit—you are leading your customers. Advertising is used to lead customers. People are eating things they had not even seen or heard the name of ten or 20 years ago, so, frankly, you lead. If you lead, do you not have to confront both GM and nano in a slightly different way than following what the consumer says?

Mr Opie: I would definitely agree that we probably need to think about the way we would even approach GM, but our statement on GM is quite clear. If consumer demand changes and consumers demand GM, we would review the position on GM. The reason we do not stock GM is because no consumers want it on the shelves.

Q201 ***Baroness O'Neill of Bengarve:*** It is definitely a follower position?

Mr Opie: Yes.

Q202 ***Baroness O'Neill of Bengarve:*** You do not attempt to lead on this?

Mr Opie: No.

Q203 ***Chairman:*** Could I pick up the point about consumer information? All of you have emphasised the need to be transparent and explain what is happening. Do you include in that support for the notion of labelling food products that have nanomaterials or use nanotechnologies in their manufacture? Would you be in favour of labelling?

Mr Opie: We always see labelling as just part of consumer information and the ability of someone to make a choice. We would think about that if we thought that consumers were in a position where they would be able to use that information to make a choice. It comes back to my very original point about maybe demystifying what "nano" means for consumers, both benefits and potential issues for them.

Q204 ***Chairman:*** You are not against labelling as one of the routes to consumer information and consumer confidence?
Mr Opie: We do not see it as a definitive thing, that we must have labelling of nanoproducts before we would put them on the shelves. We would do it if we thought it was necessary or needed for consumers to make a choice. For any product that is sold in a retail establishment, a consumer can always ask the details if they need to know. We put things on labels. The legislative stuff aside, we do not put information on by accident, we put it on to help consumers make a choice. We would need to know that consumers wanted to be able to make that choice for whatever reason, either to buy the product or to sell it, in which case you are into appropriate claims that might be made around nano and whether they can be justified, or if it is something that people just want on there so that they can avoid it, like an allergen mark or something.

Q205 ***Chairman:*** What about the manufacturers? Would you be in favour of labelling?
Dr Knowles: I agree with Mr Opie. It is something that we are discussing. It needs to be considered in the context of the discussions we have been talking about on the benefits of nanotechnology, explaining what nanotechnology and nanomaterials are so that consumers can understand whatever goes on the label. As far as many of these applications are concerned, the manufacturer is going to be making a claim. These are expensive technological developments and they are going to be used for a purpose. That purpose is going to be put onto the label in some form or another, so there will be claims related to the use of these materials, I am sure. How do we label them and what form does the label take? There is an awful lot of material on a label already. We know 95 per cent of consumers never look at it. In some cases, it is just the colour of the can that is sufficient for them to make a choice. It is something that we are not discarding. We are approaching this in the same way that the retailers are, from the basis that consumers must be aware of what the materials mean.

Q206 ***Chairman:*** I take it that you are both hedging your bets a bit on whether you think labelling is a good idea? Is that a fair summary, in a sentence? Yes or no?
Mr Opie: Yes.

Q207 ***Lord Crickhowell:*** We have talked a good deal about research and there has been some collaboration between the industry and government and academia. What about collaboration on safety testing and risk assessment between the various parties? There is an obvious difficulty here. Your companies are spending very large sums of money on producing and researching competitive products. There must be a reluctance to immediately exchange information which may give you a competitive advantage. Does that interfere with collaboration on risk assessment and testing or is there any way round? Specifically, on intellectual property rights, which are part of the same story, I would like a comment on how industry effectively is going to collaborate or is collaborating with both the researchers in academia and with the national and international regulatory bodies in providing the information that is needed.
Dr Knowles: It would fall under what we call 'pre-competitive research'. The research is going to be done on the materials themselves or examples of the materials, a nano-encapsulated material or a nano-particulate material, rather than the application in the food. It is at a stage where we are collaborating with the European Food Safety Authority in the sense that they are party to an organisation that we have in Brussels with all the companies there. The suppliers and the major food companies are members. We are looking at how one should organise the research that you are talking about in terms of in vivo ingestion of these materials as opposed to inhalation. At the same time, we are working with academia, for example, the Bilthoven laboratories of the Dutch Public Health Service, on how to measure these materials in food matrices as part of that research. It is ongoing. It is a joint activity which we hope will be translated into a major, multicentre project with the Commission funding that project, or at least funding half of it. The other half will come from the industry, as for all commissioned research of this nature. It is not difficult for us to collaborate. In fact, we are actively collaborating with each other and with our suppliers at this stage of the research.

Q208 ***Lord Crickhowell:*** All right, there is general research of that kind, but here you are, you are researching to produce this material that is going to consume less fat or whatever it is. You are clearly doing your own safety testing because you do not want to find yourself launching a product you have wasted all your money and time on and it is rejected. How inhibited are you at that point in providing information which is going to be of huge importance across the industry in dealing with this sort of product, when there may be some other competitor who is at about the same point in their development, also doing their testing? Is there an inhibition on your sharing the information that enables effective testing and risk assessment to take place?
Dr Knowles: Yes. We would not share that with a competitor, but both would be submitted to the European Food Safety Authority for the risk assessment. We would do our own risk assessment before we submitted it. If we felt it was safe, we would submit it and they would submit it. It is not unusual for EFSA to have similar submissions.

Q209 ***Lord Crickhowell:*** That means that, if a particular lesson has been learnt about safety, you may get the thing passed, but the lesson cannot easily be passed back to other people so that they benefit from it.
Dr Knowles: Once it goes to EFSA, it becomes public, so they benefit from that research immediately. The work that we carry out is published. If it is us and most other companies, we would be doing it through an academic organisation and they would publish the findings. The reports are available for the Commission. All the toxicology and details are submitted to the European Food Safety Authority, so they would be fully cognisant of all of the issues that have been addressed.

Q210 ***Lord Crickhowell:*** Your simple answer is that you believe commercial confidentiality is not an inhibition on effective sharing of safety information?
Dr Knowles: At the time when it is commercialised, no, the safety information is circulated.

Q211 ***Lord Mitchell:*** What guidance does industry need from the Government on health and safety risks for nanotechnology?
Dr Knowles: I suppose it needs the kind of guidance in more detail that has been given by the European Food Safety Authority on how to undertake appropriate hazard identification testing, how to do exposure assessments and the analysis of these materials. It is nothing that the Government in itself can do alone. It needs to work with all of the stakeholders to provide that guidance. All of the regulators and the academics need to work together with the Government to provide that information to allow the suppliers and manufacturers of nanomaterials to carry out appropriate safety testing. That is the major problem that we have at the moment.

Q212 ***Chairman:*** Is it always made clear to you or do you understand automatically which set of regulations nanotechnologies might come under? We have already heard that there is a debate about whether things would come under the novel food regulations or other food regulations.
Dr Knowles: The novel food regulations certainly of course catch probably the majority of nanotechnology applications, but the food additive regulations will also catch them and there is an amendment to those to make it so, the flavouring regulations catch them, the specifications on purity catch them and the packaging regulations catch them. All regulations that control the manufacture and sale of food are drafted in a way to pick up advances in technology, whatever those may be; they are designed to do that.

Q213 ***Lord Methuen:*** To put things in perspective, you have said that we have used nanofoods essentially for years or ingredients. If you take finely ground flour, what size would the particles be?
Dr Knowles: Significantly larger than nano, I suspect. They look small, but nano is extremely small.
Chairman: In drawing the session to a close, I would like to thank all three of our witnesses for their answers to our questions. It has been very illuminating and interesting for us. If you have any further points that you would like to make that you have not been able to express during this session, please write them down and send them in to the Committee Clerk. We would very much like to hear from you if you have additional points you would like to make. In due course, you will receive a draft of this evidence session and of course you will have an opportunity to make any amendments you wish to make to the evidence. With that, I would like to thank you all very much and end this session.

Supplementary letter from the Food and Drink Federation

Thank you for your letter of 1 June addressed to Dr Mike Knowles, with whom I have discussed and agreed this response, which is sent on his behalf.

To clarify Mike's statement to the Committee about the use of titanium dioxide (El71) in food, I can confirm that it is an authorised food colour permitted for use in all foods, except unprocessed foodstuffs and those foods in which the use of colours is specifically restricted, according to Directive 94/36/EC,[6] implemented in the UK by the Colours in Food Regulations 1995 (as amended).

Titanium dioxide is extracted from natural ores and milled to the desired particle size relative to its intended use, which is traditionally, as is the case in food, to provide optimum opacity and whiteness. As with any milled product, particle sizes will vary, and some preparations may include some particles in the nanoscale range, by which we mean below 100nm. We understand that the MRC are referring to materials of about 200nm as the average particle size, and with no novel nanoscale properties. The nano-engineered titanium dioxide used in sunscreens is, as we understand it, deliberately engineered at the low nanoscale, ie below 100nm, to be transparent. As titanium dioxide no longer imparts opacity and whiteness at the nanoscale, it self-evidently has no application in food as a white colour.

The recently adopted European Regulation on food additives,[7] which will eventually supersede Directive 94/36/EC, includes a clause requiring that any food additive already approved which is prepared by production methods or using starting materials significantly different from those covered by the existing specifications, laid down for all approved additives, should be submitted for evaluation by the European Food Safety Authority (EFSA). The Regulation specifies that: "'Significantly different' could mean, *inter alia*, a change of the production method from extraction from a plant to production by fermentation using a micro-organism or a genetic modification of the original micro-organism, a change in starting materials, or a change in particle size, including the use of nanotechnology." (Recital 14.) These provisions can be seen as clarifying the meaning, as far as nanotechnology is concerned, of the current provision in the EC legislation on additives that requires prior evaluation by EFSA before application of a new production method of food additives.

We are in regular discussion with the associations that are broadly representative of suppliers of food additives, both in the UK and at EU level. They assure us that their membership is very well aware of the ongoing debate on nanotechnology, and fully cognisant of their legal obligations, as described above, and committed to abide by them.

I hope this clarifies the position, but should you have any further questions, please do not hesitate to contact me.

1 July 2009

[6] European Parliament and Council directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs, *Official Journal* L 237/13, 10.9.94, 13–29.

[7] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, *Official Journal* L 354, 31.12.2008, 16–33.

TUESDAY 5 MAY 2009

Present	Haskel, L.	Methuen, L.
	Krebs, L. (Chairman)	Neuberger, B.
	May of Oxford, L.	Selborne, E.

Memorandum by Professor Ken Donaldson, University of Edinburgh

I am a lung particle toxicologists and so I will start of there. Nanoparticles are ubiquitous in the environment from natural and anthropogenic sources and have been throughout evolutionary time. Combustion-derived nanoparticles (CDNP; soots) are present in air, and to a greater extent in the last few hundred years than in previous times, and they are considered to drive a number of adverse effects in the lungs and cardiovascular system that are well-documented These arise, in the opinion of many experts, primarily from inflammatory effects in the lungs. There is a hypothesis that there is also translocation of such NP to the blood and the brain and there is restricted evidence that there is limited translocation, using animal and experimentally-generated NP. There is no evidence currently that translocation of NP out of the lungs occurs in humans or leads to any adverse effects, although it is possible, even likley. I personally have come to believe that there is minor redistribution of very small particles from the lungs. The question is whether this translocation is important in any adverse effects, compared to the systemic effects caused of the inflammation at the primary site of deposition in the lungs, acting on other sites like atherosclerotic plaques or even the brain. This remains unanswered at the moment.

For manufactured NP, effects will depend on exposure and on the intrinsic hazard (eg surface reactivity, fibrous shape). The majority of bulk-produced NP (silica, alumina, TiO2, carbon black) presently are low toxicity but there is concern over carbon nanotubes and other high aspect ratio nanoparticles (HARN) because of their superficial similarity to asbestos. There may be higher hazard NP to which there will be exposure and so there must be vigilance but this can be foreseen with adequate testing. All-in-all it seems unlikely that there will be any large-scale pandemic of lung disease from bulk-manufacture NP if sensible hygiene standards are used but we must be watchful for increasing production of unusual NP like HARN and some metals (Copper, silver, possibly).

The gut can be considered to have undergone similar evolutionary forces to allow it to deal with nanoparticles over evolutionary time. The gut will certainly be evolved to deal with natural particles which has always been present on food and probably only in the last few hundred years will these have been thoroughly removed by washing prior to preparation/eating. So nanoparticles in soils will be able to be dealt with by the gut. A key question is whether the gut has evolved to deal with the traffic of CDNP from the lungs that it encounters from the normal process of mucociliary clearance. This delivers 99.9 per cent of all particles that deposit in the airspaces to the gut. Its true that the stomach and its acid environment stands a key gatekeeper and that all particles will be acid-treated prior to entering the gut, but many particle will not be dissolved by the acid in the stomach and will continue, albeit with surface modification due to acid treatment, to the intestine. One of these modifications could be to the aggregation status (I don't know if it would cause more or less aggregation) and that could be important in subsequent effects on the intestine. The PM10 epidemiology literature, which documents in large part the adverse effects of CDNP, since the CDNP is probably the most pathogenic fraction of the PM cloud, does not pick up an adverse effect on the gut. This may be a result of some quirk of reporting/death certificates etc but, taken at face value, it does suggest that the delivery of CDNP to the gut from the lung does not have an adverse effect on the gut.

The question is whether any manufactured NP might have such an effect. The ante is greatly increased when the NP are added to food purposely. All toxicity is dose-related and so the likelihood of an adverse effect increases with dose and so adding NP to food definitely increases the likelihood of adverse effects. It is to be hoped that the companies that make the food have testing procedures in animals that demonstrate no ill-effects—such data should be made available to the Committee. The likely effects might include pro-inflammatory effects and immunological abnormalities.

Another problem lies with the normal flora of the gut, which could well be unbalanced if there was selective toxicity toward commensals—silver NP seem a particular threat in this area.

There is a suggestion that asbestos exposure is linked to cancer of the stomach and colon although this is disputed, and would arise from the delivery of fibres to the gut via mucociliary clearance. It is just possible that a HARN might be especially active in this regard.

Use of NP in food will greatly increase the likelihood for release of NP into the environment during manufacture and disposal and in human waste, where there might be ecotoxicological effects that are not in my area of expertise.

20 March 2009

Memorandum by Central Science Laboratory

Nanotechnologies in Food

This submission is meant to provide a brief summary of findings of the studies carried out at Central Science Laboratory (CSL) into the potential applications and implications of nanotechnologies in food. More detailed findings are submitted as two separate reports on the studies that the CSL team has recently carried out for the Food Standards Agency.

A number of recent reports and reviews have identified the current and short-term projected applications of nanotechnologies for food and beverages (Bouwmeester et al., 2007; Chaudhry et al., 2008; EFSA, 2008; Food Safety Authority of Ireland, 2008). Like other sectors, nanotechnologies are promising to revolutionise the food sector—from production to processing, storage, and development of innovative materials, products and applications. Currently, such applications in the food sector are new emergent, but their number and range is expected to increase in the coming years. Virtually all current applications of nanotechnologies in food are outside Europe, although some supplements and food packaging materials are available in the EU. Also, the global nature of food business means that more products and applications are likely to be available in the EU in the coming years. This also means that there will be a need for regulation of the risks, and establishment of liabilities at the global level.

The current and short-term projected applications of nanotechnologies include nano-sized or nanoencapsulated ingredients and additives for food, beverage, and health-food applications. A current niche for such applications is in the areas where there is an overlap between the food, medicines, and cosmetics sectors. For example, some food products are marketed as a means to enhance nutrition for different lifestyles, or as an aid to beauty, health and wellbeing. These hybrid sectors have been the first focus of nanotechnology applications, which have only recently started to appear in the mainstream food sector. Thus the vast majority of the currently available nanotechnology products is in the areas of supplements, healthfoods and nutraceuticals, with only a few products in the food and beverage areas. The main tenet behind the development of nano-sized food ingredients and additives appears to be the enhanced uptake and bioavailability of nano-sized substances in the body, although other benefits such as improvement in taste, consistency, stability and texture etc have also been claimed (Chaudhry et al., 2008).

A major application area for engineered nanoparticles (ENPs) is for food packaging. Whilst most nanotechnology applications for food and beverages are currently at R&D or near-market stages, the applications for food packaging are rapidly becoming a commercial reality. A contributing factor to such developments seems to be the expectation that, due to the fixed or embedded nature of ENPs in plastic polymers, they are not likely to pose any significant risk to the consumer. Indeed, nanotechnology applications for food contact materials (FCMs) already make up the largest share of the current and short-term predicted nanofood market (Ciehtifica, 2006).

Nanomaterials Relevant to Food Applications

The currently available information suggests that nanomaterials used in (health)food applications include both inorganic (metal, metal oxides) and organic materials. In addition to the ENPs, there is a possibility that certain microscale materials used in the food and feed area may contain a nanoscale fraction due to natural size range variation (EFSA, 2008).

Based on the available information, the ENP likely to be found in food fall into three categories: metal and metal oxide (including alkaline earth metal and silicate), surface functionalised, and organic ENPs. Examples of these include:

1. *Metal/Metal-oxides*

A number of meal/metal-oxide ENPs are known to used in (health)food products and food packaging applications. These include ENPs of transition metals such as silver and iron; alkaline earth metals such as calcium and magnesium; and non metals such as selenium and silicates. Others ENPs that can potentially be used in food applications include titanium dioxide. Food packaging is the major area of application of metal(oxide) ENPs. Example applications include plastic polymers with nano-clay as gas barrier, nano-silver and nano-zinc oxide for antimicrobial action, nano-titanium dioxide for UV protection, nano-titanium nitride

for mechanical strength and as a processing aid, nano-silica for surface coating etc. The use of insoluble metal(oxide) ENPs in food applications, especially those that are unlikely to be assimilated in the Gl tract, raises a number of concerns. The likelihood of translocation of such ENPs with potentially large reactive surfaces to various cells and tissues in the body may lead to certain risks to consumer health; for example, potential cellular damage and inflammatory reactions due to generation of reactive oxygen radical species (Oberdörster, 2000; Li et al., 2003; Donaldson et al., 2004). ENPs can also adsorb or bind different substances on their surfaces (Šimon and Joner 2008), and thus may carry potentially harmful chemicals and foreign substances into the blood and to various tissues and organs in the body.

Certain metal(oxide) ENPs, such as that of silver, magnesium oxide and zinc oxide, are known to have strong antimicrobial activity. Especially, there is an increasing use of nanosilver in a number of consumer products, including (health)food and food packaging applications. Indeed, the use of nano-silver as an antimicrobial, antiodorant, and a (proclaimed) health supplement, has already surpassed all other ENPs currently in use in different sectors (Woodrow Wilson, 2008). This has also led to concerns over its safety to human health when ingested orally. Despite this, there is no published research at present on how the intake of nanosilver via food and drinks might affect the cellular function or the gut natural microflora.

Nano-silica is known to be used in food contact surfaces and food packaging applications, and some reports suggest its use in clearing of beers and wines, and as a free flowing agent in powdered soups. The conventional bulk form of silica is a permitted food additive ($Si0_2$, E551), but concerns have been raised over the safety of nano-silica because it is likely to remain undigested in the Gl tract and thus may pose a risk due to greater uptake and translocation in the body. In this regard, a commercial product "Slim Shake Chocolate", available in the USA, is understood to incorporate nano-sized silica particles (between 4 to 6 nm in diameter) that are coated with coco to enhance the chocolate flavour through the increase in surface area that hits the taste buds.

Titanium dioxide, in conventional bulk form, is an already approved additive for food use ($Ti0_2$ E171), but there is a concern that the conventional form may also contain a nano-sized fraction. Nano-titanium dioxide is used in a number of consumer products (eg paints, coatings) and its use may extend to foodstuffs. For example, a patent by Mars Inc. (US Patent US5741505) describes nano-scale inorganic coatings applied directly on food surface to provide moisture or oxygen barrier and thus improve shelf life and/or the flavour impact of foods. The materials used for the nano-coatings, applied in a continuous process as a thin amorphous film of 50 nm or less, include titanium dioxide. The main intended applications described in the patent include confectionary products.

2. *Surface Functionalised Nanomaterials*

Surface functionalised nanoparticles are the second generation nanoparticles that add certain functionality to the matrix, such as antimicrobial activity, or a preservative action through absorption of oxygen. For food packaging materials, functionalised ENPs are used to bind with the polymer matrix to offer mechanical strength or a barrier against movement of gases, volatile components (such as flavours) or moisture. Compared to inert materials, the use of this category of ENPs in food applications is likely to grow in the future. They are also more likely to be react with different food components, or become bound to food matrices. Examples include organically-modified nano-clays that are currently used in food packaging to enhance gas-barrier properties. The nanoclay mineral is mainly montmorillonite (also termed as bentonite), which is a natural clay obtained from volcanic ash/rocks, and has a natural nano-scaled layer structure.

3. *Organic Nanomaterials*

A number of organic nano-sized materials are used (or have been developed for use) in food products. These include vitamins, antioxidants, colours, flavours, and preservatives. The main principle behind the development of nano-sized organic substances is the greater uptake, absorption and bioavailability in the body, compared to conventional bulk equivalents. However, a greater uptake and bioavailability of certain compounds, such as certain preservatives, can also be detrimental to consumer health. Also developed for use in food products are nano-sized carrier systems for nutrients and supplements. These are based on nanoencapsulation of the substances both in liposomes and micelles as well as protein based carriers. Such nano-carrier systems are used for taste masking of ingredients and additives, and their protection from degradation during processing. They are also claimed for enhanced bioavailability of nutrients/supplements, antimicrobial activity and other health benefits. There is a wide range of materials available in this category, for example, food additives (eg benzoic acid, citric acid, ascorbic acid), and supplements (eg vitamins A and E, isoflavones, ß-carotene, lutein, omega-3 fatty acids, coenzyme-Q10). The concept of nano-delivery systems has essentially originated from research into targeted delivery of drugs and therapeutics. The use of similar technology in foodstuffs is interesting in the sense that whilst it can offer increased absorption, uptake and bioavailability, it also has the potential to alter tissue distribution of the substances in the body. For example,

certain water-soluble compounds (such as vitamin-C) have been rendered fat dispersible through nano-carrier technology. Vice versa, certain fat-dispersible compounds (eg vitamin-A) have been rendered water dispersible. It is hoped that these nano-carriers are completely broken down and their contents are released in the GIT. As such, the encapsulated compounds will not be any different from their conventional equivalents. However, if a nano-carrier system is capable of delivering the encapsulated substance to the bloodstream, its absorption, tissue distribution and bioavailabiiity may be drastically different from the conventional forms. This raises the concern that some nano-carriers may act as a "Trojan Horse" and facilitate translocation of the encapsulated substances or other foreign materials to unintended parts of the body.

It is also worth mentioning that there are many other nanomaterials that are used for other applications but their use in food/food packaging is uncertain or unlikely. Examples include certain carbon-based materials (such as fullerenes, carbon nanotubes). Although, recent studies have linked carbon nanotubes with potential harmful effects in biological system, they are not likely to be used in food applications. This is because functionalities that carbon nanotubes offer mainly derive from their enhanced tensile strength and electrical conductivity, which are of little relevance to potential use in food, although there may be some applications in the packaging area.

Consumer Safety Concerns

It is known that the conventional physicochemical rules are not fully applicable at the nanometer scale, and that there can be some fundamental shifts in physicochemical properties, behaviour, and interactions of ENPs compared to their bulk equivalents. For example, quantum effects may have a much greater influence on the properties of ENPs, especially of those in the lower nanometer size range, compared to their bulk equivalents. In some cases, such changes in physicochemical properties may also lead to a change in the effects and impacts on biological systems. Some studies have suggested a deviating toxicity profile for some ENPs compared to their conventional equivalents (Donaldson et al. 2001; Nel et al. 2006. An important aspect to consider in relation to potential harmful effects of ENP is their increased ability to penetrate cellular barriers (Geiser et al., 2005; Oberdörster et al., 2004). This adds a new dimension to particulate toxicology, as ENPs can potentially reach new targets in the body where entry of larger particulates is restricted (Jani et al. 1990; Carr et al. 1996; Hillyer and Albrecht 2001; Hoet et al. 2004; Florence 2005; des Rieux et al. 2006; De Jong et al. 2008). ENPs are also known to adsorb or bind different compounds and moieties on their surfaces (Šimon and Joner 2008), and may act as a carrier of potentially harmful chemicals and foreign substances into the blood and different tissues and organs in the body.

Depending on the surface chemistry, systemically introduced ENPs have been found to interact with various biological entities, such as eg plasma proteins, platelets and cells (Nemmar et al. 2002; Šimon and Joner 2008). Such interactions may have a substantial effect on the distribution and excretion of an ENP (Dobrovolskaia 2007). In this regard, there is emerging evidence to suggest that ENPs become coated with certain biomolecules, especially proteins, and these coatings can direct them to specific locations in the body (Lynch and Dawson 2008). For example, coating with apolipoprotein E has been associated with their transport to the brain (Michaelis et al. 2006). The protein "corona" is, however, also reported to be changeable in different surroundings (Cedervall et al. 2007). This suggests that ENPs can undergo complex and dynamic interactions in biological environments, and studies carried out on "neat" ENPs under artificial conditions may not represent their true behaviour and effects in real-life situations.

Nanomaterials that are likely to dissolve/solubilise either in the food matrix or in the Gl tract are not likely to raise health concerns as, once digested or dissolved, they are not likely to behave any differently from the conventional bulk equivalents. One example is that of nano-selenium, which is being marketed as an additive to a tea product in China for a number of (proclaimed) health benefits. However, nano-selenium is likely to solubilise in food or in the Gl tract. Another example is that of a mayonnaise (currently under development) which is composed of nano-micelles that contain nano-droplets of water inside. The mayonnaise is being developed to offer taste and texture attributes similar to the full fat equivalent, but with a significant reduction in the amount of fat intake by the consumer.

It is also worth highlighting that currently there are a number of major knowledge gaps in regard to the behaviour, interactions, fate and toxicological effects of most ENPs in the Gl tract. It is possible that the ENPs added (or migrated) to food will not remain in a free form (and hence not available for translocation) because of agglomeration, binding with food components, reaction with stomach acid or digestive enzymes. Furthermore, much of the available toxicological information relates to in vitro studies, or to exposure through inhalation of ENPs, and full extent of hazard, exposure, and risk from the ingestion of ENPs via food and drinks are therefore largely unknown.

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March 2009

Memorandum by the Medical Research Council Human Nutrition Research Unit

MRC Collaborative Centre for Human Nutrition Research (hereafter HNR) was established in 1998 to advance knowledge of the relationships between human nutrition and health by providing a national centre of excellence for the measurement and interpretation of biochemical, functional and dietary indicators of nutritional status and health. HNR conducts basic research in relevant areas, focusing on optimal nutritional status and nutritional vulnerability in relation to health, including the development of innovative methodologies. HNR responds to the strategic priorities of the wider scientific community by conducting research projects, within the scope of HNR's activities, in collaboration with, and on behalf of: other MRC establishments and groups, Government departments, industry, national and international agencies, universities, research foundations and charitable organisations. HNR also acts as an independent, authoritative source of scientific advice and information on nutrition and health in order to foster evidence-based nutrition policy and practice. In light of the work carried out at HNR and the expertise of our staff, our comments are confined primarily to the role of nutrition in securing good health for the whole population.

The Micronutrient Status Research section at MRC Human Nutrition Research, Cambridge, led by Dr Jonathan Powell, has a long history of research interests in mineral based nano—and micro-particles in the gastrointestinal tract in terms of exposure, uptake and potential cellular effects. We study both endogenously-formed mineral particles (mineralised calcium) and exogenous mineral particles (eg dietary ferritin or food additives such as silicates and titanium dioxide) and we use a range of approaches from synthetic chemistry and basic cellular thought to whole-animal studies (human and murine).

Introductory Concepts

We consider a nanoparticle to be a non-living nano-scaled entity. Traditionally such particles would be considered ultra-fine, fine or coarse, depending upon size, and there is an increasing consensus that the ultra-fine fraction is equivalent in meaning to nanoparticulate, which would be of < 100 nm diameter. Biologically this makes sense because, as a rule of thumb, particles below 100 nm diameter tend not to trigger active uptake mechanisms (ie macro-pinocytosis and phagocytosis) but instead tend to be taken up through more constitutive endocytic mechanisms. Nonetheless we wish to point out that the gut is heavily exposed to fine particles (ie particles > 100 nm diameter) and that these should be considered in the overall picture. Additionally, the different mechanisms of uptake, determined by particle size, will affect intracellular exposure and outcomes.

The gastrointestinal tract is a unique environment. Unlike any other tissue the gut has specific mechanisms for the purposeful uptake of nanoparticles as well as the inevitable inadvertent pathways that nanoparticles are able to access. The major pathways are as follows:

1. Epithelial cell endocytosis. This is for true ultra-fine particles and, for example, is the route of uptake of dietary ferritin.
2. Paracellular uptake of small ultra-fines, which may be enhanced through disease processes or drugs, or dietary agents that enhance this pathway.
3. Persorption, which will allow the uptake of fine and ultra-fine particles. This is a mechanism of inadvertent permeation where an enterocyte leaving the villous tip leaves a hole through which particles can permeate.
4. M-cell uptake overlying intestinal lymphoid aggregates. This is the classical route for the uptake of fine particles and is efficient but it is likely that ultra-fines also access this route.

A further aspect of the unique gut environment is that it contains many luminal toxins and antigens and, due to entropic forces, particles will bind these in the lumen with relatively high affinity. This will change the overall properties of the particle surface and the cellular effects of the antigen or toxin. It should be noted that there are recent data showing that prion infectivity is greatly increased when prions are ingested with particulates.

Immune cells from the gut will migrate to other organs and, therefore, there is a systemic route for distribution of particles from the gut as well as the obvious routing through venous and lymphatic channels.

Gut diseases may potentially increase permeability of nanoparticle uptake.

State of the Science and its Current use in the Food Sector

- *What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?*
- *What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?*
- *What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?*
- *What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?*
- *What are the barriers to the development of new nano-products or processes in the food sector?*

We wish to make clear to the Committee that nanoparticles are not a new phenomenon, they occur naturally and that the gut has been exposed to them presumably throughout evolution. However, due to marked technological advances over the last five to 10 years, we are able to characterise nanoparticles so much better than before, which is at least one reason for their recent appearance on the scientific horizon. The main areas pertinent to the G.I tract are as follows:

1. Enhanced delivery of nutrients: nano-encapsulation or micellar protection of micronutrients and antioxidants to prevent them from degradation during manufacture and storage or under gastrointestinal conditions. These products are already in the marketplace, for example, Novasol is a product range of supplements from Aquasol which consists of pH-resistant micelles that deliver vitamins and antioxidants. Another example is Canola Active oil, produced by Shemen Industries, that delivers phytosterols to inhibit the transportation of cholesterol from the digestive system into the bloodstream.
2. Safety: nanosensors for pathogen and contaminant detection. Raflatac have recently released, commercially, a hydrogen sulphide indicator label for fresh poultry products, where the generation of hydrogen sulphide indicates spoilage. This label contains a nano-layer of silver that changes colour once it reacts with hydrogen sulphide
3. Smart packaging: Packaging that reacts to stimuli such as materials with self-healing properties when perforated or an intelligent ripeness indicator that responds to aroma as fruit ripens.
4. Reducing spoilage: nanoclays in food packaging prevent the permeation of oxygen to slow the ageing process of food or slow the ripening of fruits and vegetables. Honeywell are marketing an oxygen barrier based on nanoclays and a nylon resin that scavenges oxygen to extend the shelf-life of beer (Aegis® OX barrier).
5. Interactive food: foods and beverage products that can be personalized to fit the tastes, nutritional needs, or allergies of individual consumers. Kraft are one of the leaders in this field of research.
6. Taste or texture improvement: reduce consumption of fat, sugar and salt through the enhancement of taste characteristics. Slim Shake Chocolate is a product already in the market, which the manufacturer (RBC), claims to contain 4–6 nm silica nanoparticles that are coated with cocoa components ("cocoa clusters") and due to their high surface area provide a satisfactory sensory experience in a low fat and low sugar product. Another example comes from Unilever which aims to reduce the fat content in ice-cream from 16 per cent to about 1 per cent by decreasing the size of emulsion particles that give ice-cream its texture.
7. Equipment coating: application of nano-coating in food processing equipment to prevent the growth of biofilms that can lead to food spoilage and contamination. Many commercially available food containers are already coated with nano-silver, or anti-sticking nano-composites, and some refrigerators are coated with nano-silver. Zinc oxide is also being studied as a cheaper anti-microbial agent to replace nano-silver, and applications are expected in the near future.

8. Removal of unwanted chemicals or pathogens from food.
9. Food processing: nanosensors that can withstand extreme conditions (eg temperature, pressure, viscosity) and provide real-time data on processing conditions.

Further examples can be found in the presentation given by Dr Dora Pereira of the MSR section at MRC-HNR (Appendix, page 3) [not printed] to an audience of the Cambridge Science festival on 13 March. We would like to add that although the range of nanotechnologies that can be applied to food, or food production, is vast, and many different strategies are being developed or are already in the market, the perception of safety will determine public acceptance and may limit the growth in several areas.

Health and Safety

— *What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?*

— *Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?*

— *Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?*

— *Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?*

Gastrointestinal exposure to nanoparticles may be natural, due to inadvertent environmental exposure or due to purposeful environmental exposure. Examples of naturally occurring nanoparticles are dietary ferritin, which is about 13 nm in diameter but when digested releases iron oxide particles of around 2 to 3 nm and the endogenous calcium phosphate particles that are formed within the gut lumen and appear to have diameters of 20 to 200 nm. It is likely the majority of natural nanoparticles to which the gut is exposed are mineral based. Inadvertent environmental exposure comes through soil, dust, exhaust fumes etc. In contrast, purposeful, man-made exposure is mainly through food additives and excipients or congeners that are used in supplements and medicines etc.

We believe that traditional toxicology models are not likely to capture much information when it comes to nanoparticle adverse effects. This is because any effects are likely to be mediated immunologically and, therefore, identified through chronic exposure and by interaction with individual genotypes. It may first be useful to categorise particles as fine or ultra-fine to identify their likely route of cellular uptake and thereafter to establish their chemical stability to predict cellular processing. It may thus become possible to develop assays that will predict nanoparticle toxicity.

Several companies are developing nano-delivery systems that enhance the absorption of antioxidants known to provide health benefits. However, many of these antioxidants are normally poorly absorbed and may not be well tolerated at higher levels, which may result in "too much of a good thing" scenarios. Therefore, prior knowledge based on normal delivery of nutrients should be ignored and these nano-delivered nutrients should be treated as novel chemical entities. However, the use of naturally occurring nanomaterials (eg ferritin) may be fast-tracked in future regulatory processes providing that there is evidence of their consumption over periods of time long enough to guarantee their safety, and that their administration is not substantially above what would be found in an average diet. MRC-HNR is working on the synthesis and commercialisation of ferritin-core mimetics as novel iron supplements.

Regulatory Framework

— *Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?*

— *How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?*

— *Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?*

— *Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?*

Currently, legislation does not account for the nano-scaling of current approved excipients and additives. An example of this is noted above, namely that amorphous silica is an approved particulate which recently has been nano-sized by RBC in their Slim Shake Chocolate product and thus has "inherent" FDA approval although the original toxicity testing is likely to have been carried out on particles of tens of micrometres in diameter. We, therefore, believe that the regulatory process should be based on a case-by-case approach.

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

We have not carried out any surveys to consider the level of public awareness or perception of nanotechnologies in the food sector.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

Efforts to inform the public have not kept pace with the growth of this new technology area. This increases the risk that a false alarm over safety or health consequences could undermine public confidence, engender consumer mistrust, and, as a result, damage the future of nanotechnology, before the most exciting applications are realised.

In the latest national MORI Survey for the Office of Science and Technology (2005) a large proportion of those surveyed said that they wanted to hear about new developments in science and technology before they happen, not afterwards; and 49 per cent said that they receive too little information about science (more than twice the proportion than in 1999–2000). The Wellcome Trust document "Engaging Science: Thoughts, deeds, analysis and action report" (2006) recognises the value of a well informed public debate "to enable a wide range of opinions to feed into policy-making discussions."

If the public is to trust, debate and value scientific progress, we need a society engaged with contemporary science. Scientists themselves need to be encouraged, trained and supported in communicating their work. Stimulating public interest in science, its potential applications, misapplications and impacts, as well as the nature of science itself can be achieved through the development of a clear public engagement strategy with specific audiences identified, measurable objectives and outputs.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

The value of public engagement within the fields of science and nutrition is increasingly recognised but, to date, under-utilised. A report prepared for the Research Councils UK and the Department for Innovation, Universities and Skills highlights that "direct dialogue with the public should move from being an optional add-on to science-based policy making and to the activities of research organisations and learned institutions, and should become a normal and integral part of the process" (People Science and Policy Ltd/TNS 2008). Moreover it notes that the public increasing want more information; 8 out of 10 people agreed that "science is such a big part of our lives we should all take an interest."

The Nutrition and Health Communications team at MRC HNR has a strong track record in engaging with a variety of different audiences to drive improvements in public health. Our aim is to build bridges between our scientists and people of all ages and from all walks of life to consider, question and debate the key issues in relation to diet and health and to stimulate their awareness and enthusiasm for science in society.

Public engagement has many different levels and mechanics and is a key part of the MRC Corporate Communications Strategy. At HNR our activities tend to focus on issues directly relevant to our own research or broad nutrition and health messages about a healthier diet. Our key learnings are:

- Develop a communications plan with agreed key messages appropriate to the audiences.
- Provide an in depth briefing to journalists at an early stage and keep them regularly informed.
- Encourage and train scientists to engage with the public.
- Make scientists accessible to the media throughout the communication process.
- Engage leading medical research and scientific bodies to make a positive and proactive contribution to the debate, not just defensive responses.

Given our particular research interest in the area of nanoparticles we are at the start of a scoping exercise to identify how we might contribute to the debate across a variety of audiences, including the public. We shall observe the progress of this Inquiry in some detail and would welcome the opportunity to discuss public engagement opportunities in more detail.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

Public attitudes towards new technologies play an increasingly crucial role in supporting their development and application. The public should be provided with information on the use of nanotechnologies and nanomaterials in food productions because public opinion has the potential to influence the public policy and regulatory environment in either positive or negative directions, with recent examples including biotechnology and genetically modified crops. It also impacts on the investment environment, with investors influenced by actual and potential community and shareholder concerns.

12 March 2009

Further memorandum by the Medical Research Council Human Nutrition Research Unit

Introduction

When cells fail to recognise surface molecules or molecular structure of small particles, the fate of these particles may be determined by their physical size and no longer by their chemical composition. Nanoparticulate, nanosized and nanostructured are then descriptors that relate to a dominant characteristic.

Natural Exposure

The human gut has been exposed to non-biological particles of varying sizes for millennia. For example, dietary ferritin is a small nanoparticle (•) of 13 nm diameter when whole and 2.5 nm as the smallest core sub-unit, while dust and soil nanoparticles tend to be hundreds of nm in diameter/length (●). Four uptake (absorption) mechanisms have been proposed in the gastrointestinal tract (Figure 1):

1. Through "regular" epithelial cells (gut-lining cells) via a route termed endocytosis ("engulfing" the particle). Very small particles—tentatively generally $<$20nm in diameter.
2. M cell uptake (transcytosis) at the surface of intestinal lymphoid aggregates. This is the quintessential pathway for gut particle uptake and is very well described, especially for large nanoparticles ($\geq$ 100 nm), although smaller particles are also likely to be able to access this route. M cells have a "surveillance" role in the gut and are specialised in particle uptake.
3. Persorption. Volkhemer's concept of passage through "gaps" at the villous tip following loss of enterocyte(s) to the gut lumen. Small and large nanoparticles potentially access this route but its quantitative validity is unclear.
4. Putative paracellular (between cell) uptake. Generally junctional complexes are unlikely to allow even the smallest of nanoparticles to permeate but certain drugs and/or dietary situations, and especially diseases, may alter this situation allowing influx of very small nanoparticles. Theoretical pathway as it stands.

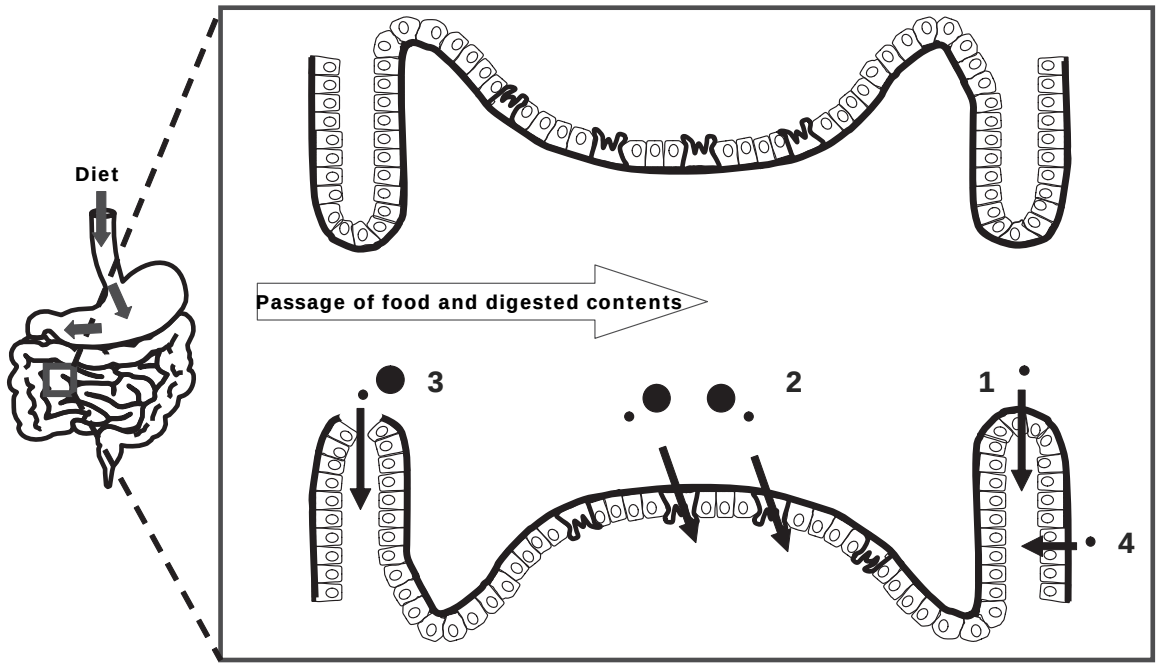

Figure 1: Schematic representation of different routes for particle uptake in the small intestine. The numbers refer to those pathways described in the text. Uptake via (1) regular epithelial cells (2) M cells of the lymphoid aggregate (3) persorption and (4) the theoretical paracellular pathway.

Regardless of mechanisms, it is clear that ingested particles across the nano-range (0-1000 nm) will be absorbed to some extent into both the circulation and the gut tissue itself. Percentage absorption will depend on many factors (eg size, surface charge, host gut permeability, etc). But even if only 0.1 per cent of a total 10^{13} ingested particles is absorbed, that corresponds to 10^9 particles absorbed/day.

From the circulation, particles will be retained by cells in the liver and other vascular organs. From the gut tissue, cells can migrate systemically with their cargo (eg particles), especially to mesenteric lymph nodes. The persistence or degradation of particles at any site depends upon the physico-chemical characteristics of the particles but even undegradable particles have some clearance through cellular-shedding in the gut and lung.

Man-made Particle Exposure—Currently

Silicates, aluminosilicates, titanium dioxide and carrageenan are among the typical man-made, or at least man-modified, particles that the human gut is now exposed to, especially in the Western world, on a daily basis. Exposure has been for decades-as food additives mainly. Except at MRC-HNR there is little research on the gut-associated effects of these although some appear to accumulate in gut tissue. Nonetheless, studies to-date suggest that, overall, these particles are safe and even if they can be shown to have any adverse effects it will almost certainly be in a small minority with a different genetic make-up. However there is no evidence for this currently.

The above particles are almost all in the larger nano-range (being $\geq$ 100 nm diameter/length). There is, in the UK, no evidence currently for the significant intake of new/man-made small nano-sized particles, although, increasingly at the global level, proposals for this are made in industry and in research studies.

Man-made Particle Exposure—Future

"Nanosizing" can have a variety of commercial advantages for certain foods, supplements (especially), medicines, food packaging and other materials that may be ingested. However, in many cases, the "nanosized" foods will undergo simple gastrointestinal digestion prior even to meeting any cells (Figure 2). Examples include "nano-salt" (1) and probably some "nano-micelles" (2). However, even with nano-micelles that are absorbed whole, they will undergo fairly rapid cellular degradation and are likely to be recognised for their molecular structure rather than their nanosize. Indeed it should be noted that yoghurt and milk are foods containing nano-micelles (40–300 nm) of casein that occur in large abundance in the intestinal lumen upon ingestion. For competitive commercial reasons, as well as the potential to lose scientific/toxicological focus, it would seem sensible that such foods are considered separately with regards to further "nano-legislation".

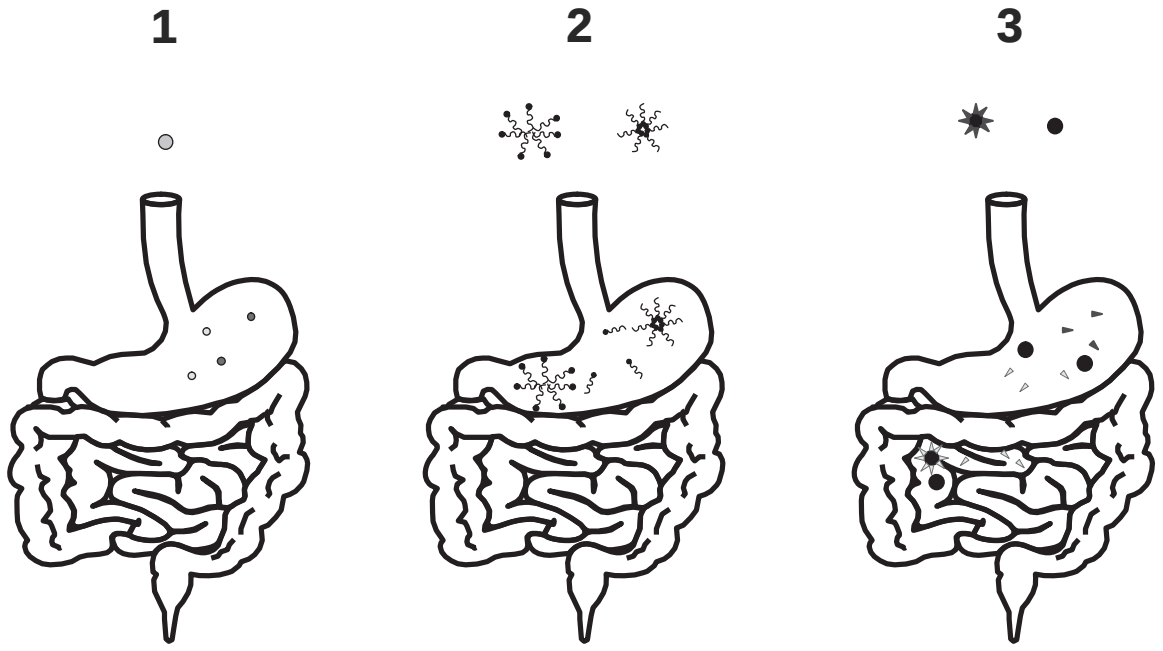

Figure 2: 1, Some nanoformulated materials, eg nanosalts, are likely to be digested in the gut before any cellular exposure. 2, Micellar nanoformulations may partially degrade in the gut or be absorbed whole, but are likely to be rapidly broken down in cells. 3, In contrast, truly or transiently persistent nanoparticles are likely to lose any surface adsorbed material in the stomach, but may themselves remain intact, and then, later in the gut, could (depending on size, surface charge etc.) adsorb other soluble luminal molecules before cellular uptake.

Thus, in the case of micellar nanoparticles it is highly likely that the constituent molecules would dictate toxicity, rather than their aggregated nature to form a nano-micelle, although this latter property could influence bio-distribution.

In the final scenario in Figure 2, novel nanoparticles may be bio-persistent, either transiently as there is gradual cellular breakdown, or truly persistent as they can only be cleared with the sloughed cells, as noted above. If the latter process is slower than the rate of uptake then particles may accumulate. Examples could *speculatively* include, nano-silver, nano-clays and nano-silica. Depending upon their size, surface charge etc., ingested particles may adsorb (to their surface) other soluble molecules, including bacterial toxins, from the gut lumen, and carry these across into cells (Figure 2:3). Probably the larger nanoparticles are better at this.

Particle Toxicity: Factors and Why Nanoparticles?

A number of poorly predictable properties dictate particle toxicity—eg crystalline structure, surface reactivity, dissolution characteristics, adsorptive properties etc. So, for example the α-quartz form of silicon dioxide is a toxic particle while the amorphous form of silicon dioxide is not. A second example, mediated by a similar process to that of quartz, is that nano-particulate hydroxyapatite may be toxic to cells while some other forms of nano-particulate calcium phosphate are considered less so.

Particle shape can also affect particle toxicity. Thus asbestos, erionite and some man-made nanotubes appear toxic due to their high aspect-ratio or "needle-like" shapes.

Finally, size. This is often poorly understood. The large majority of particles are fairly inert/non toxic unless they have some specific property, as noted above. In the absence of any "special property", particle toxicity can be considered in two simple forms:

(1) Direct toxicity. Normally mediated through "free radical" activity and, in this case, smaller particles are considerably more active than the same mass of larger particles. This appears to be a surface area phenomenon. However, just because this can happen, we must ask does it happen? Many experiments use such unrealistic particle doses that extrapolation to lower doses, that represent real exposures,

may be artefactual. The result of drinking a bottle of whisky one evening tells us little about the result of one drink per evening over a few months. Secondly, most tissues, including the gut and circulation, are armed with complex and replenishable antioxidant defences to combat such acute (short-term) exposures. In doing so, however, there may be downstream costs (long-term).

Accumulating evidence suggests that lung exposure to nanoparticles is linked with an increased risk of chronic cardiovascular disease. A second potential lesson from the lung is that certain individuals (eg those with asthma) can experience an exacerbation of disease upon acute exposure to an abnormally high environmental dose of particles (eg at peaks of urban pollution). However it is the view of these authors (but not the wider community) that this latter phenomenon, as opposed to the chronic systemic effects, could be more related to the large nanoparticle fraction (●) than it is to the small fraction (•), leading onto the second potential mechanism of general particle toxicity.

(2) Large nanoparticles (or aggregated small ones) can make good cellular "adjuvants" such that an immune response to a protein/allergen/antigen is enhanced or "polarised" when exposure is in the presence of a particle. Contact between the allergen/antigen and the particle (eg adsorption) appears important.

What is Special about Nanoparticles?

Three things. First, as detailed above, in the absence of a "special property" for particle toxicity, all particles will be more directly toxic to cells as small nanoparticles than as larger ones. The pros and cons of this observation are noted above. Secondly, as a rough guide, particles < 100 nm diameter will be taken up by cells through a different pathway to that of larger particles (Figure 3), meaning that they will access different cellular compartments and have different cellular effects. Again, "induction of free radicals" versus "adjuvant activity" are the basic differing outcomes. Thirdly, very small nanoparticles are especially mobile and motile and may access all areas of the body including even the brain and all areas of the cell including even the nucleus (being smaller than nuclear pores). It is this latter property that probably makes very small nanoparticles most worrisome to scientists and hence the translation of this concern (but not the knowledge of why) to the public.

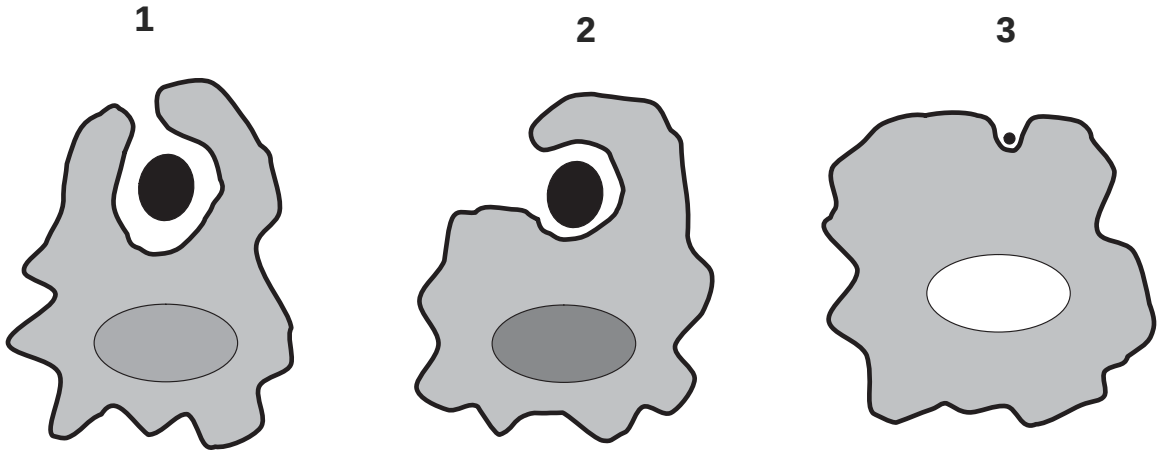

Figure 3: Schematic representation of cellular particle uptake for large particles via 1. active phagocytosis or engulfing of large particles and 2. macropinocytosis which is a different type of active particle capture. These events are triggered by the size of the particle. 3. small particles are taken up by constitutive pinocytosis and are processed by the cell in a different fashion.

Finally, it should be noted that in the absence of specific particle toxicity there is no logical reason to assume that, in the gut, smaller nanoparticles will always have worse adverse health effects than larger ones or that either will have any adverse health effects at all. It will depend on many other variables including host genotype, persistence, dose, and ability to adsorb gut luminal molecules. And thus there is no logical reason to use 100 nm as a cut-off for adverse effects, even though, as discussed, this size discrimination may help determine the type of cellular effect.

Other Important Factors

(1) Particles may aggregate so that their behaviour during at least part of the exposure process is more typical of large particles (●) even though their single unit is as a small particle (•). This is especially true for small nanoparticles.

(2) Particles are rarely seen by cells in their "native form". Most particles readily adsorb to their surface molecules and ions from their environment. In the gut, particle surfaces may be "cleared" in the acid and enzyme-active area of the stomach but re-adsorb material further down the G.I. tract. In this environment, bacterial proteins and carbohydrates are especially common.

(3) Classical toxicity or toxicology studies may be poor or even misleading at deciphering particle toxicity following oral exposure. In particular, long-term (decades) effects and host genotypes cannot be mimicked in animal studies. Instead a "logic algorithm" and some targeted *in vitro* tests may be more useful.

(4) Nanotechnology may actually serve to make some materials less toxic. For example, MRC-HNR is developing a transiently stable nano-formulation of supplemental iron which should exhibit much less toxicity to the intestinal mucosa, and therefore side-effects, than the current common therapeutic supplements, namely ferrous sulphate and other ferrous salts.

Acknowledgement

We thank Drs Laetitia Pele and Nuno Faria for their invaluable contribution during the preparation of this document.

March 2009

Examination of Witnesses

Witnesses: Professor Ken Donaldson, (University of Edinburgh), Dr Qasim Chaudhry, (The Food and Environment Research Agency), Dr Jonathan Powell, (MRC Centre for Human Nutrition Research) and Professor Michael Depledge, (Peninsula College of Medicine and Dentistry), gave evidence.

Q214 ***Chairman:*** Good morning. I would like to start by welcoming our four witnesses today, as well as the members of the public sitting behind; to remind you that the proceedings today are being webcast so the public can observe what is going on; and also to draw the attention of members of the public to the information note which sets out members' declared interests; so we will not be declaring interests as we go through the questioning. I would like to kick off by asking each of our four witnesses to introduce themselves for the record. If there are any points you would like to make in a brief opening statement please feel free to do so. Perhaps I could start with Dr Powell and then go along the row?

Dr Powell: I am Jonathan Powell from the Medical Research Council Human Nutrition Research Unit based in Cambridge. My area of expertise is minerals, particularly nanominerals in the gut.

Dr Chaudhry: I am Qasim Chaudhry. I work for the Food and Environment Research Agency of Defra. I am a research scientist and we have been working on the safety of nanoparticles through human health and the environment.

Professor Donaldson: My name is Ken Donaldson. I am Professor of Respiratory Toxicology in the University of Edinburgh, and I specialise in the harmful effects of inhaled particles on the lungs and the cardiovascular system.

Professor Depledge: I am Michael Depledge. I am Professor of Environment and Human Health at the Peninsula Medical School in south-west Britain. I am a member of the Royal Commission on Environmental Pollution. As you may be aware, the Royal Commission conducted a study on novel materials, and in particular nanomaterials, over the last two years and I have been deeply involved in that particular study. I am an ecotoxicologist and have worked on nanomaterials in lower animals.

Q215 ***Chairman:*** Thank you very much indeed. Perhaps I could kick off with an opening question of a fairly general nature and any of you might wish to respond to this. As you will understand, part of the focus of our inquiry is about possible or potential health and safety concerns relating to the use of nanomaterials and nanotechnologies in the food sector. You are all experts in this area and I wonder if you would like to express to us what you think are the potential health and safety concerns, and what evidence is available to address those?

Dr Powell: I think we know quite a lot about the uptake of particles in the gut, in terms of the route of entry; and we know a reasonable amount about the likely cellular targets. We know very, very little about what happens once those particles meet those cells. We would certainly consider persistence to be important, so that were you to ingest a particle that was broken down in the gut lumen prior to meeting its cellular target, it would in our eyes have a toxicology related to its chemistry, i.e. the components, rather than to its nanoparticulate

sizing. We do believe that more work needs to be done in terms of both nanoparticles and the larger nanoparticles or microparticles, i.e. those larger than 100 nm in diameter, in terms of what happens inside the gut.

Dr Chaudhry: In our view there are two fundamental concerns about the health and safety of nanomaterials, and both relate to oral intake of food products that contain free nanoparticles that are insoluble, indigestible and that can translocate from the gut in particulate form to other parts of the body. Essentially that category of particles is of most concern. The first concern is the ability to cross cellular barriers, and there is scientific evidence for that. Cellular barriers prevent entry of larger insoluble particulate material; but nanoparticles, because of their very small size, can override that principle and potentially reach new targets in the body, for example the brain. The second concern is the potential effects of nanoparticles, and that will depend on the chemical nature of nanoparticles, as Dr Powell mentioned. If the chemicals that constitute nanoparticles are toxic then it can be perceived that they deliver toxic chemicals to new targets in the body where those chemicals would otherwise have not gone, had they not been in nanoparticle form. The other concern is that many nanoparticles have a reactive surface and they can interfere with cellular processes, for example oxygen metabolism, and this can lead to the emission of oxyradicals. This has been shown in a number of studies. This can lead to inflammatory reactions and oxidative damage. There are other concerns: for example, some nanoparticles or nanodelivery systems can carry harmful substances out of the gut into the blood circulation from where they can lead to other parts of the body. Another concern is about antimicrobial effects of some metallic nanoparticles; when ingested they can have a harmful effect on gut natural microflora, which can ultimately harm consumers' health.

Professor Donaldson: As a non-specialist in terms of the gut, my main concern is that there is so little research on what is happening with nanoparticles in the gut; whereas there are fairly huge amounts of research funding pouring into Europe and the USA into the lungs, the inhalation hazard, and to some extent the skin, although less so. The research into the gut is much, much less. I do not think you can generalise from the effects of particles in the lungs or on the skin to the effects on the gut. The gut is a wholly different environment to me to these other situations in terms of the extremity of the conditions, for instances of acidity in the stomach. My main concern would be the lack of research in the non-generalisability of existing research to the gut.

Professor Depledge: Just to add I think it is worth emphasising the diversity of nanotechnologies and the diverse nature of nanomaterials. It is very difficult, I think, to make general statements about nanomaterials: some are very reactive; some are not; some are very persistent; some are not. I think we need to focus on that. The second point concerns nanomaterials in food, some of them are put there intentionally, and some are unintentional occupants of food, as it were. I certainly agree with the idea that the amount of evidence available with regard to the effects of nanomaterials, delivered through food or in food, is very, very small indeed and there is an urgent need to conduct many more studies. I also think that we ought to consider plausibility. We know that some of these nanomaterials are designed to be highly reactive. We know that some of them have very highly reactive surface properties; and there are little bits of evidence which show that they can convert chemicals from one form into another: so it may not be the nanomaterial itself that is toxic but the role it plays in converting substances that are non-toxic to be toxic. There is a lot of plausibility that needs investigating.

Q216 ***Chairman:*** When you look at the current developments in the use of nanotechnologies and nanomaterials in food in the evidence that both MRC and CSL submitted, you referred to various examples. Do those examples themselves trigger concerns about the lack of knowledge of toxicological effects and risk?

Dr Powell: The examples I think you are referring to are those such as nano-silver, nano-silica and nano-clays. I believe those do trigger concerns, in particular that, as has already been mentioned, when a substance is nanosized, in doing so its major cellular interaction and biochemistry may be driven by its nanoparticulate nature. If that becomes the major characteristic that drives its reactivity, then there is no doubt that some of those materials will have different properties compared with bulk materials—and I think of nano-silica in particular. The other point to make is that, as a nanoparticle in the gut, there is always the possibility of picking up local soluble molecules onto the surface, such as bacterial toxins, and that those then become delivered with almost a Trojan horse effect into cells of the gut; and of course, as has been explained by Dr Chaudhry, with the possibility of dissemination to other organs as well.

Dr Chaudhry: I think the main point is that if nanomaterials are solubalised, digested or degraded within the gut then they are of least concern, because then their properties or effects will be dependent on what sort of chemical composition they had, i.e. what chemical constituted the nanoparticle. The main concern is on insoluble, indigestible, non-degradable nanoparticles than can survive mechanisms in the gut and can come out of the gut.

Q217 ***Chairman:*** From the point of view of a toxicologist, I wonder if you might think that particular groups of consumers would be more at risk than others? If there were a risk would you think, for example, young children or elderly people would be more at risk? I think one of the points the MRC made in its evidence is that the way the body responds to free nanoparticles is an immunological response. I think that is what you said. Bearing that in mind, would you expect particular population subgroups to be more or less susceptible?

Professor Depledge: I have certainly read one study—I say *one* because it emphasises the scarcity of information—which involved rats and looking at the uptake of iodine labelled polystyrene microspheres of more than 50 nm. They have demonstrated uptake of these microspheres. It was suggested in that particular study that people, or animals with inflammatory bowel disease of one form or another, would be at greater risk. I am not aware of any other evidence.

Professor Donaldson: I think there is maybe one case where the lung data might come to hand here. Certainly in the human lung the adverse susceptibility to particles is greatly enhanced in those people who have inflammatory conditions of the lung, asthma and COPD especially. If you have inflammation already in your airways then the effect of the particles are worse. That is very strong data to support that. One would imagine that the gut would be exactly the same. The effect of particles in the gut may be much worse in someone who has got some inflammation in their gut.

Dr Powell: I can add to that in two forms: firstly, that gut permeability is enhanced in the presence of certain disease, including chronic diarrhoea; and there is good evidence that small particles or large molecules will have enhanced permeability under these conditions. The second point to make is to pick up on Professor Donaldson's point, which is that we have looked in inflamed cells from patients with inflammatory bowel disease; we have challenged them with particles and we have shown that they will have enhanced pro-inflammatory effects; again, I stress this is *ex vivo*, and there is little or no data as far as I know *in vivo*.

Dr Chaudhry: There is no evidence in scientific terms but nanoparticles may act as seeds for crystallisation of certain chemicals, but this has been shown in test tube experiments. Concerns have been raised that if nanoparticles get into, for example, the kidney and the kidney is inflamed, they might act as seeds for calcification there; but there is no scientific evidence for that.

Q218 ***Lord Haskel:*** Could I just put the layman's question: if you do get some nanoparticles in your gut and they have the reaction you describe, what can you do about it? Is there an antidote, or something like that?

Dr Chaudhry: I think, depending on the chemical nature of nanoparticles, they may not cause toxicity there and then. If they are excreted from the body, metabolised, broken down, that is another story because they will be eliminated from the body. The concern is if they become lodged into the cells and tissues and remain there and get accumulated over time and what sort of effects they may have. We are not talking about immediate effects; we are talking about medium to long-term effects.

Professor Donaldson: Jonathan would know better than me, but if we go back to the situation where someone has an inflammatory bowel condition and he already takes some medication, they would take more of it more often, I would imagine; which is the case with asthma and air pollution; people use their asthma medication more when the air pollution is high. You would make the same argument, one would imagine.

Professor Depledge: The point I would like to make is I think this demonstrates what I was saying earlier about plausibility. You can imagine scenarios of what might happen, but we are operating in an area of profound ignorance. Certainly we do not have a comprehensive understanding; I am not sure we have any real understanding of what would happen in those circumstances and whether you could pull nanomaterials out. It is actually extremely difficult to find the nanomaterials in the first place

Q219 ***Earl of Selborne:*** I would like to ask our toxicologists today how they would define nanotechnologies and nanomaterials from a toxicological point of view?

Professor Donaldson: There is an immediate problem there because the standard definition (which has been considered and thought about extensively by various nomenclature committees which Qasim has sat on) that a nanoparticle is a particle with one dimension at least less than 100 nm or 0.1 of a micron, there is no toxicological basis whatsoever for that. The idea that a 102 nm particle is safe and a 99 nm particle is not is just plain daft, it does not work that way. It is a sliding scale: we may talk later on about surface area, but as particles get smaller their surface area per unit mass increases; and it is surface area that interacts with biological systems. You can talk about smallness as well, but surface area matters a lot in terms of delivering harm.

Q220 ***Earl of Selborne:*** In order to determine potential toxicity, is it sensible to look not just at size, which you say could be relevant, but reactivity, shape, any other factors?

Professor Donaldson: Reactivity per unit surface area and shape.

Professor Depledge: Could I just add to that, when we were gathering evidence for the Royal Commission report some of the evidence we received suggested that the term "nanotechnology" was really not a very useful term and might disappear within ten to 15 years. I think the conclusion you will find in the Royal Commission's report is that it is really the functionality—the functions of the particles—that is more important when it comes to classifying them in toxicological terms.

Q221 ***Earl of Selborne:*** Eventually one would hope in Europe there would have to be detailed risk assessment and legislation; and there needs to be some assessment as to how this can be best determined in legislation. I understand that the European Food Safety Authority has recommended that an additional metric, taking your point of specific surface area, should be included in the definition of nanoscale materials, which is currently based solely on size. Is this measure of surface area going to be adequate to catch the high-risk nanoparticles?
Professor Donaldson: With surface area alone there are a large amount of nanoparticle types currently in use, like aluminosilica and titanium dioxide, and there are already many materials handled in workplaces, which are classified as low toxicity materials. The toxicity per unit surface of these is very low; as far as a particle toxicologist can ascertain, it is about as low as it gets; they have virtually no activity; but enough of them in the lung, for instance, does stir up problems in the lung. Certainly the idea that then you move up into a particle which has lots of surface area but that surface area is already active then you would start to multiply the harm.
Dr Powell: There are two answers I would like to give in response to that. Firstly, that nanosize *per se* does not to my mind make a particle a nanoparticle. I say that because there are plenty of naturally occurring substances that are nanosized but they behave chemically, biologically in many different ways. They may behave as soluble molecules or—at the other end of the scale they may be a virus, for example; these will be recognised in different ways. The term "nanotechnology" or "nanoparticulate" to our mind means that that characteristic, that nanosize, has become *the* dominant characteristic that drives the behaviour of the material. It does not mean that everything that is nanosized should be considered a nanoparticle. The second point I would like to make is that surface area may well be important in terms of the acute effect, these radical-inducing effects of particles within cells, or their potential ability to produce these radicals; it will not, however, give us a lot of information about the more long-term chronic effects. I think, therefore, there is a challenge ahead in terms of testing these particles for their chronicity; ie their long-term adverse effects rather than their acute pro-inflammatory effects.

Q222 ***Lord Methuen:*** What types of nanoparticles are likely to be used in food or packaging? Would you class any of these particles as a high potential risk?
Dr Powell: I have mentioned earlier that from what we have seen there are two types of nanoparticles that are either being used or planning to be used. The first type are the larger nanoparticles, and within the definition that people tend to think of nanoparticles, i.e. less than 100 nm in diameter; these would fall either on the edge or outside that definition; but those are already used in food in large amounts and we ingest large amounts. We have been studying these for many years and we still know very little about them. They include aluminosilicates, titanium dioxide and silicate particles; and these are used as food additives. The second type are the smaller particles. These are either being used in other countries, not in the UK, or are on the horizon and include nano-silver, the nano-clays, as well as nano-silica; and we are concerned mostly about those that show either partial persistence—ie they get through the gut lumen and into the gut cells where they may be broken down but that does not stop them being toxic—or they show whole persistence, and that means that they cannot be broken down at the cellular level either. I suspect, of those particles, nano-silver, nano-clays and nano-silica in particular will all fall into the latter categories.

Q223 ***Lord Methuen:*** Those are mainly used for packaging at the moment?
Dr Powell: Yes, the nano-silica has been introduced into at least one drink that we know of in the USA; as far as I know, it is not available in the UK, except were someone to bring it in or via the internet. That is used in one food; but the others, you are absolutely correct, are much more in packaging.

Q224 ***Lord Methuen:*** What was meant to be the benefit in this drink?
Dr Powell: The idea is that you can promote the interaction between a substance adsorbed onto the nanoparticle surface, in this case cocoa, and the tastebud; so that this provides a longer lasting interaction between the two, which then gives you a stronger flavour burst and, the idea of that being, you can use less sugar, you can use less fat and you will still get the same delivery effect but in a "more healthy" drink.

Q225 ***Chairman:*** Can I just pick up on a couple of points. One is that you mentioned that titanium dioxide is used as an additive in food. If my memory

serves me correctly, when we took evidence from the Food and Drink Federation they seemed to be unaware of the fact that titanium dioxide was used in food. They thought it was used in cosmetics but not in food. Can you be more specific and definite that it is used as a food additive?
Dr Powell: I can be very definite about that. It is a piece of work that we have done. We have done it both by direct analysis of the foods, and also by looking at people's diets. We have shown that the average intake is around 5 mg/day; that is not large in terms of weight but in terms of number of particles that is about 10^{12}, one million million particles; so it is a large number of particles that are ingested per day. It is used as a brightening or whitening agent, so it is an artificial additive that makes foods whiter or brighter. It is also added to a number of medications as an excipient; also to some toothpastes, few but some toothpastes; and also particularly to food supplements where it might be involved again in giving a slightly different colour effect to that supplement.

Q226 ***Chairman:*** I think it might be worth just checking that the Food and Drink Federation still stand by the statement they made last week, which I believe was that it is used in cosmetics and sunscreens but not in food.
Professor Donaldson: I think you have to be careful, because the word "nano" has become such a bogey term that, if you are not careful, they take the question to be, "Is there nano TiO_2 in food", and you say, "No"; but there is lots of bigger titanium dioxide in food. White cream—the cream that comes out of a can—that is white because it is titanium dioxide.

Q227 ***Chairman:*** Coming back to Dr Powell, whether particles you referred to—10^{12} that are ingested every day—were those within the definition that we have been talking about? Were those nanoparticles, or were they particles?
Dr Powell: These are within the definition that we have been talking about. They have an average diameter of 200 nm. You will find a small proportion that are smaller ie below 100 nm; but the majority will have greater than 100 nm diameter.

Q228 ***Chairman:*** May I just ask one other question before moving on. In the MRC's evidence—again this is picking up on the question of risks in current use—you refer to nanodelivery systems that enhance the absorption of antioxidants. However, many of these antioxidants are normally poorly observed and may not be well tolerated at a high level and may result in too much of a good thing. These are components of a diet that may be valuable to you in very small doses but toxic in larger doses. Is that something from the health and safety point of view one should be really concerned about; or were you simply speculating in a more general way that this is a possibility?
Dr Powell: It was more general speculation. There are a number of nutraceuticals or antioxidant-type substances that occur in diets in very, very small amounts and they are absorbed often in very, very small amounts. We were simply speculating that were you to create a scenario where you could get much greater absorption, such as through nano-encapsulation, it might not just be the nanoparticle you have to be concerned about but the substance within.

Q229 ***Lord Haskel:*** Dr Powell said that titanium dioxide was used in toothpaste as brightener. Is that correct?
Dr Powell: I believe it is used in a few now. There is a particle that is used in much greater amounts in toothpaste and that is the aluminosilicate; but I believe titanium dioxide is still used in a few toothpastes, yes.

Q230 ***Lord Haskel:*** If you go into a pharmacy there are lots of toothpastes that say they will brighten your teeth but we have been led to understand that these things are hardly used at all. Because everybody uses toothpaste, quite a number of people must be brushing their teeth with titanium dioxide?
Dr Powell: If I could just clarify. I am not an expert in this area but I think I am right in saying that titanium dioxide is used to make the food, or in this case the toothpaste, brighter. I do not think *it* itself is responsible for the brightening action on the teeth.

Q231 ***Lord May of Oxford:*** We have been talking about nanoparticles in the gut, but I am curious what actually are the risks associated with ingesting nanoparticles in the gastrointestinal tract? What are the risks that we know about? What are the things we suspect we know about? What are the unknown unknowns?
Dr Chaudhry: There are more unknowns than knowns in this case. Very little is known in fact.

Q232 ***Lord May of Oxford:*** I was not meaning to knock Rumsfeld, I should say. I thought it was one of few intelligent things he said!
Dr Chaudhry: This is a very, very topical question. What is not known is whether nanoparticles added to food will remain free; whether they agglomerate; aggregate; bind to food; whether they will be digested; whether they will be broken down by stomach acids or enzymes; or will be excreted. These aspects are completely normal for the majority of nanoparticles. Because these interactions of

behaviour and fate aspects are very important in determining what sort of risks they may pose—risk is not only hazard, it is also exposure—if they never leave the gut and are excreted from the body then obviously there is no risk; but these aspects are largely not known.

Dr Powell: I would like to point out the gut is a rather unusual organ, in that it is naturally tolerant, unlike many tissues; and that is because of course we are throwing food at it every day.

Q233 ***Lord May of Oxford:*** It has got to be!

Dr Powell: Bacteria live in there, and so it has developed in a rather tolerant fashion. That, in the main, of course is a good thing and it protects us. Just occasionally that tolerance can be broken, and broken in the most unusual ways. Unfortunately we know so little about either that process or, indeed, about particles and nanoparticles, that trying to tie those two aspects together would be nothing better than speculation, which probably would not be very useful to the Committee. Suffice to say, in my view, there really is nothing known.

Professor Depledge: If you think about the developments that are underway with nanomedicines, they are designing many, many different kinds of medicines using nanomaterials that may gain greater use in the future. Of course, some of those are designed for uptake through the gut so there are possibilities. It is plausible that particles can pass through the gut and be taken up in that way. The other thing is that it seems that many of the engineered or manufactured nanoparticles have not been fully characterised in terms of their properties and what they can do; so there are surprises with some nanomaterials that are being used, that they do other things that we do not discover until later down the line. I think, again, there may be surprises in store.

Q234 ***Lord May of Oxford:*** Specifically we have already mentioned silver. I know nano-silver is used as an antimicrobial in packaging and in foods and, for that matter, in clothing; most of the hiking kit these days tells you it has got nano-silver particles in the shirts and pants so you will not pong at the end of the day. What do we know about the negative consequences, either because they are in food or because you have accidentally got them from the packaging or something, for nano-silver on gut flora?

Dr Powell: We have not worked on that, I am afraid.

Dr Chaudhry: I know IFR has worked on that but very, very preliminary work. Yes, it has been reported and that is why companies are selling them because of their antimicrobial action. So antimicrobial action is known; but the effect on gut microflora, very few studies and not yet published.

Professor Donaldson: My understanding is it is not the particles so much as the silver ion, which is the chemical soluble form, that is released that is toxic. That is why in wound dressings and so on nanoparticles of silver do not generally leave the dressing; the ions flow from the particles. It is a chemical toxicity as much as particle toxicity.

Q235 ***Lord May of Oxford:*** Are we similarly not in a state of full understanding about the proportion of ingested nanoparticles that are able to be absorbed into the body, whereabouts and so on? Do any of you actually worry—or particularly if you are more in the food industry and the research industry, would you worry—about a second attempt to demonise this technology, as it was successful in the second attempt to demonise GM foods? Given that, the answer at least to many of the putative objections to GM foods, there were experiments and understanding, for example, that would answer the worry about super weeds—if people were to come again at this in a campaign, should we not be worrying about the fact that we would say, unlike what we could say with GM foods, "We don't know this; we don't know that; we don't know the other thing. We don't know if the particles that are aggregated together can be broken down in the gastrointestinal tract. We don't know where they are absorbed. We don't know how, for example, absorption of nanoparticles in the gastrointestinal tract might affect diseases like inflammatory bowel syndrome and things like that". Would that be a fair statement of the current position? How disturbing do you find it?

Professor Donaldson: I am concerned about demonisation because I think we already have had massive exposure to nanoparticles of all sorts, in the air for instance in traffic particles. We know that there is not *no* impact of that, but there is not a huge impact and we have evolved to deal with that. Not all nanoparticles are the same; and there is a whole generation or type of nanoparticles, these low toxicity ones, that are low toxicity. I do not think we should consider all nanoparticles to be the same. That is the first mistake people would make, to think the one word "nanoparticles" embraces all particles. It does not tell you anything about the widespread of toxicity of nanoparticles.

Q236 ***Lord May of Oxford:*** I would turn that argument around and say there are of course lots of nanoparticles we have been familiar with for a couple of hundred thousand years and they do not seem to be doing us much harm; but now we are doing specifically different things. Nanosilver has not been part of our ingestion process; and should we not, in view of some of the other unintended consequences

of well intentioned actions, be trying to know more about it?
Professor Donaldson: Yes, we should. The whole issue of demonisation—it sounds as if nanoparticles are one thing. Nobody would call big particles "a particle"; because it could be traffic dust and it could be asbestos. Nobody uses the word "particle" in generic terms. Yet people use the term "nanoparticles" in a generic way, and I think that can lead to demonisation. Scientists are human; they do not like to study things that are bland; we tend to study the toxic things; so the kind of message that goes out is that nanoparticles can be very harmful. There are a whole slew of nanoparticles that are not very harmful at all. That is really important but that message does not come out.

Q237 ***Lord May of Oxford:*** I just feel, if I want to run a campaign against this, to build the membership of my organisation, or some other reason, I have got the material to do a pretty good job.
Professor Depledge: I made the point at the beginning, and Professor Donaldson has just made it again, about the diversity of nanomaterials. I also made the point, when asked about defining nanotechnologies, that it is not a very helpful thing to do. In terms of risk assessment, I think it is hugely important that we do look at functionality, and what particular things *a* particular kind of nanomaterial is designed to do; and that would help in making risk assessments. Titanium dioxide, for example, has been used as we have said for many years, and there is not much evidence that it is doing any harm at all. I do agree with you that we need to emphasise the benefits of some kinds of nanomaterials. I think it is about opening up this whole debate and making it much clearer.
Chairman: The answers are quite technical answers to a very broad bush campaign in Lord May's terms. If the simple question is: "Are there substantial areas of uncertainty and lack of knowledge about the risks?", to come back and say, "Well, you've got to look at different definitions; you've got to look at this and that" is not going to be very helpful if people are looking for a yes or no answer.
Lord May of Oxford: I, in particular, have the belief nanosilver has been put into foods as an antimicrobial preservative; but if we do not know the effect on the gut flora, which in a somewhat broad sense resembles two microbes, that is a legitimate thing that you really ought to know more about before you do it.

Q238 ***Chairman:*** Is that fair?
Dr Powell: Yes, I think it is very fair. As I have mentioned earlier, we have been exposed to nanoparticles throughout evolution; I think the difference there is that they tend to be nanoparticles that we have established mechanisms to deal with; and that there is genuinely now the concern that new nanoparticles are coming along that we have no mechanism to deal with; ie persistent nanoparticles. I cannot think of a natural example of a persistent nanoparticle. I can think of many natural examples of persistent larger particles but not persistent nanoparticles. So were you running your campaign, I think this would be a very good starting point. I believe therefore genuinely these are areas we need to understand more about. That is not to say that it is a problem; but simply to say that the unknown exists; and where the unknown exists we should perhaps try and change that.

Q239 ***Chairman:*** I think one or two other members of the witness panel would like to come in? Professor Donaldson?
Professor Donaldson: I think the nano particle that we are most exposed to and is persistent is soot. It is made of graphene and it is highly persistent. It is like sheets of graphite—pencil lead. It is the nanoparticle we are most used to. The average soot particle out in the street here—and there is lots of it around here—is 60 nm and there is lots of it in here. We are breathing billions of them a day if you work in here. Billions of them are depositing in your lungs every day; so we are experienced through the lungs; and 99.9 per cent of all particles deposited in the lung get cleared up by the mucus escalator and we swallow them. The gut gets delivered to it large amounts of soot. I do not know what happens to soot in the stomach, but soot particles are extremely tough. I would be surprised if they are not persistent.

Q240 ***Chairman:*** Just to be clear about the last point you made—many things that we inhale end up being swallowed in the end?
Professor Donaldson: Absolutely, almost all of what we inhale, otherwise our lungs would be bunged up by now—after 60 years or so in my case—so it is cleared upwards all the time; and you swallow mucus containing particles all the time.

Q241 ***Chairman:*** Regardless of what we ingest in food, we are ingesting a lot of material that is just floating around in the air around us, including soot?
Professor Donaldson: Yes.
Professor Depledge: I just wanted to return to the issue. You were saying about the intricacy of the debate that we were getting into, but I think if you want to think about really big problems that we face, ultimately if we want to devise toxicity tests for nanomaterials in foods, then I think we should think about the practicality of doing that because there are likely to be a myriad of different forms of nanomaterials in foods; some of which we put in deliberately; others which get there for reasons of environmental contamination and access to food. If you think about evaluating the

toxicity of these various forms of nanomaterial and nanotubes, it would take years and years and years to get through the list. In terms of protecting the public, what happens in the meantime?

Dr Chaudhry: I just want to add, in this whole scenario an independent industry body is missing which can look at the whole scenario of publications. Not every application of science here is going to give us any major concerns or any hazards or any risks. The body needs to separate those applications that have no or low risk, and those applications can go ahead: but because of the nanotechnology label everything seems to be static. For example, we know from our own experiments that nanoparticles hardly ever move from packaging material into food; so that application, as far as tests show, may not cause any risk to the consumer and can go ahead: but because of the nanotechnology label, companies are afraid of declaring that it is nanotechnology-derived. Even if we do not know about hazards or exposure or many other uncertainties, we can divide applications on the basis of whether nanoparticles are free, whether they are soluble, digestible or insoluble; and we can form those categories very quickly on a hypothetical basis, whether an area of application is going to be in the high risk category or in the low risk category. We have attempted that and I have a handout if you would like to look at that.

Chairman: Perhaps you could leave that with the Committee clerk afterwards. I would like to move on now to Baroness Neuberger.

Q242 ***Baroness Neuberger:*** We have been talking about persistence. I would really like to ask you what the state of knowledge is regarding the actual accumulation of nanoparticles in the body once we know we have been ingesting them? How do they accumulate? How many of them do we not get rid of which you have been talking about earlier?

Dr Powell: The work we have done is purely around the gut and, again, around these larger nanoparticles, so generally upwards of 100 nm but not solely. We have shown that certain areas of the gut, the lymphoid tissue, does with increasing age accumulate these particles. Presumably they only represent a very small percentage of what has been taken up, so there probably is a clearance mechanism; but quite clearly accumulation does occur. As I also mentioned, we have been unable in any way to link that accumulation to any type of disease, disorder or impact upon health. We have not in our work looked beyond the gut in terms of accumulation, but I know others have and it may be some other members of the panel are better to answer that.

Professor Donaldson: There is a body of work that has been done on model nanoparticles starting from various portals of entry: inhalation and injection into the blood predominantly; not much through the skin because they do not seem to pass very readily through the skin; and virtually nothing through the gut at the moment has been published at least. If you inhale nanoparticles they find their way to the blood. Something like a per cent or so of all the material that deposits in the lung will get into the blood—let us say a per cent—and that circulates round the body and accumulates in various organs at low levels. The liver is a good place for particles to stop in. The liver monitors the blood and it has cells that grab things in the blood and it grabs particles, so they are focussed in the liver. Nobody really knows what happens to them in the liver. Do they just remain there? If someone was to get a chronic exposure through food or a particle that did get into the blood, what would be the consequence of a lifetime's accumulation of such particles in the liver? Nobody knows that. There have been no long-term studies done to know the outcome of that. There is also evidence that they get into the brain at a low level from the blood as well, and into the bone marrow and some other organs. Again, it is hard to imagine what the clearance system would be from the brain but it is not like the lungs which have a clearance system; so it comes back to this issue that Professor Depledge has mentioned about the fact that there are unintended consequences when particles get to places where particles should not get because there is no system there to clear them.

Q243 ***Baroness Neuberger:*** That actually comes back to Lord May's point, does it not? If you started explaining that and said what was not known, people might have quite good reason to get concerned; and we do not, from what you are saying, have a very adequate answer for them; we just do not know?

Professor Donaldson: No, we do not know.

Q244 ***Baroness Neuberger:*** Can I just add one other thing: we know that nanotechnology is used to encapsulate substances to make them more easily absorbed to target specific cells, organs or whatever. Do we think there may be some particular risks associated with that, so that you get exposure to certain substances from that kind of technology to too great an extent; or that they get through to some part of the body they would not normally go to; so either your liver or your brain?

Professor Donaldson: Through medical uses.

Q245 ***Baroness Neuberger:*** Yes, medical uses, with drugs, for instance.

Professor Donaldson: That is very interesting and concerning to a particle toxicologist. For example, one of the widest uses of nanoparticles is to image the plaques, the coronary artery plaques that cause most people's deaths—most deaths are from

cardiovascular diseases when this plaque, this lesion in the blood vessels near the heart, ruptures. To know when a plaque would rupture—it is called a "vulnerable plaque"—cardiologists would really like to know what a vulnerable plaque is. If you inject these iron nanoparticles into the blood, which are now licensed to be used and are used by cardiologists, they seem to localise to these plaques and you find them in the plaques if you section the plaques. The cardiologists can image these plaques using that methodology, and that is one reason they are used. That seems to me to be a really risky thing to do. One of the most powerful signals in the air pollution literature is that exposure to particles in the environment causes these plaques to rupture. It seems to me you are inviting disaster. It seems to be being used, and maybe it is a baseless concern, but to me it seems a considerable worry.

Q246 ***Baroness Neuberger:*** It is only being used diagnostically. It is not being used for any form of treatment, is it?
Professor Donaldson: No, it is not.

Q247 ***Baroness Neuberger:*** Purely diagnostic?
Professor Donaldson: There is also an idea that such particles can be used to deliver drugs to the plaques and to other places in the body. There seems to be considerable potential for the accumulation over time if the therapy went on and on. Clearly imaging only happens maybe once or twice; but for therapy you would give protracted treatment so you might get a long-term accumulation of nanoparticles in places and, as we have already said, you do not know what these places are, or the extent.

Q248 ***Baroness Neuberger:*** The last thing I would really like to ask you, maybe you have already given us some of the answer: is there research being done into any of this, about what the short or the long-term effects will be?
Professor Donaldson: The long-term I do not know. In Edinburgh we are doing some studies and the Department of Health has funded a student in our department to look at these superfine paramagnetic iron particles—to look at the effect that these might have. We have a mouse model that develops plaques and we are going to put these into the mouse model and see if they go to the plaques and if they cause the plaques to grow and become more likely to rupture and more vulnerable. I imagine there is other research as well but I do not know what that is.
Dr Powell: We are undertaking research at MRC Human Nutrition Research both in terms of short-term effects of very small mineral nanoparticles; these are iron oxide and other oxide nanoparticles in gut cells; and we are also, however—and have been for a long time—undertaking long-term studies in terms of the effects of larger nanoparticles on the human gut tissue. That research is time-consuming. It takes a very long time to get the data but we have made good progress and I hope that within a year or so we will start to see the fruits of that labour. There is work going on but it is quite tricky work.

Q249 ***Baroness Neuberger:*** Do you know of other institutions that are doing it?
Dr Powell: Yes, we have now hooked up with two institutions in Germany who have both just started to work on the gut; but prior to that we knew of no other group, certainly within Europe, who was working on large or small nanoparticles and the gut; but we have just started to work with two in Germany, as I have mentioned.

Q250 ***Lord Methuen:*** Do nanotubes feature at all in this discussion? I understand they are being used for some purposes; but are they relevant and might they come into this argument?
Professor Donaldson: I do not think they are used in food.
Dr Chaudhry: Their properties are such that they are no use in food. Their features are that they give huge tensile strength to whatever material they are put in; and also they are electrically conductive. These two features have nothing to do with food. They may find some use in food packaging but not in food *per se*.

Q251 ***Lord Methuen:*** Do they form a risk if they are in packaging?
Dr Chaudhry: If they are in the environment and they get into food as a contaminant or into the environment as a contaminant, yes, certainly. I think Professor Donaldson is best placed to answer that.
Professor Donaldson: Even when you burn gas rings you make nanotubes—not very many, but it is surprising what has been found in the air when you burn gas rings. Most forms of combustion—even probably coal burning and wood burning—produces some degree of nanotubes, so it is not a new exposure. The workplace exposure to mg and $\mu g/m^3$ of the stuff is probably fairly new. The concern has been that it has a particle hazard; it could be a harmful particle; but also they are long and thin like asbestos so they could behave like asbestos. There are two kinds of hazard associated with these materials. The question is: are people generally exposed to the particles, or to the long thin ones; because the dangers are different and the hazards are different for the two. Really it is a case where we need more exposure data. We really do not know what people are being exposed to in workplaces with this material. Certainly it has now

increased to be one of the major products of the nanotechnology industry so it is being handled in tens of hundreds of tonnes in workplaces.

Q252 ***Lord Haskel:*** Is there anything that we could learn from ecotoxicology about the dangers or the potential risks to humans of ingesting nanoparticles?
Professor Depledge: I think we can look at this in a number of ways. First of all, I think the potential use of animal models is very valuable. There has been work done with lower organisms, which are easier to deal with in experimental situations. Of course some of the conditions in the guts of lower organisms are somewhat similar to those that are in humans, so there is a model organism kind of approach. There is a great deal to be learnt there. I think it is very important to understand what routes of contamination are possible for our food items. For example, if you like eating snails or if you like eating shellfish, some of which are filter feeding organisms, they are exactly the kind of organisms which are likely to take up nanomaterials from sediment or from water bodies, and they filter vast amounts of water and so may accumulate nanoparticles. Looking at contamination of food by nanomaterials involves ecotoxicological approaches to see which organisms are mostly likely to do that. Then there is the issue of food chain transfer. If you happen to be a top predator that eats lots and lots of shellfish, do the nanomaterials accumulate in fish and so on? I think those are very important points. The other thing I would mention is that, earlier this year, I attended a meeting in the USA at Rice University where they have a major centre for nanotechnology. The discussion there turned to the use of nanomaterials in agriculture. This was voiced by the experts attending that meeting as one of their greatest concerns. There may be ways of delivering pesticides attached to nanoparticles, or phosphates and nitrates and other fertilisers and so on, and also maybe agriceuticals and pharmaceuticals that are given to domesticated animals, cows, sheep and so on; and we have no idea, to my knowledge at least, of how these materials might get into the food products that we eat. I think there is some evidence from the literature that if you expose fungi to nanomaterials, they will take up certain kinds of nanomaterials. You can see the uptake of nanomaterials in the roots of plants. You can actually get nanomaterials into plants by spraying them on the leaves. Then of course the organisms eating those plants and fungi are likely to be subjected to those nanomaterials as contaminants. There is plausibility of uptake by those routes but actual evidence of uptake into humans and where it ends up in humans I think is absent at the moment, or I am not aware of it anyway.

Q253 ***Lord Haskel:*** People have been eating snails for years, they have been eating shellfish for years, they have been using agricultural chemicals for years. If we have been ingesting nanoparticles from that source, we have been doing for hundreds or thousands of years. Can we take any comfort from that?
Professor Depledge: I do not think so and the reason I do not think so is because you are quite right, we have been taking up nanoparticles by that route but we have not been taking up engineered nanoparticles by that route for long. Particular types of nanomaterials are engineered to do specific things. If something like nanomedicines were to become widely used in the future—and we have heard about nanoimaging materials and so on—one should be aware that these materials do end up in the environment, just as the pharmaceuticals that we use in our daily lives: antibiotics, analgesics and even cancer chemotherapy agents can be detected in British rivers having passed through sewage works and so on. If we ended up with that kind of issue with nanomedicines being delivered into rivers or being deposited in sewage sludge on fields, with the potential uptake into plants, again the plausibility of getting our nanomaterials excreted back again should be investigated, in my view.

Q254 ***Lord Haskel:*** Is there any work going on to investigate this?
Professor Depledge: Not to my knowledge at the moment, other than studies in the laboratory where a variety of fungi, plants, animals, bacteria are being exposed in laboratory tests in a very limited range of nanomaterials.

Q255 ***Chairman:*** Could I just clarify in my own mind your comment about a possible accumulation in the food chain, rather like the story with DDT where it was concentrated in the top predators and that, in a sense, was the danger signal—the canary in the coal mine that warned us of the risk. Have there been studies of accumulation in higher predators in the food chain that perhaps consume molluscs or other invertebrates that may be the primary filter and absorbers?
Professor Depledge: Not to my knowledge and at the meeting that I attended in the US where many of the experts were gathered together nobody mentioned that as an issue.

Q256 ***Lord Methuen:*** What research has taken place into the health and safety risks associated with nanomaterials, and how much in the UK and how much worldwide?
Professor Donaldson: There is a lot now. It is safe to say, though, that that is focused fairly much on the lungs and inhalation exposure. As I said, perhaps 10

or 20:1 against the skin and hardly at all for the gut. So in the UK there is funding from all the major research councils now, MRC, NERC and the EPSRC I think as well. The European Union FP7 has funded large studies, several of which I have been involved in. In the USA the Nanotechnology Programme is huge in NIOSH and in EPA. In Japan and Korea again they all have big programmes. There is a huge amount of ongoing research but it is focused very much on environmental exposures to the lung and I think increasingly in ecotoxicology.

Q257 ***Lord Methuen:*** Are you worried about the lack of attention to what happens with food in the gut?
Dr Chaudhry: There is one project call that has come out from the Food Standards Agency recently, which is very topical, which aims to study toxicokinetics; i.e. how these nanoparticles move out of the gut, where they go and what sort of toxic effects they have, but that project is still to be started and done. The funding call has just been announced.

Q258 ***Lord Methuen:*** We have already talked about the range of these particles and how you know which ones to concentrate on. Is that not the real problem?
Professor Depledge: I agree with you; I think it is a real problem. Currently there are in a broad sense something like 600 or 700 products on the market that contain nanomaterials, according to the Woodrow Wilson Center in the US, and they have been through standard toxicity testing, and we have some doubts about how well it works. I think there is a general consensus that conventional toxicity testing is not very useful, and so the OECD has set up a programme to develop new toxicity tests specifically designed to evaluate nanomaterials. They have chosen 14 model substances that are being investigated, two per country, and I think some of these model materials have not actually been taken up by anybody yet, but they are trying to develop full characterisation of these particles and also develop toxicity tests. To my mind, that will be of value but of limited value in the sense that we do not know that we are looking at the right kinds of nanomaterials and whether you can actually use 14 different representative nanomaterials from the myriad of different forms that have been produced I have some doubt.
Lord Methuen: I find it quite frightening.

Q259 ***Lord May of Oxford:*** I wanted to ask: is this general area of research one at which the UK is as well represented among the leaders as it is in many things? I have in mind the fact that if you look, for example, at some of the eastern European or the EU accession countries, they are very good at the physical sciences but not quite so at the cutting edge in life science because the mechanisms are less agile than those that have characterised the Scandinavian, Anglo and other countries? Some of the things that have happened in some of the research councils that are deliberately trying to identify applications and so on, I just wonder whether you feel these things are helping or hindering and just more generally what is the state of British facility in this area on the world stage?
Professor Donaldson: If you take human toxicology, the UK has always punched above its weight in terms of particle toxicology historically because there was such a focus in the UK in the dusty industries and dusty trades. For instance, the Coal Board is the seat of particle toxicology in the UK and it was in Wales and it was in Edinburgh. That is why I am in Edinburgh because I went to work for the Coal Board first of all. I think the Coal Board was very important in driving forward in the UK particle toxicology and it took over the Asbestosis Research Council. That is not to say that there was not also a recognition of a particle toxicology problem in the US or in other places; there certainly was in Germany for instance a very famous history of particle toxicology. We have punched above our weight but there was not very much funding in the UK until relatively recently. We have kind of caught up but we were slow to get off the mark compared to America, definitely.

Q260 ***Lord May of Oxford:*** There does seem to me, and I may be wrong, that it is a subject which is inherently at the interface between the physical and the life sciences, so that it does require a certain amount of willingness to cross boundaries that not everyone is good at.
Professor Donaldson: That is absolutely right. It is an interdisciplinary undertaking. To study the environmental and human health consequences of particles, you have to understand the particle and you have to understand the toxicology and the toxicity, so you definitely have to have a multidisciplinary team.
Professor Depledge: I think that is right; it has to be a multidisciplinary activity. I think in the UK the ecotoxicological investigations of nanomaterials are again punching above their weight. There are a number of groups around the country, but I would point out that I think the amount of resource available for undertaking research on the effects of nanomaterials on the environment and human health is extremely small compared with the amount of money that is being invested in the development of new nanotechnologies, in new materials. It is tiny in comparison with the investment. It is also to me very interesting that we have some of the research councils in the UK providing resources to look at the impacts on the environment and human health, whereas other

research councils are actually promoting the development of new nanotechnologies and new applications, so you have one chasing the other. This is happening at a grand scale in Europe where in the Framework 7 programme, the environment and climate part, there is relatively limited resource available for looking at the impacts of nanomaterials on the environment and human health, but in other programmes within the EU there are vast amounts of money available for stimulating European industries to adopt nanotechnology methodologies, and indeed there is a suggestion that one-third of all industrial manufacture in Europe will involve nanotechnologies within 10 to 15 years.

Dr Powell: Just to add very quickly concerning your specific remit here, I think there is little or no work, either in the UK, Europe or even on the world scale, in terms of the gut, foods and nanoparticles. Most of what we know about comes from the work, as Ken Donaldson said, from the lung, a little bit from the skin and the tiny amount that has been done in the gut. In terms of what is going to happen, I believe that there is now access to certain research grants. What needs perhaps to be done is to try and enhance the interest so that more work around the gut is undertaken around foods and I think, again as Ken has said, in the UK we should be fairly well placed at the global level to be leaders in this area.

Q261 ***Chairman:*** If we focus that question very specifically on the regulatory requirements for risk assessments, if you had to summarise in a few sentences what would be the top research priorities for risk assessment of nanotechnologies, nanomaterials in food and packaging in relation to regulation, what would you pick out?

Dr Powell: I would argue that because of where we are currently at, that is to say we have nanoparticulates coming through already, if not in this country I am sure soon to come and certainly in other countries, and yet we do not have regulations and knowing how slow the latter are compared to the former, we need to do something fairly quickly. For me therefore the priority would be a logic model, and that logic model would unfold in a fairly simple way, starting with the question of: are these particles degraded in the lumen—ie do they reach the cells? If they do not, then we consider them one way. If they do reach the cells, are they degraded in the cell? Do they bind constituents of the gut lumen? Then, if they do not get degraded within the cells, where do they go thereafter and what are the basic cellular aspects; are there concerns for toxicity. I would like to see a fairly rapid logic model develop because I think it will address the gap.

Q262 ***Chairman:*** Once the model is developed, can it be populated or do you need new research to populate those different stages?

Dr Powell: I think the model I would try to run with would use current techniques and current technologies that are fairly easily available. That is not to say it is foolproof because it will not be but I do believe it will address to a large extent our concerns and it will at least get us to a point where we can say that there is no logical reason to worry about this particle or, yes, there is a logical reason to worry this particle. The second very quick point to make is that we need to consider how necessary are these particles. So we have titanium dioxide, we have heard about earlier, which is completely unnecessary—it makes food whiter or brighter, which is not necessary—versus particles which might contribute to food safety in this country, which clearly is very necessary. So I think that would be an important part of this model.

Professor Donaldson: You could do a lifetime feeding studying rats of some selected nanoparticles. All right, there is a problem to choose which ones but you might choose some of the ones that are most commonly used in foods. You could start with titanium dioxide, I would suggest. A lifetime feeding study in rats, including toxicokinetics, to their full life span, could be undertaken, just to see if you find any adverse effects in these animals. Also, there are a number of genetic models you get nowadays, and is there a mouse model for an inflammatory bowel condition that could be used, Professor Powell?

Dr Powell: There are a number of mouse models, yes.

Professor Donaldson: That could perhaps be coupled with some studies in these mouse models where they have an inflammatory gut condition. Looking at toxicokinetics in these I think would go a long way to allay people's fears, if a couple of these studies came up showing nothing very much, and, if they did come up with something, then that should raise some warning flags.

Professor Depledge: I wholeheartedly agree with those two comments. The other thing that I think that is important is to build into the design of some of these materials ways of getting them to biodegrade, for example in the pH of the gut into harmless forms. A great deal more could be done with the design of these materials to ensure that they do not have a protracted lifetime.

Dr Chaudhry: I agree with the comments made by Dr Powell and Professor Donaldson that long-term studies are needed but also they need to be linked with histopathology. We do not know which new targets in the model might arise because of nanoparticles, so not only long-term studies but also linked with histopathology to find if there are any novel targets for these particles.

Q263 ***Lord Haskel:*** We are learning that nanotechnology is a huge field. Are there any other areas of research in nanotechnology which can help research into nanotoxicology? Do we learn from any other areas?
Dr Powell: I think certainly in terms of imaging and analysis there is a very good cross-over between the two areas and really our success in detecting these particles in tissue, the histopathology that Dr Chaudhry has referred to, has on many occasions relied on physics and such technicological advances to allow us to look at them. To my mind, and we do a lot of work in the imaging and analysis area, that has been wholeheartedly down to advances technologically on the physics and the engineering.
Dr Chaudhry: Another area which has a cross-over is nanomedicines and nanomedicines are being developed for oral intake and they are supposed to leave the gut and take the medicines and deliver them to specific tissues and organs. A lot can be learnt from that mechanism about how particles can translocate out of the gut and where they go and where they end up.

Q264 ***Lord Haskel:*** What about nanomedicines? Professor Depledge has mentioned nanomedicines a couple of times. Is there anything we can learn from that?
Professor Depledge: Yes, I think there is a great deal we can learn from that because we can study the design of nanomedicines where we are trying specifically to deliver nanomaterials or drugs or coatings or whatever to particular parts of the body. So I do think that that is important. Clearly in nanomedicine imagining techniques are being driven forward in that area too. It is also interesting—and whether it is possible to do it I am not sure—that the military have a wide variety of applications for nanomaterials and are also developing techniques for measuring nanoparticles in the environment. There may be some cross-over there in appropriate circumstances.

Q265 ***Lord Haskel:*** There are more and more nanomaterials being used in our clothing. Is there anything that we can gather from that about the toxicology?
Professor Depledge: I think there is a great deal that can be gained from that but again it spills over into where do these materials end up. We are talking about measurement techniques. It is hard enough to visualise nanomaterials in tissues and in organs in humans, but imagine the problem of detecting nanomaterials actually in the environment because there is a background of nanomaterials around that are just naturally produced and to actually identify engineered nanomaterials against that background is a terrific problem. Nanomaterials are one of the few kinds of materials that we put into the environment about which we do not know how much is there, how long they persist, what they transform into, where they go. We do not know the answers to those questions.
Professor Donaldson: I think there is an informative example also from nanomedicine. The nanomedical people have designed a nanoparticle that crosses from the blood into the brain. The blood-brain barrier is usually a very tight barrier and most things do not pass over. The brain is very privileged and protected. The nanomedical people have designed particles that cross the blood-brain barrier, so there should be something that tells us if somebody came up with a particle having a similar surface as that one, then it should not be used for any other purpose. You do not want these things locating to the brain unless you want them to locate to the brain. I think there are lessons to be learnt generically about a big picture of what it is about particles generally that makes them do anything. Just a big structure activity relationship for particles is what we need. If you had that, you would be home and dry really, but that is not going to happen tomorrow.

Q266 ***Chairman:*** I know that at least two of you are authors on this large report that we have recently received called EMERGNANO produced by the Institute of Occupational Medicine in Edinburgh. I have to confess to not having read it page by page, line by line—I am sure you have all read it—but the bottom line seems to be that there are still major gaps in the knowledge base with regard to characterisation, exposure of toxicology of nanoparticles and nanomaterials. In terms of us drafting our report, would you recommend us to take this as an assessment of the current state of knowledge on health risks and risk assessment?
Professor Donaldson: Not really; it is not a review of literature but a review of ongoing, research funding by government at European level. It is not a review of the literature. It is quite important to appreciate that it is research that is going on and us saying that the research is not looking in this and that place. It is quite well focused (for instance nanotubes get quite a lot of attention) but it does show the kind of flightiness of research that is very dependent on fashion. When you look across the research, you can see that nobody seems to be interested in the gut but everybody wants to look at nanotubes for example. It is a problem.

Q267 ***Chairman:*** Would you say, as a follow-up to that, and one of the issues we have been talking about is gaps in knowledge as far as risk assessment is concerned, that one of the issues is the capacity in the UK or elsewhere in terms of toxicological experts working on absorption through the gut? Is that one of the limiting factors? I think we have heard previously from Dr Powell that he collaborates with others in

Germany but not with others in the UK, presumably because there are not other groups doing gut absorptive nanoparticles?
Dr Powell: I think the joined-up-ness between the two groups is going to be very important. I have seen a number of early studies, either started or proposed, not in this country but elsewhere, which in terms of the gut and in terms of the dietary aspects have schoolboy errors in them. They have been undertaken by toxicologists. I am sure the toxicology downstream would be fantastic. I am sure were we to try to address toxicology alone, we similarly would make errors, and therefore it is important that the two sides get together, people such as ourselves who have expertise in particles and the gut and diet and those who have expertise with the toxicological outcomes. I do not think that has happened and that probably needs to happen.
Professor Donaldson: I think we are reaping what we sowed. If we look at the Royal Academy/Royal Society report, there was a really important paragraph that there should be a central core-funded chunk of research and expertise brought together to design a programme that would look systematically at nanoparticle toxicology, and that was ignored. We had response mode funding where people just put forward what they wanted to do, so what you get is piecemeal. There is no cohesive approach to trying to understand particles as a whole. Until we have a proper structure function view of all particles, then there will we will not be home and dry. The only way you can do that is to have a central core-funded programme that looks at all the different aspects and target organs and brings people together to try and drive forward such a programme. You do not get it from response mode funding; you get the kind of expertise that is already out there multiplied up. People who do work on the lung, all put money in for work on the lung and there is nobody doing work on the gut, so nobody puts forward research on the gut. If you had a programme that recognised the gaps and saw the big picture, then you would go down all these pathways. We are reaping what we sowed.

Q268 ***Chairman:*** The view is that that recommendation has not been effectively taken up?
Professor Donaldson: No, it was not taken up.

Q269 ***Chairman:*** Is it being taken up in any other country?
Professor Donaldson: The best is America probably.
Professor Depledge: The US is taking it up and they have set up a number of centres. They started off with just one or two centres. One of the biggest was at Rice University, but now they have set up some other centres as well and they are trying to bring together diverse groups of scientists. Just going back to what we were saying, I think the point that there is a lack of toxicologists and ecotoxicologists in the UK and also across Europe is being widely recognised now.

Q270 ***Baroness Neuberger:*** We have been talking about the need for, if you like, a strategic programme of research. If you were looking at what industry should do, and you have already said that there is a need for an independent industry-wide body, Dr Chaudhry, what health and safety research would you expect industry to be doing now and what methodologies would you expect them to be looking for when they are looking at a new food product containing nanoparticles to make sure that it is safe for the consumer?
Dr Chaudhry: First of all, I think detection technologies are missing in the whole scenario. People can detect nanoparticles in neat solutions and in isolated cells and all that. When it comes to very complex matrices like food and varieties of foods, then it suddenly becomes very difficult. This is being taken up at the European Commission level and at the Seventh Framework Programme they are going to fund some of the projects specifically designed to develop and validate methodologies for that purpose. That will be done or it is being addressed. The other issues are in terms of safety; what are the long-term effects. We are not talking about short-term or acute types of effect because maybe you need very high doses for that, which may not be present in food products which contain nanoparticles. We are talking about long-term effects and again long-term studies coupled with histopathology to find out what is going on in the body—animal models, *in vitro* tests. Some of the *in vitro* tests can show, for example, initial indications of mutagenicity. Particle exposure may lead to mutagenicity. This is what industry needs to do so that if they are going to use nanomaterials for a specific purpose or a composition, they can ensure that all the safety aspects are being addressed.

Q271 ***Baroness Neuberger:*** Do you expect them to have done that for a new product?
Dr Chaudhry: This has been debated for some time by industry and by some other quarters. Industry's view was that these are not new materials. Because the regulations did not at that time recognise them as new materials, then they thought: We are already using titanium, why should we worry about nanotitanium; if we are using iron, why should we be worried about iron and things like that. But now there is a realisation and there are proposals to change some of the legislation so that it is clear in the word of the law that if someone is going to use food additives, even if they are already approved but someone starts making a nano form of them, then they will be recognised as having been made by a different process; i.e. a new

material. That means that the company is going to have to produce safety data to show that these are safe to be put in food. Also, if someone is developing a normal food with nanotechnology, the wording of the law was a bit unclear and it did not clarify whether any food produced using nanotechnology would automatically be qualified to be considered as novel food, but now there is a proposal which will go into European legislation to make it clear. In the next few years hopefully we will see lots of clarification at a legalistic level. That will then trigger companies to ensure that they do not put anything into the food which they assume is already approved.

Q272 ***Baroness Neuberger:*** There is a real issue, is there not, coming back to Lord May's point, that if this is something that was widely known—and we are waiting for the law to clarify before people have to be seen to do be doing those kinds of health and safety studies—it is not very satisfactory for the consumer, is it?
Dr Chaudhry: Our food laws come under national legislation. They are made in Europe and then filtered through down to national level. This is now being taken up at European level and then it will come down to national level.

Q273 ***Baroness Neuberger:*** Coming down to national level, do you think the FSA or some other body ought to be responsible for holding a whole register somehow of health and safety research by industry to ensure that the work that is done is fit for purpose and that the lessons learnt and the methodologies can be shared, which I think was your point about having an industry-wide body?
Dr Chaudhry: To be fair, government has done quite a lot. They have founded the Nanotechnology Research Co-ordination Group (NRCG) which is headed by Defra; the FSA and other agencies are part of that. It deals with across-the-board issues and then every agency is responsible for its own remit. In that sense, the FSA are responsible for the food area. Usually what happens is that a new technology emerges and regulation and technology feed each other and that is how the system goes, but this technology has taken everyone by surprise. It emerged out of lab benches and suddenly people thought: let us put these materials into products—cosmetics, food, paints and coatings, and variety of other things. The production volume certainly started to increase from milligrams to grams to kilograms to multi-tonne and now we are talking about thousands of tonnes of some materials. It has taken everyone by surprise. To be fair, regulators are doing what is needed. They may have been a bit slow but everything is being done, in my view as much as possible.
Dr Powell: I just want to make a couple of very quick points. We do of course have at least one example which has been mentioned a couple of times here from the USA where one particular particle that was passed as safe to use by the FDA was never in any way intended to be in nanoparticulate form and never was but, as legislation did not prevent that, it suddenly came into being in a nanoparticulate form. I do believe that there are fairly simple procedures and tests that could be undertaken and, if not within the industry itself, certainly they could be outsourced reasonably cheaply. That would in the short to mid term, whilst we are getting our act together in terms of understanding and legislation, provide I think a fairly rational approach to determining nanoparticulate safety in the foods I talked about.

Q274 ***Baroness Neuberger:*** Do you think that would be a relatively easy thing to do?
Dr Powell: Yes. As I said earlier, I do not think it is going to provide 100 per cent proof but, in terms of effectiveness for 80 to 90 per cent, this would really be a pretty quick, cheap and easy way to proceed. These are not complicated assays that I am talking about.

Q275 ***Chairman:*** Could you just clarify what you are talking about?
Dr Powell: Yes. I am thinking firstly about simply *in vitro* assays, test tube assays that will allow us to ask the question: under simulated conditions of digestion, is this nanoparticle persistent or does it get broken down? Secondly, if we take two simple cell types, the one that lines the gut (the epithelial cell) and the underlying immune cells and we challenge those with the nanoparticles in the presence and absence of some bacterial toxins that are found in the gut, do we then see effects on those cells in terms of maybe three simple outcomes that are quite well established—reactive oxygen species, cytokines and cell surface markers—and look at degradation of the particle. If we see no effects there and we see degradation of the particle, I would be fairly well reassured that that is likely to be safe. If however we see effects on the cells, or we do not see degradation of the particles, I might then suggest that we look into just how necessary is that particle to bring into the food environment at the moment.

Q276 ***Chairman:*** Are there any other points that any of you as witnesses would like to make? We have reached the end of our questioning but there may be a point that you feel we have not covered or issues you would like to raise at this stage. No. Of course, if at a later stage you feel that there are points you would like to write in about again, and already a number of you have submitted written evidence, please feel free to do so to the committee clerk sitting on my left. Also, I should remind you that there will be a transcript of this

session and you will have a chance to comment on it before it is finalised. Just in closing and in thanking you for coming to give evidence to us, I would like to revert back to an earlier question to be absolutely clear. In the early part of this morning's discussion, you all in different ways emphasised the heterogeneity of what might be considered to be nanoparticles and considered issues like whether they were persistent or not, their reactivity or lack of reactivity on the nanoscale. I just wanted to go back to cases that we have heard about of potential application which are really of nanoengineering of items that are already in the diet. For example we have heard about the notion of nanosized salt particles to increase the surface area and therefore the saltiness so you can have less salt in food. Another example was a mayonnaise with a nanoemulsion with I think fat droplets enclosed in water droplets, or maybe the other way round, I cannot remember how it was. I want to ask you whether the concerns that you expressed in relation to unknowns about risk assessment would apply to those engineered, naturally occurring, already existing components of food or whether it was more to the components that are not already existing or naturally occurring.

Professor Donaldson: Obviously with something soluble like sodium chloride, like salt, all that would happen in a nano form is that it would be much more rapidly soluble. I cannot see that changing the toxicity or lack of toxicity in general that salt has at all. Likewise, changing the size of micelles, lipid micelles, I do not think would have a big effect. Our concern here is, for want of a better word, about hard particles or things that are added in. That is my feeling.

Dr Powell: I completely agree with that. I would also just add however one small caveat. It is still possible to take naturally occurring soluble molecules and make them nanoparticulate but not make them rapidly biodegradable. Just because they have naturally occurring components does not immediately transfer to safety.

Dr Chaudhry: This is the area, going on from Dr Powell's comment on nanoparticles naturally occurring but made into less degradable ones, that is the basis of a nano delivery system, so that they take materials out of the gut. Although they may be composed of naturally occurring molecules, they may take things out of the gut into other cells and tissues.

Professor Depledge: My concerns are the materials that are added to food that are designed to be toxic in one way or another, perhaps to bacteria or those kinds of things. I also emphasise again that contaminant nanoparticles in food are important, things that are designed to be toxic but somehow or other end up contaminating food. With later generations of nanomaterials, in the third or fourth generation where they combine with other systems, synthetic biology systems and so on, for the future there needs to be even greater care taken.

Professor Donaldson: If I can I say one word in closing, it is not to be too hung up on the 100 nanometre cut-off and to be concerned at things of 200. I do not know where the cut-off is to say that things are fairly close to the size that nature makes, maybe 500 per micron, but certainly we should not be too struck on the idea that 100 nanometres means harmfulness beneath it and harmlessness above it.

Q277 ***Chairman:*** That is a very helpful comment and one we have heard before.

Dr Powell: I am sorry but there is just one brief point, which is that I would like to re-emphasise something we probably have not said enough about today and that is that the gut lumen is a very unusual environment; it is full of bacterial toxins and ingested particles really have the ability to bind to their surface these kinds of toxins and other molecules and can, at least in theory, and we now have evidence for this, carry them across into the gut mucosa. You are dealing with quite a complex situation.

Chairman: You did mention that earlier but it is useful that you remind us of it. I would like to draw the session to a close and thank all of our witnesses for an excellent session. You have answered our questions patiently and very clearly and been very helpful to us. Thank you all very much indeed.

Further supplementary memorandum by Medical Research Council

Thank you for the opportunity to present the MRC's work relevant to nanotechnology and food to the Select Committee. This response addresses issues raised during the evidence session and provides an update on several matters.

Transfer of Nanoparticles Across the Placenta

This question was raised during the evidence session, and has been addressed in a separate response from BBSRC, to which the MRC contributed. To summarise, cross-placental transfer of nanoparticles is the subject of debate in the research community. There is limited data on this matter, but an unpublished (and therefore not peer-reviewed) study showing that transfer may occur in rats. There are probably a variety of routes of access, as with gut absorption, and different particles may behave in different ways. On balance, it is possible that some nanoparticles can cross from mother to foetus, but this has yet to be formally shown.

Activity in the UK: Worldwide Comparisons

The select committee asked how the United Kingdom's research effort rated compared to other countries, and at the time we could not give an assessment. The EMERGIMANO report which we referred to in the evidence session, has now been released at http://randd.defra.qov.uk/Document.aspx?Document = CB0409_7911_FRP.pdf provides information on the relative activity in environment, health and safety research on nanomaterials and nanotechnology in countries worldwide. The United Kingdom was found to conduct l5 per cent of studies, placing it second behind the USA. Additionally, a high number of studies had been completed (third, behind the USA and Canada), suggesting a leading position in the field.

While these findings are encouraging for United Kingdom nanotechnology/nanotoxicology research, there is no doubt that there remain significant gaps in our knowledge, and the report highlights these well. The report covers all research funded by Research Councils (or their equivalents) and by agencies closer to policy making needs and regulation. We expect that combined efforts of several funders will continue to be needed, to cover the gaps across basic and applied, ideas-led and needs-led. The MRC, in combination with the other Research Councils, will play an important role in generating the scientific knowledge required to fill these gaps. Regulators, particularly the Food Standards Agency, DEFRA and the MHRA, will have an equally important function, using basic research findings to create an appropriate and balanced legislative environment for nanotechnology and food.

MRC Highlight Notice: Nanotoxicology

The highlight notice in nanotoxicology, which was first released in March 2007, is at Annex 1, and on the MRC website at:

http://www.mrc.ac.uk/Fundingopportunities/Highlightnotices/Nanotoxicology

This is currently the second version of the notice, with further revisions currently under consideration. Revisions will include a focus on "oral route" nanotoxicology, as discussed in the evidence session.

Highlight notices are one of several mechanisms available to the MRC to increase funding in a particular scientific area. Although there is no specific funding associated exclusively with an area, highlight notices should not be considered inferior to other mechanisms; since they are not time-limited, it is often possible to do more through a highlight notice than other options. They also offer the potential for gradual revision as the scientific landscape changes, and as such offer an adaptable long-term commitment to an area. Our past experience has shown them to be highly effective in increasing the funding associated with the area in question.

Nanotoxicology at the MRC Collaborative Centre for Human Nutrition Research

Since the evidence session, this programme of research (led by Dr Jonathan Powell) has been scientifically reviewed by the MRC. It was found to be of high quality, and the reporting subcommittee recommended its continued support.

Annexes

Annex 1—MRC Highlight Notice in Nanotoxicology.

Annex 1

MRC HIGHLIGHT NOTICE IN NANOTOXICOLOGY

Nanotoxicology Highlight Notice

The 2004 the Royal Society and Royal Academy of Engineering report on nanotechnologies and subsequent United Kingdom Government reports raised concerns that the investment in research to develop new nanotechnologies is not accompanied by research addressing the health impact of these new materials in order to underpin their safe use. In the light of the recommendations in these reports the Molecular and Cellular Medicine Board wishes to encourage innovative, high quality research applications in nanotoxicology relevant to human health with the aim to help inform policy development in this important area.

Background

Nanotechnology involves the production and application of substances and structures at the nanoscale; within this size range substances can have very different properties when compared to material in bulk form, reflecting surface area, surface properties and quantum effects.

While engineered nanoparticles offer significant potential benefits, there are also uncertainties with regards to potential risks to human health. This was a key finding of the Royal Society and Royal Academy of Engineering report *Nanoscience and Nanotechnoloaies: opportunities and uncertainties,* commissioned by the United Kingdom Government and published in July 2004. The report concluded that many nanotechnologies pose no new health and safety risks. However, there were concerns over the potential impacts of engineered nanoparticles and nanotubes (in a free rather than embedded form) and these materials were identified as a priority area for research.

Highlight notice

In accordance with the *Government response* to the report, a cross-Government Nanotechnology Research Co-ordination Group (NRCG) has been set up to coordinate research efforts relating to the potential human health and environmental exposure, hazards and risks posed by the products of nanotechnologies. This work is aimed at leading to the development of an appropriate framework and measures for controlling any unacceptable risks. The *NRCG's first report,* published in November 2005 sets out a programme of 19 research objectives to characterise the potential risks posed by engineered nanoscale materials; Objectives 11–16 are relevant to the remit of MCMB and include research to establish: a clear understanding of the absorption of nanoparticles via lung, skin and gut, their distribution in the body and potential target tissues; inter and intracellular transport and localisation of nanoparticles and their cellular toxicity; whether oxidative stress, inflammatory effects and genotoxicity apply to nanoparticles; and the deposition, distribution, toxicity, pathogenicity and translocation potential and pathways for nanoparticles in the airways and lung and their potential impacts on the cardiovascular system and brain; A subsequent progress report was published in October 2006.

In the light of working in partnership with the Department of Health and other stakeholders MCMB encourages innovative, high quality applications relating to the potential human health hazard of nanoparticles, focussing on areas highlighted in the above Government reports. Since launch of the nanotoxicology highlight notice four awards were made (Nanotoxicology Awards). In the light of these recent awards, MCMB now wishes to encourage in particular proposals which investigate the health impact of nanoparticles *in vivo* or aim to validate *in vitro* tests against in vivo models with a particular emphasis on studies addressing the mechanisms of toxicity. This is in accordance with the recommendations of the recent Royal Commission on Environmental Pollution report (2008) on Novel Materials in the Environment: The case of Nanotechnology.

Application Process and Schedule

Applications are invited through the normal MRC funding schemes and will be considered at the regular MCMB Board meetings. These will be in competition with other applications received, but the Board will be mindful of the policy importance of this area to Government.

17 July 2009

TUESDAY 2 JUNE 2009

Present	Crickhowell, L	Mitchell, L
	Cunningham of Felling, L	Neuberger, B
	Haskel, L	O'Neill of Clackmannan, L
	Krebs, L (Chairman)	Selborne, E
	Methuen, L	

Memorandum by Which?

SUMMARY

1. Which? considers that nanotechnologies have the potential to offer consumers many benefits, including in the food area. However, we consider that there needs to be a more co-ordinated and strategic approach to ensure that nanotechnologies are developed safely and responsibly and are used to tackle some of the major challenges facing the food supply chain.

2. We are concerned that fundamental knowledge gaps and uncertainties are not being addressed with sufficient urgency. These include gaps in knowledge about what is on the market, being supplied to the food industry and what is being developed for the future; basic research to underpin meaningful risk assessment; regulatory requirements for pre-market authorisation and understanding of consumer attitudes to potential developments.

3. Our consumer research has highlighted a lack of public awareness of nanotechnologies, but suggests that people are interested in nanotechnology developments, including in the food sector, provided that they see real benefits and are assured of their safety and can make an informed choice. We have made a series of recommendations in relation to the areas highlighted in the call for evidence which are summarised below and explained in full in our evidence:

STATE OF THE SCIENCE AND CURRENT USE IN THE FOOD SECTOR:

— The lack of agreed definitions needs to be urgently resolved so that there is clarity over how to classify nanomaterials.

— A mandatory reporting scheme should be introduced for manufactured nanomaterials to enable a more accurate assessment of developments.

— The food industry needs to be more transparent about the status of developments.

— The government, particularly the Food Standards Agency (FSA), needs to more pro-actively engage with this issue in order to understand likely applications.

— There needs to be more effective engagement between regulators, the research councils and broader research community and the food industry in order to understand what is going on.

— This needs to be done in collaboration with other stakeholders, including consumer organisations, leading to a more defined and strategic "roadmap" for nanotechnologies and food.

— International regulatory co-operation is also essential in order to understand what is happening in other parts of the world, particularly as many developments are taking place in Asia and the United States.

HEALTH AND SAFETY

— Efforts to ensure that research is undertaken to address key uncertainties need to be dramatically accelerated in order to enable effective risk assessment.

— Current knowledge should be drawn upon in order to make some general conclusions about which materials are likely to pose most risk and which may be of little concern in order to identify priority areas for action, restrictions and to direct future developments.

Regulatory Framework

— There must be clarity across all food legislation (eg. through clear guidance or updating of relevant legislation) that materials produced using nanotechnology are subject to mandatory independent pre-market assessment and approval (ie by the European Food Safety Authority (EFSA)) and that materials that have already been approved in their conventional form need a separate assessment and approval if in nano form. This needs to be addressed as part of the current review of the EU novel foods regulation.

— There must be effective enforcement so that any products that are on the market which have not been approved are removed. This requires clear guidance to be given to local authorities by the FSA.

— There should be greater clarity about how broader consumer and other social issues are to be taken into account as part of the approval process.

— There needs to be effective monitoring by the FSA of the extent to which other non-food nanomaterials may be contaminating the food chain and any associated risks.

Public Engagement and Effective Communication

— More effective consumer engagement at the earliest opportunity is needed specifically focused around potential food developments so that it can be ensured that research priorities and regulatory approaches are in line with consumer expectations and address their concerns.

— Once there is a fuller understanding of the potential of nanotechnologies for food, greater consideration needs to be given to any social and ethical issues that may be raised and how these can be addressed.

— There should be a requirement that manufactured nanomaterials used in food products have to be labelled in the list of ingredients. The current EU discussions around the new food information regulations provide an opportunity to address this.

— Greater effort is needed across government to increase public awareness of nanotechnologies and the issues that they raise in a balanced way.

Introduction

4. Which? welcomes this opportunity to submit evidence to the House of Lords Science and Technology Committee's Inquiry into Nanotechnologies and Food.

5. Nanotechnologies have the potential to offer consumers a wide range of benefits, including in the food sector, but we are concerned about the way that developments are being handled. There has been a failure to take a sufficiently strategic approach to the issue and ensure that advantage is taken of nanotechnologies so that they help to tackle the many challenges currently facing the food supply chain—from the need to encourage healthier eating and produce safe food to reducing the environmental impact of food production and consumption. Concerns have repeatedly been raised by leading expert bodies at national and EU level about the many uncertainties that hinder effective risk assessment of nanomaterials and about gaps in the current regulatory framework. However, we are concerned that these are not being addressed with sufficient urgency, to discriminate those applications that are likely to be beneficial and should be given greater priority, from those that could potentially put consumers at risk.

6. It is therefore very timely for the Committee to be reviewing this whole area and we hope that the Inquiry will lead to a more pro-active and joined up approach by government so that it can be ensured that consumers genuinely can take advantage of the benefits offered by nanotechnologies, while being able to make informed choices and be confident that they are not being put at unnecessary risk.

State of the Science and its Current Use in the Food Sector

7. There is the potential for nanotechnologies to benefit food production in a variety of ways. Traditionally, many foods have relied on manipulation at the nanoscale in order to give them particular characteristics, although this was not explicitly seen as "nanotechnology", for example, the manufacture of custard or mayonnaise. Advances in microscopic techniques have made it possible to deliberately manipulate materials at the nanoscale, enabling them to take on new properties that would not otherwise be possible.

8. It is, however, very difficult to gain a clear picture of the extent to which nanomaterials and nanotechnologies more generally are being used in food production—or the extent to which research is taking place into future applications that will come to market and could be impacting on consumers in the next five, 10 or 20 years. This information is essential if we are to have an informed and transparent debate about the

role of nanotechnologies, ensure the adequacy of risk assessment, management and communication approaches and if it is to be ensured that nanotechnology applications take place in line with consumer expectations. The situation is also further complicated by the lack of any agreed international definitions as to what falls under nanotechnologies or should be considered a nanomaterial.

9. A few years ago, leading food companies were quoted in the trade press as taking an active interest in using nanotechnologies.[1] Kraft was, for example, quoted as looking at the potential of "smart nano-filters" to limit allergic reactions and investigating "smart packaging", while Nestle was also reported to be looking at the possibility of using nanotechnologies to customise and personalise food with precisely targeted delivery of nutritional and health benefits. However, the main food manufacturers now state that they currently are not using nanotechnologies, although some chemical companies are supplying nanomaterials and there are several "nano" food supplement products available to buy over the internet. It is, therefore, essential that there is transparency across the entire supply chain.

10. Based on a recent overview produced by the Food Safety Authority of Ireland, the main areas of interest appear to be:[2]

— sensory improvements (flavour or colour enhancement, texture modification);

— increased absorption and targeted delivery of nutrients and bioactive compounds;

— stabilisation of active ingredients such as nutraceuticals in food matrices;

— packaging and product innovation to extend shelf-life;

— sensors to improve food safety; and

— antimicrobials to kill pathogenic bacteria in food.

11. The types of nanomaterials likely to be used include:

— nanoparticles, such as silver and iron used in food supplements;

— nanofibres, such as globular proteins used as thickening agents;

— nanoemulsions and dispersions, such as oil in water to produce low fat products; and

— nanoclays, such as clay composites used in packaging materials to extend shelf-life.

12. A recent review of nano food developments by *Chaudhry et al*[3] concluded that virtually all known applications are currently outside the UK and Europe, mainly in the USA, Australia, New Zealand, South Korea, Taiwan, China and Israel. Two exceptions were highlighted: a synthetic form of lycopene, found in tomatoes, produced by BASF in Germany; and a nano-micelle-based carrier system NovaSOL produced by Aquanova, also based in Germany.

13. The online Woodrow Wilson Center's Inventory of nano products[4] and the "Nanoshop" web-site[5] include a range of nano products that are available to buy, including food supplements, food packaging materials and food containers. The lack of agreement over definitions makes it difficult to be clear what is definitely a nano product, but examples of products claiming to be "nano" include:

— Solgar's Nutri-nano CoQ10 and Nutri-nano CoQ10 with Alpha Lipoic Acid[6] (from the UK) food supplements, part of "the first-line of nutritional supplement to use nanotechnology to deliver unprecedented bioavailability".

— Canola Active oil by Shemen[7] (from Israel) "an oil enriched with free phytosterols".

— Nano selenium rich tea[8] (from China).

— Nano calcium and magnesium food supplement[9] (from the USA) "a potent 100% available and absorbable ionic solution when dissolved in water".

[1] A mini revolution, Food Manufacture, 1 September 2004
[2] The relevance for food safety of applications of nanotechnology in the food and feed industries, Food Safety Authority of Ireland, 2008.
[3] Applications and implications of nanotechnologies for the food sector, Quasim Chaudhry *et al,* Food Additives and Contaminants, March 2008, 25(3): 241–258
[4] www.nanorechproject.org/inventories/consumer
[5] www.nanoshop.com
[6] www.solgar.co.uk
[7] www.shemen.co.il
[8] www.369.com.cn
[9] www.magi-i-cal.com

— ASAP solution food supplement[10] (from the USA) "an engineered silver nano particle mineral supplement" which is "an immune system support".

— Nanoceuticals Slim Shake Chocolate by RBC Lifesciences[11] (from the USA) "with a blend of high quality protein, fiber (*sic*), complex carbohydrate and the proprietary Cocoaclusters or Vanillaclusters [this formula] provides a nutritious and low calorie meal that will help you lose those unwanted pounds once and for all".

— Skybright Natural Health Colloidal Silver Liquid[12] (from New Zealand) "support the body's immune system and natural defences, for natural healing".

14. EFSA recently approved the use of Titanium nitride as a food contact material for use in PET bottles.[13] It also issued an opinion on a silver hydrosol food supplement that it was unable to assess because the data was inadequate.[14]

15. Overall, it is therefore very difficult to gain a clear indication of what developments are already taking place and what we could see in the future. Defra has trialled a voluntary reporting scheme for manufactured nanomaterials, but this has had a very limited response with just 11 submissions since it was launched in September 2006.

16. We therefore consider that the following actions are needed:

— The definitional issue needs to be urgently resolved so that there is clarity over how to classify nanomaterials.

— A mandatory reporting scheme should be introduced for manufactured nanomaterials to enable a more accurate assessment of what developments are taking place.

— The food industry needs to be more transparent about the status of developments, including the food supplement industry and suppliers across the food chain, such as ingredients and packaging material manufacturers.

— The government, particularly the Food Standards Agency, needs to more pro-actively engage with this issue in order to understand what applications are likely.

— In line with this, there needs to be better and more formalised engagement between regulators (eg FSA, Department of Health and Defra), the research councils and broader research community and the food industry in order to understand what is going on.

— This needs to be done in collaboration with other stakeholders, including consumer organisations, leading to a more defined and strategic "roadmap" of where food-related nanotechnology developments are currently going and where they should be going in order to meet the key food policy priorities around food safety, quality, nutrition and sustainability.

— International regulatory co-operation is also essential in order to understand what is happening in other parts of the world, particularly as many developments are taking place in Asia and the United States.

Health and Safety

17. We are also concerned that there remains too limited an understanding of the risks that could be posed by some manufactured nanomaterials. Despite relatively early warnings from the Royal Society and Royal Academy and Engineering back in 2004[15] that some nanomaterials may pose different risks to materials in their bulk form, many uncertainties still remain.

18. While some nanomaterials may be of little concern, recent opinions by the EU's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[16] and the European Food Safety Authority's (EFSA's) Scientific Committee[17] have again highlighted a number of uncertainties that need to be addressed.

[10] www.asapsolution.com
[11] 813312.rbclifesciences.com
[12] www.skybright.co.nz
[13] 21st list of substances for food contact materials—Scientific Opinion of the Panel on food contact materials, enzymes, flavourings and processing aids (CEF) Question number: EFSA-Q-2005-151, EFSA-Q-2006-324, EFSA-Q-2006-323, European Food Safety Authority, 27 November 2008.
[14] Inability to assess the safety of a silver hydrosol added for nutritional purposes as a source of silver in food supplements and the bioavailability of silver from this source based on the supporting dossier—Scientific Statement of the Panel on Food Additives and Nutrient Sources added to Food (ANS), European Food Safety Authority, Question number: EFSA-Q-2005-169, 26 November 2008.
[15] Nanoscience and nanotechnologies: opportunities and uncertainties, The Royal Society and The Royal Academy of Engineering, 2004.
[16] Risk assessment of products of nanotechnologies, Scientific Committee on Emerging and Newly Identified Health Risks, 19 January 2009.
[17] The potential risks arising from nanoscience and nanotechnologies on food and feed safety, Scientific Opinion of the Scientific Committee, European Food Safety Authority (Question No EFSA = Q-2007-124), 10 February 2009.

As well as highlighting the lack of information available to enable the potential exposure to engineered nanomaterials (ENMs) to be assessed, EFSA highlighted some fundamental gaps in knowledge around toxicokinetics (the absorption, distribution, metabolism and excretion of substances in the body) and toxicology.

19. The breadth of the uncertainties were summarised in EFSA's overall conclusions: "Current uncertainties for risk assessment of nanotechnologies and their possible applications in the food and feed area arise due to presently limited information in several areas. Specific uncertainties apply to the difficulty to characterize, detect and measure engineered nanomaterials (ENMs) in food/feed and biological matrices and the limited information available in relation to aspects of toxicokinetics and toxicology, including optimal methods for testing ENMs. There is limited knowledge of (likely) exposure from possible applications and products in the food and feed area and of environmental impacts of such applications and products. The current usage levels of ENMs in the food and feed area is unknown".

20. The lack of knowledge is fundamental. For example, the understanding of the potential toxicity after consuming manufactured (or engineered) nanomaterials has only been studied for a very limited number of materials and only a few studies have compared the toxicity of the nano and conventional form of the same chemical species. EFSA, therefore, concluded that the data are insufficient to draw general conclusions. It stressed the importance of a case by case approach to risk assessment, but emphasised that under the current circumstances any individual risk assessment is likely to be subject to a high degree of uncertainty—and that this would remain the case until there was more data on, and more experience with, testing of engineered nanomaterials.

21. Defra over-sees the UK's Research Co-ordination Group on nanotechnologies and has published and set out a series of research priorities,[18] but we are concerned that these gaps in understanding are not being addressed with sufficient urgency. This is compounded by the failure by government to get to grips with what is actually on the market, either in terms of specific food and applications or other non-food developments that could have implications for the food supply chain.

22. We therefore consider that the following action is needed:

- Efforts to ensure that research is undertaken to address key uncertainties needs to be dramatically accelerated in order to enable effective risk assessment. Leading scientific bodies are repeatedly producing lists of key knowledge gaps and uncertainties—the most recent coming from research the SCENIHR and EFSA committees.
- As part of this, current knowledge should be drawn upon in order to make some general conclusions about which materials are likely to pose most risk and which may be of little concern in order to identify priority areas for action and to direct future developments, including identifying where any restrictions need to be placed.

Regulatory Framework

23. Under the Food Safety Act 1990 and the EU's regulation on food law,[19] there is a general requirement that food should be safe. The issue in relation to nanomaterials used in food production is how this can be ensured in practice given the uncertainties highlighted above.

24. Many food applications that are relevant to the use of nanotechnology are subject to specific EU legislation that requires a pre-market authorisation, including a risk assessment by EFSA (eg food additives, food contact materials and food supplements). The recent review of the food improvement agents package of legislation which included food additives, flavourings and enzymes, for example, was used to clarify that an additive produced in nano form was considered a new material compared to its bulk form and therefore required specific approval.[20]

25. It is essential that there is clarity over how nanomaterials are to be dealt with. This is difficult without agreed definitions as to what is classed as a nanomaterial. However, it is essential that consumers are not exposed to risks from nanomaterials while the debate over definitions is resolved.

26. One specific gap has been in relation to novel foods. The novel foods regulation is currently being reviewed and considered by the European Parliament and Council. The European Commission proposed that products produced using nanotechnologies (as well as any other "new production process") should fall under the definition of a "novel food" and therefore require pre-market approval, but only if it gives rise to "significant

[18] *Characterising the Potential Risks posed by Engineered Nanoparticles:* A Second UK Government Research Report, HM Government 2007.
[19] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[20] http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm

changes in the composition or structure of the food which affect its nutritional value, metabolism or level of undesirable substances."[21] We are concerned that this is too limited as it relies on a company making an assessment as to the relevance of any changes before a product would be subject to an independent risk assessment. The Regulation should therefore be clear that if a product is produced using nanotechnology—and does not fall under any specific food regulations as outlined above—it should be considered a novel food and require a pre-market assessment by EFSA and EU authorisation before it can go on the market.

27. The general food law regulation (EC 178/2002) acknowledges in Article 6 that as well as risk assessment, risk analysis should also take account of "other factors legitimate to the matter under consideration and the precautionary principle". Nanotechnologies are likely to raise a wide range of issues some of which will go beyond safety aspects. It is essential that these broader social and ethical issues are understood and are taken into account as part of authorisation processes. This is also consistent with the FSA's role of protecting public health and "other consumer interests in relation to food".[22]

28. The call for evidence seeks views on the role that voluntary self-regulation may play in this area. Given that food is generally a highly regulated area compared to other products in view of the potential widespread health consequences if it is unsafe, we consider that it would be a backward step to rely on a voluntary approach to control the issues raised by manufactured nanomaterials. This is a highly competitive area and is also an area where there is a great deal of uncertainty. Our experience from working with a range of other stakeholders as part of an initiative to develop a Responsible Nano Code[23] is that it is only likely to be possible to reach agreement on broad principles, rather than on the specific measures that are needed in order to ensure the safe and responsible development of nanomaterials. This has also been reinforced by the poor response to Defra's voluntary reporting scheme.

29. In relation to inter-governmental co-operation, the Organisation for Economic Co-operation and Development (OECD) has established a Working Party on Nanotechnology and a Working Party on Manufactured Nanomaterials looking at health and safety aspects. The International Standards Organisation (ISO) is also undertaking several pieces of work and has been leading on efforts towards standardisation of definitions. The relevant international standards body for food regulation is the Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) Codex Alimentarius Commission. While it is essential that there is international co-operation on this issue, experience from the development of standards for other emerging technologies has been that these bodies can take many years to reach agreement on standards—and often come after products have been on sale for many years. It is therefore important that the UK and EU actively participate and take a leadership role in these discussions, but waiting for international consensus could put consumers at risk.

30. There is a more specific initiative to ensure regulatory co-operation between the US and EU as part of the Trans-atlantic Economic Council established by the previous US administration and the German Presidency of the EU.[24] This work is important to ensure that there is a common approach to the regulation of this technology, avoiding any potential trade disputes and ensuring that consumer protection is not undermined.

31. As well as addressing the concerns raised above specifically in relation to the review of the novel foods regulation, we consider that the following issues need to be addressed:

- It should be ensured that there is clarity across all food legislation (eg through clear guidance or updating of relevant legislation), that materials produced using nanotechnology are subject to mandatory independent pre-market assessment and approval (ie by EFSA) and that materials that have already been approved in their conventional form need a separate assessment and approval if in nano form.
- Effective enforcement should be ensured so that any products that are on the market which have not been approved are removed. This requires clear guidance to be given to local authorities by the FSA, including over how to deal with products available over the internet.
- There is a need for clarity over how broader consumer and other social issues are to be taken into account as part of the approval process, in line with the recognition that "other legitimate factors" play a role and need to be taken into account by risk managers in the EU's general food law regulation.
- There should be effective monitoring by the FSA of the extent to which other non-food nanomaterials may be contaminating the food chain and any associated risks.

[21] Proposal for a Regulation of the European parliament and of the Council on novel foods, COM (2007) 872 final, 14.1.2008—proposed Article 3.
[22] Food Standards Act 1999.
[23] http://www.responsiblenanocode.org/
[24] Framework for advancing transatlantic economic integration between the European Union and the United States of America, April 2007.

32. In addition, as highlighted above, in relation to current uses and health and safety aspects:

— Regulation needs to ensure that there are robust definitions in place that cover all potential food applications that may be considered to exhibit different properties because they are manufactured using nanotechnology.

— Regulation is needed to ensure that manufactured nanomaterials have to be reported to the regulatory authority (ie Defra or FSA).

Public Engagement and Consumer Information

33. Which? conducted a survey in October 2008 which found that only 45 per cent of people had heard of nanotechnology.[25] This was a slight increase from our last survey in November 2007 when 37 per cent were aware,[26] but even those who had heard about it were unclear what it is. Respondents were asked what first thing they think of when they hear the term "nanotechnology" and around half (52 per cent) couldn't come up with anything at all. Around one in five (22 per cent) made mentions relating to size and slightly fewer (18 per cent) mentioned electronics, science or technology. Awareness was higher among men than women (53 per cent compared to 37 per cent) and those over 65 were likely to be less aware (37 per cent). When asked where they thought nanotechnology is currently being used to produce consumer products, just 3 per cent mentioned food—and only 6 per cent when prompted with a list of possible applications.

34. In November 2007, we commissioned a citizens' panel in order to understand consumer attitudes towards nanotechnologies.[27] This looked at food applications as well as medicines, cosmetics and other consumer products. A summary of the findings and the full report conducted by Opinion Leader are enclosed.

35. The Panel was made up of 14 people, broadly representative of the population. They met over three days and heard evidence from a range of experts. Although 14 people is a small number, we felt that it was appropriate to use this type of deliberative technique over other research methods given the complexity of the issue and lack of consumer awareness.

36. The Panel indicated that people are unlikely to have blanket opposition to the use of nanotechnologies for food products. Some people were positive about possible developments, such as intelligent packaging, although others were slightly more wary of getting into areas they considered to be unnatural. Overall, people expect there to be effective regulation in place. They also wanted to know where manufactured nanomaterials are being used and called for labelling. However, the panellists recognised that this would only be useful if backed up by broader information about nanotechnologies that would make the information on the label meaningful.

37. It is also likely that many food companies will want to make claims about the benefits the use of nanomaterials offer. This is already the case in relation to the nano products that can be found on the internet. It is, therefore, essential that these claims can be independently substantiated and that enforcement action is taken over misleading claims.

38. Lessons from the introduction of other new technologies, most notably the introduction of genetically modified (GM) foods, has been that it is essential to engage the public at the outset and ensure that there is a two way exchange, leading to the development and use of the technology in a socially acceptable way that brings genuine consumer benefits. Although this has been widely acknowledged as necessary in relation to nanotechnologies by the government and various engagement activities have been organised and overseen by a Nanotechnology Engagement Group, we are concerned that these have been too limited. Part of the problem is that until the government has a better understanding of what the use of nanotechnologies in the food area is really going to mean for consumers, it is difficult to have a meaningful debate. Most of the engagement exercises to date have been quite general and while giving a general insight into how consumers expect new technologies to be regulated, they have not explored likely reactions to different developments so that the public's views can help to shape the research and regulatory agendas.

39. We therefore consider that the following actions are needed:

— More effective consumer engagement at the earliest opportunity specifically focused around potential food developments by the FSA so that it can be ensured that research priorities and regulatory approaches are in line with consumer expectations and address their concerns.

[25] October 2008 face to face survey of 977 adults aged 16+ representative of adults in the UK.

[26] November 2007 face to face survey of 2,091 adults aged 16+ representative of adults in the UK.

[27] Opinion Leader Research conducted a Citizens' Panel on behalf of Which? with 14 members of the public. Panellists were selected broadly to reflect the general public and sat for three days from 29 November–1 December 2007. The venue was Birmingham University and panellists were recruited from Birmingham and the wider West Midlands area. Expert witnesses were called upon to explain nanotechnologies, the overall benefits and issues, applications in particular areas (including benefits and issues) and the policies and controls in place. The Panel was overseen by a steering group, with a range of expertise and interests, who advised on the approach, agenda and selection of witnesses.

— Once there is a fuller understanding of the potential of nanotechnologies for food, greater consideration needs to be given to any social and ethical issues that may be raised and whether these can be addressed or whether some applications are inappropriate as a result.

— There should be a requirement that manufactured nanomaterials used in food products have to be labelled in the list of ingredients. The current EU discussions around the new food information regulations provide an opportunity to address this.[28]

— Greater effort is needed across government to increase awareness of nanotechnologies and the issues that they raise in a balanced way.

March 2009

Memorandum by the Soil Association

Introduction to the Soil Association

The Soil Association was founded in 1946 to achieve sustainable and healthy agriculture. It is now the main organisation of the organic movement in the UK and certifies about 56 per cent of organic farmers and 70 per cent of the organic food sold in the UK. Organic farming is a management-based system which harnesses natural ecological and biological processes, rather than using synthetic chemical inputs. Organic farming now accounts for about 4 per cent of UK farmland. Sales of organic food are worth almost £2 billion per year.

The Sustainable Development Commission has called organic farming the "gold standard" for agricultural sustainability. Research shows that it has significant environmental advantages over non-organic farming. It supports higher levels of wildlife, whilst reducing agrochemical pollution, waste, and halving the amount of fossil fuels needed to produce food. Because of these benefits the Government wishes to expand organic farming. Defra adopted an action plan for organic food and farming in 2002, with a target of 70 per cent of the UK organic food market to be supplied by UK farmers by 2010, and public procurement to include organic food.

Soil Association Standard on Nanotechnology

As of January 2008, the Soil Association banned the use of man-made namomaterials from all Soil Association certified organic products. We were the first organisation in the world to take a practical stance on the use of nano particles to protect the public, ahead of any governments. Our lead has since been followed in Australia, where the Biological Farmers of Australia (BFA), the country's largest organic body, have now banned manufactured nanoparticles in certified organic products.

Under the Soil Association standard, organic producers and processors must not use ingredients containing manufactured nanoparticles, where:

— the mean particle size is 200nm or smaller; and

— the minimum particle size is 125nm or smaller.

We recognise that this standard will have implications for some established manufacturing processes that produce nanoparticles incidentally, such as milk homogenization. However, we are not in a position to prohibit these now for many reasons: these processes are currently well established, there is relatively little awareness of this issue among the general majority of organic consumers and licencees, we currently do not know which processes produce nano-particles and to what extent. Until we research these more fully, we will not apply this standard to them.

There are many cases of naturally occurring nanoparticles, for example from volcanic eruptions or in wood smoke; these fall outside the scope of this standard.

The standard does apply to engineered nanoparticles.

Summary of Reasons for the Ban

The following section outlines the key issues and documentary evidence that led the Soil Association to develop the nanotechnology standard.

[28] Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers, COM(2008) 40 final, 30.1.2008.

Organic farming methods are based on the use of natural biological and ecological processes. The use of synthetic nano-particles which would not exist in nature and whose basic physical structure has been modified at a very fundamental level is incompatible with this important organic principle as well as unnecessary. Specific concerns are based on information from:

(1) the The Action Group on Erosion, Technology and Concentration (ETC Group),

(2) reviews of nanoparticle safety undertaken by the European Commission and European Parliament and Swiss Reinsurance,

(3) the nanotechnology report by the Royal Society (RS) and the Royal Academy of Engineering (RAE), and

(4) the UK government response to the RS and RAE report.

The RS and RAE state in the recommendations section of their report that "The lack of evidence about the risk posed by manufactured nanoparticles and nanotubes is resulting in considerable uncertainty . . . We recommend that the UK research councils set up an interdisciplinary centre to research the toxicity, epidimiology, persistence and bio-accumulation of manufactured nanoparticles and nanotubes as well as their exposure pathways." The report also recommends a prohibition on environmental releases of nanoparticles and strict regulation of new nanomaterials. For details of the full report see http://www.nanotec.org.uk/report/chapter10.pdf

The UK Government Response to the RS & RAE Report

(*see* http://www.ost.gov.uk/policy/issues/nanotech_final.pdf)

The UK government acknowledges the need for regulation of and the lack of scientific knowledge about nanotechnology. It places a moratorium on use of nanoparticles for environmental remediation and states that "As a precautionary measure, in the interim, exposure in the workplace and releases to the environment should be minimised until the possible risks posed by nanoparticles and nanotubes are better understood".

In a report commissioned by the European Parliament's committee on Industry, External Trade, Research and Energy (ITRE) it is noted that "The release of nano-particles in the environment should be avoided. The state of research concerning [sic] . . . the behaviour of nano-particles is actually rather limited, preliminary as well as contradictory. Nevertheless, the advice to avoid the release of nano-particles to the environment might be appropriate and would be in accordance with the Precautionary Principle."

(Haum, Petschow, Steinfeldt, Nanotechnology and Regulation within the framework of the Precautionary Principle. Final Report. Institut für ökologische Wirstschaftforschung (IÖW) gGmbH. Berlin).

A subsequent preliminary risk analysis of nanotechnologies carried out by the Health and Consumer Protection Directorate of the European Community:

— highlighted that some engineered nanoparticles may have the potential to pose serious concerns,the most significant ones relating to nanoscale technologies within the next 3–5 years and require further studies (Subsection 1.1.1.2);

— revealed that panel experts were of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of normal bulk material; and

— exposed the limits that preclude a complete risk assessment today, in particular the present scarcity of dose-response and exposure data (Subsection 1.1.1.3) http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm

Swiss Reinsurance, in a 2004 review of risks associated with nanomaterials (and nanoparticles in particular) noted that:

> "Nanomaterials are already contained in numerous products worldwide and occur in various applications. There are indications that certain nanomaterials are potential health hazards. The danger is most probably not of an acute but chronic nature and it could be some time before it manifests itself. This is where the real risk for insurers lies, and the comparison with asbestos should be seen in this light."

They recommended that:

> "In view of the dangers to society that could arise out of the establishment of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties"

(Nanotechnology, Small Matter, Many Unknowns, May 2004)

ETC Group articulate further concerns that:

— there are biosafety risks of using DNA, viruses, prions and bacteria in novel ways through nanobiotechnology;

— nanotechnology will impact on labour, including farmers, especially when related to self-assembly, crop surveillance and the replacement of agricultural commodities with new artificial nanomaterials;

— nanotechnology increases the scope for patents on nature and wide matter monopolies;

— there is strong potential for new "nano bioweapons" through nanotechnology;

— there are significant cultural and ethical concerns that flow from altering nature at this fundamental level; and

— nanotechnology is currently an example of where there is little democratic governance over technologies that determine our future.

HRH The Prince of Wales (Soil Association Patron): "My final point concerns the apportionment of benefits and risks. The benefits will largely accrue to those who invest successfully in these technologies and to those who can utilise them. But these new applications will inevitably displace existing technologies. Who will lose from that process, and will it widen the existing disparities between rich and poor nations? What exactly are the risks attached to each of the techniques under discussion, who will bear them, and who will be liable if an when real life fails to follow the rose tinted script." (*Independent on Sunday, 11 July 2004).*

ETC has published a report listing 10 areas where research has uncovered significant cause for concern over the safety of engineered nanoparticles. (*see document link* http://www.etcgroup.org/documents/GT_TroubledWater_April1.pdf)

Fit with organic principles

Nanotechnology does not fit with organic principles which state that:

— organic is a whole system approach to farming and food production and recognises the close interrelationships between all parts of the production system from the soil to the consumer; and

— new or novel technologies, ingredients and processes are not automatically applied to organic food manufacturing.

The lack of accountability of nanotechnology does not fit with organic principles in which there is:

— respect for natural systems;

— ecological responsibility in food production; and

— consideration of the social impact of agricultural systems.

Impact on the environment

Nature, in 2003 reported ". . . nanoparticles could easily be absorbed by earthworms, possibly allowing them to move up the food chain and reach humans", *see document link* http://www.etcgroup.org/documents/GT_TroubledWater_April1.pdf).

The European commission has noted that "In the environment, natural enzymes can change the surface properties of nanoparticles such as fullerenes/the C60 molecule consisting of 60 carbon atoms bonded in a nearly spherical configuration also nicknamed "buckyballs". Fullerenes can form aqueous suspended colloids . . . termed nC60 and become re-suspended after evaporation. In their native form, the small size, colloidal characteristics, and reactive surfaces of colloidal fullerenes make them ideally suited to carry toxic material over long distances. Thus, potentially, colloidal fullerenes could pollute aquifers." *See* "Nanotechnologies: A preliminary risk analysis" subsection 1.1.1.1.1 Toxicology and ecotoxicology - http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm

Impact on human health

Titanium dioxide/zinc oxide nanoparticles used in some sunscreens have been found to cause free radicals in skin cells, (*see document link* http://www.etcgroup.org/documents/GT_TroubledWater_April1.pdf). The toxicity of particles is increased the smaller they are and they can cross the blood brain barrier. Gold nanoparticles have been found to cross the placenta from mother to foetus. Cadmium selenide nanoparticles can break down in the human body potentially causing cadmium poisoning (*see document link* http://www.etcgroup.org/documents/GT_TroubledWater_April1.pdf). Both the Trades Union Congress and the UK Health and Safety Executive have raised concerns about the impact of nanomaterials on worker health during manufacturing and use. The TUC believes that the production and use of nanoparticles should be carried out in a contained process so that employees are not exposed to the potential health risks. Presently there are no agreed safe handling guidelines. *See* www.tuc.org.uk/h_and_s/tuc-8350-f0.cfm

Impact on animal health/welfare

All the concerns of impacts on human health (above) should also be of concern in relation to animal health. In addition, research in 2004 found that buckyballs [carbon nanoparticles] cause brain damage in juvenile fish along with changes in gene function (*see document link* http://www.etcgroup.org/documents/GT_TroubledWater_April1.pdf).

Consumer acceptability and benefits

Some concern has been reported in the national media as a result of the work by Jim Thomas/ETC and the speech on this issue by HRH The Prince of Wales. However, it appears that other than a small, informed minority, there is little awareness of the technology amongst consumers. The use of nanoparticles does not currently have to be declared on labelling although this was a recommendation of the RS & RAE report and the UK Government accepts this may be necessary. The report entitled: *Market research on public attitudes to Nanotechnology* carried out by the BMRB (British Market Research Board) and published on 15 March 2004, can be found at http://www.nanotec.org.uk/PressMediaMar042.htm. The report mentions that the overwhelming majority of people have not heard of nanotechnology. Participants drew a parallel with GM when considering the ethical implications of nanotechnology because of the perception that both involve changes at the most fundamental level to form something that does not occur in nature. Both GM and nanotechnology could be seen as "messing with nature" in a specific way by "manipulating the building blocks of nature". They expressed concerns about whether scientists are trying to "play God".

Soil Association Concerns on Regulatory Process

Case-by-case approval

We do not agree with controls based on case-by-case assessment of the scientific evidence as the principal regulatory response for the forseeable future for free nano-scale products, at least for products to which people are exposed to regularly and directly via food and health and beauty products. Such controls cannot in practice be reliable, evidence-based, cost-effective, or proportional. This is because of the lack of both a history of experience and a robust body of scientific understanding of the impacts of such materials on the biology of organisms, and on ecological interactions, and because it is completely unrealistic to imagine that the full range of required safety data could and would be generated for each and every product (and it would normally be completely disproportional to do this even if it were possible). Inevitably, with such an approach, decisions will be strongly based on personal judgements, and thus open to the bias of expert advisers, politicians and influence by commercial lobbyists, whilst being presented and defended as "evidence-based".

A supposedly "evidence-based" approach is how GMOs are being dealt with now by the Food Standards Agency. We and very many others see this as totally unsatisfactory because of the poor level of scientific knowledge and shortage of relevant, independent evidence, and we consider that the risks to the public are significant. With every GMO submitted for approval, despite the long list of scientific uncertainties about the health impacts in each case and the emerging evidence of general health risks with the genetic engineering process, the benefit of the doubt is always given to the GM company (not a single product has been rejected despite scientific concerns always being raised). This deeply flawed approach is, in our view, the basis of the high controversy and public and market rejection of GMOs. We believe the same will occur with nano-scale materials, if they are regulated in the same way. We and others would certainly raise these concerns in public, in the way we have GMOs.

We instead propose that the principal regulatory approach must be a generic assessment of the safety of engineered nano-scale materials, at least for products to which there is direct and regular public exposure. This should comprise (i) a review of whether there is an adequate and reasonably robust body of scientific understanding to enable case-by-case assessment and approval; (ii) an assessment of whether the current

understanding and evidence suggests there could be health or environmental risks in at least some cases (though which cases would not be known); (ii) and an assessment of the viability and cost-effectiveness of generating the required range of data to enable comprehensive reliable case-by-case assessment.

There should lead to a general decision on the use of free engineered nano-scale materials, at least for nano-scale materials in food and health and beauty products. Because of the inevitable negative outcome of this generic review, we believe there should be a general prohibition against the use of free engineered nano-scale particles in agriculture and the food chain and in health and beauty products. Only where there is a clear and specific societal benefit (excluding economic benefits which can always be delivered in many other ways), should the necessary data be generated and case-by-case assessment considered

This should not be considered a lost opportunity. Unnatural products introduce new chemical and biological interactions and therefore have a comparatively high likelihood of disrupting natural processes with negative effects, compared to natural processes. They also have a high likelihood of displacing as yet unidentified benefits of existing natural substances. Artificial products also generally involve a high level of embodied energy in their production, compared to management approaches and natural processes. Moreover and importantly, there is no significant general societal need for nano-scale materials in food, agriculture, or health and beauty products.

Voluntary reporting

It is not reasonable for the public or other stakeholders that the reporting scheme is voluntary. This will mean that the results will not be reliable as a basis for developing appropriate controls as the results will under-represent any negative effects. It is very likely (and must be assumed) that evidence showing negative impacts from products already on the market will sometimes be withheld or not clearly communicated (as is the case with GM research). A voluntary approach would there go against the aim of the scheme to gather evidence of the risks and produce a reliable basis for controls to allow "responsible development".

A voluntary approach would also not be reasonable with respect to the companies involved, as it would create an unlevel playing field. It would effectively reward companies that withhold evidence of negative effects—and facilitate those applications, and penalise companies who release evidence of negative effects—and discourage those applications.

Commitment to research

There is a major need to build up a robust and comprehensive general body of scientific understanding of the impacts of nano-scale materials on the biology of organisms and on ecological interactions, aside from whether there are any identified toxic effects. (The lack of a basic body of understanding of the biological impacts of GMOs has been the major weakness of the GMO regulatory regime, as the scientists have little general information on which to decide on the implications of the inevitable numerous gaps in knowledge for individual products. Commercial and political pressures means they have therefore always decided in favour of the products, with no scientific basis).

Good practice must include product labelling, product registers, the quality of safety studies (eg. sample sizes and time-scales that are adequate for protecting public health) and complete transparency with regard to the results for any commercialised products and products being submitted for approval. However, at the moment, only moratorium is acceptable for products to which the public would have regular direct exposure, ie in food, health and beauty products.

March 2009

Memorandum by Friends of the Earth, Australia

Executive Summary

Friends of the Earth Australia (FoEA) has serious concerns about the use of nanotechnology in agriculture, food and food packaging because:

- Nanoparticles ingested via food or food packaging, to which workers are exposed during product manufacture, and which are released to the environment via waste streams or agricultural use have the potential to cause long term pathological effects or short-term toxicity.
- Decreased particle size may increase the production of free radicals leading to increased toxicity.
- A number of properties apart from size determine the toxicity of a nanoparticle.

— There are serious knowledge gaps in our understanding of the behaviour and toxicity of nanoparticles that present obstacles to designing appropriate new risk assessment.

— *In vitro* and preliminary *in vivo* studies of some nanoparticles used in agriculture, food, food packaging or food contact materials have shown that these materials pose serious new toxicity risks.

— The ecotoxicity of nanoparticles remains poorly understood, however early studies suggest that they may cause serious environmental harm.

— Nanotechnology's widespread use in food and agriculture, resulting in greater consumption of more highly processed foods may have serious social and cultural implications and deleterious impacts on public health that go far beyond the toxicity risks of nanoparticle ingredients.

— Nanotechnology's use in food and agriculture may undermine efforts to support ecologically sustainable, locally controlled, relocalised agriculture and food production that delivers economic, social and environmental benefits to rural communities and that help redress the global food crisis.

— There are ethical, social and cultural reasons that the public may not wish to support nanotechnology's use in food and agriculture. Non-science based concerns about nanofoods must be recognised explicitly by governments as legitimate and the public given the opportunity to reject nanotechnology development in this sensitive area.

The regulation of nanotechnology in food and food packaging warrants a precautionary approach. To address our concerns, we recommend that the following steps are taken:

— Define manufactured nanoparticles and nanoscale food components as all ingredients and additives that are added to food or packaging, including as processing aids, which:

  — measure <0.3 -300nm in one or more dimension, or that have a structure that exists at this scale, or

  — in which particle size is important to achieving the technological function or may relate to a difference in toxicity

— Soluble manufactured nanoparticles and nanoscale food components to be included in nanoparticle definitions, disclosure and safety testing requirements.

— Define as nanoparticles agglomerates and aggregates whose primary particles are nanoscale or which possess nano-structures and subject them to nanoparticle-appropriate risk assessment and exposure metrics.

— Define manufactured nanoparticles and nanoscale food components as a new class of chemicals. Each nanoparticle or nanoscale food component, irrespective of its solubility, must be subject to case by case safety testing that is tailored to the unique risks of nanoparticles, with pharmacological endpoint testing. Testing requirements must be clearly stated rather than being left to the discretion of regulators or the applicant.

— Identify foods to which manufactured nanoparticles or nanoscale food components have been added or which are wrapped in packaging to which manufactured nanoparticles have been added as novel foods and require them to face pharmacological endpoint safety testing. Testing requirements must be clearly specified rather than being left to the discretion of regulators or the applicant.

— Apply a moratorium to the sale of all nanofoods until new nanoparticle risk assessment and detection methodologies are developed and validated, as recommended by the Austrian Ministry of Health.

— Label all nano ingredients, and foods produced using nanotechnology, to give people the capacity to make an informed choice, as well as for public health reasons (to trace adverse effects).

— Apply social and public interest assessment to all applications for use of nanotechnology in agriculture or food production and packaging.

— Assess specifically the potential for nanotechnology to further globalise agriculture and food production and trade and to erode efforts to relocalise food production to address food sovereignty.

— Assess specifically the potential for nanotechnology to promote greater consumption of highly processed foods in preference to minimally processed fruit and vegetables and its implications for public health.

— Recognise explicitly the right of the public to reject nanotechnology's use in food and agriculture

— Develop mechanisms for meaningful involvement of the public in nanotechnology policy and decision making.

Friends of the Earth Australia (FoEA) has serious concerns about the use of Nanotechnology in Food and Food Packaging

Ingested nanoparticles have the potential to cause long term pathological effects or short-term toxicity

The potential for nanoparticles ingested via food or food packaging to cause long term pathological effects or short-term toxicity is poorly understood and of grave concern. A small number of clinical studies suggest that nanoparticles and small microparticles that are not metabolised can over time result in granulomas, lesions (areas of damaged cells or tissue), cancer or blood clots[1]. Scientists have also suggested that nanoparticles and particles up to a few hundred nanometres in size in foods may already be associated with rising levels of irritable bowel and Crohn's disease[2]. There have so far been no long-term nanoparticle feeding studies and so the potential for pathological effects remains very poorly understood. Such studies are clearly required to inform the safety assessment necessary before nanoparticles are approved for use in foods.

In vitro *and preliminary* in vivo *studies of some nanoparticles used in food, food packaging or food contact materials have shown that these materials pose serious new toxicity risks.*

As particle size decreases, in many nanoparticles the production of free radicals increases[3], with increasing potential for toxicity. *In vitro* studies have shown that nanoparticles which are now used commercially in food, food packaging or food contact materials, including zinc, zinc oxide, silver, and titanium dioxide, pose serious new toxicity risks[4]. In a test tube experiment 20nm nanoparticles of titanium dioxide caused complete destruction of supercoiled DNA[5]. Also in the absence of UV, in another test tube experiment titanium dioxide produced reactive oxygen species in brain immune cells[6]. Pilot data from test tube experiments show nanoparticle titanium dioxide exposure negatively affected cellular function[7] and caused death of brain immune cells after 24 hours exposure[8]. *In vitro* studies also demonstrate that silver nanoparticles are highly toxic to rat brain cells[9], mouse stem cells[10] and rat liver cells[11]. An *in vitro* study found that for some cultured cells, zinc oxide nanoparticles were more cytotoxic than asbestos[12]. Preliminary feeding studies have demonstrated that high oral doses of nanoparticle zinc oxide and titanium can cause toxicity or changes in physiological function[13].

A number of properties apart from size determine the toxicity of a nanoparticle

Size is a key factor in determining the potential toxicity of a particle. However it is not the only important factor. Other properties of nanoparticles that influence toxicity include: chemical composition, shape, surface structure, surface charge, solubility, aggregation/ agglomeration[14], catalytic properties[15] and the presence or absence of "functional groups" of other chemicals[16]. The large number of variables influencing toxicity means that it is impossible to generalise about health risks associated with exposure to nanoparticles of a given chemical composition. Each new nanoparticle must be assessed individually and all material properties must be taken into account, including the presence or absence of coatings or functional groups and all physico-chemical characteristics.

The ecotoxicity of nanoparticles remains poorly understood, however early studies suggest that they may cause serious environmental harm

The ecotoxicity of nanoparticles remains poorly understood. However, there is early evidence that nanoparticles of titanium dioxide can cause mortality[17] or behavioural[18] or physiological[19] changes in species such as water fleas, fish or algae that are used as environmental indicator species. Byproducts associated with the manufacture of single-walled carbon nanotubes, mooted for future use in food packaging, caused increased mortality and delayed development of a small estuarine crustacean *Amphiascus tenuiremis*[20]. Earthworms exposed to double-walled carbon nanotubes produced significantly fewer cocoons in a dose-dependent response[21]. If such exposure resulted in reduced numbers of earthworms, this would have a serious negative impact on soil health. Exposure to high levels of nanoscale aluminium has been found to stunt root growth in five commercial crop species[22].

The antimicrobial properties of many nanoparticles now used in food packaging and food contact materials have led to concerns that they may shift into microbial populations and disrupt signalling between nitrogen-fixing bacteria and their plant hosts[23]. Any significant disruption of nitrogen fixing could halt plant growth and have serious negative impacts for the functioning of entire ecosystems. This would have significant ecologic and economic impacts.

To Address our Concerns, we Recommend the Following:

Define manufactured nanoparticles and nanoscale food components as those ingredients that are added to food or packaging which:

- *measure <0.3 -300nm in one or more dimension, or that have a structure that exists at this scale, or*
- *in which particle size is important to achieving the technological function or may relate to a difference in toxicity*

Particle size can be important to achieving the technological function or result in different toxicity of a food additive, nutritive substance or novel food ingredient. However this alone is not sufficient to ensure that all manufactured nanoparticles and nanoscale food components added to foods and packaging are subject to appropriate new risk assessment. The effect of a nanoparticle ingredient on technological function or toxicity may be unknown to the food manufacturer, even in instances where the nano ingredient does pose novel risks that would be detected were an appropriate risk assessment to be performed. A universal size-based definition of nanoparticles is therefore essential to ensure that all manufactured nanoparticles and nanoscale food components are subject to appropriate risk assessment.

Friends of the Earth Australia recommends defining nanoparticles as "particles having one or more dimensions measuring between 0.3nm and 300 nanometres (nm)". That is, we recommend that 300nm be the particle size at which nanoparticles are considered to be new chemicals and requirements for new health and safety assessments are triggered. This definition of nanoparticles must include soluble particles, and also aggregates and agglomerates composed of nanoscale particles or which have nanostructures. Particles that are larger than this size but that also exhibit novel, nano-specific behaviour should also be permitted to be assessed by regulators as nano-ingredients.

Particles up to a few hundred nm in size share many of the novel biological behaviours of nanoparticles than <100nm in size, including very high reactivity, bioactivity and bioavailability, increased influence of particle surface effects, strong particle surface adhesion and strong ability to bind proteins[24]. As with even smaller particles, particles <300nm in size have the capacity to be taken up into individual cells[25]. Particles up to a few hundred nm in size may also pose similar health and environment risks to particles <100nm.

Recent studies finding that carbon nanotubes can cause the same disease as asbestos fibres received world wide attention[26]. Yet many of the nanotubes in the studies measured >100nm and so would not be considered to be "nanoparticles" using a <100nm size-based definition. Poland et al.[27] found that two samples of long, tangled multi-walled carbon nanotubes caused asbestos-like pathogenicity when introduced into the stomachs of mice. One of their two samples had a diameter of 165nm and a length of greater than 10μm. Similarly, Takagi et al.[28] found that in a long term study, more mice died from mesothelioma following exposure to multi-walled carbon nanotubes than died following exposure to crocidolite (blue) asbestos. In this study >40 per cent of sample nanotubes had a diameter >110nm.

Several studies have also reported nanoparticle-like biological behaviour in particles 200nm in size—suggesting strongly that even 200nm is not an appropriate upper limit for defining nanoparticles. In an *in vitro* study Ashwood et al.[29] found that 200nm particles of titanium dioxide adsorb bacterial fragments to their surface and "smuggle" these into human intestinal tissue where they mimic invasive pathogens and can provoke inflammation. Linse et al.[30] found that in an *in vitro* study, along with smaller nanoparticles, the large surface area and surface charge of 200nm nanoparticles catalysed protein fibrillation (mis-folding). Protein fibrillation is involved in many human diseases, including Alzheimer's, Creutzfeld-Jacob disease, and Type 2 diabetes. Cedervall et al.[31] also found strong interactions between proteins and 200nm particles.

Require disclosure and safety testing for all manufactured nanoparticles and nanoscale food components that are used as food processing aids

We emphasise that given the uncertainties surrounding the physiological and biological behaviour of nanoparticles, including in relation to agglomeration, aggregation, de-agglomeration and de-aggregation processes, risk assessment must be performed on the manufactured nanoparticle or nanoscale food component that is added to the food or packaging, including as a processing aid. This is especially important given the huge deficiencies in existing nanoparticle detection capacity.

Soluble manufactured nanoparticles and nanoscale food components to be included in nanoparticle definitions, disclosure and safety testing requirements

The European Food Safety Authority's "Draft Scientific Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" recognises the significant knowledge gaps regarding the behaviour of nanoparticles, including with respect to solubility. EFSA recognises that even where nanoparticles are of soluble substances, given uncertainty regarding their behaviour, the substance should be treated as a nanoparticle, unless it can be proved that it dissolves with no change to its risk profile. This is particularly important given early results showing that partially soluble substances such as zinc oxide can pose extremely serious cytotoxic risks[32].

Soluble nanoparticles (eg micelles, nano-liposomes and nano-encapsulated active ingredients) must be included within the definition of "nanoparticles". Soluble nanoparticles must be subject to new nanotechnology-specific safety assessments and exposure metrics given the large gaps in our understanding of how their potentially far greater bioavailability, solubility and potency will influence their biological and toxicological behaviour[33].

Nano-sizing or nano-encapsulating food additives including vitamins, enzymes or preservatives results in greater bioavailability, improved solubility and increased potency of these substances compared to larger or micro-encapsulated form[34]. These novel nanoparticles are already being exploited commercially. For example AquaNova markets its nanoscale micelles for use in foods and cosmetics *because* they deliver "significantly higher bioavailability" of enclosed active ingredients once ingested or applied to the skin[35]. Omega 3 food additives have in the past been added to food in 140-180,000 nm micro-capsules, for example micro-encapsulated tuna fish oils used by Nu-Mega Driphorm® to fortify Australia's Tip Top bread line (Personal communication with Nu-Mega representative 2007). However to increase the Omega 3 potency and bioavailability, companies such as Aquanova and Zymes are now selling 30-40nm nano-forms or nano micelles of Omega 3 – an incredible 4,000 times smaller than the Nu-Mega range[36].

If nano-nutritional additives and supplements provide an excessive dose of some vitamins or nutrients these may have a toxic effect or interfere with the absorption of other nutrients. Dr Qasim Chaudhry who leads the nanotechnology research team at the United Kingdom's Central Science Laboratory told the Times Online that nanoparticle and nano-encapsulated food ingredients may have unanticipated effects, far greater absorption than intended or altered uptake of other nutrients, but warned that little, if anything, is known currently[37].

Define as nanoparticles agglomerates and aggregates whose primary particles are nanoscale or which possess nano-structures and subject them to nanoparticle-appropriate risk assessment and exposure metrics

If nanoparticles fuse together, they form aggregates which are hard to separate. These nano-structured aggregates may be larger than 100nm—or even larger than 300nm. However in many instances aggregates will have close to the same surface area as the nanoparticles they are made from and will have "nooks and crannies" on their surface structure that are nano-sized. Where toxicity is driven by surface characteristics, the toxic properties of aggregated nanoparticles may be very similar to that of the primary nanoparticles that compose them. In fact some early studies exposing animals to large nanoparticle aggregates showed effects that appeared to be associated with these primary particles, although the primary particles were more potent in many respects (see reviews in Maynard and Kuempel[38] and Oberdörster et al.[39]). In other instances, nano-structured aggregates may result in greater damage than that associated with the primary nanoparticles. In an inhalation study using mice Shvedova et al.[40] found that aggregates of single walled carbon nanotubes were the focal point of granulomatous inflammation.

Nanoparticles that form clusters but do not adhere so strongly together are called agglomerates. Agglomerates have similar structures and surface properties to aggregates and so may also share the toxicity risks associated with the primary nanoparticles that compose them. Additionally, in principle agglomerates can also change shape or come apart[41]. If particles do not de-agglomerate, their size could reduce their bioavailability relative to that of their primary nanoparticles[42]. However this may not necessarily reduce their toxicity. For example Muller et al.[43] found that two months after intratracheal installation of multi-walled carbon nanotubes in rats, pulmonary lesions were caused by the accumulation of large carbon nanotube agglomerates in the airways.

It is still unknown to what extent aggregates and agglomerates will break down into smaller particles in our bodies, eg after ingestion. Researchers routinely use surfactants to "debundle" single and multi-walled carbon nanotube samples for physicochemical investigation[44]. Biological fluids that contain surfactants or proteins may similarly promote de-agglomeration[45] or even break up of aggregates[46] into smaller particles or even the primary nanoparticles.

The poor understanding we have of disaggregation and de-agglomeration processes and the early evidence that aggregates and agglomerates may share both surface characteristics and toxic properties with the primary nanoparticles that compose them demand that regulators take a precautionary approach and treat these particles as nanoparticles.

Define manufactured nanoparticles and nanoscale food components as a new class of chemicals. Each nanoparticle or nanoscale food component, irrespective of its solubility, must be subject to case by case safety testing that is tailored to the unique risks of nanoparticles, with pharmacological endpoint testing.

The United Kingdom's Royal Society and Royal Academy of Engineering have recommended that given the emerging evidence of serious nanotoxicity risks, nanoparticles should be treated as new chemicals[47] and be subject to new safety assessments prior to their inclusion in consumer products[48]. They further recommended that factories and research laboratories should treat nanoparticles as if they were hazardous[49], and until the environmental impacts of nanoparticles are better known, their release into the environment should be avoided as far as possible[50].

To date food regulators world wide have not treated nanoparticles as new chemicals nor required food and food packaging manufacturers to conduct new safety testing of nano ingredients. The risk assessment process used by regulators for nanoparticle ingredients, additives, nutritive substances, processing aids and contaminants of food or food packaging should be specific to their new risks (eg by requiring full physico-chemical characterisation of particles and nanoscale food components including size, shape, charge, surface properties, solubility, catalytic properties, coatings, presence or absence of functional groups etc). A nanoparticle-appropriate metric must be used for dose (eg particle surface area or number of particles rather than mass). The process used for risk assessment must be explicitly stated rather than left to the discretion of regulators or the applicant.

Identify foods to which manufactured nanoparticles or nanoscale food components have been added or which are wrapped in packaging to which manufactured nanoparticles have been added as novel foods and require them to face pharmacological endpoint safety testing.

The Austrian Health Ministry has called for the European novel food regulations to specifically apply to all foods produced using nanotechnology or nanoscience[51]. Friends of the Earth Australia recommends that the novel foods standard also specifically apply to all foods produced using nanotechnology or to which manufactured nanoparticles or nanoscale food components have been added as ingredients, nutritive additives, processing aids or contaminants, or to foods which have been wrapped in packaging to which manufactured nanoparticles have been added.

In the recently released "Draft Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety", the European Food Safety Authority emphasised the serious nature of the knowledge gaps regarding the toxicity of nanoparticles used in food and feed. EFSA suggested that pharmacological endpoints may be needed to ensure that risk assessment of nano ingredients in food and feed did not pose unacceptable health risks:

"The available data on oral exposure to specific ENM [engineered nanoparticles/ manufactured nanoparticles] and any consequent toxicity is extremely limited; the majority of the available information on toxicity of ENM is from *in vitro* studies or *in vivo* studies using other routes of exposure… *There may also be additional toxic effects caused by ENM that are not readily detectable by current standard protocols. Additional endpoints not routinely addressed and pharmacological endpoints may need to be considered in addition to traditional endpoints*" [52] [emphasis added].

The call for nanofoods to be identified as novel foods and subject to a rigorous standard of safety testing using pharmacological endpoints appears eminently sensible. This is especially appropriate given the use of nanotechnology to increasingly blur the lines between foods and nutritional additives ("nutraceuticals") and to promote further use of functional foods that are marketed as having an enhanced health benefit. It is important that packaging is included in this high level of safety testing, given that increasingly nano packaging is being designed to interact with the food it contains. However it should be noted that the Deputy Head of Sector, Safety and Efficacy of Medicines at the European Medicines Agency has suggested that even existing pharmacological endpoints may need strengthening to manage the new risks and challenges of nano-medicines[53]. It is likely that such new standards will also be required for the assessment of nanofood and food packaging ingredients.

Until new nanoparticle risk assessment and detection methodologies are developed and validated, a moratorium should apply to all nanofoods, as recommended by the Austrian Ministry of Health

Given the huge uncertainties surrounding the physiological behaviour and toxicological risks of nanoparticles and the lack of reliable nanoparticle detection methodologies, the Austrian Health Ministry has called for a European-wide moratorium on nanofoods until validated methods for identification and risk assessment have been developed[54].

Friends of the Earth Australia supports this call. As we have said previously, a moratorium on the commercial sale of all nano-products should apply until the safety of nano-products can be demonstrated, all nano-products are clearly labelled, and the public is given the opportunity to be involved in nanotechnology decision making.

All nano ingredients, and foods produced using nanotechnology, should be clearly labelled to give people the right to make an informed choice, as well as for public health reasons (to trace adverse effects)

Manufacturers of products that contain added nanoparticles are not required to acknowledge the presence of nano-ingredients on product labels. This denies consumers the right to make an informed choice about whether or not they wish to eat nanofoods, or foods wrapped in nano-packaging. Failing to label nanofoods precludes tracing any future adverse effects back to their source and also precludes carrying out post-release monitoring.

A recent poll of 1010 Australians carried out by Essential Research and commissioned by Friends of the Earth found that 92 per cent support mandatory labelling of all nano ingredients in foods and food packaging[55]. The poll found that only 15 per cent of people would be prepared to purchase nanofoods, whereas 40 per cent said that they would not purchase nanofoods at all. That is, more than nine in 10 people want the capacity to choose whether or not to eat nanofoods or food wrapped in nano-packaging, and given the choice, more than twice as many people would not purchase nanofoods. Mandatory labelling of nanoproducts has also been a key recommendation of the United Kingdom's Royal Society[56] and the Austrian Ministry of Health[57].

Foods produced using nanotechnology or nanoscience should also be labelled. Consumers are now looking for labelling not only for ingredients, but also for preparation instruction, storage information, nutrition information panel and processes used in the manufacture of foods. We currently label other foods according to the processes used, for example organic or kosher foods, and this is also important with respect to nanotechnology.

Apply social and public interest assessment to all applications for use of nanotechnology in agriculture or food production and packaging.

Beyond the need for new regulation to manage the serious new toxicity risks associated with nanofood and nano agricultural products, Friends of the Earth Australia is calling for "fourth hurdle regulation" to require manufacturers to demonstrate the social benefit of products they wish to sell. There is very rarely a requirement for product manufacturers to "justify" risk exposures in terms of social benefits[58]. Too often, it is an entrenched and unchallenged assumption that the market release of a new functional food or antibacterial product will necessarily deliver public health benefits. In many instances, putative benefits are argued by product proponents to justify or counterbalance the potential for new risks, despite potential benefits rarely being subject to the same kind of scrutiny and scepticism to which claims of potential risks are subject. Friends of the Earth Australia therefore supports the recommendations of Wynne and Felt[59] for the inclusion of a social benefit test, supplementing the more usual investigations into efficacy, safety and environmental risk, as part of the regulation of nanotechnology in food and agriculture.

Assess specifically the potential for nanotechnology to further globalise agriculture and food production and trade and to erode efforts to relocalise food production to address food sovereignty.

Nanotechnology in food and agriculture is emerging at a time when global food systems are under unprecedented stress. Friends of the Earth suggests that by entrenching our dependence on the industrialised, export-oriented agricultural system and the chemical and technology "treadmills" that underpin it, nanotechnology is likely to exacerbate the problems that caused the current global food crisis.

Recognition by governments, industry and inter-governmental forums of the right of small scale farmers to control food production to meet local food needs,—"food sovereignty"—has been a key demand from farming and peasant communities[60]. Around 75 percent of the world's hungry people live in rural areas in poor countries. If rural communities can meet more of their own food needs via local production, they will clearly be less vulnerable to global price and supply fluctuations. La Via Campesina's has argued that: "Small-scale

family farming is a protection against hunger!"[61] This view was supported by the four year International Assessment of Agricultural Science and Technology for Development which emphasised that to redress rural poverty and hunger, a key focus of agricultural policy must be empowering small scale farmers to meet their own food needs[62].

The potential role of new technologies in responding to the global food crisis is controversial. As with genetically engineered (GE) crops, proponents have argued that nanotechnology will redress food shortages by promoting greater agricultural productivity. However the recent IAASTD report notes that whereas GE crops have had highly variable yields, they have also had negative broader economic consequences for farmers by concentrating ownership in agricultural resources and introducing new liabilities for farmers[63]. Similarly, Friends of the Earth suggests that nano-agriculture is not required to achieve strong yields, but will add to the capital costs faced by small farmers and increase their reliance on technology, seed and chemicals sold by a small number of global agri-business companies.

By underpinning the next wave of technological transformation of the global agriculture and food industry, nanotechnology appears likely to further expand the market share of major agrochemical and seed companies, food processors and food retailers to the detriment of small operators[64]. Nano-encapsulated pesticides, fertilisers and plant growth treatments designed to release their active ingredients in response to environmental triggers, used in conjunction with nano-enabled remote farm surveillance systems, could enable even larger areas of cropland to be farmed by even fewer people[65]. By dramatically increasing efficiency and uniformity of farming, it appears likely that nano-farming technologies could accelerate expansion of industrial-scale, export oriented agricultural production which employs even fewer workers but relies on increasingly sophisticated technological support systems that have increasing capital costs. Such systems could commodify the knowledge and skills associated with food production gained over thousands of years and embed it into proprietary nanotechnologies. It could also result in the further loss of small scale farmers and further disconnection of rural communities from food production, undermining efforts to achieve sustainable, relocalised food production.

Defending and reinvigorating sustainable small-scale farming requires action by governments to support agriculture that prioritises food production for local populations. This requires land reform, including control over and access to water, seed, credits and appropriate technology. It also requires the removal of trade policies and financial subsidies that preference industrial-scale farming for export or that promote the adoption of technologies or farming practices that will undermine the viability of small-scale farming.

Assess specifically the potential for nanotechnology to promote greater consumption of highly processed foods in preference to minimally processed fruit and vegetables and its implications for public health.

Nanotechnology is likely to influence the eating habits of urban consumers, with associated public health and cultural implications. By enabling manufacturers to promote nano-reconstituted, nano-fortified or nano-packaged foods as delivering superior health benefits, hygiene or convenience, it is likely that nanotechnology will encourage even greater consumption of highly processed foods at the expense of minimally processed fruits and vegetables. Beyond the need to ensure the safety of nanofood additives, it is also useful to question whether or not fortifying food with nano nutrients is actually desirable from a public health perspective. There is a growing number of manufacturers prepared to claim that their nano-fortified beverages or foods will meet a large part, or even the entirety, of an individual's dietary needs. For example Toddler Health's range of fortified chocolate and vanilla "nutritional drinks", which include 300nm particles of SunActive® iron, is marketed as "an all-natural balanced nutritional drink for children from 13 months to five years. One serving of Toddler Health helps little ones meet their daily requirements for vitamins, minerals and protein"[66]. Yet no matter how fortified, nanofoods cannot substitute for the nutritional value of a diet based on a variety of fresh, minimally processed foods. There is a real possibility that the promotion of nano-fortified foods could be one factor in people eating less fruit and vegetables, with associated negative public health outcomes.

By extending the shelf life of "fresh" and processed foods, it is also likely that nanotechnology will further promote the eating of foods out of season and far from the place of their production. In this way, nanotechnology may further erode the relationship that exists (or once existed) between consumers and producers of foods, as well as peoples' cultural connection to traditional and minimally processed whole foods. The development of a cola drink that could be marketed as having the nutritional properties of milk is a case in point[67]. With the increasing use of nanotechnology to alter the nutritional properties of processed foods, we could soon be left with no capacity to understand the health values of foods, other than their marketing claims.

Recognise explicitly the right of the public to reject nanotechnology's use in food and agriculture

There is an urgent need for regulatory systems capable of managing the many new risks associated with nanofoods and the use of nanotechnology in agriculture. Alongside managing nanotoxicity risks, governments must also respond to nanotechnology's broader social, economic, civil liberties and ethical challenges. To ensure democratic control of these new technologies in the important area of food and agriculture, public involvement in nanotechnology decision making is essential.

Mandatory labelling of all nanofoods is required to enable people to make an informed choice about whether or not to eat them. However beyond the need for labelling to enable informed purchasing choices, the public must be given the opportunity to be involved in decision making about the use of nanotechnology in the food and agriculture sector. Given the significant implications of nanotechnology for our relationship with food and agriculture, and for food producing communities worldwide, we call for public involvement in all aspects of decision making, including the right to say no to nanofoods.

Develop mechanisms for meaningful involvement of the public in nanotechnology policy and decision making.

Public awareness about nanotechnology remains very low. However, early surveys show that once given information about nanotechnology, people do not want to eat nanofoods or foods wrapped in packaging that contains manufactured nanomaterials. Public engagement initiatives and experimental studies suggest that once provided with information about nanotechnology, the public is concerned about many of the same issues identified in relation to GE food: a lack of transparency, a lack of choice about exposure, risks to health and the environment, unfair distribution of risks and benefits, a lack of socially useful applications and a lack of public participation in decision making[68]. The significant challenges of a powerful, transformative and controversial technology demand a reciprocal significant government investment in the establishment of new mechanisms for meaningful involvement of the public in nanotechnology policy and development, the allocation of research priorities for public funding and the establishment of governance measures. We commend wholeheartedly the establishment of this consultation process, but it must be recognised explicitly that the public interest issues associated with nanotechnology's use in food and agriculture go far beyond those associated with risk assessment, and a far greater involvement of the public in decision making in this area are required.

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March 2009

Examination of Witnesses

Witnesses: Ms Sue Davies, Which?, Professor Vyvyan Howard, Soil Association and Ms Georgia Miller, Friends of the Earth Australia (via video link), examined.

Q278 ***Chairman:*** Good morning, I would like to welcome the two witnesses we have in the room, Sue Davies from Which? and Professor Vyvyan Howard, representing the Soil Association but also to welcome Georgia Miller who is joining us by video link from Australia and she represents Friends of the Earth Australia. I would also like to remind the witnesses and members of the Committee that the proceedings are being webcast and also that the information note available for members of the public—who are also very welcome in this session—sets out the declared interests of members of the Committee so they will not be repeated whilst asking questions. In welcoming our witnesses to this fifth public hearing of our inquiry into nanotechnologies and food I would like to invite each of you in turn to introduce yourselves for the record and at that same time if there is anything you would like to say by way of brief introduction before we move to the questioning then this is your opportunity. I would also like to emphasise that given that we are working with a video link the sound quality is very good but there is a slight delay between what we say and what Georgia hears and likewise in the other direction, so please remember to speak slowly and to pause if necessary for Georgia's response to come through. May I now invite the witnesses, starting with Sue Davies, to introduce yourselves?
Ms Davies: Thank you very much and thank you for the opportunity to come and give evidence to you today. I am Sue Davies and I am Chief Policy Advisor at Which?, the consumer organisation, where I work mainly on food issues. Which?—in case you are not aware—is an independent not-for-profit consumer organisation that campaigns on a range of issues on behalf of all consumers and we are funded through the sale of our consumer information, so *Which?* magazine, *Good Food Guide*, *Which? Online*. This is an issue that we have been looking at in quite a bit of detail over the last couple of years because we recognise that nanotechnologies offer a lot of benefits for consumers but they also raise potential risks, and so we want to make sure that they are developed in a responsible way so that consumers can take advantage of them but not unnecessarily be put at risk.

Q279 ***Chairman:*** Thank you. Professor Howard?
Professor Howard: Thank you very much for the opportunity to come here today. My name is Vyvyan Howard; I am a medical doctor, pathologist and I specialise in toxicology, I am Professor of Bioimaging at the University of Ulster. I have just finished six years serving on the Advisory Committee for Pesticides. I have sat on two European expert panels concerning nanotoxicology; I am in receipt of two EU grants to investigate the toxicology of nanoparticles. I also gave scientific evidence to the Soil Association for their consideration in the preparation of their report. I think we will be talking about the specifics of it later, but those are the main things.

Q280 ***Chairman:*** Thank you very much. Georgia, would you like to introduce yourself?
Ms Miller: Thank you. My name is Georgia Miller. I have coordinated Friends of the Earth Australia's nanotechnology project since 2005 and the application of nanotechnology in food and agriculture is something we are very much interested in. Last year I was one of the two primary authors of an international Friends of the Earth report in relation to nanotechnology in food and agriculture. I guess that there are four key things that I am hoping we can talk about in this session. The first is really the scope and I want to suggest that we are looking at more than a question of food safety, we are actually looking at quite a broad issue of food policy. The

second is the need for precautionary management given how little we know both about risks and also how to assess those risks. The third is the need to really critically assess claimed benefits because I want to suggest that many of these benefits actually come with significant costs. The fourth is the need for public involvement in decision making which I understand will be addressed in some of the questions later.

Q281 ***Chairman:*** Thank you very much. That is a very helpful introduction from all of our witnesses. I would now like to kick off with opening the questioning myself and I would like to ask each of the witnesses what you feel are the potential benefits as well as the risks related to nanotechnologies and nanomaterials in food, either in food itself or in relation to packaging. You have all expressed views about this in your evidence but I would like to hear now a summary of your position.
Ms Davies: I think one of the difficult issues in this area is that it is hard to get a sense of exactly what is happening now and what could be happening in the future in order to determine whether or not there are products that are going to offer real consumer benefits. From looking at some of the discussions in the scientific press and some of the food technology literature it seems that there is a lot of potential for things like improved nutritional characteristics, improved sensory qualities, potentially less waste in terms of improved packaging, better food safety; there are a whole range of potential benefits that could be offered by nanotechnologies. However, our concern is that it is quite difficult to work out exactly what we are going to be seeing and over what timescale. It would be nice to have a clear idea of what is on the market now and have a sense of what is going to be here in five years, ten years, 20 years and what kind of issues are those going to raise. We do think that it seems there are going to be some genuine benefits but we also think there needs to be a more proactive approach to actually make sure that the investment is really going into tackling the problems we are facing in terms of food policy. How can nanotechnology be used to help tackle obesity and diet-related disease, improve food safety, reduce the environmental impact of food production? There is not really enough transparency or enough open discussion at the moment about what is being done and what could come along. If you look at the Nanoshop website or you look at the Woodrow Wilson website, which seems to be the main source of information about nanofoods, most of the developments to start with are in the food supplement area which are making claims about improved bioavailability or absorption of nutrients, or packaging materials (EFSA has already approved one type of packaging material, for example). That seems to be where the main interest is at the moment and it seems that there could be benefits, certainly in the case of packaging materials, but we are concerned that we want to make sure that these are genuine benefits and that consumers, as Georgia said, are not being duped into buying things at the moment that are not really offering any benefits beyond conventional products and paying more for it. Of course this all needs to be balanced against the risks. Do you want to come on to the discussion about the risks now?

Q282 ***Chairman:*** If you could briefly way what you think the main issues are about risk then we will cover it in a bit more detail later.
Ms Davies: The interesting thing in this area is that the people who are really excited about this technology are also really open about the fact that there is an awful lot that we do not know about it at the moment; precisely the reason why nanotechnologies are going to offer lots of new benefits because of the change in properties of materials could also bring new risks that we do not fully understand. The recent EFSA opinion on this, for example, highlights that there are some really key knowledge gaps in different areas that need to be addressed urgently. We think that we need to have a clearer sense of what products are coming along so that we can get a sense of what are the benefits and what will be really useful for consumers, but also we need to get a sense of what is being developed now so that we can properly understand what kind of risks they could be posing and make sure that we have adequate regulation in place as well.

Q283 ***Chairman:*** Thank you. Professor Howard?
Professor Howard: I want to highlight some of the knowledge gaps and areas of potential hazard. Under Framework Seven of the EU Programme there are 1.4 billion euros earmarked for nanotechnology but every project must have a safety aspect to it. The two grants that we have so far total 5.7 million euros. There are also targeted funds from research councils in the UK so there is certainly an awareness that we need to know more. Indeed I and other colleagues around the world are trying to do that. There are two basic questions. One is, if you have a nano-product—a particle in a food substance—where does it get to and how long does it stay there? That is question number one and in a way that is one of the easier questions to address. The second question is, does it matter if it does get there and stay there that long? That is actually much more difficult to appraise. I think we have to think about the nature of food. If you consider how much we spend on doing toxicological testing of pharmaceuticals and agro-chemicals, where we

might expect to be exposed over a lifetime to micrograms or milligrams, our consumption of food is measured in tons over a lifetime. So the potential dosage is extremely high and I think that does mean that we have to take a precautionary stand. The main area that I am worried about is that if you nanonise materials into mobile nanoparticles they become more mobile within the body. The reason for that is that there are processes going on in the cell walls which are continuous and it is the way that viruses get round it, it is a process called endocytosis. There are quite a few studies on this—Wolfgang Kreyling has done a lot of work in this field—which show that if you do expose animals or humans to nanoparticles they will travel and they will get across places like the blood-brain barrier where we have evolved methods of keeping out molecules that we do not want. So they can act as a sort of "Trojan horse". Which particular spectrum of disease do we need to think about most? Well, there are a series of diseases called protein misfolding diseases. Most of them occur in the central nervous system; there are 42 known in humans currently (including Alzheimer's, Parkinson's disease, spongiform encephalopathy). Nerve cells cannot reproduce themselves; they have to internalise any misfolded protein that is insoluble and some of these fragments can be toxic. The worry would be that if we are exposing ourselves to large doses of nanomaterials and they are able to get into areas like the brain, they might be able to increase the rate of protein misfolding and that is what our second grant is all about. We are actually studying that now.

Q284 ***Chairman:*** I wonder, because we are short of time, if you could keep it pretty succinct. We can always follow up with more detailed supplementary evidence.
Professor Howard: I think that is the main point I want to make, that it is chronic long-term pathology which may be rather more worrying than short-term toxicity.

Q285 ***Chairman:*** What about potential benefits? Do you see any benefits?
Professor Howard: I think Sue has already mentioned those: a cut in waste, a cut in bacterial contamination; those sorts of things.

Q286 ***Chairman:*** Georgia, would you like to comment on the potential benefits and risks?
Ms Miller: Vyvyan has just talked in some detail about potential risks and I saw the excellent presentation that the nanotoxicologists made to you a month ago, so I do not want to talk in great detail about the risks. I do want to observe that the uncertainties around nanocharacterisation and risk assessment are so great that experts anticipate that it will take us years before we can actually do a validated risk assessment, that is until we know the right questions to ask, the right tests to do. I find this very concerning so that is one thing I do want to draw to your attention. I guess the other thing that I am concerned about is the size definition. Again I heard a recurring theme when the nanotoxicologists gave evidence to you a month ago that 100 nanometers really does not capture biologically relevant nanoparticles that may be 200 or 300 nanometers in size, so I think that is something we are also concerned about. In relation to the so-called benefits, I really want to challenge the notion that widespread use of antibacterials, for example in packaging, will deliver socially useful outcomes. This is for a couple of reasons. We are very concerned that widespread use of potent antibacterials in the form of nanomaterials could actually cause a lot of unanticipated problems. We are already suffering massive problems with bacterial resistance to antibiotics in a medical setting. There is some emerging evidence that use of silver in a medical setting is also being met with resistance. What are the implications of the widespread use of nano-antibacterials in food packaging, in refrigerators, in storage containers, as well as in socks and computer keyboards and dishwashers et cetera? I think there are some very real challenges here that we need to deal with. While we do not think any illness as a result of food contamination is ever acceptable, I emphasise that in the UK there is 50 times greater illness as a result of poor diet than as a result of safety problems. I think we need to ask: will nanotechnology as a whole result, for example, in greater consumption of highly processed food and less consumption of fruit and vegetables? Will the addition of nano-additives to junk foods enable them to be marketed for health values, for example increased nano-encapsulated omega-3 or iron fortification? Will this perhaps further confuse people and lead to a further loss in terms of people's diet choices? If the answers to those things are "Yes" then it is possible that nano will actually result in poorer health outcomes. I do think we need to query a lot of these claimed benefits, really interrogate them, rather than just accepting them at face value.

Q287 ***Chairman:*** Thank you very much. I just want to ask one supplementary question here. I think that Friends of the Earth Australia as well as the Soil Association are calling for a moratorium on the sale of nano-foods whereas I think Which? has not called for a moratorium. I wonder if Sue could indicate from the point of view of Which? why you do not think a moratorium is necessary, and then I will ask

Vyvyan and Georgia briefly to say why they think a moratorium is necessary.
Ms Davies: I suppose our focus has been much more on understanding what developments are taking place and could be taking place, making sure that we have an effective regulatory framework in place, making sure that nanomaterials have to be approved before they come to market and that we have enough research to enable effective risk assessment to be able to carry that out. We do not really think that a moratorium is very meaningful. We have issues around definition, it is very difficult to find out what is actually happening, so even if we thought that a moratorium was useful we do not understand how it would practically be enforced and applied.

Q288 ***Chairman:*** Professor Howard, could you briefly indicate why you think a moratorium is necessary?
Professor Howard: Data gaps have already been mentioned and we find it very difficult to construct a meaningful risk assessment given the level of data gaps that we have in most areas of nanoparticle fate and toxicity. Given the potential dose that people would be receiving in food, the Soil Association has come to the conclusion that they would prefer to see a hold on development while some form of risk assessment can be developed.

Q289 ***Chairman:*** Would that apply to naturally occurring as well as engineered nanoparticles?
Professor Howard: I think that applies mainly to engineered nanoparticles, things that we have not encountered hitherto during our evolutionary history.

Q290 ***Chairman:*** Georgia, very briefly, reading the evidence from Friends of the Earth Australia, you wish to broaden the definition of nanotechnologies in food to include both engineered and naturally occurring nanoparticles. That is as I understand it; is that correct or not?
Ms Miller: No, that is not correct. What we have suggested in terms of broadening the definition is that we consider, for the purposes of health and safety assessment, particles up to 300 nanometers in size as nanoparticles and I believe there is good reason given the evidence that a number of particles that are around 200 nanometers or so in size are still, for example, showing protein binding characteristics that Vyvyan referred to earlier as a cause for concern. We have focused specifically on the issue of manufactured nanoparticles and manufactured nano-additives to food. We do highlight the issue of nanoparticles which are in a sense a by-product of contemporary high intensity processing technologies as an area which does warrant further investigation, but we have not called for a moratorium to extend to those sorts of nanoparticles.

Q291 ***Lord Haskel:*** Of course our relationship with the European Union is very important and central to this. The European Parliament has proposed that when the Novel Foods regulation is revised it should explicitly apply to all nanomaterials; it does not differentiate. Do you think the government should accept this advice?
Ms Davies: We think that a distinction does need to be made between manufactured nanomaterials and the types of nanomaterials that have been traditionally used and may use nanotechnology, so things like custard or mayonnaise for example that have been around, not to say that these are inevitably risk free. We think that manufactured nanomaterials should be the focus of the Novel Foods regulation. We think that the definition that was proposed by the European Parliament which talks about in the order of one to 100 nanometers is probably quite useful but you need to be careful about being too strict about definitions because there is still an awful lot that we do not understand and some people are asking whether we should be talking of up to 300 nanometers for example and the surface area is obviously a crucial aspect and how do you take that into account. The proposal from the Commission takes into account the advice from the European Food Safety Authority. We think it should be focused on the manufactured nanomaterials but it is also important to look at other pieces of regulation as well as the Novel Foods regulation to make sure that they are fit for purpose as well. The European Commission has said that it feels that under the food additives legislation, for example, if something was in nano form it would have to be reassessed and, even if its conventional form had already been approved, it would have to be resubmitted and approved again. Similarly with food supplements, if you are using vitamins and minerals in a nano form they would have to be submitted. There is a lack of clarity in the regulations and with the associated guidance that all needs sorting out at the moment and we are concerned, about how you can you be sure that people who are potentially looking at producing these types of products actually understand what applies to them and what route they need to go through, and whether the enforcement people on the ground, the trading standards officers understand. It is hard to believe that looking at whether people are using nanomaterials is a particular priority at the moment given all the things that trading standards or environment health officers are looking at. We

think the Novel Foods regulation needs to be focused but it needs to be broad enough to take account of all manufactured nanomaterials. But we also need to focus on the other pieces of legislation that may be relevant to make sure that they take account of the unique properties of nanomaterials. It is no good just having it in the legislation; you need to make sure that the people on the ground actually understand what the implications are as well.

Professor Howard: I approach these problems by saying that if we have been exposed to something throughout our evolutionary history it is quite likely that we are going to be adapted to it and be able to cope with it. When something is brand new—you only have to look at some of the chemicals that we have created that bio-accumulate and persist and have hormone-disrupting capabilities—you have to take a precautionary stance and then look at where it might have unforeseen effects and do a proper risk assessment.

Lord Crickhowell: I have one question which I think does arise from regulation and the re-examining of regulation. I would be interested to hear Georgia's comments. We have been talking entirely about food but she referred to agro-chemicals and I do wonder whether included in her concerns are fertilizers and agro-chemicals. I would like to know whether this is part of the package or not.

Q292 ***Chairman:*** Georgia, would you like to comment both on the European regulation but also particularly whether you think we should be concerned about the use of nanotechnologies in fertilizers and pesticides, agro-chemicals?

Ms Miller: It was not my understanding that the new European Parliament's suggested amendments were to encompass naturally occurring nanoparticles so I do not want to comment specifically on that because that was not my understanding. I do agree with both Sue and Vyvyan that we need to focus our attention on intentionally manufactured nanomaterials which are novel materials to which we have no history of exposure. I do want to emphasise though that where manufacturers are intentionally producing nano-scale micelles or using nano delivery systems for active ingredients this may introduce new issues and so we should consider those as intentionally manufactured nanomaterials where there are intentionally putting active ingredients, for example, into 30 nanometer micelles; there may be a biological implication there. On the issue of whether we should also be looking at nano formulated agricultural pesticides and fertilizers, yes I believe we should. I think we need to engage with some of the broader framing which is going on. When we read some of the predicted uses to which nanotechnology will be put in agriculture the vision is really quite broad and encompassing, whether it is nano-automated farm systems or whether it is the use of smart interactive nano-encapsulated pesticides and fertilizers, or whether it is the use of nanoparticles to extend the reach of genetic engineering in seed manipulation. There is a broad range of proposed uses for nanotechnology in the agricultural context and I think these are very relevant to a discussion of nanotechnology in food.

Q293 ***Lord Haskel:*** How practical is it to engage in this differentiation? For instance, we modify existing natural products into nanoparticles; are those manufactured and engineered or are those natural products? It seems to me that we are approaching a regulatory minefield here.

Ms Miller: I think it is confusing so the approach we have taken is to focus very squarely on intentionally manufactured nano ingredients and additives, not so much to look at how nano science is informing our historical use of emulsions and production of emulsions but rather to look at things like nanoscale zinc which is being intentionally put in as a food additive or nanoscale silver which is being added to food packaging or whatever it is; to look very clearly at those intentionally manufactured nanomaterials. Having made that distinction and focusing very squarely on that range, people are going to a lot of trouble and expense to actually produce these things in nano form and then to put them into food or food packaging. We then recognise that there is a need to actually look at the things which are, for example, by-products of modern food processing technologies. We are not including these in our call for a moratorium and we are not suggesting even that they be addressed by the regulatory system, but we are recognising that contemporary food processing technologies do generate a lot of foods which have nano fragments, nanoscale emulsions within them. I think it behoves us to ask: is there any public health implication there? I do think that if we all focus very clearly on the intentionally manufactured nanomaterials both for regulatory purposes and for the purposes of this inquiry I think we will be better off.

Professor Howard: I think that if you take a natural product and you treat it in some way by, say, encapsulating it, and you change its dynamics from the way it normally behaves, that is the time you have to look. Just harping back for a second to pesticides, as I said before I have just finished six years on the Advisory Committee for Pesticides which is where risk assessment for pesticides is done, and they can see this nano revolution coming. I did flag it up a couple of years ago and I think they are considering maybe getting someone on that Committee who has expertise in the field to maybe

be able to put some input; they are certainly going to need it.

Q294 ***Chairman:*** Before moving on to ask Lord O'Neill to introduce the next question, could I just try to nail this question of definition and what your concern is. We have heard from the expert toxicologists in previous sessions that their concern is particles that are persistent or have particular functionality or reactivity in the body on a nanoscale, not whether they are manufactured or natural. You seem to be focusing on manufactured versus natural as opposed to persistence and reactivity or functionality. Could I just be absolutely clear where you think the critical issue lies?
Professor Howard: Persistence for how long is a good question. Clearly if they are metal nanomaterials they may persist for years but if you look at what the pharmaceutical companies are doing they are using microsomes to encapsulate drugs to increase penetration to the brain. There is a lot of research going on; it is a difficult place to get drugs but they find that if they use micro-encapsulation techniques they can increase penetration of the blood-brain barrier. That has to tell us something about what will happen in food products and if there are things that do not normally go there they may only have a half life in the body of somewhere around half an hour to an hour, but if you are taking in a very large dose of those there may be significant penetration. It really depends on what you mean by persistence and what it means for that particular set of particles. I do agree in general that long-lived metallic nanoparticles are things that we have to be very careful about.

Q295 ***Chairman:*** Georgia, did you want to add anything on that because you have quite a broad ranging definition in your evidence?
Ms Miller: I did not actually see that distinction in the evidence that the nanotoxicologists gave you; I did not see them suggesting that we encompass naturally occurring nanomaterials in the sort of dialogue that we are having right now. In fact it seemed to me that they were talking about their concern about nanomaterials to which we do not actually have a long history of exposure. However, I do agree that persistence and functionality are obviously going to have biological implications for the impacts that nanomaterials may have when introduced to our bodies. The thing that concerns me is that when we talk about persistence that presupposes a level of knowledge about the biological behaviour of nanomaterials that we just do not have. I think that is one of the reasons that we have made this strong emphasis on focusing on intentionally manufactured nanomaterials because these are things which we are producing in this very tiny form and, as Vyvyan says, sometimes in this very tiny form there are unique biological availability and behavioural characteristics of these materials. I do think it is useful to focus on manufactured nanomaterials and I would include in manufactured nanomaterials things which have been nano-encapsulated for the purposes of altering their bioavailability or their behaviour in the body. I do think there is a danger in defining nanomaterials by biopersistence when we have so little understanding of their biological behaviours.

Q296 ***Lord O'Neill of Clackmannan:*** Perhaps I could come back to Vyvyan Howard. We have been talking about problems of definition and we have been saying that there are categories in which there is a reasonable degree of consensus, but then when it comes to issues of control you would apparently favour, as it were, a one size catches all approach; you would favour the generic approach rather than a case by case element of control. Could you perhaps say how that sits alongside the categorisations which you have been groping towards in the previous questions?
Professor Howard: I feel there are many generic aspects to this. Clearly size is something which is associated with mobility, whatever the material. If you consider the amount of money that is being pumped into grants for labs like Ken Donaldson's (who was here) and my own to actually look into these generic problems where we have vast areas of ignorance and are trying to find out the way they perform and what the consequences are likely to be, I think to ask individual manufacturers to go and do that level of research is going to be impossible for them really, it is much too expensive and they would not have the expertise. My feeling is that we need to fill in some of these boxes in the hazard assessment of these materials so that we can start to categorise them and know that this size range looks as if it is relatively safe or this size range is to be avoided because it gets to certain places. I think there is a lot more spade work to be done before we start to put the onus on manufacturers.

Q297 ***Lord O'Neill of Clackmannan:*** Are there difficulties or dangers implied in a box ticking exercise which does not get behind the questions in quite the way that the safety considerations that we all have would seem to require addressing?
Professor Howard: In 2004 I sat on a committee which met in DG SANCO and as part of that exercise we tried to construct a comparative hazard assessment with hazard triggers (which can be done with pesticides where there is a lot of toxicological information; you can actually make a sensible stab at it) and all the boxes that we made for hazard triggers we realised very rapidly were unknown; we

did not know the answers. That is the main thrust of the research that is going on now, to try to actually get that knowledge so that we can attempt a meaningful risk assessment, but we are not there at the minute. It is a very expensive avenue of research; it requires extremely expensive instruments (electron microscopes and things like that). My feeling is that we are at the stage still where we want to learn more before we potentially expose a population to high dose.

Q298 ***Lord Cunningham of Felling:*** I address my question to all three witnesses, if I may. What would be the merits of a register of nano-derived foods and food contact materials as part of a comprehensive regulatory framework?
Ms Davies: We think it is something that is essential because at the moment—I think for the last few years—we seem to have been going around in circles where it is very difficult to get a sense of exactly what is happening in this area. A few years ago there was a lot of talk, as we put in our written evidence, in some of the food technology press about all the potential applications and research that was going on, that leading food companies were conducting, but now the food industry says that in general it is not using nanomaterials in its products. If you look on the internet you will find various products: you will find cooking oil, you will find food supplements that are on sale coming from different countries claiming to be using nanomaterials. It also seems that some of the kind of intermediaries like the chemical manufacturers are also producing some food additives that are produced in nano form. It is very difficult to get a sense of exactly what is on the market. We think the regulators—mainly the Food Standards Agency—need to be much more proactive in actually going out and seeking the information and finding out what is happening in this area, including talking to the chemical companies who are producing food additives or food pesticides and understanding exactly how much they are producing and who they are supplying to. We also think there needs to be a requirement that you should register if you are going to use manufactured nanomaterials in your products and that should apply to food but should also apply across the board in relation to nanotechnologies and nanomaterials.

Q299 ***Lord Cunningham of Felling:*** Do you think the FSA is the appropriate regulatory body?
Ms Davies: For food definitely and we think it should be mandatory because, as I am sure you know, Defra has had this voluntary reporting scheme that was launched over two years ago and has only had 11 submissions on a voluntary basis. I think it has to be mandatory but you also need to think carefully about what the information requirements are so that companies are not put off by something that is incredibly onerous and complicated to fill in but gives the regulator the key information that they can then follow up if they need to.

Q300 ***Lord Cunningham of Felling:*** What about consumers being put off if it became a sort of black list?
Ms Davies: We do not think that would be the case. The danger is more in not being open about what is happening in relation to nanotechnologies. We conducted a citizens' panel at the end of 2007 where we wanted to get a sense of what consumers thought about the use of nanotechnologies, not just in the food area but also in relation to medicines and cosmetics and other consumer products. People were not against it, if anything they were surprised it was happening because nobody had heard about nanotechnologies at all before they came along to the citizens' panel. Some people were obviously more excited than others but people were interested in it and felt that you should be open about it. I think the danger is that if you are not open about it at this early stage people will wonder why we have been hiding something and then think there is something suspicious going on.

Q301 ***Lord Cunningham of Felling:*** Professor Howard?
Professor Howard: I agree.

Q302 ***Lord Cunningham of Felling:*** What about Georgia?
Ms Miller: We also support a mandatory register. I do agree with Sue that the information required for something like that should not be too burdensome but at the same time we need to make sure that we have information that actually enables us to compare apples with apples. For example, it is not much good if someone just says that they are using nano-titanium dioxide and we do not know what shape, what size, what surface coating. We need to make sure that it is sufficiently detailed and enables rapid comparison of different known materials in use. However, I would just say this, if you are concerned about the public concern about the use of certain nanomaterials in food to be such that it did serve as a black list, I do not think that is a reason not to pursue this initiative. I think one of the things that comes through really clearly in the early public engagement around nanotechnology is that this is the most sensitive area of nanotechnology application. People feel strongly about food and should people, particularly given the early warning signs of risk and the huge safety gaps, choose not to buy food that contains manufactured

nanomaterials then I would say that is their right and that is something that the government should reassure them on. That it will enable them to exercise that right because, as Sue said, I think the worse thing that could happen at the moment is that people feel they do not have access to relevant information and that is a cause for future concern.

Q303 ***Lord Cunningham of Felling:*** What are the implications then of having such a mandatory register in one country but not in others?
Ms Miller: I would suggest that countries everywhere at the moment are actually looking at these issues. For example, Canada has already announced a mandatory register of all companies who used a kilo or more of nanomaterials last year; they will have to provide information on the nanomaterials but also on the safety data they have. France has announced its intention to do something similar. There are calls in Australia from the unions for mandatory notification to workers. This is something that countries around the world are having to deal with right now. I do note in the recent proposals from the European Parliament they are suggesting that nanomaterials should not be permitted in foods without mandatory labelling on the product. That is something that we would support too.

Q304 ***Chairman:*** Can I just ask a mini-supplementary to that to you, Georgia, since you have a good knowledge of the international situation. What is going on in China?
Ms Miller: That is a good question because of course people have very limited information about what is going on in China and I would suggest that we have very limited information about what is going on in many parts of the world. I think there are serious language gaps and I also think there are serious deficiencies in governments relying so heavily on the OECD as the primary vehicle for communication about risk research and policy responses because a lot of the world is not represented in OECD and a lot of the OECD's communication is happening exclusively in English. I think we are faced with some very serious challenges.

Q305 ***Lord Methuen:*** You have all mentioned in your evidence the need to take into account the public and society's interests and views when considering the future of nanotechnologies in the food sector. I think we all want to avoid a situation like the GM food fiasco. Could you expand on what you think these views and interests might be, and what government mechanisms should be considered as part of any approval process?
Ms Davies: I think that the interests are quite broad ranging and it is really going to depend on the particular applications, so it kind of comes back again to the point about getting a clearer understanding of what is happening now and what we could be seeing over the next few years as well in order to have a proper understanding of what the issues are that could be raised. The obvious concern is about safety and making sure that products are not coming onto the market that could raise unacceptable levels of risk. There are issues around the sorts of claims that products are making and making sure that consumers can have confidence in them and that they are not mislead. For some products it may be that they will raise broader ethical concerns that people may have concerns about and may want to avoid for those reasons, but it is very difficult at the moment in these early stages to understand exactly what the breadth of concerns could be. We think it is important to engage with the public at this early stage but to try to actually talk about the potential applications that could be coming along to get a sense of how people would react to them. Ultimately I think you need to have much clearer information in order to actually look at it on a more specific basis in order to understand what kind of issues are going to be raised for consumers.
Professor Howard: Certainly from discussions with people who are in the industry, they definitely want to avoid a GMO type scenario so they want to engage stakeholders. I would say that transparency at all levels is the best way forward and I think that is why I and the Soil Association would support mandatory labelling of products as well as this register so that everybody knows what is going on and awareness will be raised through that.
Ms Miller: I think that the report from the UK Nanotechnology Engagement Group is worth a look; it is quite extensive but well indexed. It was published in 2007 after a couple of years of public engagement on nanotechnologies in the UK. Their key findings were that people were concerned about three key areas which were uncertainty and regulation and, in particular, whether or not regulation could deal with uncertainty and keep pace with risk management; the distribution of benefits and risks; and the question of public involvement. They made the point that these are issues that were also of concern during the GM controversy and I would suggest in relation to food a key question is: do we need nano in food? Why should the public accept any new risk at all when a lot of the applications are to improve the aesthetic properties of food or the flow properties of ketchup or to extend the shelf life of food which might be very useful for the food distributor or the food retailer but perhaps be of little use for the consumer?

Why should the public accept new risks? I think these are three key areas that will be of concern to the public and I think perhaps the most challenging is the question of involving the public in decision making about nanotechnology in this very sensitive area. I think that is quite essential.

Q306 ***Lord Haskel:*** Could I just ask Professor Howard, obviously an important part of public engagement is the way all these trials and tests that you have been urging us to carry out are carried out. For instance, are they going to be done on humans or are they going to be done on animals? How is it going to be done? Do you think this is an important part of public engagement? How do you think we tackle that?

Professor Howard: We are not allowed to experiment on humans. The work we are going to do on Alzheimer's, for example, is in a mouse which has got a human Alzheimer gene in it—it is a well-characterised progress of that disease—and we are going to see if we can perturbate the progress of that disease by challenging it with various nanoparticles. That is the basis of the Neuro Nano EU project. When we have finished these studies they will be published in peer review journals and then after that hopefully, if they show anything, will become adopted in policy. That is a problem, in that policy obviously has to lag behind scientific knowledge. The most difficult step in a risk assessment is hazard identification. I can remember a number of us saying four or five years ago, "Well, with nanotubes they might have an asbestos-like activity" and other people said that that was just a theoretical thing, there was no evidence of that. Now we have two papers which give an indication that there might be a grain of truth in that. With these long term degenerative diseases—the protein misfolding diseases—we have the knowledge to say that that could be biologically plausible. We need to investigate it and assess it I think before we start dosing people. That is my feeling. I think all these things will feed into that risk assessment eventually.

Q307 ***Earl of Selborne:*** I would like to continue this theme about public engagement. I would like to ask you all how you structure this public engagement dialogue. Clearly in the absence of concrete examples of nano food products the debate has to be at a fairly fundamental level. How do you engage the public in what many of us would see as a rather hypothetical exercise? Does the government have a role? Does industry lead? What role should consumer associations play? Perhaps Georgia could give us her views first on how you structure such a public engagement dialogue.

Ms Miller: The first thing I would say is that before talking about how one does effective public dialogue (which is usually the focus of discussions in the social science literature and elsewhere), I think the primary question to ask is why. Unless the government is in a situation where it is prepared to really commit to taking on board findings, not to being led by them but certainly being informed by them and really committing to integrate the outcomes of public dialogue in its own process of policy development, then I would suggest that public engagement is actually of little value. I think that key question must be answered first: why? What are the objectives and what are the constraints and to be really clear about that. Secondly I would suggest there is an effective role for stakeholders such as consumers' advocacy organisations and other groups. I would suggest that there should be a broad range of community as well as industry, research and government stakeholders involved in dialogue together, but I do think that ultimately you need to hear what the general public think. There are a number of different ways that you can use deliberative models to actually resource random groups representing members of the public to consider various issues and I am sure you have all encountered different forms of consensus conferences or citizens' juries or what have you, but I would suggest that what you actually need is an oversight group which comprises stakeholders and government members and public participation practitioners to sit down once you have worked out what the goal of the objective is and to develop a programme that contains a variety of activities that has a discrete start and end point and it gives you some basis on which to start. I think that would be quite useful.

Q308 ***Baroness Neuberger:*** Can I just follow that up with Georgia because I thought that was really interesting. You are saying that if government is not prepared to take what comes out of such public engagement seriously there probably is not a lot of point in doing it. If I were to suggest to you that even if government were not that interested maybe manufacturers and consumer groups would be, then would it not be worth doing even if government were not going to incorporate it into policy but maybe consumer groups and manufacturers would and maybe that has a value in itself?

Ms Miller: I think it is certainly true to observe that of the many public dialogue activities which have been carried out to date and which have not resulted in any observable change to government policy, they have nonetheless had a value. I think that is certainly true and it is important to say that they have helped add to our understanding of what members of the public think about these issues, they

have certainly been valuable for the groups who participated. However, I guess my point is really that for the government to back a public dialogue programme on this issue it would be of limited use if it is not seen to be genuine, so to have a genuine commitment to a two-way dialogue not just to, in a sense, engage for the sake of engaging without actually wanting to hear.

Q309 ***Chairman:*** Sue, would you like to add anything?
Ms Davies: I would agree with a lot of what Georgia has said and I think there has been a tendency with some of the public engagement that has been done in this area to do it in a very general sense so far and then kind of question the value of it saying, "Well, the public said what they always say about new technologies and it has not really taken us any further forward". I think it is important that you use deliberative techniques and it is as grounded in the potential applications as much as possible, and that there is a commitment to enabling it to feed into policy. It is also important to think about at what stage it actually happens as well and I think a crucial stage is looking at the type of research that is underway at the moment and what the focus of that should be, and understand what the public's views are. There are some interesting examples from the nano-medicine area, for example, where there was a citizens' panel that was held by the EPSRC (the Engineering and Physical Sciences Research Council) which directly fed into their decisions about what research to fund in this area. I think there is a role for public engagement at that kind of stage, but then there also needs to be government-funded research to understand what the public think more specifically in relation to nano-foods. When we did our citizens' panel—obviously there are limitations on what you can do—we found it very helpful to have people coming in and talking from different research associations. We had Vic Morris (who I think has given evidence) and Qasim Chaudhry come and talk about the potential applications and the regulations. It is very interesting how, over three days, the people who had no knowledge and potentially no interest in nanotechnologies at the start of the process became really, really engaged in it and by the end had developed quite sophisticated views on what they thought should be happening and what kind of regulations should be in place.

Q310 ***Chairman:*** Could I just come back to you, Sue, on the point that Georgia made as to why one would want to start a public engagement exercise. Georgia made the point that if government is not going to take any notice of it there is no point in them initiating it, which then Baroness Neuberger put a slightly different slant on. If the government were going to take notice of public engagement, what would that notice consist of? Would it be to ban foods that the public were suspicious of? Or would it be to place public opinion ahead of science? What would the role be?
Ms Davies: I think at this early stage where the debate is about what type of regulation we should have in place, it is to make sure that there is scope to deal with those concerns within the regulation. We talked about the Novel Foods regulation and one of the amendments that was adopted by the European Parliament was that you should have to take into account other legitimate factors, which is obviously a very vague term. As well as the scientific risk assessment there should be this scope within the regulation. If something appears to present very little risk but maybe raises some fundamental ethical concerns, then you have the scope within the regulations to say in certain cases that it is not appropriate to put that onto the market. It is partly about the regulation and it is partly about understanding how far that needs to go in terms of the type of information consumers want about nanotechnology development, but also in terms of shaping the research agenda that government is funding as well as just generally setting out a broader strategy for the way that nanotechnologies should evolve. There are obviously a lot of risks that need to be tackled but there are potential benefits and you need to make sure that it is taken forward in a way that ensures society in general benefits. That is also the purpose of public engagement. I would also agree with the points that were made about industry's role in this. Lord Selborne will know from the development of the Responsible NanoCode that one of the things that was proposed in that context was that industry should have some responsibility for doing some kind of public engagement as it develops products as well. I think one of the lessons from GM—you always have to be careful about comparing this to GM because it is obviously so very different—is that there was a real failure by the people who were developing the technology at the start of the food chain to properly appreciate the issues that were going to be raised at the end of the supply chain when products went on sale and what supermarkets' approaches would be to it as well. I think it is important to try to make sure that the people right at the very start of the food chain are actually understanding what kind of implications and what kind of expectations consumers may have, whether that is about product labelling or whether it is about the types of claims that are made as well.

Q311 ***Lord Mitchell:*** Several organisations, in particular Which?, have suggested that there is a lack of awareness by the general public with respect to nanotechnologies, I think not surprisingly. I think all

of you in your evidence have said in your evidence that products should have labels which talk about the inclusion of nanoparticles in food. I ask the question, given the plethora of information that is already on many food products, whether this is such a good idea.
Ms Davies: I think it is a very difficult issue and it is very difficult while people know very little about the technology. We did a survey in November last year and 45 per cent of people said that they had heard of nanotechnologies—this was a representative sample of the UK—but when we actually asked them about what it meant very few people really understood what it was. I think there is the issue that any labelling has to be provided in the broader context of the need to provide more information to the public about what nanotechnologies are. It is something we asked when we did our citizens' panel just to try to get a sense of what people thought about it and the people who had been exposed to all this information about nanotechnologies for three days said that they definitely thought that they should know whether something was produced using nanotechnology, not for safety reasons (because they thought safety should be a given and you should sort out the regulatory processes and make sure you could do proper risk assessments) but because they thought it was a new development and it was something they would want to know about. They recognised that if we had asked them that on the Thursday before they had come for the weekend and had all this information it would not really have meant very much to them at all. On balance it is important in terms of transparency and it is also important in terms of having traceability not just for the end consumer but also throughout the whole supply chain, but it does need to be done and backed up with much broader information so that consumers understand what it means. I think at the moment we have a bizarre situation—I have brought a product with me—where you do have products on the market that say they are nano but there are other products that are produced using nanotechnology and they are not telling you that they are produced using nanotechnology so you are going to have an incredibly complicated situation. The other thing is that, as you probably know, the cosmetics regulation has recently been reviewed by the EU and within that there is a requirement that ingredients in cosmetics will have to say whether they are produced using nanotechnology or not. If consumers start to become familiar with cosmetic products stating whether or not the ingredients are nano then it would seem very bizarre not to give them that kind of information in relation to food.

Q312 ***Lord Mitchell:*** Do you not think that there is so much information that appears on things that we buy, then to have that on is a degree of overkill? Maybe the solution would be to have an internet site that people could go to to get this information.
Ms Davies: That is often put forward as a solution for labelling problems. I appreciate there is a lot of information on the labels and there is a real move to reduce packing size as well at the moment. However, I think it still excludes an awful lot of people who are not going to actively go to a website and a lot of people want the information at the point when they are making decisions about buying products so I think that means that it should be on the label. If it is put in the ingredients list it is not too onerous. At the end of the day people are choosing to buy a particular product and people are genuinely interested in knowing what the ingredients are and if there are any new types of production processes that have been used in that product. I think it comes back again to getting a clearer picture of exactly what kind of developments are taking place and maybe further down the line there will be some applications that people are not particularly so interested in as others, but I think as a general principle it is important that consumers can have this kind of information.

Q313 ***Chairman:*** I wonder if Georgia would like to add anything to what has been said about labelling.
Ms Miller: I think actually that Sue's point is a really good one, that people may not care so much about labelling when they have not heard very much about nanotechnology but once they become familiar with nanotechnology and its applications, then labelling becomes something that they support quite strongly. This to me suggests that over the next few years, as public awareness about nanotechnology grows, so too will support for labelling and clear mandatory labelling at the point of sale so that people can make informed purchasing choices. If that is something that is not supported now, particularly in relation to food, I think we can expect a backlash from the community later on as public awareness about nanotechnology grows. I also just wanted to add something to the previous conversation about the ways in which public participation can inform decision making around nano because I actually think there are perhaps four or five key areas. One is around innovation policy and in a sense we need to think about both nanotechnology policy and how it relates to other innovation objectives, and technology and non-technology options to meet key areas of social and environmental need. The other is around food and agriculture, what sort of food and agriculture policy we want to support and whether or not nanotechnology actually complements or undermines other objectives we might set ourselves, for example improving the ecological sustainability of agriculture or reducing food miles or helping improve local food security and issues like this. The other is around government strategy and I think that

the public should have some opportunity to be involved in setting the strategy as far as nanotechnology oversight in the UK and elsewhere. The third area is in research priorities which is something that we have talked a bit about already and where the research money should be invested. We must recognise that, like any technology development, nanotechnology is mutable and what we get at the end will be partly influenced by what we put in at the beginning in terms of research focus. The fourth area is in commercialisation. I am not so familiar with the situation in the UK but I know certainly in Australia our Government supports commercialisation of nanotechnology products; it gives grants to companies to bring to market certain products. This is quite an influential area of innovation policy but again all of these areas that I have talked about so far are outside regulation; they are outside the area that we typically focus all our attention on. I guess that the point I wanted to make is that we really need to open up innovation strategy, research priorities and some of the upstream parts of technology development to public dialogue and not just focus on regulation because if we do that then in a sense we have already committed ourselves to a certain path.

Q314 ***Lord Crickhowell:*** Georgia has taken me to the question that I wanted to ask and I was going to address it probably to Professor Howard. In all our sessions we come up with three things: do not know, lack of research (particularly in critical areas like the gut), difficulty of validation and risk assessment. How do we get the research focus better? This is a worldwide thing, but clearly the research focus is not ideally where it should be at the moment.

Professor Howard: I think that the EU and some of the research councils here in the UK are giving very focused research grants to look at specific problems. They are to do with uptake studies, distribution studies and toxicology. That is what we need. There is quite a large amount of money being devoted to that. If I could harp back for one second to what was being said before, I think the very term "nanotechnology" is a problem for the industry because it does encompass a large number of enabling technologies going from microscopes to nano-structured surfaces on self-cleaning glasses, many of which are not in the slightest bit threatening, but they all come under that heading. What we are addressing here with food is a specific problem of increased and inappropriate mobility of substances through the body. I think that because it is that subset it might be rather easier than we think to communicate that. That is certainly where the research is focused at the minute, mobility and toxicology.

Chairman: Thank you very much. I would like thank all of our witnesses for helping us to explore some of the issues that we put before you. I would like to confirm that copies of the transcript will be available for you to comment on before it is finally published. Also, if there are any points that you have not been able to elaborate on sufficiently that you would like to write into us about, please feel free to do so and those points would also be published along with the rest of our written evidence and with the transcript. With that I would like to thank you all very much indeed for joining us, including Georgia from Australia. Thank you very much, Georgia.

Supplementary memorandum by Friends of the Earth Australia

Friends of the Earth Australia (FoEA) suggests that a moratorium on commercial use of manufactured nanomaterials in foods is essential until:

- validated, nano-specific risk assessments and detection methodologies are designed and implemented, and regulatory gaps are closed;
- nanotechnology's broader implications for food and agriculture are assessed, in particular its implications for public health, and for food security and food sovereignty;
- the public is given the opportunity to participate in nanotechnology decision making, including the right to reject the development and sales of nanofood; and
- all nanofoods face mandatory labelling on products at point of sale.

FoEA suggests that there are six key reasons to support a moratorium:

- the science demands a precautionary approach to risk management;
- the public expects governments to ensure food safety—which is not currently possible in relation to nanofoods;
- the public has not been given an opportunity to be involved in nanotechnology decision making, but early findings suggest that people do not support the use of nanotechnology in food;

— there is no social benefit in permitting the sale of nanofoods before they have undergone rigorous, validated nano-specific safety assessment, broader socio-economic challenges have been assessed, and the public given the opportunity to take part in decision making;

— at a time of global food crisis, nanotechnology's broader implications for food security and food sovereignty must be assessed critically; and

— a failure to support a precautionary, transparent and inclusive approach to decision making in this sensitive area of nanotechnology development is likely to result in a further erosion of public confidence in science and technology governance.

The science demands a precautionary approach to risk management

The scientific justification for requiring proponents to demonstrate the safety of nano-products before they can be sold was accepted in 2004 by the United Kingdom's Royal Society and Royal Academy of Engineering. In their report they recommended that: nanomaterials be treated as new chemicals; nano-ingredients in products be required to pass rigorous safety assessment before commercial use is permitted; nano-ingredients in products be labelled; nanomaterials in factories and workplaces be treated as if they were hazardous; and the environmental release of nanomaterials be avoided as far as possible (RS & RAE 2004). Global reinsurance agent Swiss Re called even more explicitly for precautionary management of nanotechnology risks: "In view of the dangers to society that could arise out of the establishment of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principle should be applied whatever the difficulties" (Swiss Re 2004, p 47).

The 1992 Rio Declaration on Environment and Development describes the precautionary principle as follows: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation" (United Nations 1992). There is preliminary evidence of serious nanomaterial health and environment risks (UK RCEP 2008; SCENIHR 2009), acknowledgement by leading researchers that the extent of uncertainty is such that even design of reliable risk assessment systems for nanomaterials is impossible (EFSA 2009; Hansen 2009; Oberdörster, Stone, and Donaldson 2007) and predictions that validated nano-specific risk assessment methodologies may take up to 15 years to develop (Maynard *et al* 2006). It is for circumstances such as these that the precautionary principle was intended.

The public expects governments to ensure food safety—which is not currently possible in relation to nanofoods

It is perhaps self-evident, but useful to highlight nonetheless, that the public expects that the government will implement rigorous safety assessments for all food ingredients, but especially those produced by uncertain new technologies, prior to products being permitted for commercial sale. Early public engagement exercises show that key public concerns relate to the new health and environmental risks associated with nanomaterials, and the ability of governments to ensure their appropriate regulation (Macoubrie 2006; Gavelin *et al* 2007; German FIRA 2006; Halliday 2007). It would be a major breach of the public's trust to permit the sale of nanofoods, containing manufactured nanomaterials that may introduce serious new risks to human health and the environment, when experts including the European Food Safety Authority agree that it is as yet impossible to design nano-specific risk assessment procedures in which we can have confidence (EFSA 2009; Hansen 2009; Oberdörster, Stone, and Donaldson 2007).

The public has not been given an opportunity to be involved in nanotechnology decision making, but early findings suggest that people do not support the use of nanotechnology in food

Public awareness about nanotechnology remains very low. However, early surveys show that once given information about nanotechnology, people do not want to eat nanofoods or foods wrapped in packaging that contains manufactured nanomaterials. Public engagement initiatives and experimental studies conducted in the UK suggest that once provided with information about nanotechnology, the public is concerned about many of the same issues identified in relation to GE food: a lack of transparency, a lack of choice about exposure, risks to health and the environment, unfair distribution of risks and benefits, a lack of socially useful applications and a lack of public participation in decision making (Gavelin *et al* 2007).

Public concerns about nanotechnology are greatest when nanotechnology is applied to food. Participants in a 2006 consumer conference in Germany, organised by the German Federal Institute for Risk Assessment (BfR), expressed the most serious reservations about nanotechnology when it was applied to foods (German FIRA 2006). A year later the BfR conducted a survey of 1,000 people and found that a majority of people not only do not personally want to eat nanofoods, but also think that nanotechnology should not be used in food applications at all. 60 per cent of survey respondents were against the use of nano-additives to prevent spices

from becoming lumpy; 84 per cent rejected the idea of using nanomaterials to make foods look appealing for longer (Halliday 2007).

A study conducted in the German speaking part of Switzerland also found that people did not want to eat nanofoods or foods wrapped in nano packaging (Siegrist *et al* 2007). Similarly, a United States survey of 1,014 adults found that only 7 per cent of respondents were currently prepared to purchase foods produced using nanotechnology. 29 per cent would not purchase food produced using nanotechnology, while 62 per cent wanted more information about health risks and benefits before they would consider buying nanofoods (Peter D Hart Research Associates 2007). Polling of 1,010 Australians commission by FoEA and carried out by Essential Research found that 92 per cent of Australians supported mandatory labelling of nanofoods, 96 per cent supported mandatory nano-specific safety testing of nano-ingredients in food and packaging, and only 15 per cent were currently prepared to purchase nanofoods (Essential Research 2008).

Mandatory labelling of all nanofoods is required to enable people to make an informed choice about whether or not to eat them. However beyond the need for labelling to enable informed purchasing choices, the public must be given the opportunity to be involved in decision making about the use of nanotechnology in the food and agriculture sector. Given the significant implications of nanotechnology for our relationship with food and agriculture, and for food producing communities worldwide, we call for public involvement in all aspects of decision making, including the right to say no to nanofoods.

There is no social benefit in allowing the sale of nanofoods before they have undergone rigorous, validated nano-specific safety assessment, broader socio-economic challenges have been assessed, and the public given the opportunity to take part in decision making

There have been claims by some proponents that nanofoods will deliver a social benefit that should be weighed against new toxicity risks. FoEA rejects this framing of weighing "benefits" against "risks" for three key reasons. Firstly, we recognise that such framing ignores social concerns related to nanotechnology ownership, access, controllability, equity, sustainability and other issues. These issues, which have nothing to do with risk, were all important to the UK public in relation to genetically engineered foods, and early studies suggest that they are similarly important to the UK public in relation to nanotechnology (Gavelin *et al* 2007). Secondly, we recognise that many of the claimed benefits are either trivial, accrue to manufacturers rather than consumers, or come with their own health and social costs. Thirdly, we think it is entirely inappropriate to use claimed benefits to counter-balance risks, particularly given that the qualitatively new types of hazards associated with nanotechnology demand a greater use of precaution than ever before (Dupuy and Grinbaum 2006; Ravetz 2005).

Beyond the need for new regulation to manage the serious new toxicity risks associated with nanofood and nano agricultural products, Friends of the Earth Australia is calling for "fourth hurdle regulation" to require manufacturers to demonstrate the social benefit of products they wish to sell. Too often, it is an entrenched and unchallenged assumption that the market release of a new functional food or antibacterial product will necessarily deliver public health benefits. In many instances, putative benefits are argued by product proponents to justify or counterbalance the potential for new risks, despite potential benefits rarely being subject to the same kind of scrutiny and scepticism to which claims of potential risks are subject. Friends of the Earth Australia therefore supports the recommendations of Wynne and Felt (2007) for the inclusion of a social benefit test, supplementing the more usual investigations into efficacy, safety and environmental risk, as part of the regulation of nanotechnology in food and agriculture.

We would like to comment briefly on three areas of nanofood development where we believe that the potential for social benefits has been misrepresented:

(i) Food safety

A key claim by nanotechnology proponents is that nanotechnology will improve food safety, including by the incorporation of antibacterial nanomaterials in food contact materials and edible food coatings. There has been rapid growth in the use of antibacterial nanomaterials such as silver, zinc and titanium dioxide in food packaging, food storage containers, crockery, cutlery, refrigerators and dishwashers. We are concerned that such widespread use of antibacterial nanomaterials (additional to their use in non-food items such as clothing, cosmetics, children's toys, personal care products, household cleaners, industrial disinfectants, computer keyboards, vacuum cleaners, clothes washing machines and many other products) will actually promote dangerous antibacterial resistance. This could render ineffective the use of nano-silver and other potent antibacterial nanomaterials in a medical context (for burns victims, in wound dressings etc) where they are of most use. This is particularly concerning given that silver is experiencing a revival in hospitals across Europe,

partly because of the growing bacterial resistance to commonly used antibiotics (Chopra 2007). Bacterial infections already contribute to 110,000 deaths a year in Europe.

Biocidal nanomaterials could also interfere with beneficial bacteria in sewage and waste water treatment plants, and could contaminate water intended for re-use. There are also serious concerns that nano-antibacterials will pose unacceptable toxicity risks to human health and to environmental systems in to which waste products are released. A recent study by imminent UK nanotoxicologists advised that there is sufficient evidence to suggest that silver and titanium dioxide nanomaterials may be harmful to the environment and therefore the use of the precautionary principle should be considered (IOM 2009).

While any illness as a result of food contamination is unacceptable, it is important to remember that for every person in the UK who suffers illness as a result of food poisoning, there are 50 who suffer ill health as a result of poor diets and inadequate consumption of fruit and vegetables (Lang and Rayner 2001). If processed, nano-packaged food is marketed successfully as safer than eating fresh, unpackaged foods, and consumption of fresh foods declines further, it is possible that the net outcome will actually be poorer health.

(ii) Nutrition and obesity

We are concerned that nanotechnology will enable manufacturers to promote nano-reconstituted, nano-fortified or nano-packaged foods as delivering superior health benefits, hygiene or convenience than minimally processed "fresh foods". If this proves true, it is likely that nanotechnology will encourage even greater consumption of highly processed foods at the expense of fruits and vegetables. Beyond the need to ensure the safety of nanofood additives, it is also useful to question whether or not fortifying food with nano nutrients, or using nanotechnology to reduce the fat or sugar content of junk foods, is actually desirable from a public health perspective.

There is a growing number of manufacturers prepared to claim that their nano-fortified beverages or foods will meet a large part, or even the entirety, of an individual's dietary needs. For example Toddler Health's range of fortified chocolate and vanilla milkshakes ("nutritional drinks"), which include 300nm particles of SunActive® iron, is marketed as "an all-natural balanced nutritional drink for children from 13 months to five years. One serving of Toddler Health helps little ones meet their daily requirements for vitamins, minerals and protein" (Toddler Health undated). Yet we challenge the claim that fortification of highly processed foods using nano-encapsulated or nano-scale vitamins or health supplements can deliver the same health benefits as improving peoples' diets. Rather than settling for the risky techno-fix of nano-fortification, the nutrition challenge requires government intervention to encourage better eating habits and more affordable healthy foods. This should involve action at the level of pricing policies and subsidies, school lunch programs, junk food advertising and other social policies.

We are similarly concerned that the use of nanotechnology to reduce the fat or sugar content of junk foods may simply entrench and expand poor eating habits. Even a fat-reduced chocolate bar or donut will have inferior health and nutritional habits compared to fresh fruit or a "real" meal. The most straightforward to reduce the growing problem of obesity in our community is to promote healthier eating habits and more active lifestyles. Using nanotechnology to reduce the fat content of chips, donuts and chocolate will not address the root causes of obesity in our community, nor will it deliver the public health benefits associated with reduced consumption of highly processed junk foods, greater consumption of fruit and vegetables, and a more active lifestyle.

We suggest that the food industry's key motivation in using nanotechnology to fortify or reconstitute highly processed foods has less to do with a public health concern and more to do with the significantly greater profit margins on processed foods compared to fruit and vegetables.

(iii) Reducing the environmental footprint of food production

We challenge the assertion that nanotechnology will necessarily reduce the environmental footprint of food production. Even if, because of their greater potency, the quantities of nanomaterials used in agrochemicals, food ingredients and production inputs are far smaller than the usual quantities of their bulk counterparts, the environmental impact could be far greater. The Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars has suggested that the toxicological impact of 58,000 tonnes of manufactured nanomaterials might be the equivalent of 5 million or even 50 billion tonnes of conventional materials (Maynard 2006).

We also note that the manufacture of nanomaterials has a very high environmental footprint (Şengül *et al* 2008). This is related to the highly specialised production environments, high energy and water demands of processing, low yields, high waste generation, the production and use of greenhouse gases such as methane and the use of toxic chemicals and solvents such as benzene. In a life-cycle assessment of carbon nano-fibres,

Khanna *et al* (2008) found that producing carbon nano-fibres may have the potential to contribute to global warming and ozone layer depletion, and cause environmental or human toxicity that is as much as 100 times greater per unit of weight than those of conventional materials like aluminium, steel and polypropylene. Early nanomaterial life cycle assessments led the scientists to conclude that any environmental gains of nanomaterials (for example through greater potency enabling smaller quantities of materials to be used) may be outweighed by the environmental costs of their production.

Furthermore, many applications of nanotechnology in food packaging and edible food coatings are specifically intended to increase the shelf life of foods. It appears inevitable that one result of this will be the transport of foods over longer distances, increasing the "food miles" travelled, and increasing the climate costs of food transport.

In short, we recognise that there are many potential social "costs" and new health and social challenges associated with nanotechnology's use in food and agriculture that require careful assessment. There is certainly no reason that the public should accept exposure to poorly understood risks posed by nanofoods, on the basis that there is a social benefit to be obtained from their sale prior to validated, nano-specific risk assessments being developed and implemented, full product labelling introduced, social assessment carried out, and the public given an opportunity to be involved in decision making.

At a time of global food crisis, nanotechnology's broader implications for food security and food sovereignty must be assessed critically

Nanotechnology in food and agriculture is emerging at a time when global food systems are under unprecedented stress. Recent decades have revealed the high environmental costs associated with industrial scale chemical-intensive agriculture, including biodiversity loss, toxic pollution of soils and waterways, salinity, erosion, desertification and declining soil fertility (FAO 2007). The escalation of the global food crisis has also underscored the fundamental failure of global food and agriculture systems to meet the food needs of nearly a billion people. Price rises have had the worst impact on poor people reliant on buying food. Food riots occurred in over 30 countries where the world's poorest people could no longer afford basic food.

Around 75 per cent of the world's hungry people live in rural areas in poor countries (FAO 2006). If rural communities can meet more of their own food needs via local production, they will clearly be less vulnerable to global price and supply fluctuations. Global small farmers' advocacy organisation La Via Campesina has argued that: "Small-scale family farming is a protection against hunger" (La Via Campesina 2008). This view was supported by the four year International Assessment of Agricultural Science and Technology for Development which emphasised that to redress rural poverty and hunger, a key focus of agricultural policy must be empowering small scale farmers to meet their own food needs (IAASTD 2008).

The potential role of new technologies in responding to the food crisis is controversial. As with genetically engineered (GE) crops, proponents have argued that nanotechnology will redress food shortages by promoting greater agricultural productivity (IFRI 2008). However the IAASTD (2008) report notes that whereas GE crops have had highly variable yields, they have also had negative broader economic consequences for farmers by concentrating ownership in agricultural resources and introducing new liabilities for farmers (IAASTD 2008). Similarly, FoEA suggests that nano-agriculture is not required to achieve strong yields, but will add to the capital costs faced by small farmers and increase their reliance on technology, seed and chemicals sold by a small number of global agri-business companies.

By underpinning the next wave of technological transformation of the global agriculture and food industry, nanotechnology appears likely to further expand the market share of major agrochemical and seed companies, food processors and food retailers to the detriment of small operators (Scrinis & Lyons 2007). By dramatically increasing efficiency and uniformity of farming, it appears likely that nano-farming technologies could accelerate expansion of industrial-scale, export oriented agricultural production which employs even fewer workers but relies on increasingly sophisticated technological support systems that have increasing capital costs (Scrinis & Lyons 2007; ETC Group 2004). Such systems could commodify the knowledge and skills associated with food production gained over thousands of years and embed it into proprietary nanotechnologies (Scrinis & Lyons 2007). It could also result in the further loss of small scale farmers and further disconnection of rural communities from food production, undermining efforts to achieve sustainable, relocalised food production.

A failure to support a precautionary, transparent and inclusive approach to decision making in this sensitive area of nanotechnology development is likely to result in a further erosion of public confidence in science and technology governance

The House of Lords Select Committee on Science and Technology is already very familiar with the crisis of public confidence in science and technology governance that emerged in the late 1990s in the UK. We note that in the Committee's 2000 report you recommended that: "direct dialogue with the public should move from being an optional add-on to science-based policy making . . . and should become a normal and integral part of the process". We are grateful for the opportunity to present evidence to you as part of the current Inquiry and recognise the Committee's efforts to actualise its recommendation. Nonetheless, we observe that despite initial efforts to engage the UK public in a dialogue on nanotechnology development, this has to date not been specifically undertaken in relation to food and agriculture, nor has it been attached to a policy or governance decision making process.

We suggest that as the public awareness about nanotechnology grows, and specifically in relation to its use in food and agriculture, it will be essential for the government to demonstrate that it has taken a strongly precautionary approach to risk management, that it has considered broader social challenges alongside scientifically measurable risk issues, and that the public has had a genuine opportunity to be involved in decision making. A perceived or actual failure in relation to any of these issues risks further eroding public confidence in science and technology governance, and taking us back to the BSE and GM controversies.

APPENDIX

CIVIL SOCIETY GROUPS WHICH HAVE CALLED FOR A MORATORIUM ON NANOTECHNOLOGY'S USE IN FOOD AND AGRICULTURE

Growing numbers of civil society groups have called for a moratorium on the commercial release of food, food packaging, food contact materials and agrochemicals that contain manufactured nanomaterials until nanotechnology-specific regulation is introduced to protect the public, workers and the environment from their risks. Some of these groups are also insisting that the public be involved in decision making. Groups calling for a moratorium include: Corporate Watch (UK); the ETC Group; Friends of the Earth (Australia, Europe and the United States); GeneEthics (Australia); Greenpeace International; International Centre for Technology Assessment (US); International Federation of Journalists; the Loka Institute; Practical Action; and The Soil Association UK. The International Union of Food, Agricultural, Hotel, Restaurant, Catering, Tobacco and Allied Workers' Associations, representing 12 million workers from 120 countries, has also called for a moratorium.

The Nyéléni Forum for Food Sovereignty was a civil society meeting of peasants, family farmers, fisher people, nomads, indigenous and forest peoples, rural and migrant workers, consumers and environmentalists from across the world. Delegates were concerned that the expansion of nanotechnology into agriculture will present new threats to the health and environment of peasant and fishing communities and further erode food sovereignty. The forum also resolved to work towards an immediate moratorium on nanotechnology (Nyéléni 2007—Forum for Food Sovereignty 2007).

The organic sector is also beginning to move to exclude nanomaterials from organic food and agriculture. The United Kingdom's largest organic certification body announced in late 2007 that it will ban nanomaterials from all products which it certifies. All organic foods, health products, sunscreens and cosmetics that the Soil Association certifies will now be guaranteed to be free from manufactured nanomaterial additives (British Soil Association 2008). The Biological Farmers of Australia, Australia's largest organic representative body, have also moved to ban nanomaterials from products it certifies.

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June 2009

TUESDAY 9 JUNE 2009

Present	Crickhowell, L	Methuen, L
	Cunningham of Felling, L	Mitchell, L
	Haskel, L	O'Neill of Bengarve, B
	Krebs, L (Chairman)	O'Neill of Clackmannan, L
	May of Oxford, L	Selborne, E

Memorandum by Professor Derek Burke

1. My submission to this inquiry is focused on regulatory aspects of the introduction of nanotechnology into the food industry. It draws on my own experience as the first Chair of the Advisory Committee on Novel Foods and Processes (ACNFP) from 1989 to 1997. I consider that this issue is of considerable current importance.

2. The ACNFP first considered the issue in 2005 with a brief report on "Nanoparticles in food[1]". The Committee agreed "that the use of nanoparticles in food was an issue of increasing public interest that would require further consideration… Members also indicated that the committee might require input from additional experts if it is to examine this area in depth." This report was based on a committee paper (ACNFP/70/4)[2] which defined nanotechnology, referred briefly to the Royal Society/RAE Report[3] and highlighted the following conclusions:

— That the toxicity of chemicals in the form of free nanoparticles and nanotubules cannot be predicted from their toxicity in larger form and that in some cases they will be more toxic than the same mass of the same chemical in larger form.

— That regulatory bodies and their respective advisory committees include future applications of nanotechnology in their horizon scanning programmes to ensure any regulatory gaps are identified at an appropriate stage.

3. In November, 2004, the environmental group ETC published a report "Down on the Farm: The Impact of Nano-scale Technologies on Food and Agriculture"[4] which identified a number of current and projected uses of nanoparticles in food manufacture. These included:

— The current practice of using nano-scale carotenoids as colourings in lemonades, fruit juices and margarines. The small particle size improves dispersion and stability of the ingredient.

— The current practice of micro-encapsulating nano-scale active ingredients in functional foods, for example when adding fish oils to bread. The oils are released from the micro-capsules in the stomach and so do not impair the taste of the product.

— The projected practice of using oxygen impermeable coatings on confectionery, made from nano-scale silicon dioxide, to improve shelf life.

4. The conclusions in this ETC report included, *inter alia*:

— That national governments must establish a *sui generis* regulatory regime specifically designed to address the unique health issues associated with nano-scale materials used in food.

— That in keeping with the Precautionary Principle, all food, feed and beverage products (including nutritional supplements) incorporating manufactured nanoparticles should be removed from the shelves until such time as regulatory regimes are in place that take into account the special characteristics of these materials, and until the products have been shown as safe.

5. The Food Standards Agency has recently (August 2008) published "A review[5] of the potential implications of nanotechnologies for regulations and risk assessment in relation to food". They concluded:

— On the basis of current information, most potential uses of nanotechnologies that could affect the food area would come under some form of approval process before being permitted for use.

— This review has not identified any major gaps in regulations but there is uncertainty in some areas whether applications of nanotechnologies would be picked up consistently. In these cases there are relatively straightforward options to address this uncertainty. As food regulations are harmonised at EU level, the Agency will seek to address them at EU level through the European Commission and other Member States. The Commission's Nanotechnology Action Plan commits it to coordinating an approach to such issues.

— The view of the independent advisory Committees on Toxicity, on Carcinogenicity and on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, is that the existing model for risk assessment is applicable to nanomaterials *although there are major gaps in information for hazard identification.* (My italics) Risk assessment relies on provision of sufficient reliable information to inform an assessment in each case. Risk assessment procedures will need to include procedures for provision of information to inform risk assessments, for example in relation to an application for approval for a new product or process. The Agency will support the development of risk assessment in this area in close partnership with other Departments and the independent advisory bodies in the UK and the EU.

6. My own view is that this is a somewhat complacent conclusion. For example in Paragraph 35 headed "Gaps in regulation", the review points out that "The legislation as it stands does not differentiate between chemicals produced routinely by current methods and those that may be developed by nanotechnology." I suggest that this misses the whole point of nanotechnology which is that properties of substances change when they are very small, in particular as the surface area to volume ratio changes.

7. The Food Standards Agency also consulted a number of relevant stakeholders on a draft of this report. Only six responses (42 individual comments) were received[6] but the responses are helpful and important. For example, Friends of the Earth commented "A regulatory framework must be established that is specifically designed to address the unique health and environmental issues associated with nanomaterials used in food and agriculture. This must be part of an integrated Government approach to nanotechnology, which takes into account the wider issues beyond food applications." Similar comments were received from Professor Vic Morris and the Institute of Food Science and Technology (IFST) which made a number of pertinent and thoughtful comments, in particular comments about the way in which EU regulatory directives and regulations bore on this issue. I considered that the FSA response was rather cool and I suggest that there are a number of these issues that the committee might wish to follow up. Too often the FSA response was "The Agency has noted these comments." My own experience in Brussels suggests to me that the faith placed by the Food Standards Agency places in a speedy regulatory response from Brussels is over optimistic.

8. I have not been able to find any more recent material, in particular any record of activity by the ACNFP since the publication of the FSA review last August. My overall impression is that the FSA are being too complacent. The history of regulation of new technology arising from discoveries in the biosciences is that regulatory issues are often only spotted after they have arisen (my own personal experience of genetically modified foods and crops bears this out), and one of the lessons of the last 10 years is that regulatory issue should be anticipated, and responses framed in advance if at all possible.

9. There are therefore a number of areas which I suggest that the Lords Science Committee might consider, including:

— I have not found any record of horizon scanning on nanotechnology by the FSA or the ACNFP, but maybe this is in train. But such horizon scanning, which is an important part of FSA strategy, would be very important in this area. So the questions are: what has been done, what is planned, and if nothing has been done, when is it going to be started?

— The next obvious question one is whether the current regulatory framework will be able to cope with the likely developments in nanotechnology. The Research Councils recently hosted a one day workshop with members from the Research Councils, FSA, ACNSP, Royal Society etc on possible new regulatory issues arising from the development of synthetic biology, which I attended. In this particular instance, it concluded that the current regulatory regime is capable of handing all foreseeable developments. Maybe such a workshop has taken place or is planned for nanotechnology?

— From the current list of ACNFP members[7,8] I cannot see anyone with expertise in nanotechnology, although this might be present, since the list of members' interests[9] has not been updated since April 2005. If not, it would seem an important skill to add to that committee.

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1 Advisory Committee on Novel Foods and Processes, Annual Report, 2005, p.15.

2 http://www.food.gov.uk/multimedia/pdfs/acnfp_70_4.pdf

3 http://www.nanotec.org.uk/finalReport.htm.

4 http://www.etcgroup.org/article.asp?newsid=485

5 http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf

6 http://www.food.gov.uk/multimedia/pdfs/consultationresponse/nanoconsultsummary.pdf

7 http://www.acnfp.gov.uk/acnfpmembership/135812

8 http://www.acnfp.gov.uk/acnfpmembership/members/

9 http://www.food.gov.uk/multimedia/pdfs/acnfpmembersfactsheet.pdf

11 March 2009

Memorandum by Dr Robert Falkner, London School of Economics

1. The evidence provided below focuses on the regulatory framework for nanotechnologies in food. It is based on research currently being carried out as part of an international project on "*Regulating Nanotechnologies in the EU and US: Towards Effectiveness and Convergence*", which is funded by a grant from the European Commission and involves four institutions: the London School of Economics and Chatham House in the UK, and the Environmental Law Institute and the Project on Emerging Nanotechnologies in the US.[1] Research assistance by Nico Jaspers and Carmen Gayoso is gratefully acknowledged. Please note that the evidence below is given in a personal capacity and does not represent the views of the project consortium or the European Commission.

Q: *Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?*

2. A clear-cut answer to this question is not possible. The regulatory framework *may* be fit for purpose, but given existing knowledge gaps about the presence of nanoscale materials in commercial use, their environmental and health risks, and methodologies for assessing such risks, changes to the regulatory framework are likely to be needed. In any case, greater efforts need to be undertaken to gain better knowledge about the potential risks involved in the use of nanotechnologies in food and other areas, as a first step towards a more robust regulatory environment.

3. Emerging nanotechnologies and nanomaterials are being regulated through existing laws and regulations at UK and EU level, in the fields of chemicals, food, cosmetics, pharmaceuticals, among others.[2] Given that nanotechnologies are best conceived as enabling technologies for a wide range of industrial applications, nanotechnology risks are likely to be dealt with by sector-specific and product-based, rather than comprehensive and process-based regulation. Current regulatory efforts in the UK, the European Union and other industrialised countries are focused on applying existing regulations to nanotechnologies and amending these in order to fill any potential gaps in the coverage of nanotechnology risks. Given existing knowledge gaps—about health and environmental risks, appropriate methodologies for risk assessment and the state of commercialisation of nanomaterials—it is not possible to establish with sufficient certainty whether the regulatory framework is fit for purpose.

4. A central problem in nanotechnology regulation concerns the very definition of what constitutes the "nanoscale". Efforts are underway to establish common scientific and technical standards in this area, through the International Organization for Standarization (ISO) and the OECD (see below, paragraphs 15–17). However, the absence of reliable definitions has made it difficult so far to establish precisely what types of nanomaterials are in use in the food sector and whether these are adequately covered by existing regulations. The food industry has failed to provide comprehensive information about the size or properties of nanomaterials it currently uses as food ingredients, in food processing and in food packaging. Part of the

[1] For further information, see the project website: http://www.lse.ac.uk/nanoregulation.

[2] For a review of existing EU regulation and how it applies to nanotechnologies, see Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Regulatory Aspects of Nanomaterials COM(2008) 366 final, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF.

problem is that, in the absence of clear defintions, the use of the term "nano" or "nanoscale" remains at the discretion of companies. Efforts are underway to address the uncertainty and incoherence surrounding company reporting, including by the European food and drinks industry association CIAA, which has set up a Nanotechnology Task Force. But governments will need to take the lead in removing uncertainty about definitions and establish unambiguous disclosure requirements about the presence of nanomaterials in food production and products.

5. In principle, imported food products should be covered by existing regulations in the same way as domestically produced food products. As with domestic producers, the main problem at the moment is the absence of reliable market data. Governments should therefore consider, as an immediate priority, the creation of a comprehensive reporting system for nanomaterials in the food industry, covering domestic and imported products. Given the limitations of voluntary reporting initiatives in this area (see below, paragraphs 7–13), disclosure and reporting of nanomaterials in food should be mandatory.

6. The need to update and revise existing food safety regulations in light of newly emerging nanotechnology applications has recently been confirmed by the European Food Safety Authority (EFSA). According to the agency's draft strategic plan for the next five years, nanotechnology is seen as one of the key "new challenges" that will require regulators to "upgrade existing and design new risk assessment practices to keep up with the pace of science and innovation".[3] More recently, EFSA emphasised that available data on risks relating to exposure to specific nanomaterials in food is "extremely limited". Given the limited knowledge of current usage levels and likely exposure products in the food area, the agency warned that lack of validated test methodologies could make risk assessment of specific nanoproducts "very difficult and subject to a high degree of uncertainty".[4]

Q: *How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?*

7. The short answer is "not very effective". Industry has introduced a number of voluntary initiatives that address issues relating to nanotechnologies risk, and some governments have provided frameworks for reporting and codes of conduct for research that are of a voluntary nature. Many of these schemes have only recently been initiated, and little systematic evidence exists on industry self-regulation, but first assessments of governmental programmes for voluntary reporting suggest that such initiatives are not sufficiently effective.

8. Preliminary findings of a study currently being conducted at the LSE suggest that the majority of companies that have initiated voluntary initiatives on nanotechnology risk are to be found in the chemicals and pharmaceuticals sectors. These companies have a long tradition of engaging in corporate social responsibility initiatives and have been at the forefront of developing commercial applications of nanotechnology. Such CSR initiatives involve, for example, codes of conduct for nanotechnology applications (eg BASF, Evonik), participation in international research on environmental and health risks of nanotechnologies (eg American Chemistry Council Nanotechnology Panel; Occupational Safety & Health Consortium), nanotechnology-related statements in CSR reporting (eg Novartis, Hoffman-LaRoche) and public and stakeholder engagement activities. DuPont has recently developed a Nano Risk Framework in partnership with the US environmental organization Environmental Defense, which provides a guidance document for nanotechnology users for identifying and reducing potential risks as part of product stewardship programmes.

9. The food industry has been comparatively slow to develop voluntary initiatives for dealing with nanotechnology risk, but is faced with growing demands for greater transparency about its use of nanomaterials. So far, no industry-wide system of self-regulation has been created that could provide reliable information on the use of nanomaterials in food production and promote safety standards. Momentum is growing, however, for disclosure initiatives as a first step towards industry self-regulation. Investor activist groups in the US, for example, have filed resolutions for the 2009 annual meetings of Avon Products, Kellogg Company, Kraft Foods, and McDonald's Corporation and are requesting that companies publish a report detailing their use of nanomaterials in products and their overall nanomaterials policy.[5] In Europe, the food and drinks industry association CIAA is currently developing an industry-wide Code of Conduct for Nanotechnologies, which is expected to provide a first steps towards a self-regulatory framework.[6]

[3] http://www.euractiv.com/en/sustainability/eu-food-safety-watchdog-outlines-future-challenges/article-176074.
[4] http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true.
[5] http://www.merid.org/NDN/more.php?id=1654.
[6] http://www.ciaa.be/e-newsletter/nsl2.asp?nsl_id=21&nsldet_id=134.

10. Governments have also sought to promote voluntary initiatives. The UK has been at the forefront of developing voluntary reporting schemes to improve the informational basis for risk assessment and management of nanotechnologies. DEFRA launched the UK Voluntary Reporting Scheme (VRS) for Engineered Nanoscale Materials, the world's first such governmental reporting scheme, in September 2006. Its two-year pilot phase of the project came to an end in September 2008, and DEFRA is currently considering how to develop a future reporting scheme. The record of the pilot phase has raised concerns about the effectiveness of voluntary reporting. Since its launch in 2006, DEFRA received only 12 submissions, which represent about a third of the companies currently manufacturing nanomaterials.[7]

11. The UK's experience with voluntary reporting is mirrored by the limited response to the US EPA's Nanoscale Materials Stewardship Program (NMSP), which was launched in January 2008 and is also meant to run for two years. NMSP invites voluntary reports on engineered nanoscale materials that are being manufactured, imported, processed or used in the US. A separate in-depth program invites producers to develop and submit data, including testing, over a longer time frame.[8] In its interim report of January 2009, EPA states that 29 companies or associations had submitted information to EPA covering 123 nanoscale materials and a further seven companies have outstanding commitments to do so. Four companies have so far agreed to participate in the in-depth program.

12. Although EPA concludes that "the NMSP can be considered successful", it notes that "a number of the environmental health and safety data gaps the Agency hoped to fill through the NMSP still exist". Few of the reports received by NMSP contain information on health and environmental aspects of nanomaterials and, as EPA states in its review, "approximately 90 per cent of the different nanoscale materials that are likely to be commercially available were not reported". Furthermore, commenting on the low take up of the more ambitious in-depth program of NMSP, EPA notes that "most companies are not inclined to voluntarily test their nanoscale materials". It is therefore not surprising that the agency is now considering how to use existing authorities under US chemicals legislation to fill those gaps, which signals a move to strengthen mandatory requirements in the coming years.

13. Other governments have already concluded that mandatory reporting is now needed to deal with the existing and emerging information gaps. France proposed in January 2009 to introduce a mandatory reporting requirement of manufactured and imported nanomaterials, including environmental and health data.[9] Canada announced in February 2009 that will introduce a mandatory reporting requirement for information relating to nanoscale materials.[10] In the absence of effective voluntary schemes, I would expect more governments to follow the lead of France and Canada in creating mandatory reporting requirements.

Q: *Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?*

14. We cannot establish with any degree of certainty that current regulations will be able adequately to control the next generation of nanotechnologies and nanomaterials. The nanosciences is a field of rapid innovation, and current indications suggest that the convergence of nanotechnology with biotechnology, information technology and the cognitive sciences will create new challenges and risks that will require more fundamental changes to existing regulatory frameworks. The project on "*Regulating Nanotechnologies in the EU and US: Towards Effectiveness and Convergence*", together with the Project on Emerging Nanotechnologies, commissioned two new reports on next generation nanotechnology and synthetic biology that shed further light on the regulatory challenges that industrialised countries are likely to face in coming years.[11]

Q: *Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?*

15. The main forum for international cooperation on nanotechnologies regulations and standards is the Organization for Economic Cooperation and Development (OECD). Two OECD working groups have been established with an explicit focus on nanotechnologies: the Working Party on Manufactured Nanomaterials (WPMN) was created in 2006 in the Environment Directorate and comprises 30 OECD member countries,

[7] http://www.defra.gov.uk/environment/chemicals/achs/081125/minutes081125.pdf; http://www.defra.gov.uk/environment/nanotech/pdf/vrs-seventh-progress-report.pdf.
[8] http://www.epa.gov/oppt/nano/stewardship.htm.
[9] http://www.safenano.org/SingleNews.aspx?NewsID=590.
[10] http://www.nature.com/news/2009/090204/full/457647a.html
[11] Michael Rodemeyer, "New Life, Old Bottles: Regulating First-Generation Products of Synthetic Biology", Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, March 2009, forthcoming; and J. Clarence Davies, "Oversight of Next Generation Nanotechnology", Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2009, forthcoming.

the European Commission, five non-OECD countries and a small number of observers from international organizations, industry and civil society. It focuses almost exclusively on co-operation in safety assessments and on testing a representative set of nanomaterials.[12] The OECD's second group is the Working Party on Nanotechnology (WPN), which was set up in 2007 in the OECD's Directorate for Science, Technology, and Industry. Its remit is focused more broadly on emerging policy-relevant issues in science, technology and innovation, including nanotechnology research and development, outreach and public dialogue.[13]

16. The OECD working groups are widely seen to be the most important forum for international coordination in the field of nanotechnologies regulation. They are likely to produce greater convergence in the development of the basic building blocks for nanotechnology risk assessment. What is less clear, however, is whether the OECD can serve as the basis for developing a broader international framework for coordinated and convergent risk management practices. Some observers have expressed concerns about the OECD's suitability in this context, particularly with regard to its limited membership basis as an industrialised countries organization, its perceived lack of transparency and the limited nature of stakeholder involvement particularly by civil society groups.

17. The other main forum for developing internationally harmonised standards is the International Organization for Standardisation (ISO). Its technical committee on nanotechnologies (TC 229) promotes the standardisation of terminology, definitions, toxicity testing and environmental studies protocols, measurement techniques, calibration procedures, and reference materials. Much of this work will feed directly into regulatory developments at national and international level, as ISO standards are likely to be adopted in definitions of nanoscale materials and their properties.

18. Other international organizations have also begun to address policy issues arising from the rapid development and commercialisation of nanotechnologies, but none has so far provided a forum for inter-governmental cooperation on regulation and standards. The WHO's Intergovernmental Forum on Chemical Safety (IFCS)[14] has issued the "Dakar Statement on Manufactured Nanomaterials", which notes the "lack of an inclusive global policy framework" and recommends increased efforts to fill gaps in scientific understanding, promote information sharing, international cooperation on the development of national codes of conduct, among others.[15] The United Nations Environmental Programme (UNEP) has called for "swift action" by policy makers to properly evaluate the new science of nanotechnology. UNEP's 2007 Geo Yearbook identifies nanotechnology and the environment as a key emerging challenge for international policy-making but stops short of outlining an alternative vision for international nanotechnologies regulation.[16]

13 March 2009

[12] http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html.
[13] www.oecd.org/sti/nano
[14] http://www.who.int/ifcs/documents/forums/forum6/meet_docs/en/
[15] http://www.who.int/ifcs/documents/forums/forum6/f6_execsumm_en.doc.
[16] http://www.unep.org/geo/yearbook/yb2007/PDF/7_Emerging_Challenges72dpi.pdf.

Examination of Witnesses

Witnesses: Professor Derek Burke and Dr Robert Falkner, London School of Economics, examined.

Q315 ***Chairman:*** I would like to start by welcoming our two witnesses, Professor Derek Burke and Dr Robert Falkner, to this the sixth public session of our inquiry into nanotechnologies and food. I should inform our witnesses that the proceedings are being webcast as usual. For the large number of people in the audience behind, I would like to draw your attention to the information note which is available setting out the declared interests of the Members of the Committee, and so we will not be declaring our interests whilst are asking questions. Perhaps I could start by inviting the witnesses just to introduce themselves for the record, Professor Burke first and then Dr Falkner. Equally, if you wish to make any brief opening statements, please feel free to do so.
Professor Burke: I am Derek Burke. I am initially an organic chemist by first degree and PhD. I then had an academic career: a couple of years at Yale; nine years in Aberdeen; then I started biological sciences at Warwick. I then spent four years in a biotechnology company in North America as Scientific Director. I was Vice-Chancellor at the University of East Anglia. I retired in 1995 and I have kept myself busy ever since. I was persuaded to chair the new committee on novel foods and processes in 1989, which was almost a new committee, and I was Chairman for nine years. That is really my background for this particular discussion, since we had to, for example, decide what a novel food was and so there were lots of questions about definition and scope which are not different, in kind anyway, from what is being faced here. I have been on the EPSRC Societal Issues Panel, where nanotechnology is discussed, and I am still on the BBSRC Bioscience for Society Panel.

Q316 ***Chairman:*** Thank you.
Dr Falkner: Thank you, first of all, for inviting me to this Committee. I am Senior Lecturer in International Relations at the London School of Economics, so I should point out that I am a political scientist not a natural scientist, and I am not a lawyer either. I do, however, work on questions of international risk regulation and have been researching and writing about the international GM food controversy for the last ten years. I followed the international negotiations on the Cartagena Protocol, which is a model international treaty on international risk in the food and novel technology area, and for the last two years I have been leading an international research project involving the London School of Economics and Chatham House here in London, and, on the US side, the Woodrow Wilson Center and the Environmental Law Institute. That research project is looking into the comparative dimensions of nanotech regulation in the US and the EU. We will be producing a major report in September and we will be holding an international conference here in London on 10 and 11 September. I mention this now because I am thereby extending an invitation to you all to that conference—which I will do in writing, of course, when we get closer to the date. That report will produce an overview analysis of how the EU and the US are dealing with emerging nanotechnology risks in chemicals, cosmetics and food, and so my main focus has been and is on the international and comparative dimensions of nanotechnology.

Q317 ***Chairman:*** Thank you both very much. I would like to start the questioning with a really very general question about the adequacy of the current regulatory framework with the use of nanotechnologies and nanomaterials in food and food packaging. I think both of you in your evidence you have submitted have raised questions about the adequacy of the framework and, indeed, of the risk assessment that might populate that framework. I know that Professor Burke said in his written evidence that the Food Standard Agency in its review was somewhat complacent. I wonder whether you could comment on your concerns about the current regime, both in relation to products and in relation to packaging and where you think we should go from here.
Professor Burke: I started from scratch and tried to find out from the web what the current regimes were and had some difficulty. What I found most straightforward was on the Food Standards Agency web page. They say there that the Food Standards Agency "will not assess the safety of using nanotechnology in the food chain unless it is asked to do so." That struck me as a rather defensive position. "If a company wants authorisation to market food products using nanotechnology, then the Agency is obliged to assess the food safety implications." It is the voluntary end of a voluntary process at the moment, and I am unclear whether any submissions have been made. I simply do not think that is adequate. I am not in favour of heavy legalese, by all means, but I am in favour of getting started on a case-by-case basis, looking at issues coming through of nanotechnology additions or processing of foods because we really do not have any case law to go on. The situation is a bit similar to the way novel foods started in 1989, where we did not know what a novel food was. We had to define a novel food and we finally decided that a novel food was that food which was novel to the UK population. It included all the foods that came in from the waves of immigrants coming in to London in the late 1980s and early 1990s which were freely purchased on market stalls, for example, as well as all the fancy foods that were being sold that would reduce your blood cholesterol, and,

of course, it included genetic modification which became ultimately the sort of motif of the Committee. I am really quite concerned that although we have known about this issue for a long time, seven eight years, so little has been achieved. I went back and looked at the web and I found a paper in 1982 from *Chemical & Engineering News* which could have been written last week. Nothing very much seems to have been done since then.

Dr Falkner: Perhaps I could add to that a dimension that touches more on the European Union side of the equation, which is, of course, what I am concerned with in my work. I would distinguish two aspects: one is regulatory coverage and the question of whether emerging nanomaterials in food are covered by existing laws, and the second question would be whether the existing regulatory coverage then provides for an effective treatment of the risks associated with nanomaterials. On the first question I would say that we do have a range of laws and regulations in place from the Novel Foods Directive, as we mentioned, to food additives, food supplements, food labelling, food contact materials regulations and directives, et cetera, so we have a broad range of instruments available to us that we can use to cover emerging risks from nanomaterials. I think, on that front, from what we know—and there is a great deal of uncertainty about that, of course—it is fair to say that we can work with that framework and we should work with that framework. I think there is not an immediate need to start from scratch. There are some questions about regulatory coverage in certain grey areas, and we can come back to that perhaps later, but I want to focus on the second question, whether the existing regulatory framework has been providing effective regulation, and I think there are much greater concerns in that area. This is to do with the uncertainty regarding definitions and characterisation of nanomaterials. If you have no means to distinguish clearly between a nanomaterial and a non-nanomaterial and if you are therefore uncertain whether existing laws apply, that restricts the application of the framework that you have identified. The European Commission, in its own review of regulations which was published last year in May, has admitted that, while they think regulatory coverage is provided, the application of existing laws is questionable. A first point would therefore be to look at the very question of definitions. This then continues into the question of testing methods, the ability to detect nanomaterials in food and to establish potential impacts on human health. Again, this is a question of how to implement existing regulations and whether those regulations pick up certain risks, and this then continues into other areas, such as the very knowledge of what is in the market-place and whether companies themselves that have a duty to carry out risk assessment are able to pick this up. I think that is where a number of grave questions exist.

Q318 ***Chairman:*** I am sure we will come back and elaborate on some of those points very shortly. I wonder whether you think, in addition to the regulations you have mentioned, REACH might play a role in the regulation of nanomaterials. Is that an important contribution to the regulatory regime in your view?

Dr Falkner: I think so very much. REACH is probably the most important regulatory instrument to catch the wide range of nanomaterials. In a sense most nanomaterials enter the regulatory framework at the level where they are produced by chemical companies for use by other industries and that is where REACH kicks in. I think any consideration of the food cycle would need to look at the chemical side as well. The EU itself is making that point very clearly. However, there are concerns about whether REACH is fit for purpose itself.

Professor Burke: The very point of nanotechnology is that substances change their properties at the nano level, because otherwise it would not be a new technology and there would be no point in using them. The extrapolation of toxicology, for example, from the macro history of toxicology, where we know a great deal through nanomaterials, is an extrapolation that seems to me to be not on secure ground. The FSA review says quite openly that the precedents they have from testing chemicals at the macro level, which is what REACH will do, is not adequate to deal with chemicals when they are in the nano form.

Q319 ***Chairman:*** Do you think these uncertainties are sufficiently important in your view to justify what some of the pressure groups have been calling for; namely a moratorium on the use of nanotechnologies in food until further research is done and a more robust regulatory framework has been established?

Professor Burke: I am not in favour of moratoria because they tend to be situations where nobody does anything . I am hoping we can be more positive than that. What I do think is needed is the direction of a procedure which offers European governments a defence position against accusations of the ones you have just been making. The whole point of a regulatory procedure is that it looks at nanomaterials in food, so it is not only the chemistry that is going to be important or the switches in physical properties, but the presence of other components: oils, emulsions. It is also going to be moving to the route through the body, the excretion and so on. There are a lot of things we can do which do not seem to have been started. In the burgeoning field of synthetic biology there was a meeting at which I was present where we looked at the extent to which the current

regulations picked up the issues. It was a brainstorming group, put together by Defra I think. That was extremely useful. Nobody seems to have looked at nanotechnology with a variety of backgrounds and skills there, asking the question you just asked us and then asking what should be done about it.

Dr Falkner: On the question of a moratorium, I think it is a difficult instrument because it is a broad-brush instrument and so it covers a wide range of nanomaterials that perhaps do not deserve to be covered under a moratorium. A selective moratorium may be required when there are no risk assessment methods available to test the long-term impacts on health. I would just like to bring to your attention one provision in the European Union's Code of Conduct, a voluntary code of conduct that has been issued to all governments with a view to implementing it for researchers and everybody engaged in this. In 4.1.17, that Code of Conduct states: "As long as risk assessment studies on long-term safety is not available, research involving deliberate intrusion of nano-objects into the human body, their inclusion in food (especially in food for babies), feed, toys, cosmetics and other products that may lead to exposure to humans and the environment, should be avoided." That clearly states the precautionary approach to the use of nanomaterials in food and other consumer products where there is no risk assessment method available. I think that speaks volumes.

Chairman: We will make sure we have a copy of that. There are three Members who would like to ask follow-up questions. I will try to keep the questions and the responses brief, so that we can move on to others.

Q320 ***Lord Crickhowell:*** Some of us were on this Committee when we looked at REACH when it was being introduced. Of course nanotechnology really was not on the table at that time and so it was not considered when REACH was prepared. The Government comments on REACH that this is the way to proceed, but functionality rather than size, and, of course, there is a quite large, one-tonne threshold for import and so on before REACH comes into effect. It is what you do with the chemicals in the manufacturing process afterwards that may be the more significant element. Clearly REACH is going to have to be revised very considerably and reviewed. Is the European community approaching in an urgent enough way the revision of REACH so that it really does apply to nanotechnology?

Dr Falkner: I understand, having talked to Commission officials about this issue, that the Commission is well aware of the potential gaps to do with the one-tonne threshold above which the registration requirement kicks in. Most people within DG Environment (the responsible DG within the Commission) believe this can be addressed through implementation guidelines. However, they are also open to the idea that this will need to be renegotiated through legal change. The problem there seems to be that all the energies in Europe are vested in getting REACH off the ground and implementing it and the task there is tremendous. There does not seem to be much political energy in reopening REACH at this stage to deal with the small problem, namely nanotechnology and its coverage. I suspect that if we want urgent treatment of that problem, the question about REACH's ability to pick up nanomaterials, we should look at the implementation guidelines and get some more sense of urgency into the Commission on that front. But I would not rule out the need for regulatory reform.

Q321 ***Earl of Selborne:*** If we want to proceed with the urgent review of REACH, recognising how long REACH took to put in place in the first place, I know the Royal Commission did indeed urge for the Government to proceed with the European Commission to urgently review REACH to facilitate the effective application to nanomaterials. Are we being realistic? It took ten years to get REACH going in the first place.

Dr Falkner: I think there is a greater chance to achieve any reforms in the nanotechnology area, partly because all the concerned parties seem to be in agreement that REACH needs to work on nanotechnology. Nobody is keen within the chemical sector to start discussion of a separate nanotechnology instrument. Most parties, including industry, including the European Union officials, are keen to make REACH work. I think you have the potential there for a broad consensus on targeted reform. I agree with you entirely that it is going to take a long time and the European processes are systematic and comprehensive. I would suggest that this will not be a quick solution, but I think there is political momentum growing. The European Parliament is very keen to close the loophole. In fact, in all the current reforms going on in the cosmetics and food areas, it is the European Parliament that is putting in provisions, on definition on nanotechnology, on labelling provisions, and I think it is possible to move on that front. I think your Committee could very well make strong recommendations in that area.

Q322 ***Lord Cunningham:*** Dr Falkner referred to a selective moratorium. How could that be implemented and made practical in effect?

Dr Falkner: I suspect I am the wrong person to answer that question. Having proposed it, though, I feel in a bind to say something about it. I would love

to ask Professor Burke to comment on his own experience.

Professor Burke: If you are going to segment a field, I think I would segment out pregnant mothers and very young children first of all. I am not a toxicologist, and Professor Holgate is, but my knowledge is that they are particularly sensitive and difficult to predict. We are back in the situation where we have no evidence. Politically, it seems to me so sad that neither the UK nor any other advanced nation has tried to seize the high ground and move this debate on, because we are going to lose the ground.

Q323 ***Lord Methuen:*** We have heard about the problems of defining nanotechnologies and nanomaterials. We started off with a nominal 100 nanomaterials, which is just a magic number. It could be 250 or anything really. What role do you think the Government should play in this debate of defining nanotechnology? Do you think any definition has to be adopted both internationally and by the EU to be effective?

Dr Falkner: I think the Government should play an active role. It does already play a role. It is difficult for me to establish just how active the UK Government is in that area because much of that debate is led by representatives of the European Union at the level of the OECD and then by experts from industry and regulatory institutions at the International Standardisation Organisation. There are a number of processes under way. Some of these processes, such as the ISO process, are led by private actors. My concern there would be that governments need to ensure that they get the definitions that serve regulatory purposes and not only purposes of relevant industry communities. I think that is where the Government needs to step in to make sure that definitions work for all parties concerned and particularly for regulatory purposes. It seems to me this process is underway and has been underway for some years and there could be a greater sense of urgency about this process. Again, that could be an area where the Government can step in and invest more energies. We have had the first set of definitions come out of the ISO technical committee recently and the OECD itself is looking into definitions as well. All parties that we have spoken to in our project have voiced concern that this process is not going fast enough, because industry depends on definitions in order to establish where safety assessment is needed and regulation is needed to apply existing laws.

Professor Burke: I am in favour of a pragmatic approach. It is what happened with novel foods. All sorts of things came up which we had not anticipated. I remember a yoghourt was fermented with micro-organisms isolated from a Caucasian gentleman 110 years old—which might be of interest to Your Lordships' House. We had some really curious applications. Sometimes we could say nothing and sometimes it was clear that we had missed something. I am not in favour of lawyers trying to decide what is a nanomaterial. I am in favour of looking at what is coming up the line and seeing if we can deal with it, and if we cannot, then thinking of a way of dealing with it. I am a principled pragmatist, really.

Q324 ***Lord Methuen:*** The BRASS Centre, whose representatives cannot be here today, have raised concerns about the use of a technology-based approach to novel foods rather than a product-based approach in the European Commission's proposals for the new Novel Foods Regulation. Could you please explain your concerns? How you would view that?

Professor Burke: I do not think I am well-equipped to deal with that question. It was on a product basis?

Q325 ***Lord Methuen:*** Yes, whether you should define novel foods on a product-based or technology-based approach.

Professor Burke: I can see arguments both ways on that. I do not think I am competent to say. Novel is by definition product based, because it is something that you have not eaten before. On the other hand, articles produced by genetic modification tend to be treated as a group. I think that is a distinction without meaning personally.

Dr Falkner: The Novel Foods Regulation as it exists has a process-based trigger mechanism in article 1(2)(f). It says very clearly that "food and food ingredients to which has been applied a production process not currently used" require regulatory action, so that is already settled. I am not sure what the background to that concern is but, if anything, I would imagine it is to continue into a revised health foods regulation that then applies to nanomaterials. Indeed, in the draft that currently exists in the revision process, nanotechnology would then be mentioned as an example for a technology that would trigger regulatory action.

Q326 ***Chairman:*** What BRASS says in their written evidence is, "Some caution, however, should be expressed in respect of its technology-based approach to regulation"—this is the Commission's approach—"rather than a product-based approach in which the novelty of nanotechnology is determined on a case-by-case basis according to their individual properties, functions and hazards remains preferable." That is where BRASS is coming from. I wonder whether you agree with that.

Dr Falkner: I am not sure whether I can see the difference between that approach that is advocated here and the current technology-based approach, because as I understand it nanomaterials are categorically novel because they exhibit new

characteristics and behave differently. That is the whole point of creating nanomaterials. Even a product-based approach would probably yield very broad coverage of all nanomaterials. If they behaved similarly to bulk materials, there would be no need to look at them.

Professor Burke: I think it is much easier for a regulatory committee to look at a particular product and say what are its properties: Is it going to be taken in by the mouth? What is going to happen in the gut? How long does it stay in the body? Otherwise, if you go back to the technology-based approach, you finish up with the "all genetic modification is wicked" sort of approach, which helps a lot of groups but it does not help the politicians or governments and it does not help the regulators.

Q327 ***Lord Mitchell:*** Professor Burke, I have one point of clarification. I think you said with respect to regulation that you feel this should not be defined by lawyers. I am just asking how that occurs?

Professor Burke: I am not against lawyers—far be it.

Q328 ***Lord May of Oxford:*** Why not?

Professor Burke: We learned in novel foods by looking at cases, and then we had to generalise. I suppose my position is that we first of all look at the problems that the field is throwing up to us, and then we try to generalise. If you legislate, you almost inevitably have to try to define, and you then get a very poor definition which includes many things that are not necessary. The approach that is going on in synthetic biology is to say: "Are there any instances coming up the line which our current regulations will not look after?" That seems to me a more open and robust way.

Q329 ***Lord Haskel:*** Professor Burke, you have just said that regulation should be based on looking at each product on its own merits. But the European Parliament has proposed that when the Novel Foods Regulation is revised, it should apply explicitly to all nanomaterials. Presumably they are saying that regulation should cover nanomaterials as a whole and that we should not differentiate between food and other uses such as cosmetics. Would you agree with that? Do you think that is an approach that the Government should support?

Professor Burke: I am not personally in favour of that because I can see situations in which the toxicological implications would be different. I think that is too broad a brush. But I am sure that Dr Falkner has a position on that.

Dr Falkner: As I understand it there are two movements going on in Europe, one to reform the Novel Foods Regulation and one to turn the Cosmetics Directive into a regulation. In both these regulatory re-drafts, the European Parliament has inserted provisions of the kind that you have described, references to nanotechnology. As I understand it, they would merely clarify an existing assumption among European regulators that this is already the case. European regulators argue that all nanomaterials in foods fall under the Novel Foods Regulation, although there is no separate explicit reference to it, so the European Parliament would like this to be clarified and strengthened. I think the difference is one between legal text and regulatory practices and the two are very close. I do not think this will produce a dramatic change. However, it would, politically speaking, change the terms of the debate, as you have just suggested, Professor Burke, that we would begin to think much more in terms of regulating technology rather than materials. One could look at the precise wording here. If it were a case of regulating nanomaterials rather than technologies, if it was a case of novel products in foods rather than across different uses, then I think that would be a preferable solution.

Q330 ***Lord Haskel:*** If we try to regulate the technology rather than the use, do you think this would lead to things being condemned as a whole, as happened in other novel materials?

Dr Falkner: I think that is what the GM debate has taught us. However, I note with interest that it is scientists who themselves have created a buzz around the word "nanotechnology" and who have perhaps falsely argued for many years that every bit of research that goes on at the molecular level is now part of a big nanotechnology effort. In fact, I understand some would like to move away from that because what works well in terms of getting research funding does not work well when you then sell the outcome of that research to the consumer. We may well end up with a more nuanced debate as we move away from technology.

Professor Burke: But there are situations where you have to protect laboratory workers: the radioisotope regulations; the regulations over genetically modified organisms that I worked with back in the 1980s, where we had extreme regulatory controls of category 3 organisms, for example. Those were necessary in the nascent field to protect the operatives. That is appropriate to apply to a whole technology. Then you break down the instances case by case, as was ultimately done, and so on. But that is not quite what we are talking about. We are talking about protection of the consumers of the European Union by its national governments.

Q331 ***Lord O'Neill of Clackmannan:*** We have been talking about prospective regulation but we have been told that there is in fact a general food safety law which prohibits, across the EU, the placing of unsafe foods or products on the market. Do we need to

reinvent the wheel? How effective is this existing provision?

Dr Falkner: I think it provides a sort of first coverage of emerging nanomaterials. It puts the burden on industry to carry out safety risk assessment. Therefore, it is an important element, but on its own I do not think it would suffice. One of the reasons for that is that industry itself is uncertain about what new materials it needs to test and with what methodologies with regard to what kind of risks. The uncertainty that exists with regard to definitions, methodologies, exposure and hazard types is preventing that general safety provision from working properly. I think that is why you need a second regulatory layer on top of it to make sure there are clear guidelines.

Professor Burke: I can remember examples where what you suggest was necessary. It is often retrospective. The food inspectors found that there was selenium being sold as an additive to pills available in drugstores and selenium is toxic. But this was picked up by the scrutiny process that works under the Food Act. It is retrospective; it is not really protecting the population *ab initio*. I do not think it is adequate politically on its own.

Q332 ***Lord Crickhowell:*** The FSA is apparently considering a register of nano-derived foods and food contact materials. Would you support such a register? Do you think it should be voluntary or mandatory?

Professor Burke: I am certainly in favour of a register. We have to start. "We have hardly started" is the message that we are conveying. A register would be useful. I think you probably have to make it voluntary to start with, because I do not know what this net is going to draw in. It would at least give the nascent regulatory committee something to work with, some real meat to start putting through the regulatory machine. Ultimately, voluntary procedures are not very satisfactory politically because in Europe especially governments are expected to look after their citizens and prevent harm. My understanding is that in the US you can sue the manufacturer. Corning was driven out of business by suits over the silicone breast implants, for example. But that procedure is much less easy to use in this country, and in the face of blood contaminated with CJD it was government ultimately who picked up the bill.

Dr Falkner: I think a register is needed for two reasons: one, it is in the nature of a globalised food chain that a lot of new food ingredients, food materials, are being traded that we as a society but also the regulators do not know about. For that reason we need to move in the direction of greater transparency in global food chains. The question is then, of course: Is a register, whether voluntary or mandatory, the best tool for that? I think we have had some experiments with voluntary measures. Defra has run a two-year pilot programme. The evidence, as reported by Defra after the first two years, shows that only a third of the companies known to operate in the UK and producing nanomaterials reported to Defra, so two-thirds did not feel the need to follow voluntary reporting requirements. In the United States, the Environmental Protection Agency is running its own two-year voluntary pilot project. While arguing in the opening section that it was a great success, towards the end of the report EPA noted that only ten per cent of all nanomaterials known in the US have been reported under this scheme. For that reason, I think both agencies are now considering very carefully whether to move from a voluntary to a mandatory system. In fact the Canadian Government and the French Government have already issued statements to the effect that they are now planning to introduce mandatory requirements for companies to report nanomaterials. Whether this will have a broader impact in Europe is hard to see but the European Commission is likewise looking into a mandatory system.

Q333 ***Chairman:*** Is one Member State allowed to introduce a mandatory system without reference to the European Commission?

Dr Falkner: I do not know the European law on that specific matter, and it would depend under which legal category it would fall, whether it is only about food or whether it is about all materials, perhaps under the chemicals regulation more generally. I would have to look that up. This is only an intention, as yet. We have not had any development in that area.

Chairman: Perhaps we could follow up whether that is a European competence or a national competence.

Q334 ***Lord Methuen:*** What worries me, coming back to the food chain, is how far do you go, including fertilisers, pesticides, animal feed stocks?

Dr Falkner: It is a difficult question. As long as those new novel materials end up in the human body, whether it is through pesticide use or feed or, indeed, the use in food products, I think there is a good reason to require all such uses to be included. I think what we are talking about at this stage is only a register of materials in use. There is a more demanding register that one could imagine, which is to cover also environmental health and safety dimensions, which is a much more difficult one.

Professor Burke: But there is a network of committees which have been working for many years alongside the Novel Foods Committee. There is a committee—which of course the Chairman was a member of, I believe—on the release of genetic modifications into the environment, which supervised all plant trials;

there is a committee on toxicology; there are committees that are concerned with the safety of newborn children. The ministries and departments run a network of committees with cross-representation and often the transfer of material from one committee to another. I found that worked very well and the civil servants are very expert at guiding it through the system, so I think that problem is solvable.

Q335 ***Lord Cunningham of Felling:*** Can we learn any lessons from our past regulatory experience on novel foods and processes which would apply to nanotechnology?
Professor Burke: There are some things which we did which survived and some things which did not work. The Novel Foods Committee had a consumer representative on it very early who effectively had a veto. It had an ethical adviser who could say whether, in his or her view, this raised ethical issues which needed wider discussion. My successors as chairmen have operated the Committee in public. Agendas are now published beforehand, of course. All those have come to stay under the general principle of transparency. We were very fierce about conflict of interest in my time, and that has continued. A number of potential problems were dealt with. What we did not anticipate was a food that went into a very large number of products—and I am thinking of soya—produced by an American multinational, with claims which needed investigation that it was toxic to rats, coupled with a great sensitivity of the public to food risks because of BSE and other problems, and we got blown away. The Committee did do some gazing, some horizon scanning in my time, and since then—

Q336 ***Lord Cunningham of Felling:*** Excuse me interrupting, but do you think we should do that in respect of nanotechnology?
Professor Burke: Yes. I think scientists work very well that way. You get a group of about this size in a room and we ask ourselves, "What could go wrong?" Well, we thought of lots of things that could go wrong but not the one that did go wrong, but that is sometimes the nature of the game. We had a whole research programme looking at what happened to genes from genetically modified plants in—

Q337 ***Lord Cunningham of Felling:*** Forgive me, but I just want to get at who should organise the horizon scanning?
Professor Burke: That can be done by the government departments through their committees. I think all of us who have been working scientists have experienced horizon scanning, and in fact we do it every time we write the research grant. We look at the future and think what needs to be done. That is a style which I think scientists take very readily to. Particularly with the input from social sciences and people like Robert here, those can be very productive conversations. I do not think they have taken place.

Q338 ***Lord May of Oxford:*** You said in passing there that you were very fierce about conflicts of interest. I wonder what you meant by that. Protocols for science advice and policymaking, that the UK Government has and has had from 1997, very clearly state that conflicts of interest should be clearly identified but should not be used as a reason for excluding anybody. There are interesting examples where, in seeking to avoid conflict of interest, you exclude from the Committee anybody who knows anything about what is going on. No representative of the pharmaceutical industry may be on a Department of Health committee, which is clearly ludicrous. What did you mean by saying you were fierce about conflicts of interest?
Professor Burke: I can just say what our practice was. We had people from commercial backgrounds on the ACNFP in my time. We had one person I can think of specifically who was an expert on large scale fermentation whose input was unique and necessary. The regulations were read out at the beginning of each meeting, people were asked if they had any possible conflict of interest, they were then asked to explain what that possible conflict might be, and the committee made a decision whether the person could stay or not. It was a committee decision as to whether they thought there was a conflict. There was a consumer person there. I do not think we had a problem, but meeting in public is of course a much better way of dealing with this issue.

Q339 ***Lord May of Oxford:*** Clearly conflicts of interest should be very transparent and exposed, but I find curious the idea that you may exclude somebody, because there are always vagaries in the definition of conflict of interest. A commercial interest is a clear conflict of interest, but many of the NGOs or even the academic interests of social scientists are in some sense interests and they should be clearly identified and welcomed.
Professor Burke: The playing field is not quite level. People from companies bring skills which are essential for the regulatory process which are not found in the academic world.

Q340 ***Lord Cunningham of Felling:*** I want to go back, if I may, specifically on this point of conflicts of interest and people with knowledge and understanding of what is at stake. Do not people who have widespread knowledge and experience, maybe commercial, industrial, scientific or whatever, have something to say about how these new nano products would develop and how regulations for example are

going to have to run very, very quickly to keep abreast of them?
Professor Burke: I am ignorant. Do you know if there has been any discussion in the scientific community?
Dr Falkner: I think there is a lot of discussion going on in different stakeholder groups. I do not think there is an overall consensus on what needs to be done. If you look, for example, at the various industry interests, food producers are very different from food retailers. The food producers are very keen to keep labelling requirements, any identification of content, at bay; food retailers are much more open to such discussions. They have burnt their fingers over the GM issues. They put the labels on before legal requirements for labelling came into force and they feel this is the only way for them to remain neutral in the debate and to retain their reputation for food safety. In my research I have found that retailers tend to be much more open to a stricter, more intrusive and more comprehensive regulatory regime, because, ultimately, it beefs up their claims of food safety. The manufacturers, at least in Europe, where there are not many nanomaterials in use, seem to be sitting on the fence a little bit, watching the debate and trying to see which way it goes. They can see clear potential. They would like the science to continue to find new applications, but at the same time they know that if they have a huge brand value, if you take Unilever, for example, one of the big food manufactures, they could be easily tarnished with just one nanotech product that goes wrong. They are much more careful about those intrusive regulations. With regard to scientists I am not too knowledgeable about those things, but there is a lot of debate going on about what needs to be done to shore up public confidence.
Professor Burke: Scientists do not talk a lot about regulation. It is something that you have to do but it does not get you an FRS and it does not win any grants, so it is a duty as a citizen rather than an academic pursuit.
Dr Falkner: Could I respond to an earlier point about the lessons of the GM controversy and add a social science perspective to this?

Q341 ***Chairman:*** Yes.
Dr Falkner: I would make three points. I know it sounds very academic, but let me do this nevertheless. I think it will not do in the political area to insist that, on a scientific risk-assessment basis, nanomaterials are safe to eat. Even if we could reach that point—and there are great question marks about this—it will not do because food is part of a cultural system. People perceive food not just as a safety issue but as part of a broader system of engaging with nature.

Q342 ***Lord Cunningham of Felling:*** You are talking about manufactured nanomaterials.
Dr Falkner: Manufactured nanomaterials. I think we need to look at the ethical cultural dimensions. A narrow focus on scientific risk assessment will not do. Second, consumers demand transparency. Producers themselves have learned the hard way in the GM debate that if you even give the appearance of not wanting to be transparent (that is, not disclose food content) then you are suspected of devious practices.

Q343 ***Chairman:*** What you said about the voluntary reporting was that in the UK less than one-third of companies using nanotechnology report voluntarily and in the United States around ten per cent. That would imply that they have not necessarily learned the lessons about transparency.
Dr Falkner: But there are competitive issues at work. In a voluntary scheme you are at a disadvantage if you are transparent but your competitors are not required to be in the same way. That is why I would argue for a mandatory regime to level the playing field and to let the industry, in a sense, come out and declare what is in the food. The third point I want to bring in is the international dimension. We approach many of these issues from a national or European perspective, but any regulatory system that we end up with for nanotech food will have an impact on the global food trade. As we have seen in the GM trade debate, it caused huge furore in our transatlantic relationship: it led to a very contentious negotiation over the international biosafety treaty which the United States has so far refused to ratify. I think we also need to look at the international context in which any of these rules are set, therefore. We should seek internationalisation at an early stage.

Q344 ***Baroness O'Neill of Bengarve:*** You have led us to the very topic that is the last in this session, whether you think it is important to develop international co-operation on standards and regulation with the nanotechnologies and nanomaterials in the food sector. How can it be done?
Dr Falkner: We are going to produce a 140-page report on that very question, but it will not be until September.

Q345 ***Chairman:*** That is a Readers Digest—
Dr Falkner: It is what I tell my students: keep it short, brief, succinct. I would say that international regulation and harmonisation is very important. We have a couple of processes going on. The OECD is at the moment the main forum for regulatory interaction between the US and the EU. They are looking mainly at what I would call the scientific building blocks: the methodologies for assessing risk. They are running a couple of pilot projects to focus on the existing uses of nanomaterials; they are also now looking into co-ordinating research efforts; and they have just set up a new register of international

research projects that look at environmental health and safety research. The first steps have been made but I would say that they are very slow and they are not entirely transparent. The OECD does not have a great reputation for fast, dramatic and transparent action. It is a bit of a gentlemen's club for intergovernmental co-operation. It works well, in the sense that it creates space for regulators to talk to each other and to learn from each other, but it certainly will not be the main platform for developing internationally harmonised regulations. Whether we need an international treaty on this, I do not know. I have my doubts about that. We are not at the stage where this could be done in any meaningful way. There may well need to be such a treaty. If existing national regulations in the US and in Europe—but also think of the emerging economies (Brazil, China)—go in different directions, there will be a need for harmonisation. We are not at that point yet. I think much more needs to be done to, in a sense, prevent regulatory divergence. We are at a historical moment where we can do this without the heated political debate getting in the way. I think regulators on both sides of the Atlantic have that political space there to co-ordinate, but of course without the political pressure they do not feel the need to harmonise their own approaches. They very much focus on the national needs and that is what is missing at the moment, that sense of urgency.

Q346 ***Baroness O'Neill of Bengarve:*** Do you have specific concerns about the regulation of imported food products containing nanotechnologies and nanomaterials into the EU and into the UK?
Dr Falkner: In principle, all imported food products should be covered in the same way as domestically produced, so there is no legal distinction, as I understand, between those categories. The question for me seems to be one of detection and for that reason I would say international co-ordination of voluntary or mandatory reporting requirements is needed to harmonise those reporting requirements to make different national registers compatible with each other and to facilitate greater information exchange. It is quite extraordinary to go to international meetings on this subject and to find that regulators are very keen just to find out what the other side is doing about these matters and what is in their market. There seems to be a great deal of uncertainty about the presence of nanomaterials in food, and of course there are emerging producers, China and others, which do not have a good track record in that area.

Q347 ***Chairman:*** I would like to thank both of you for an excellent session and for the time you have taken to explain your views on the various questions we have put to you. In closing, are there any additional points you would like to make? I would also offer you the opportunity to write in with additional points if you think there are things we have not asked that we should have asked or where you have not had the chance to expand as fully as you would have liked to. If there are any brief comments you would like to make now, this is the opportunity.
Professor Burke: Just a concern, as a UK national, about the question I raised about complacency. I really worry that we may get caught by a repeat of the GM soya scenario with some product coming in from a wicked multinational based in North America about which ETC makes statements which no-one can refute and where we do not even have a protocol working in this country to look at things. I think we are in a weak defensive position politically and I am hoping your Lordships will stir the pot a little, because you are in the position to do it when maybe others have their minds elsewhere at the moment, to get something moving and to get the scientific community involved in some way. I was quite concerned when I looked at the ACNFP website to find that it was out of date and the interests of the group were out of date. I was not impressed by the urgency with which this topic was being tackled. A report from the House of Lords is a wonderful lighter of blue touch-paper.
Chairman: Thank you very much. That seems a very positive note on which to end. You will be sent a transcript of this session to make sure that it is accurate from your perspective. Once again, I would like to thank you both very much indeed for coming in to join us in this morning's session.

TUESDAY 9 JUNE 2009

Present	Crickhowell, L	Methuen, L
	Cunningham of Felling, L	Mitchell, L
	Haskel, L	O'Neill of Bengarve, B
	Krebs, L (Chairman)	O'Neill of Clackmannan, L
	May of Oxford, L	Selborne, E

Examination of Witnesses

Witnesses: PROFESSOR NICK PIDGEON, University of Cardiff, and MR SIMON BURALL, Director, Involve, examined.

Q348 ***Chairman:*** I would like to welcome both of you to the sixth of our public hearings in the inquiry into nanotechnologies and food and thank you both very much for joining us for this evidence session. I would remind you that the proceedings are being webcast, so the great public out there can watch and listen if they wish. I would like to draw to the attention of members of the public that the information note does list the Members' declared interests, so we will not be repeating those during the questioning but they are there for you to see. Before we start with the questioning, I would like to invite the two witnesses, Mr Burall and Professor Pidgeon, briefly to introduce themselves. If you wish to make any opening statement, this is an opportunity to do so.

Mr Burall: Thank you very much for inviting us to this inquiry. I am currently Director of Involve. We are an organisation that is about three years old and we are public participation specialists. We carry out research and practice into how you engage the public in challenging issues. In 2005—and Professor Pidgeon was involved in this—we formed, along with Cambridge University and the Office of Science and Innovation, the Nanotechnology Engagement Group and we carried out some research into six projects that tried to engage the public in discussions about nanotechnology. I am here today to talk a little bit about that and to draw on our much wider experience in engaging the public in challenging decisions.

Professor Pidgeon: Thank you again for the invitation to come and speak. I am Professor of Environmental Psychology at Cardiff University. I treat myself as an interdisciplinary researcher, spanning psychology, sociology and geography. I have had an interest for a number of years in research on public attitudes and public engagement with science and technology issues, including GM foods which we may get on to a little later on. My involvement in nanotechnology began in 2003 when I was asked to be a member of the Royal Society & Royal Academy inquiry. Since that time I have served on the Responsible NanoCode Initiative. Also, at a research level—sponsored independently, I might add, by the Leverhulme Trust, a charity, and also through collaboration with the USNSF Center for Nanotechnology in Society at Santa Barbara which is looking at risk perception and public response to nanotechnology in both the USA and the UK—as a collaborator and investigator, I have been looking at a number of these issues. The one opening remark I would make is that we are at a very early stage in trying to understand public understanding and perception on nanotechnology, both as a general concept and as food. The inquiry is timely, in the sense that if you had asked me to come here three years ago I would have come with very little evidence. There is a small amount of evidence now. I hope we can cover that during the session.

Q349 ***Chairman:*** Thank you very much. Perhaps I could kick off with a very general question. Both of you in your different investigations have looked into the question of how the public perceive nanotechnology in food at the moment. I wonder if you could just give us a brief thumbnail sketch of where you think we are in the question of public understanding of public attitudes to the use of nanotechnologies in foods.

Professor Pidgeon: If I may start. The first point is to make a distinction between public understanding and attitudes towards nanotechnology as a general category and public understanding and attitudes towards nanotechnology in food. You need to make a distinction between the two and I will just cover the evidence on the former first, which is just nanotechnology in general. We have had about six years of research on this in the US, in the UK and in Europe and there are really two evidence streams—there have been 12 or 13 surveys to date which are nationally representative in various nations and also more deliberative and qualitative work that has been conducted by groups of researchers in various locations. I will take the surveys first. What we know is that there are very low levels of awareness of nanotechnology amongst

the general public as a category. When we asked this question in 2004 of a British representative sample for the Royal Society inquiry over 70 per cent had not heard anything at all about nanotechnology. That result is pretty well replicated over time, with ups and downs in various locations, but there does not seem to be a big shift to more or less knowledge. There are therefore very low levels of awareness; that is very important to bear in mind in all of this discussion. But if you then go and ask the question do you think the benefits of nanotechnology will outweigh the risks or the risks will outweigh the benefits, a majority will give you the answer we think the benefits of this new technology will outweigh the risks. On first sight, putting those two together, that is a bit of a paradox; how can you judge that the benefits will outweigh the risks when you have just said that you do not know anything about it? But what is happening here is that people are bringing in a judgment about general technological progress, so when they are being asked about nanotechnology in surveys they think it is a new technology and we know from other surveys of attitudes towards technology in general, not in specific, the public remain very positive about science and technology. So that is what is partly basing that judgment. We also know that knowledge has an impact in some surveys, trust has an impact, gender also can be important in judgments about nanotechnology, so those are the surveys and we have to be very careful with these surveys because of this very low level of awareness. Anything more detailed asked in a survey makes it very difficult to interpret what the response really means from somebody. The more deliberative work, which has the advantage that you take a group of citizens, either in a focus group or in a longer citizens' jury, through a series of discussions on nanotechnology and maybe give them exposure to experts, has slightly more nuanced findings. There are initial difficulties engaging with the topic in a lot of these exercises, but as people become engaged they do start to understand and get going with it. The views on risks and benefits are more mixed. They are still on balance positive despite several attempts of research teams to raise the possible risks of nanotechnologies or the governance questions here, you still get on balance a positive response. But it seems to be application-specific, that is one of the emerging findings. In work that we did, in both Cardiff and Santa Barbara, we had groups looking at energy in nanotechnology and health and enhancement in nanotechnology and it was quite clear that the energy groups were much more positive about the energy applications, in fact they did not really see that there were many large risks with energy issues. That work is now published in *Nature Nanotechnology*. Where concerns come in—and this is not specific to nanotechnology, this would be generic with most new, uncertain technological issues that you put before a group of the public—is you do get concerns for long term unknowns, so what will the scientists do about unknowns at this point in time, and also concerns about the control of the new technology, so people will ask who can be trusted to manage or control it. That is nanotechnology in general. When we drop down to food we have got far less data but just one or two studies have come out in the last two or three years. If we accept from the general work that application matters you would expect—and I think this is likely to be the case—that nanotechnology in food will have a unique risk perception signature so you cannot necessarily extrapolate easily from responses to nanotechnology in aviation, let us say, or nanotechnology in cosmetics to food. The very few studies we have got—and I stress it is limited evidence—suggest at this stage that food applications, and I am quoting the International Risk Governance Council here in their recent report of 2009—

Q350 ***Chairman:*** Sorry, could we just collapse it a little bit because we have got quite a few more questions to get through.
Professor Pidgeon: Some Swiss studies suggest that nano inside is less acceptable than nano outside; for example, in the body versus packaging nano-applications. Nano-food applications are also less acceptable than energy and health and, to sum up, I have argued in a number of publications that it is difficult to say whether or not nano will be like GM, but in the food domain it looks very close to some of the things that caused some of the public controversy around GM in terms of its risk perception signature. There is also this question of lack of industry transparency currently, which was also affecting the GM controversy here, and also a question of trust in the food industry or not. When you take all those things together—going into the body, trust in the food industry and transparency—then nano in food looks closer to GM than many of the other nano applications.

Q351 ***Chairman:*** Thank you. Is there anything very brief that you would like to add to that?
Mr Burall: Three very brief points. The research in the six studies that we looked at showed that people are concerned about potential toxicity of nano particles, and they are concerned about both the risks and benefits. I would echo this point about trust as well, trust in the institutions both that regulate but also are developing technologies, and just the final point that echoes this is that food producers are very reluctant to participate in any of

the public engagements that we studied. A lack of trust kind of permeates this whole thing.

Q352 ***Chairman:*** We have heard from a number of sources that the food companies are reluctant to become the public face of nanotechnologies in food because they are afraid of a negative reaction. Do you think that is a reasonable position for them to adopt or is it counterproductive?
Mr Burall: It is both counterproductive and reasonable because the debate is contentious, the technology is uncertain and the risks are uncertain. The public is uncertain, the policymakers are uncertain and the public debate about what we should be using nanotechnology for, what the risks are, what risks we are willing to bear and what benefits we are willing to accept on the back of that risk are all uncertain. Industry is seen as pushing a particular commercial line—industry cannot lead this. In response to one of the questions you are going to ask later I was musing on the fact that if you are going to run an effective engagement with the public what you need to have is a neutral space where that happens and it needs to be convened by a neutral body. The industry cannot be that neutral body; even if it wants to push itself forward it cannot be that neutral body.
Chairman: That leads on neatly to a question from Lord Mitchell.

Q353 ***Lord Mitchell:*** It does. Let me preface it all by saying that in chats with my reasonably intelligent friends when I talk about this whole subject, particularly to do with food, number one they do not seem to know much about it and then they recoil in horror. I just wonder if there anything more we can do about public engagement. You started on that point but I will push it a little further forward because it is key to much of what we have heard.
Mr Burall: As I said we looked at six different studies—they were very small-scale—and we published a report two years ago, so Nick may have some more recent evidence. What was clear was that those that were more successful were those that spent time up front educating the participants in what the science was about, what the effects of the science might be and some of the boundaries of scientific knowledge. That was an important precondition. Secondly, having the public talk about it amongst themselves was not enough, you needed both the policymakers and the scientists in the room at the same time as well, because what was important coming out of these deliberations was not the policy recommendations that could be read in Whitehall, it was actually the discussions about the technologies themselves, it was the process that was important. Unless scientists and importantly policymakers are involved in that conversation what comes out of it has a much lower impact, so if you are going to go down the route of engaging the public you do need to, one, educate them so that they have got the level of understanding but, two, then properly engage and not have it as a conversation between a limited number of participants.

Q354 ***Lord Mitchell:*** I was just going to add that the Nanotechnology Engagement Group produced a report in 2007 documenting the results of a series of public engagement activities with the public about the development and governance of nanotechnologies. The report made a number of recommendations to Government and I just wondered how effectively you think those recommendations have been taken forward.
Mr Burall: I am not sure that I can answer that question very effectively. My sense is that things have not really moved very far forward since that report was written and that the field of public engagement has not really progressed much further. The clear starting point for all public engagement, whether it is about nanotechnology or anything else is that whoever is commissioning it needs to be very clear about why they are doing it.

Q355 ***Lord Mitchell:*** Do you sense it is different in other countries or the same?
Mr Burall: I certainly cannot answer that question, I am sorry.

Q356 ***Chairman:*** Professor Pidgeon, have you got any views about other countries?
Professor Pidgeon: I can partly answer that question. In the US they are starting to do engagement but are behind the UK and Europe. In Europe there are a number of activities that have been going on. In defence of the funding of public engagement in the UK, the Royal Society recommended public engagement around nanotechnology and, looking back over the five to six year period since that report and its recommendations have bedded in, there have been a number of experiments in the UK, some directly funded by government, others partly funded by NGOs or the Research Councils. The one thing I would say is that there has been a reluctance by industry in the food domain to get involved. So if there is a gap, looking back, then it is here and it is on this topic, and I guess that is one of the reasons why you are holding an inquiry into this. If I were to evaluate the Government's funding of this and the work that has been done over the past six or seven years, my colleagues and I would say that the UK has actually established a lead in public engagement around nanotechnology compared to most other countries.

Q357 ***Lord Crickhowell:*** Can I ask a specific question about this 159-page report of the Nanotechnology Engagement Group? You have already commented about the pluses and minuses for industry of being involved in the public debate, but what I found extraordinary reading this report is that there is the participation of public groups finding out, there are policymakers and there are academic scientists, but nowhere in this report could I find any participation by representatives from industry who are actually developing the technologies which we are concerned with. It seemed to me an extraordinary omission in a study of this; was it deliberate or why is there no input? Surely if we are going to have a serious discussion on this issue the people who are actually moving on from the pure scientific research to develop the kind of products are a vital input?
Mr Burall: I would agree with that, industry is clearly a vital input. What the Nanotechnology Engagement Group was doing was evaluating other people's studies and the studies that were evaluated were the ones that were happening in the UK at the time, so it kind of exposes what you are saying, that those experiments in public participation were not including industry. Clearly that is a huge gap and it is a gap, I guess, particularly in the food areas as has already been said, that it is very difficult to fill because the food industry is struggling to give itself a public face in this arena.
Professor Pidgeon: One example would be that Unilever sponsored a very important public engagement exercise at the back end of the 1990s on GM food, crops and agriculture. It has been very difficult to get companies like that to do what they did at that time with this issue. It is partly the GM saga that has influenced opinions there—there is a nervousness there.

Q358 ***Lord Crickhowell:*** Did they refuse to take part in this exercise or were they not invited to participate?
Professor Pidgeon: Remember there was a whole group of exercises convened by different bodies and parties and funded in different ways. My guess would be that industry was asked at various points and where they were asked maybe they felt they could not take part. Maybe it was easier just to do it at this stage with academics and NGOs and other partners—the Government had some input as well, as I have indicated, to some of these exercises.

Q359 ***Earl of Selborne:*** I want to come to another initiative, the Responsible NanoCode initiative, which Professor Pidgeon reminded us that he participated in and I remind the Committee that I was also involved in it. I would just remind the Committee that it was a voluntary effort in the absence of national and international regulation to try and set out a code for how all participants might address the issue of how you market and regulate voluntarily nanoproducts and Unilever, Tesco, banks, trade unions and others were involved, so it was a good representative group. I would ask Professor Pidgeon in particular, as he was involved in this exercise, whether voluntary codes like this have any real relevance in the face of commercial imperatives and, furthermore, whether there is a role for their proposal, which was that there should be a permanent Nano Commission-style organisation to continue to engage stakeholders and advise government on issues, or is it all inevitably doomed to failure until proper regulation is put in place.
Professor Pidgeon: The argument is of course that voluntary codes are useful where there is an absence of regulation or where the regulatory framework has taken time to follow developments in industry and elsewhere. So of voluntary codes for example the Forestry Stewardship Council and others are held to work well. The aim with the NanoCode is to fill a gap that was clearly there two or three years ago when the parties were brought together. Whether or not a voluntary code works well will depend upon who signs up and the principles of the code. In fact there are about four such codes that have been developed independently and say not exactly the same thing but a basic set of principles that are fairly similar, so in the absence of a broader framework it is right that that initiative went ahead and that the code is there. We shall see in practice. The question of a Commission we debated on the Royal Society inquiry fairly extensively. I am personally somewhat ambivalent about that: recommendation 21 of the Royal Society inquiry was for a wider body because we felt at that time that just to focus on nanotechnology might be too narrow. There was, and remains, a case for horizon scanning, looking at some of the ethical and social issues and looking at some of the emerging risk issues across the new technology domain. That is actually a recommendation that government has not fully taken up and in a sense it is a shame that it has not. But for nanotechnology specifically, I am not sure that the case could be made now that really was not made then. What would tip the balance is if it were clear that there really were serious potential public sensitivities and serious risk issues that needed to be coped with in the near future, and it may well then be the case that there would be strong pressure to have something like a Nano Council.

Q360 ***Chairman:*** Mr Burall, do you have anything to add to that?
Mr Burall: I guess codes alone, whether they are voluntary or not, probably are not enough in this area because of public trust. One of the key elements of this has to be engaging the public in understanding and perhaps even developing the codes to try and build an element of trust into the system. That would

be one point. On the question of the Commission there is clearly a need to develop a better infrastructure for engaging the public on much broader issues than just nanotechnology, again because of the trust issue. We are doing some work with the Danish Board of Technology, which is part of the Danish Parliament and has been going for 30 years. Their role is to facilitate discussion—I see many heads nodding—between Parliament and the public. They say it takes five years to train a professional to do that sort of thing properly. One, we do not have the capacity to do these things and, two, setting up independent commissions on different issues probably is not good enough because there is a range of technological issues. Secondly, building the links between those commissions and the infrastructure that is funding, that is regulating and so on, these different technologies is actually really quite challenging, and unless there is a body that is really properly institutionalised and is having a dialogue both with the public and backwards into these institutions that are trying to take on board the recommendations, actually it is very difficult to get things to happen. I would say again that unless there are some significant terms that arise actually to have a broader commission that can have a broader dialogue about many of these different types of issues would be a much better idea.

Q361 ***Lord Haskel:*** You have told us an awful lot about how important the process of engagement is, but it all seems to be a bit ad hoc. Whose responsibility is it to carry out or to run public engagement? Is it the Government, is it industry, is it academia, is it charities or is it some independent neutral bodies? If this is going to be successful whose responsibility is it to get it done?
Mr Burall: It is in everybody's interest to get it done and the question is where can the muscle come from to have it happen and, secondly, how can you make it happen in a way that makes it work effectively as a process of dialogue. Government has to make it happen but whether government is the convenor and facilitator of it I am less certain and it may well depend in part on the issue, which may again speak to why you may need a broader commission than just trying to do this on an ad hoc basis depending on the issues. It needs significant clarity in terms of money, in terms of being able to communicate the results, being able to communicate the process and so on, but it needs neutrality. Perhaps government facilitating this through Parliament may be one very good route to do this.

Q362 ***Chairman:*** What about the issue of trust here because earlier on one or the other of you said it is difficult for the industry to take a leadership role because if they did people would be suspicious about what it was they were trying to foist on the public or cover up? Do you think that the issue of trust leads you in a particular direction in response to Lord Haskell's question?
Mr Burall: Also to Lord Crickhowell's point earlier, why is industry not part of this? Probably one of the reasons industry has not been part of the things that we studied for the Nanotechnology Engagement Group was precisely because they did not trust the process. So trust is absolutely critical and it has to be trust from all sides—the public, scientists, stakeholder groups, Parliament, government. That trust has to be across the board and how you create that trust depends on the process you set up. It is not an easy thing.

Q363 ***Chairman:*** Professor Pidgeon, do you want to add anything?
Professor Pidgeon: Just briefly. One convenes an independent steering panel. That has been done with a number of the exercises that have been conducted so far. That would then include a number of the interests involved: industry, NGOs, scientists, government as well because of the link back into regulation. That is the way to deal with this irrespective of where the funding or the initial sponsoring of the debate comes from. You avoid an overemphasis on the interests of the sponsor if you already have an independent steering panel.

Q364 ***Lord Haskel:*** How would you introduce the ethical element, which is important?
Professor Pidgeon: The people who take part introduce the ethical element because partly this is about trying to understand the people's values, and in the previous evidence sessions on food and GM it was about cultural issues, so that comes very much from the people who are deliberating. You are trying to present a neutral space with some science, some evidence and some positions that have been set out by the NGOs, industry and others for people to then debate and decide some of the ethical issues or at least raise them for us.
Mr Burall: It is really important to be clear about why you are setting it up. Are you setting it up in order to inform policy and inform research or are you setting it up in order to give some democratic legitimacy to the policies that come out of it? Real clarity about why you are setting it up will impact totally on who you involve, on the process you use to get there, so being absolutely clear and explicit about what you are trying to achieve by establishing a body is really absolutely vital, it will fail if you are not certain about that, not clear about it.
Chairman: Thank you. That leads to the next question. Lord May.

Q365 ***Lord May of Oxford:*** The next question really continues this. My question is what do you think is the best way of going about making sure that public views and concerns are integrated into the making of policy in ways that do help ensure that public opinion and concerns inform the regulatory framework and also inform the questions you want to be asking about research topics that are still insecure? I realise you have already said a lot of sensible things about this but I wonder if in addressing that regulatory framework and research priorities you could pay a bit of attention to the fact that we use the word "public" when the public is a very protean concept. Very often the mechanisms which are most convenient for engaging something that is called the public engage subsets of them that are not necessarily representative.

Mr Burall: One of the things about the challenge you are highlighting there is the difficulty of actually getting a representative sample because if you write to 1000 people perhaps only ten will turn up to something that is about nanotechnology, so actually getting a representative sample is a challenge in and of itself. If you are looking for public engagement to be one of the bits of evidence that informs the development of a regulatory framework and the intervention of research then holding not one-off events but events that happen on a number of different occasions that involve giving the public information first of all and then allowing them to deliberate, absolutely crucially as I said before, with scientists and policymakers, then what you can get is some real insights from both the public and from scientists about the direction of the research. One of the fears we found in our research of scientists going in was that the public would be ill-informed, anti-science and anti-nano and a number of the quotes in the report make it very clear that actually that was not the case. On the other side the public were really frightened that scientists would be aloof and arrogant and, again, that misconception was broken down. So it is possible to run these things in a way that breaks down misconceptions and has a dialogue that then can inform research, and there are a number of examples in that report of scientists who have gone away and said "I am actually going to look at this question now, it had not occurred to me before", so by running a proper, deliberative two-way process you can inform research and therefore regulation.

Professor Pidgeon: A number of the dialogues that have occurred in the UK already have findings which regulators ought to look at. The UK Nano Jury said to treat nano-materials, if there are any uncertainties, as new materials for regulatory purposes. That is not rocket science but it was a recommendation of the public. Also there is some sensitivity about voluntary reporting and other systems for health and safety, so some of that evidence is already there. The difficulty is linking it into the policy process; even if you have a government sponsor for some kinds of deliberation it is not transparently clear that a recommendation would immediately then go to Defra or FSA or wherever and would influence their policy. That has always been the gap in this and it is always a great difficulty. What often happens though is that influence occurs further downstream: so a deliberation will occur, some findings will get into the public domain, and then when something is being designed in government eventually somebody takes notice of that in a more indirect fashion—the evidence shows that it is often much more of an indirect impact. It is difficult to do, therefore, at a regulatory level. On the research level this idea of bringing panels of citizens to debate research priorities should not be the sole arbiter of funding decisions either. I am sure we would all agree that that is actually funded and sponsored but it is a guide to what, potentially, the public would want to see public money spent on.

Q366 ***Lord May of Oxford:*** Specifically what do you think is the role of consumer groups in this process and, coming back to Lord Crickhowell's question, what do you think is the role of industry in being engaged in this process? Against that background what is your opinion of the recent EPSRC study of engagement activities in nanotechnology and healthcare in light of the discussion we have been having?

Professor Pidgeon: Consumer groups are trusted by the public, that is the first thing, so you would have to have them involved in the same way as the green organisations are trusted in relation to environmental issues, so if one is interested in the trust question they have to be part of the stakeholders who are involved in these processes. I looked at the EPSRC process—Simon probably has comments as well—and I thought the process was reasonable. There were some issues, perhaps they wrote it up quite quickly and as a social scientist I would have spent longer analysing the data properly, but the findings resonated with some of the findings from other research and deliberation activities. Again, the question then is how does that influence policy, how does that influence funding? It is quite a difficult thing to go from a list of priorities and applications and then to say do we prioritise funding or not? That is for the EPSRC and the Research Councils to decide for themselves really.

Mr Burall: It comes back again to what are you trying to do and that will determine who should be in the room. Clearly there are a number of processes where you would not want to cut out the consumer groups or the industry, particularly where you are engaging in a much more political discussion about what the regulations might be, but if what you are trying to do is inform the regulations and you want to get an understanding of what the public thinks about the issue you may not want them in the room because you are trying to do something different. Again I am going

to bang on about this: being very, very clear about what you are trying to achieve is absolutely critical to determining who will be in the room.

Q367 ***Lord Haskel:*** If you say that what you are trying to achieve is the acceptance of nano products in food and you do all of these things, at the end of the day I imagine you will find that some people will say that nano products in food are going to poison you and others will say they are fine. What do you do then?
Mr Burall: If you are trying to push in one direction the acceptance of nanotechnology in foods then the process will potentially immediately be distrusted, if that is what your objective is and you are essentially doing a PR or communication exercise.

Q368 ***Lord Haskel:*** What about the acceptance of nanotechnology in food?
Mr Burall: If what you are trying to do is build an understanding and a consensus about what the social benefits might be, what the risks might be and where society stands on those, and that is leading to policy decisions about regulation and the direction of research, then that is a different thing. If the public felt we were pushing the acceptance of nanotechnology they would hear "you want us to drink grey goo". If what they hear is "we are interested in understanding where you think the risks and what your attitude to the risks is", that is very, very different and will lead to acceptance of some things and not of others, so that is why what you are trying to achieve is absolutely critical.

Q369 ***Lord Crickhowell:*** Coming on to the question of labelling, do you think that products using nanotechnology or containing nanomaterials should be labelled at point of sale and do you think that this will be useful to consumers?
Professor Pidgeon: It is a very difficult one because again nanotechnologies have a multitude of applications. If we are thinking about food, labelling only works when a consumer also knows what to do, so has some control over the risk management individually and is able to adapt their behaviour in some way, either by not buying the food or using it in a different way. It is a very difficult one and again, going back to the Royal Society inquiry, I know there was a small labelling recommendation but the consensus of the discussion from even the consumer group that was represented there was that this is a very difficult issue. You have the difficulty that you might stigmatise a whole set of products just because one has a health and safety issue associated with it. What do people do with this label anyway? You just end up with a packet that is full of labels about this, that and the other and it may not provide useful information. The question therefore is how do they provide a consumer with useful information that would help them to actually make a decision or behave in a different way, and that is the difficult one.
Mr Burall: I would echo all of that and just go on to reflect that we also do not want to get into a situation where we have a profusion of labels, so if we are going to go down the route of labelling it would seem sensible to try and get to an understanding of what a label can allow a consumer to do. Also the body that labels—again trust is absolutely critical here—has to be seen to be neutral, and industry would appear to be in a poor position to do the labelling from that perspective, but it may or may not be to their benefit to label.

Q370 ***Chairman:*** Do you think there is any analogy here with the labelling requirements for GM? The argument there was of course that people should have the right to choose; it was not anything to do with safety it was about consumer choice. Do you think there is an analogy here?
Mr Burall: I suspect, given the level of debate and understanding about nanotechnologies at the moment, there probably is, and the question is can you get society to a state where it feels it understands the risks and benefits of the technology? Perhaps the debate is not in that space, but at the moment it probably is there I would say.

Q371 ***Lord Crickhowell:*** This is obviously the problem that the Food Standards Agency has identified and is exactly the problem that you have been talking about. Those of us who look at labels are worried about the quantity of information that is on the label and whether it has any meaning, but there is a sort of curious danger. I came across it in one of those magazines that advertise travel products someone calling it a nano product. I thought it was an entirely meaningless phrase but there is a danger if people start calling nano as being vaguely a selling point, and therefore if we are going to label it from the point of view of informing the public you have to be very clear about what you are going to put on that label which is meaningful, is that not right?
Mr Burall: The term nanotechnology itself, coming back to objectives again, appears to cover a vast swathe of products as you say, and if it is small it is nano—we have got a car called Nano have we not? There is clearly a huge issue about terminology here that is obscuring the public debate or preventing a meaningful public debate.

Q372 ***Lord Crickhowell:*** Until we get a definition of some clarity about regulation really it is not a route that we can seriously go down, is it?
Mr Burall: It is not something we are expert in but personally it seems to be quite challenging.

Q373 ***Lord O'Neill of Clackmannan:*** The Government in its response to the Royal Commission of Environment Pollution report on Novel Materials said that it would establish a pilot website that the public can access to give a balanced source of information on nanotechnologies including research, products and regulation. Do you think that this is a worthwhile initiative or is it window-dressing?
Professor Pidgeon: I know a little bit about the development as well because it has grown partly out of the NanoCode activities. It is a big task, it is part of the process of making nanotechnology and the issues around nanotechnology transparent to the public, so anything that adds to that in a sensible way is a good thing that we should support. But it will depend on a number of things—in particular adequate funding and commitment over a period of time. If the pilot is seen to work then it requires a very long term commitment. It will require, to come back to this point, the involvement of trusted parties from the public's point of view, whether you are running it as an independent process or with an independent steering board. So there have been a number of things put into place. Also one of the difficulties is that because nano is very much upstream there are still a lot of uncertainties—that is why we are talking about the risks—there is a difficulty about what you put on the website. That is not to say that it is not a useful thing.

Q374 ***Lord O'Neill of Clackmannan:*** You are damned if you do and damned if you do not.
Professor Pidgeon: You then have to come back to Sir John Krebs and the Food Standards Agency response to BSE and the Lords' Science and Society Report of 2000 where they were very clear—and they were very successful in doing this—that where there was an uncertainty they would say "Okay, we are not going to just say nothing, we say there are uncertainties here, this is what we are doing, there is research being done and there are regulatory steps being taken", so you explain how in some sense these issues are being dealt with. That was a very successful strategy as far as I could see, both for the Agency and for those who wanted to get information from the Agency. Part of that process, if it can be done properly, then looks to be welcomed, yes.
Mr Burall: Just two points, one to echo that is the need for transparency, it cannot come across as being a PR and communications exercise for the industry or for government trying to push a particular line. It has to be open about the risks and open about where there are "known unknowns" to steal a phrase. That is one thing, absolute transparency to build on trust. The second is not to just launch into it but actually to understand what the public might want from it and what stakeholder groups or consumer groups might want from it. The last thing you want is to, one, produce information that people do not want or in a way that people cannot access it and understand it or, two, only provide partial information and you then get another group that is putting up contradictory information. If it is going to exist it has to be the portal for this information.

Q375 ***Lord O'Neill of Clackmannan:*** There have been identified research, products and regulation. Do you think there is anything else required of the website, or under these headings is it just as important to keep updating it, which in itself might be an expensive and difficult operation? What are your feelings on that?
Mr Burall: I would just say that what appears to be missing is what the public's understanding of the technology is and the public's views of it. That would not just be about producing surveys and giving survey results but actually saying that communication of this sort cannot be the only strategy, engaging the public on an ongoing basis and then feeding that and the results of that onto the site would seem to be absolutely critical.

Q376 ***Lord Cunningham of Felling:*** Should there be a register of nano-derived food products and food wrappings associated with this?
Professor Pidgeon: There is a simple answer to that; I would say yes, it would be a good thing to have and it comes back to the transparency question immediately; it is very important. There was also the subsidiary question of voluntary or mandatory and again my advice would be that it should be mandatory because there is always a suspicion in the public mind about voluntary systems that they will not work properly. In fact, in research that we conducted last year in the US in a survey, refusal to voluntarily report when presented to members of the public was an extremely trust-destroying item. People are very suspicious that industry will not voluntarily report, so that would be the benefit of a mandatory system. Of course, there are all sorts of practical difficulties with mandatory systems, IPR et cetera, but surely it should be possible to overcome that in the interests of transparency?

Q377 ***Lord Cunningham of Felling:*** Who should operate it?
Professor Pidgeon: The Food Standards Agency could operate it, I guess, as the regulator, with some kind of independent board.

Q378 ***Lord Cunningham of Felling:*** Is there any point in having such a mandatory register in a single country?
Professor Pidgeon: Someone has got to start the thing off.

Mr Burall: I guess if you feel it cannot be enforced then probably not. I have just two reflections: one is that a register seems to be a sensible idea because the last thing you want is rumours about nanotechnology in this or that food or this or that product, so a register seems to be a good thing, but reflecting also on the discussion that was being held earlier about labelling, unless the public can actually do something with that—

Q379 ***Lord Cunningham of Felling:*** When you say nano products you mean manufactured ones because there are nanomaterials occurring naturally.
Mr Burall: Indeed, absolutely. A register seems to be a good thing as a way of countering rumours but it runs into many of the same issues that labelling would appear to run into.
Professor Pidgeon: There is a caveat on that though. When you do focus groups with members of the public about this very issue, about openness, whether it is nuclear energy or GM, what you do find is that people want the information to be in the public domain. If then you ask the question would you yourself go and actually consult it most people generally say "No, not necessarily, unless I have a health issue or there is something specific in my family that prompted it, but I want it in the public domain because I know then that somebody else can look at it, so that somebody can perform a watchdog role." That is the idea of having a public domain register; you personally do not actually go to it but you are aware that potentially somebody is looking at it and scrutinising it. It is the opportunity for others in civil society to look on your behalf.

Q380 ***Chairman:*** I wonder if I could just ask a general question about public engagement, which is this: can you point to examples of where the kind of public engagement exercise that you have discussed with us has been successful in the sense of changing public attitudes, depending on what it was, maybe from scepticism about a technology to acceptance of it, or is there a cynical view, that this is a nice little earner for academics and the public engagement industry and is all very well, but actually public attitudes and opinions are affected by what is in the *Daily Mail* as opposed to what is done by academic researchers or public engagement? How would you respond to this two-pronged question?
Mr Burall: I would respond by perhaps not drawing on the field of technology but by talking, briefly, about two case studies that are kind of outside that area. One, British Columbia was struggling with the voting system which was delivering very odd results; a Liberal Government got in in 2001 or 2003 and pulled together a citizens' assembly to discuss voting systems. Citizens engaged every second weekend for six months on understanding this issue, discussing this issue and coming up with a recommendation that went to referendum. The referendum was expected to fail because public understanding of the issue was very low, but it just missed getting a double majority. The follow-on story would suggest that in the end that was a failure but what it was successful in doing was demonstrating that the public is able to engage with these issues and that they can make sensible policy recommendations that can have an impact on political debate. We also ran a process in Jersey where there were issues of an aging population, of low tax base and so on and, to cut a long story short, the State of Jersey had very few policy options. At the end of this process there were a series of policy options that involved tax, immigration and so on that were not open to them before, so it is possible to have these debates about very, very contentious issues and widen policy choices and impact on the public debate, but they have to be run properly.

Q381 ***Chairman:*** But neither example is to do with novel technologies. Professor Pidgeon, are there any examples that relate to novel technologies where public engagement has "worked"?
Professor Pidgeon: It depends what it is for, because you do not do public engagement to change attitudes on a broad societal level, that is the first thing to say.[1] I am thinking of the one that did not work, which was GM Nation, because the people in the room in many of the activities had prior positions and clearly did not change. I go back to the UK Citizens' Jury on nanotechnology which was run in 2005 and the recommendations there. It was a six-week process, there were a number of evidence sessions with witnesses. At the end the recommendations were fairly ad hoc and fragmented at one level because they did not have very clear direction at the start of the process, but people had gone from "We know nothing about this"—and it was actually quite a deprived community that they drew people from for that citizens' jury, so it was not the chattering classes doing this—to a series of balanced recommendations which said we need to think about this but actually nanotechnology could be a very good thing for society. You did not get an amplification of risk around the engagement, you got quite a sensible discussion at the end of that debate, so in a sense that group of 12 or 16 people had their attitudes changed, or better described as formed, as a result of the engagement and that was a positive thing. I would not say it was a failure.

[1] " A recent US National Research Council report "Public Participation in Environmental Assessment and Decision Making", 2008 (ed. T. Dietz and P.C. Stern, Washington, National Academies Press) is relevant. Chapter 7 in particular reviews the evidence measuring the impacts of dialogue on participants. The report concludes that 'best practices in public participation can advance decision quality, legitimacy and capacity simultaneously' (p 92)."

Chairman: Thank you. One final comment from Lord Cunningham.

Q382 ***Lord Cunningham of Felling:*** Can you tell us, what is a democratic technology?
Mr Burall: A democratic technology?

Q383 ***Lord Cunningham of Felling:*** As it says on the front of this report.
Mr Burall: I am always slightly sceptical of scientific metaphors coming into social sciences but what it is attempting to say is that we have relied on representative democracy for 100 year to take democratic decisions but there are other ways of doing it as well, there are many different ways that you can get the public to deliberate. They may be around citizens' juries, they may be around huge citizens' panels, the word technology refers to a different type of process, about getting people into a place where they can discuss things.
Chairman: I would like to draw this session to a close by thanking both Simon Burall and Professor Nick Pidgeon for joining us and for answering our questions so thoroughly. I would like to also invite you if you have any additional points you would like to make, that either we did not ask or we did not give you time to expand on fully, please do write in. If you make additional points they will be included in the written evidence that we will take into account and publish. I would also mention to you that the transcript of this session will be sent to you to enable you to check for any errors or misrepresentations of what you said before we finally publish it. With that I would like to thank you both very much indeed.

TUESDAY 16 JUNE 2009

Present	Crickhowell, L.	Mitchell, L.
	Cunningham of Felling, L.	Neuberger, B.
	Krebs, L. (Chairman)	O'Neill of Clackmannan, L.
	Haskel, L.	O'Neill of Bengarve, B.
	Methuen, L.	Selborne, E.

Memorandum by Research Councils UK

Summary

Nanotechnologies offer a broad range of potential applications in the food sector. For example:

— Food production and agricultural processes may be improved through the use of nanotechnologies in the applications of pesticides, or in crop monitoring.

— Use of nanotechnologies in both packaging and edible film coatings for food products may help to extend product shelf life by reducing exposure to moisture or gases.

— Nanoencapsulation technologies for improved delivery of food functional ingredients and manipulation of dietary nanoparticles to optimise absorption of nutrients offer benefits to human health.

The Research Councils fund relatively little research relating directly to the applications of nanotechnologies in the food sector, but support a much wider portfolio of nanotechnology research which underpins a variety of potential application areas, including applications relating to food, in areas such as nanotoxicology, nanometrology, characterisation and detection, nanotechnology-based sensor devices, food manufacturing and processing, and food structure.

While the use of nanotechnologies and nanomaterials in the food sector offers the prospect of significant benefits, there are uncertainties about the potential risks of nanoparticles to human health (as well as potential environmental impacts, though these are outside the scope of this inquiry). More evidence is required to inform policy and regulation.

Regulatory considerations, economic viability and consumer acceptance will ultimately dictate the success of nanoproducts and nanotechnologies in the food sector. It is therefore important that clear regulatory and risk assessment frameworks are established as soon as possible, and that public engagement activities are initiated at an early stage and are continued as the technologies and applications develop.

Introduction

1. Research Councils UK[1] (RCUK) is a strategic partnership set up to enable the seven UK Research Councils to work together more effectively and enhance the overall impact and effectiveness of their research, training, innovation and public engagement activities.

2. The Research Councils welcome the opportunity to respond to this Inquiry. This evidence is submitted by RCUK on behalf of the following Councils:

— Arts and Humanities Research Council (AHRC);

— Biotechnology and Biological Sciences Research Council (BBSRC);

— Economic and Social Research Council (ESRC);

— Engineering and Physical Sciences Research Council (EPSRC); and

— Medical Research Council (MRC).

[1] Further details are available at www.rcuk.ac.uk

3. It represents their independent views, and does not include or necessarily reflect the views of the Department for Innovation, Universities and Skills (the sponsoring Government department for the Research Councils).

4. This response focuses mainly on research, training and public engagement, in keeping with the Research Councils' missions and roles. Annex 1 provides summary information about relevant cross-Council research programmes, and Annex 2 sets out some definitions.

5. The field of nanotechnology is one in which the UK has considerable investment and an increasing potential for exploitation in industrial applications to the benefit of the UK economy and society. All Research Councils have activities associated with this broad area of research. Examples of Research Council activities are highlighted throughout this response.

6. All of the Research Councils, with the exception of AHRC, are members of the cross-agency Nanotechnology Research Co-ordination Group (NRCG) and the Nanotechnology Issues Dialogue Group (NIDG). The RCUK Nanotechnology Group, which has representatives from all Councils and the Technology Strategy Board, co-ordinates Research Council activities in the area of nanotechnology, including Research Council inputs to NRCG and NIDG. All of the Research Councils and the Technology Strategy Board are partners in the EPSRC-led programme Nanoscience through Engineering to Application.[2]

State of the Science and its Current Use in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

7. An overview of potential applications of nanotechnology in agriculture and food is available on the Nanowerk internet portal at: http://www.nanowerk.com/spotlight/spotid=1846.php

Food Production and Agriculture

8. Nanotechnologies will play an important role in the food supply chain from "farm to fork", where improvements in food quality, efficiency of processing and supply, and reduced losses of food bring major benefits, including in terms of increased choice, higher quality and lower costs for consumers. Nanotechnology promises new products and approaches to assist crop protection. For example, smart sensors and delivery systems may help combat viruses and other crop pathogens through early detection of disease, and monitoring of soil conditions to improve application of water, fertilisers and pesticides. In addition, new products may help plants' ability to absorb nutrients.

Food Safety and Quality

9. The application of nanotechnologies and nanomaterials in food packaging may contribute to increased food safety, eg nanoprinting for product authentication and identification, or nanoscale in situ sensors for food quality monitoring.

10. Nanotechnologies used in both packaging and edible film coatings for food products may help to extend product shelf life by reducing exposure to moisture or gases. For example, the MRC funds work into the development of nanoparticulate surfaces that inhibit bacterial biofilm formation, with potential applications to food storage. Increased shelf life for foods subject to rapid spoilage such as fruit and vegetables not only impacts on food quality, but could also contribute to reducing household waste, and so food demand. In the UK, roughly a third of the food bought by consumers is thrown away.[3]

11. Nanotechnologies may also be used to improve the textural properties of food, or to enhance flavours.

Health

12. Food based nanotechnologies have the potential to improve health. The range of potential benefits is large, and likely to be underestimated.

13. Absorption of nutrients may be optimised by manipulating the properties of nanoparticles in the diet. For example, current fortification and supplemental forms of iron are poorly absorbed and potentially toxic in the circulation and/or gastrointestinal tract. Scientists at MRC Human Nutrition Research (HNR), Cambridge, are exploiting nanoparticle technology to synthesise novel ferric iron structures that mimic natural food iron, allowing optimal bioavailability. These are currently being tested in human volunteers, and may lead to better treatment of iron-deficiency anaemia. This nanotechnology is also being used to control levels of other key

[2] http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/Intro.htm
[3] WRAP, The food we waste, http://www.wrap.org.uk/retail/food_waste/research/the_food_we_waste.html

molecules, including through sequestration to reduce harmful accumulation in disease. Further evidence on this work will be given orally to the Select Committee by MRC scientists, although further written details can be provided on request.

14. Improved delivery of food functional ingredients (eg vitamins, antimicrobials, flavourings, colourings, preservatives) through use of nanoscale carriers is another potential application. Nanoscale delivery systems for micronutrients (essential for human growth and development eg vitamins and minerals), and neutraceuticals (non essential but confer health benefits and contribute to prevention of some diseases) are intended to maximise delivery to, and release at, the desired site of action. Nanoencapsulation of functional ingredients such as preservatives and flavourings may improve functionality whilst minimising concentration by protecting against degradation and allowing controlled release.

15. Nanoparticles may be used to protect people with food allergies by blocking the surface structures which trigger the response.

16. Nanotechnologies and nanomaterials may be used to make food healthier (eg by increasing the nutrient content, inclusion of antioxidants) without adversely affecting the taste.

17. Nanotechnology also has the potential to improve food processes that use enzymes to confer nutrition and health benefits. For example, enzymes are often added to food to hydrolyze anti-nutritive components and hence increase the bio-availability of essential nutrients such as minerals and vitamins. To make these enzymes highly active, longlived and cost-effective, nanomaterials can be used to provide superior enzyme-support systems due to their large surface-to-volume ratios compared to traditional macroscale support materials.[4]

18. The MRC funds a range of nanotechnology-based projects with therapeutic potential, although these are mainly outside the scope of the present inquiry.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

Food Products

19. Publically available information on the use of nanomaterials in food products is limited. The Woodrow Wilson International Centre for Scholars (The Wilson Centre) has established an online inventory of consumer products using nanotechnology,[5] identified by the manufacturers. As of August 2008, this inventory indicated that of 803 products or product lines using nanotechnologies, 80 products were in the food and beverage category, none of which were produced by UK based companies. Of these 80 products, just three involved use of nanoscale materials as ingredients in food products. However, this inventory relies on information provided by companies about the scientific characterisation of their materials, and is therefore unlikely to present an accurate reflection of the current state of the market.

Food Production Processes including Packaging

20. As part of the food supply chain, nanotechnology has already delivered improvements to pesticide delivery through encapsulation and controlled release methods. Capsules can be inert until contact with leaves or insect digestive tracts, at which point they release the pesticide.[6] In combination with the use of nanoemulsions (suspension of nanoparticles), pesticides can be applied more easily and safely.

21. Nanotechnology is used in packaging to improve the shelf life of foods, for example by the inclusion of silicate nanoparticles that prevent oxidation and spoilage.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

22. Nanotechnologies and nanomaterials which will have particular relevance in the food sector[7] include:

(a) Nanoscale encapsulation technologies, such as nanoemulsions (suspensions of nanoparticles) and biopolymeric nanoparticles (nanometer sized particles derived from food grade biopolymers such as proteins or polysaccharides), which can be used to encapsulate, deliver and release food functional ingredients. These nanomaterials offer better release efficiency, improved protection from degradation, and controlled delivery systems for functional ingredients, compared with traditional encapsulation technologies. The use of nanomaterials in food to sequester, and then enable the excretion of, unwanted materials from the body is also being explored by MRC scientists.

[4] http://www.nanowerk.com/spotlight/spotid=1846.php
[5] http://www.nanotechproject.org/inventories/consumer/
[6] http://www.syngentaprofessionalproducts.com/to/prod/primo/
[7] http://members.ift.org/NR/rdonlyres/FA9DE19E-1AFF-4B94-9012-CDAC3C45B0FF/0/Nanotech.pdf

(b) Food-grade nanoscale coatings (comprising two or more layers of material with nanometer dimensions) which can be used in the production of edible films for foods such as fruits, vegetables, meats and chocolate. These edible films protect foods from (spoilage caused by) exposure to moisture, lipids and gases, and can also be used to improve the textural properties of food, or serve as carriers of colourings, flavourings, antioxidants, nutrients and antimicrobials. Nanoparticulate surfaces may also be used directly to inhibit bacterial growth.

(c) Nanofibres and nanotubes derived from food biopolymers may have applications in the food industry as elements of environmental friendly food packaging, as scaffolding for bacterial cultures or to provide support systems for enzymes

(d) Sensor devices which use nanotechnology (eg lab-on-a-chip, cantilever devices) might be used to monitor foods either for impurities/contaminants or for spoilage.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

23. The Research Councils support a broad range of activities relating to nanotechnology, which includes support for research which has or may have applications in the food sector. Some indicative figures on recent Research Council investment in the area are provided in paragraphs 24–35 below.

24. The MRC spent £3.8 million on research into nanotechnology (including nanotoxicology) in 2007–08. The MRC has a current commitment of £900k for two grants which have/may have an application within the food sector. The MRC is also supporting a programme in one of its units with relevance to the area, with a spend of £840k in 2007–08.

25. The MRC's mission is to improve human health through world-class medical research. Within this remit, research into both the health benefits and potential health risks of nanotechnology is supported. Research in this area is funded in responsive-mode and as part of the MRC's intramural programme. As the potential therapeutic uses of nanotechnology in food begin to be realised, the MRC expects to receive increasing applications from the scientific community in this area. In particular, nanotoxicology has been identified as a topic for one of five MRC "highlight notices", encouraging applications in nanotoxicology relevant to human health. The highlight notice has recently been refined, particularly to promote applications involving an *in vivo* component. The aim of this highlight notice is to help inform policy development in this important area.

26. EPSRC leads the cross-Research Council Programme on *"Nanoscience through Engineering to Application"*,[8] which supports investigator-led research and training as well as infrastructure/equipment to ensure the best use of resources. The programme has also identified a series of "grand challenges" in nanoscience and nanoengineering, focused on the areas of energy, healthcare and the environment, spanning basic research through to application. All of the Research Councils and the Technology Strategy Board are involved in the programme.

27. In total EPSRC has committed over £220 million to nanotechnology research in the last five years. None of this is directly related to food research although a significant amount supports underpinning research in areas such as nanometrology, characterisation and detection that might lead to new measurement or processing techniques that would be of relevance to the sector.

28. BBSRC has an extensive portfolio of food research (covering the entire food supply chain, from agricultural processes to dietary impacts), with an estimated spend of £185 million in 2007–08. BBSRC also has an active nanotechnology portfolio (based on a specific definition of nanotechnology, set out at Annex 2), with an estimated spend of £6.1 million in 2007–08. The total BBSRC spending in 2007–08 on research relating to nanotechnology (as defined above) and food was £0.7 million. Other grants in the BBSRC nanotechnology portfolio might also have downstream applicability to the food sector.

29. Some of the underpinning technologies developed in areas related to nanotechnology, such as drug delivery, materials and sensors, could also potentially be applied to the food sector. Using a broader definition of nanotechnology (encompassing related areas of drug delivery, materials, sensors, tissue engineering and tools), the total BBSRC estimated spend in 2007–08 on research relating to nanotechnology and food was £4.5 million.

[8] http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/default.htm

30. Many conventional food materials contain structures at the nanoscale. BBSRC supports research on food structure and processing within a broad category of "food manufacturing". BBSRC's estimated 2007–08 spend on food manufacturing research (a subset of the food research portfolio) was £5.3 million, a significant proportion of which was awarded as Core Strategic Grant funding to the Institute of Food Research. The Institute of Food Research will be providing independent evidence to this inquiry.

31. ESRC has funded research on more cross-cutting issues which relate to food. Research questions include: what are the key drivers of public and scientist perceptions of risks and opportunities of nanotechnologies in this application?; what is the likely impact on industry and economies, including from the convergence of nano with other technologies?; how will the global development of science and innovation and their multi level regulation-affect these technologies?; how, when and why will public engagement and social influences affect development of these technologies?

32. The ESRC has also carried out an authoritative review of the social, ethical and economic aspects of development of nanosciences and nanotechnologies. The reports, published in 2003[9] and a follow-up in 2007,[10] explain what nanotechnology is as well as its existing and potential consequences, and identify important issues for research and society.

33. In January 2009 a workshop on *"Nano: Regulation and Innovation: The role of the Social Sciences and Humanities"*, facilitated by a UK academic and supported by the Research Councils was held at the RCUK Beijing Office. The workshop, jointly presented by both UK and Chinese academics, covered aspects of ethical challenges, and governance and regulation.

34. Cross-Research Councils programme and activities relating to nanotechnology are outlined at Annex 1.

35. Details of Research Council Units, Centres and sponsored Institutes that conduct research relevant to this inquiry are at Annex 3.

What are the barriers to the development of new nano-products or processes in the food sector?

36. Regulatory considerations, economic viability and consumer acceptance will ultimately dictate the success of nanoproducts and nanotechnologies in the food sector.

37. Continued uncertainty over EU/UK regulations for the use of nanotechnologies and nanomaterials in the food sector may stifle research and development in the area. A clear regulatory and risk assessment framework would serve to increase (public) confidence in technologies, and stimulate investment in food-related nanotechnology research.

38. Development of new nanoproducts or processes must be coupled to appropriate research into, and risk assessments of, the potential effects of those technologies. Adequate funding for research into the environmental and health and safety implications of nanotechnologies will be essential to their application and acceptance in the food sector.

39. Further underpinning research to develop understanding in areas such as molecular self-assembly, surface engineering and techniques such as electrospinning, will be vital for reliable production of nanoscale structures. Further research is also needed on measurement and characterisations systems so that they can be deployed on a widespread basis.

40. There are limited funding opportunities targeted directly at nanotechnology applications in the food sector, compared with competing application areas (eg healthcare, energy). In the current economic climate, where industrial/commercial sector funding for research may also be limited, there is a risk that the development of new nanoproducts or nanoprocesses related to food will be restricted.

Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?

41. Nanotechnologies have the potential to cause harm as well as benefit, but their toxicology and toxicokinetic properties are not well understood. The same unique properties that confer many of their benefits may also cause damage to the body in unexpected ways. The MRC has made awards at a total level of £3 million for research projects in the area of nanotoxicology. This research aims to better understand the uptake of nanoparticles into cells and the functional consequences including oxidative stress, inflammatory response, cell death and genotoxicity. By linking this information to the physical and chemical characteristics of

[9] http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/Nanotechnology_tcm6-5506.pdf
[10] http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Nano07_tcm6-18918.pdf

nanoparticles, predictive models for nanoparticle toxicity can be developed that will help risk assessment. A lot of this work is currently focused on the lung and, although some of the principles may be transferable to other organ systems, more evidence is needed to inform policy and regulation.

42. The MRC has a current commitment of £900k (see para 26 above) for two grants relevant to the health and safety implications of the use of nanotechnologies in relation to food.

43. ESRC's remit covers research into the health and safety implications of nanotechnologies and nanomaterials in the food sector, however currently there are no projects being funded directly related to this area.

44. EPSRC funds potentially relevant research in the area of developing new methods of measurement and characterisation.

45. The Research Councils also support research into the environmental impacts of nanomaterials and the potential effects of environmental exposure on human health, for example through the Environmental Nanoscience initiative and the Environment and Human Health initiative, both led by the Natural Environment Research Council (NERC). However, this is largely outside the scope of the present inquiry.

Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?

46. The Research Councils have a variety of funding mechanisms through which research into the health and safety implications of nanotechnologies and nanomaterials can be supported:

- Responsive mode—applications are accepted at any time and in any research areas which fall within the Council's remit. Highlight notices, signposting or identification of priority areas may be used to encourage submission of applications in particular areas.
- Research programmes at Research Council Units, Centres and sponsored Institutes (see Annex 3)
- Nanotechnology grand challenges[11]—the primary delivery mechanism for the cross-Council programme *"Nanoscience through Engineering to Application"*, each Grand Challenge works through a stage gate process, starting with the basic science but looking to the issues of scale up, including reliability, reproducibility and safety considerations. The two Nanotechnology Grand Challenges established so far do not relate directly to food sector applications, though safety issues identified in other application areas (eg healthcare/nanomedicines) may be of relevance.

47. The current Research Council funding portfolio for research relating to the health and safety implications of nanotechnologies and nanomaterials in the food sector is relatively small (see paragraphs 41–45 above). It is likely that further research will be needed to inform policy and regulation, and the Research Councils will continue to welcome applications for research in this area through the mechanisms described in paragraph 46 above.

Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

48. The draft scientific opinion published by the European Food Safety Authority,[12] highlights current uncertainties for risk assessment of nanotechnologies (specifically engineered nanoparticles—ENMs) and their possible applications in the food sector. The reports states that: "Current toxicity testing approaches used for conventional materials are a suitable starting point for case-by-case risk assessment of ENMs. However, the adequacy of currently existing toxicological tests to detect all aspects of potential toxicity of ENM has yet to be established", and recommends that "risk assessment of ENM in the food and feed area should consider the specific properties of ENM in addition to those common to the equivalent non-nano form". The report recognises that formulation at the nanoscale changes the physico-chemical characteristics of materials as compared to the dissolved and macroscale forms of the same substance, and that properties such as particle size, surface-to-mass ratio and surface reactivity will be important for new applications, and in establishing the associated potential health and environmental risks.

[11] http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/RC/grandchallengesnanotech.htm
[12] European Food Safety Agency, Draft opinion of the Scientific Committees on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety, (October 2008) http://www.efsa.europa.eu/cs/BlobServer/DocumentSet/sc_opinion_nano_public_consultation.pdf?ssbinary=true

Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?

49. Many foods naturally contain nanoscale materials; these are not considered to require additional regulation. For manufactured nanomaterials, even when derived from naturally-occurring nanomaterials, appropriate assessments of risk and safety should be made. In many cases, there is no prior reason to expect that manufactured nanoparticles would be any more hazardous than naturally-occurring ones. Regulations should then be risk-based and proportionate.

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

50. here are currently no internationally accepted definitions of "nanotechnologies" or "nanomaterials", leading to problems both for industry and regulatory bodies in terms of labelling protocols, risk management strategies and methods for regulatory data capture.

51. Regulations should ideally cover the entirety of the process—from basic idea to product development and commercialisation—in a consistent manner. International mutual recognition of standards should be a parallel consideration.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

52. The UK Voluntary Reporting Scheme for engineered nanoscale materials, co-ordinated by Defra, was set up for industry and research organisations to provide Government with information relevant to understanding the potential risks posed by free engineered nanoscale materials, though this was not specific to the food sector.

53. It may be beneficial to compare the UK's experience of voluntary reporting with the impacts of new regulations elsewhere in the world, eg Canada's proposed mandatory reporting requirement for nanoscale materials.

54. Use of voluntary regulatory codes in other areas has often been directed more at public relations than at standard setting. As such voluntary codes cannot be considered as adequate replacements for effective regulation.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

55. Regulatory and risk assessment frameworks should be informed by research into the environmental and health and safety impacts of nanotechnologies and nanomaterials in the food sector. Regulations should be reviewed regularly to ensure they remain fit-for-purpose as new technologies and materials are developed.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

56. Intergovernmental co-operation should address the responsibility in research, and the need to share knowledge of potential or emerging hazards between stakeholders in a reasonably open way.

57. Depending on the definition of "standards", ISO (International Standards Organisation) TC229 (Technical Committee) is defining basic standards such as "nanotechnology"; the UK is well connected with this and chairs the Committee (Defra leads in this activity) There is also a significant OECD activity in this area, where the UK is playing a significant role (Defra leads in his activity), though this may be outside the scope of "food".

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

58. An initial point to note with reference to public awareness of nanotechnologies is that although terms such as nanomaterial or nanotechnology have specific meanings to scientists, their definitions are blurred in popular language. This is indicative of the limits of the information available with which to engage the public. There is little information about how commercial and public developers intend to use nanotechnology, few if any commercially available products and no specific formal risk assessment and regulatory processes are in place.

59. Further, it should be noted that the debate around nanotechnology and food is likely to be a "lightning rod" for a range of other issues which will require careful handling, for example corporate control, use of patents, relationship between government regulatory procedures and industry, and in particular the precautionary principle and the safety of nanoparticles. This poses a risk that any possible issues specific to nanotechnology and food become lost in wider debate. Framing of the engagement to avoid or minimise this is therefore required, though it is also important to maintain an awareness of public engagement activities undertaken in related areas (eg nanomedicines), where comparable issues may be raised.

60. The industrial, scientific and regulatory community should not take public acceptance for granted, especially whilst potential safety risks are being openly acknowledged. Despite a deficit of "hard facts", the public could and should be involved, even at an early stage, in identifying key concerns and laying down benchmarks so that systems are in place to deal with issues as they arise when more evidence emerges. The Research Councils have been involved in several public engagement activities (see paragraph 63 below).

61. In depth focus groups (conducted for the ESRC SCARR network by Cardiff University School of Journalism, Media and Cultural studies) found the following:

— few people who participated in the research knew anything at all about nanotechnology;

— if people "know"' anything about nanotechnology they tend to associate it with medical treatments (eg mini robots healing sick people) or minaturisation serving consumer convenience (eg "Ipod Nano" brand);

— the current association of nanotechnolgy with medical science or consumer-senstive business gives it a different—more positive—profile than GM crops (GM was most associated with food and industry-out-for-profit).

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

62. All of the Research Councils are committed to public dialogue and engagement around the research they fund, and recognise the need to be as open and transparent as possible about the publically-funded research they support. Details of funded research grants, including any industrial or other commercial co-funding, are published on the relevant Research Council website.

63. The Research Councils have been involved in several public engagement activities used to examine public perceptions of nanotechnology (see Annex 4), though these have not related specifically to the use of nanotechnologies in the food sector, where public acceptance will be critical.

64. Initially, small scale deliberative dialogues may be an appropriate way to engage the public about nanotech applications in the food sector. This would help to scope a wider public engagement, and could follow a format similar to, and build on, those that have already taken place around other aspects of nanotechnology. This would enable an understanding of likely public attitudes including nanotechnologies specifically associated with foods, and reactions to some specific actual or possible applications. This will inform as to how the technology and its potential might be discussed most constructively both to raise public awareness and engender public participation in shaping research and policy development, and regulation (including labelling).

65. Public engagement should be independently co-ordinated (eg not by Government or industry) and overseen by a panel representing a wide range of stakeholder opinion.

66. It is important to ensure that industry are involved in public dialogue surrounding new technologies from an early stage, to build trust between public authorities, industry and NGOs.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

67. The timing of public engagement is important. In the past, engagement activities have been most successful (eg stem cells) where they have been pre-emptive of significant breakthroughs in the development of new technologies, but where the underlying principles are widely available and disseminated. This has allowed the public to help influence the direction that the technology takes and to ensure that it is regulated to a level that they feel comfortable with. The Royal Society/Royal Academy of Engineering report *"Nanoscience and Nanotechnologies: Opportunities and Uncertainties"*[13] (2004) strongly recommended "upstream" public engagement.

[13] http://www.nanotec.org.uk/finalReport.htm

68. Limited current awareness of nanotechnology and its breadth as a subject and range of potential applications in food, will be challenges in public dialogue. Whilst the public will have many, probing questions which they will rightly expect answers to, the information may simply not be available to answer those questions. Engagement activities should handle this uncertainty openly and positively, so that it does not trigger negative attitudes towards nanotechnology even before the benefits of the technology are apparent.

69. Applications in food, as opposed say to medical uses, are likely to raise concerns about ownership, consumer choice, and adulteration of natural processes, as seen in the GM debate.

70. Organisations such as AHRC/SCRIPT and Innogen have long-standing experience in related fields (eg biotechnology, GM food etc) on which it would be prudent to draw.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

71. Previous experience with GM food has shown that the public values transparency and choice. This suggests that it would be advisable to provide information or even labelling, about products that contain nanotechnologies or nanomaterials. However, this might inadvertently imply hazards, or be completely meaningless or confusing to consumers. Any information that is provided should be accurate, impartial and balanced, and clearly distinguished from any advertising.

72. Public engagement should involve asking people what information they want. Information about why products are made in a particular way and what the benefits are is likely to be of more interest than technical information.

March 2009

Annex 1

CROSS-RESEARCH COUNCIL PROGRAMMES AND PARTNERSHIPS RELATED TO NANOTECHNOLOGY

RCUK Nanotechnology Group

A cross-council group which co-ordinates Research Council activities in the area of nanotechnology, including Research Councils' inputs into the NRCG/NIDG. This group also includes representation from the Technology Strategy Board.

Nanoscience Through Engineering to Application

http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/Intro.htm

A cross-Council programme which operates primarily through a series of Grand Challenges aimed at enabling nanotechnology to make a unique contribution to areas of societal importance such as energy, healthcare or the environment. Each Grand Challenge works through a stage gate process, starting with the basic science but looking to the issues of scale up (reliability, reproducibility, safety etc). The programme has also supported, through EPSRC, three centres for doctoral training and an equipment sharing scheme. The Programme is managed by the RCUK Nanotechnology Group.

Annex 2

DEFINITIONS

RCUK has adopted the following definitions, provided by the Royal Society/Royal Academy of Engineering report *"Nanoscience and Nanotechnologies: Opportunities and Uncertainties"*[14] (2004):

Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.

Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer scale.

In conducting portfolio analyses, BBSRC used the following definitions:

Nanotechnology is the field of science focused on the design, synthesis, characterisation and application of materials and devices at the nanoscale. This involves the control and characterisation of properties at a molecular level, rather than inferring (hence controlling) properties from macro-scale performance. More

[14] http://www.nanotec.org.uk/finalReport.htm

broadly, nanotechnology includes the many techniques used to create or manipulate structures at a size scale below 100 nm.

Includes:

- fabrication of DNA nanowires, DNA tweezers or DNA based nano structures and machines;
- lithography techniques;
- molecular self-assembly techniques;
- molecular motors;
- molecular machines;
- studies involving scanning probe microscopy and arrays/microarrays;
- MEMS (microelectromechanical systems); and
- miniaturisation and single molecule studies.

Excludes:

- Research included in the broader definition of bionanotechnology, ie drug delivery, biomaterials, sensors, tissue engineering, tools—unless included according to the definition above.

Annex 3

RESEARCH COUNCIL UNITS, CENTRES AND INSTITUTES RELEVANT TO NANOTECHNOLOGY AND FOOD

BBSRC Institutes

www.bbsrc.ac.uk/organisation/institutes/sponsored_institutes.html

The BBSRC institutes conduct long-term, mission-oriented research using specialist facilities, some of which are unique in the UK or internationally (such as animal disease containment facilities, long-term field experiments). They maintain strong interactions with industry, government departments and other end-users of their research to provide advice and promote knowledge transfer, and are leading partners in numerous overseas collaborations. BBSRC institute that conduct research of particular relevance to this inquiry are:

- Institute of Food Research (Norwich)—food structure, quality and safety, diet & health. The Institute of Food Research will be providing independent evidence to this inquiry.
- John Innes Centre (Norwich)—plant and microbial science underpinning crop production.
- Rothamsted Research (Harpenden) and North Wyke Research (Devon)—arable and grassland agricultural systems, including long-term field experiments (some continuous since 1843).

ESRC Centres

CARR, the ESRC-funded Centre for Analysis for Risk and Regulation[15] is an interdisciplinary research Centre which focuses on the organisational and institutional settings for risk management and regulatory practices. CARR has identified that there is a great deal of regulation and governance research which is at the core of CARR's work; for example: learning from the attempts to regulate previous novel materials; issues around the framing, enforcement and impact of regulation; examination of how risk and uncertainty are handled in regulation and governance situations Another aspect of CARR's remit is analysing how different groups work together and regulate ie state regulators and regulators who are situated beyond the state eg Professional groups (eg scientists), industry groups and other forms of self-regulation. Also relevant of course is the potential for public engagement.

Cesagen (the ESRC Centre for Economic and Social Aspects of Genomics),[16] a collaboration between the Universities of Cardiff and Lancaster, focuses on the social, policy, economic, ethical and legal aspects of "genomics" and associated developments. This is focused primarily upon genomics-related sciences, and such molecular-scale sciences and interventions encompass nano research and innovation. Issues such as whether the development of nanotechnology requires the development of new ethical and/or regulatory approaches or principles are being researched.

[15] http://www.lse.ac.uk/collections/CARR/
[16] http://www.genomicsnetwork.ac.uk/cesagen/

Innogen (ESRC Centre for Social and Economic Research on Innovation in Genomics)[17] is a collaboration between the University of Edinburgh and the Open University. Research includes work on strategies to facilitate interdisciplinary science (as in nanotechnology), company strategies for the development of socially beneficial innovations, and the effective governance of life sciences; and key researchers are involved in the development of a new approach to risk governance of nanotechnology, particularly to bring in more effective public engagement and a more sensitive approach by companies to public concerns.

SCARR (Social Contexts and Responses to Risk) is a recently completed research network which looked at risk in everyday life and how the actual risk, or those risks identified as high priority by organisations such as government or business, may differ from people's perceptions.[18] This included work in the field of nanotechnology.

STEPS (Centre for Social, Technological and Environmental Pathways to Sustainability at the University of Sussex) has investigated nanotechnology as one example of the effects of new technologies on people and the environment, in the context of developing countries.

BRASS (Centre for Business Relationships, Accountability, Sustainability and Society at the University of Cardiff), produced a policy briefing entitled *"Nanotechnologies: Gaps in the Regulatory Framework"*.[19] The current regulatory framework was designed to regulate traditional technologies. The policy brief considers a report produced by BRASS and asks whether the current regulatory framework is sufficient to regulate free engineered nanoparticles (development, manufacture, supply, use and end of life).

MRC Units and Centres

http://www.mrc.ac.uk/Ourresearch/Unitscentresinstitutes/index.htm

The MRC funds a range of directly-supported units, several of which conduct work relevant to nanotechnology and food:

— MRC Human Nutrition Research (Cambridge)—this "collaborative centre" exists to develop the evidence underpinning public health nutrition strategies. It provides a national centre of excellence for the measurement and interpretation of biochemical, functional and dietary indicators of nutritional status and health. Work currently conducted in this Unit includes the use of nanotechnology to regulate mineral uptake from foods, and the associated heath (and safety) implications of this technology.

— MRC Toxicology Unit (Leicester)—this Unit aims to study and understand the fundamental mechanisms of toxicity, particularly mechanisms of cellular and tissue response to injury caused by drugs, chemicals and endogenous molecules. The study of nanotoxicology comes within this remit. The MRC Toxicology Unit also manages the Integrative Toxicology Training Partnership (ITTP). ITTP aims to build capacity in toxicology and related disciplines that is required to ensure the save and effective development of drugs, chemicals and consumer products through partnerships between academia, industry and government. The initiative has a budget of ~£3.5 million and so far 20 studentships and one career development fellowship have been awarded to UK Universities, including projects to investigate the toxicity in nanoparticles.

Annex 4

RCUK INVOLVEMENT IN PUBLIC ENGAGEMENT ACTIVITIES RELATED TO NANOTECHNOLOGY

EPSRC Consultation on Nanotechnology for Healthcare

As part of the nano Grand Challenge in Healthcare, developed through the cross-council theme *Nanoscience through Engineering to Application*, EPSRC conducted a public dialogue exercise. Information on this activity is available at: http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/RC/ConsultNanoHealthcare.htm

NanoJury UK

BBSRC provided financial support to NanoJury UK, which took place in summer 2005.

This "citizen's jury" brought together 20 people, chosen to represent a broad cross section of society but also inclusive of a number of ethnicities and religions, to discuss issues surrounding nanotechnology.

The report summary is available on the BBSRC website at: http://www.bbsrc.ac.uk/society/dialogue/activities/nanotechnology.html

[17] http://www.genomicsnetwork.ac.uk/innogen/
[18] http://www.kent.ac.uk/scarr/scarrprojects/scarrprojects.htm#media
[19] http://www.brass.cf.ac.uk/uploads/NanotechPBD.pdf

NanoJury UK was sponsored by Greenpeace UK, The Guardian, The IRC in Nanotechnology at the University of Cambridge, and the Policy, Ethics and Life Sciences Research Centre at Newcastle University

Nanodialogues

The Nanodialogues project, led by Demos, was a series of four public engagement experiments about nanotechnology, which ran from 2005–07.

BBSRC and EPSRC were involved in the second of the four experiments, which set out to answer two questions:

- What are the sorts of questions that are likely to determine future public response to nanoscience and nanotechnologies?
- What should public engagement with early technologies look like and how can Research Councils build public value into their work?

The project report and evaluation are available at:

http://www.bbsrc.ac.uk/society/dialogue/activities/nanotechnology.html

BBSRC "What is Nano?" Exhibition and "Nanotechnology and You" Meeting

The Government's 10 Year Investment Framework for Science and Innovation, and the think-tank Demos in their leaflet *"See-through Science"*, called for public engagement early on in the development of technologies, such as nanotechnology.

BBSRC's first "Nanotechnology and You" discussion meeting took place at Edinburgh International Science Festival in April 2006, supported by BBSRC's *What is nano?* Exhibition. A summary of the discussion meeting is at: http://www.bbsrc.ac.uk/society/meetings/archive/meeting_nanotech.html

BBSRC's "What is Nano?" exhibition is available to view at: http://www.bbsrc.ac.uk/society/meetings/archive/exhibition_nano/exhibition_nano.pdf

March 2009

Examination of Witnesses

Witnesses: Dr John Wand, Engineering and Physical Sciences Research Council; Dr Declan Mulkeen, Medical Research Council; Professor Peter Fryer, and Dr Amanda Collis, Biotechnology and Biological Sciences Research Council, examined.

Q384 ***Chairman:*** I would like to welcome our four witnesses to this, the seventh public hearing of our inquiry into nanotechnologies and food. Just to inform you that the proceedings are being web cast and also to draw attention to the information note which is available to members of the public which sets out members' declared interests, so we will not be repeating those whilst asking questions. Before we come on to the questions that we wish to put to you, I would like to invite the four witnesses to introduce themselves briefly, starting with Dr Collis and moving along the row, and also to put a request to you that when answering our questions you keep your answers as succinct as possible because we have got quite a lot to get through in the hour or so we have ahead of us and that would be helpful to us. Perhaps I could invite Dr Collis to lead off, introduce yourself and if there are any opening points you would like to make, please do so.

Dr Collis: Thank you, my Lord Chairman. I am Dr Amanda Collis from the Biotechnology and Biological Sciences Research Council where I am Head of Engineering, Data and Tools. Within that remit nanotechnology, and specifically bio-nanotechnology, falls. Thank you.

Dr Mulkeen: Good morning. My name is Declan Mulkeen from the Medical Research Council. I am the Director of Research and Training. I have overall responsibility for the research programmes supported through the MRC's boards and special calls.

Dr Wand: Good morning. My name is John Wand. I am from the Engineering Physical Sciences Research Council where I am head of that Council's Nanotechnology Programme and also leader of the cross-Council Programme on Nanoscience through Engineering to Application.

Professor Fryer: Good morning. I am Peter Fryer. I am Professor of Chemical Engineering at the University of Birmingham. I am on BBSRC Council. My research interests are applications of engineering principles to food processing, and Fryer is probably an unfortunate name in that context, and I have published on food nanotechnology and have experience in that area.

Q385 ***Chairman:*** Thank you very much. Perhaps I could kick off with a rather general question to ask you as representatives of the Research Councils. How

are funding priorities in relation to research in nanotechnologies determined? What mechanisms do you have for that? How will you monitor progress in funding and the implementation of any plans that you have in relation to funding nanotechnologies?
Dr Wand: If I start from the cross-Council perspective. We have an allocation for the cross-Council programme from what was DIUS. We work through that on a continuous basis through a cross-Council group called the RCUK Nanotechnology Group, which I chair, and part of what we do then feeds into the cross-governmental exercise, in particular through the Nanotechnology Research Coordination Group.

Q386 ***Chairman:*** How large is this programme in terms of annual fund?
Dr Wand: For the three year Spending Review period it is £50 million.

Q387 ***Chairman:*** So £50 million over three years?
Dr Wand: Yes.

Q388 ***Chairman:*** Does anybody else wish to add anything to that?
Dr Mulkeen: Could I come in from the MRC's perspective. The MRC's investments divide into two parts: one would be about medical applications of nanotechnology and the other is related to safety. In the earlier days of Research Council work on nanotechnology we actively promoted interdisciplinary work through Discipline Hoppers and other grant schemes to try to link medical, therapeutic and diagnostic science with the sort of science that the EPSRC and other Councils were supporting. That field is now being managed mostly through response mode, so although there is a general body of work across Councils to raise the profile of the area, there are not special calls out for it. We are still in response to advice from CST, the Royal Academy of Engineering and RCEP actively promoting and calling for proposals in areas related to nanotoxicology and safety. So we have reached the stage within the MRC where part of our work is managed in a more laissez faire way and part of it is managed more proactively.
Dr Collis: If I may add from the BBSRC perspective, when we look at our research portfolio in the broad area of nanoscience, nanotechnology, there are three categories. A lot of bioscience takes place at the nano scale anyway, and has done for thousands of years and, indeed, that is one class, and quite a large class, of the work that we support. Then we have a class of what I would term nanoscience which in the context of food is perhaps using new analytical technologies that provide better resolution, greater detail of food structures to understand better the nature of those structures. Then we have the bio nanotechnology which has principally been in the area of nanomedicine and also the development of new analytical technologies. With regard to the process through which we identify priorities, following on from Declan's comments, that is very much informed by reports such as the Royal Academy of Engineering/Royal Society report and the work of groups such as the NRCG and the NIDG, but also receiving input from our advisory boards, such as our Tools and Resources Strategy Panel and also our Strategy Advisory Board.

Q389 ***Chairman:*** Thank you. Just referring back to the Royal Society/Royal Academy of Engineering Report, one of the recommendations was that the Research Councils should establish an interdisciplinary centre to research the health and safety implications of nanoparticles, to coordinate research in this area and to liaise with regulators. That has not happened but how do you justify the alternative approach that you have taken?
Dr Mulkeen: The Safety Science community in the UK is quite small but it is quite well networked. One of the challenges that we have realised we face in the UK is that toxicology in Safety Science was a discipline that was shrinking rather than growing in the academic base and over the last few years we have had to take steps to strengthen that. The aim was more to get the centres that had strength in toxicology and Safety Science engaged with the nanotechnology agenda rather than to try to reorganise.

Q390 ***Chairman:*** Are there other comments to add to that? Dr Wand?
Dr Wand: Yes, from a cross-Council perspective we coordinate things through the RCUK Nanotechnology Group and through the Nanotechnology Research Coordination Group. As a result of that we have done a number of things from a multiple funders' perspective, perhaps not in the area of food safety specifically but if you take the environmental area, for example, with the Environmental Nanoscience Initiative which NERC has led on, but that has had involvement in phase one in a major way from Defra and the Environment Agency and co-funding from BBSRC and EPSRC. As we move into phase two we have had to involve EPSRC again and also Defra and the Environment Agency in a supporting role as well, and jointly with the US Environmental Protection Agency in that regard. In a lot of these areas the research spans more than just the Research Councils' areas of interests, so how can we work together as a more coordinated body in order to bring all these interests to bear in a coordinated way?

Q391 ***Chairman:*** Are any of you familiar with the German initiative to establish a virtual laboratory called NANOTOX?
Dr Collis: No.
Dr Mulkeen: No, sorry.

Q392 ***Chairman:*** I was going to ask whether you thought this would be a useful initiative for the UK to consider as a possible model.
Dr Mulkeen: My Lord Chairman, we are not familiar with it but there is a very useful report coming out on mapping the international efforts in—

Q393 ***Chairman:*** Sorry, where is that coming out from?
Dr Mulkeen: The EMERGNANO report in the last day or so.
Dr Collis: The EMERGNANO report, which I understand is commissioned by Defra reporting into the NRCG and is being undertaken by one of the projects funded through the Micro Nanotechnologies Programme, will imminently publish a worldwide assessment of the research that is ongoing in the health and safety aspects of nanotechnology and nanotoxicology. That, of course, will be something which Research Councils will consider when setting their priorities in this area and it helps us to coordinate and not duplicate what is happening within the UK but also more widely within Europe, the US and the rest of the world.
Dr Mulkeen: I raised that because while not familiar with the German initiative in its detail, we think we are getting close to the stage in the UK where we will need to take a more active approach to networking across the various research groups. Our focus within MRC over the last few years has been about developing strands of toxicological and Safety Science in one or two more generations, and we might talk about that later. Over the next few years we need to start looking at other areas of science that should be connected with that core of nano safety science and also to look at how that science as it starts to create valuable knowledge is networked with the various companies from engineering and materials science and the various companies on the food science side so they can start to factor in at an earlier stage. I think it would have been premature to do that a couple of years ago, but looking at the small portfolio that we have got, looking at its quality and its potential, we are getting to the point where we need to start doing that.
Professor Fryer: Certainly in the States a lot of the large companies are now driven very much by how the FDA would respond to these sorts of issues and the FDA are having some questions about how they would regulate nanotechnologies, so the need is to bring these together.

Q394 ***Lord Haskel:*** Just following on from this, we have had a lot of evidence that there are major gaps in the scientific knowledge base required for risk assessment of nanotechnologies and nanomaterials in food. We have also been told that there are products nearing the market which have either been processed with or contain this technology. What are the Research Councils doing to ensure that these knowledge gaps are filled before these products actually reach the market and the public?
Dr Mulkeen: The problem of products emerging for which there is not an adequate science base to assess the safety is a real problem and it is one that is a concern for the regulators as well as the Research Councils. We see the Research Councils' primary responsibility as making sure that the fundamentals of the generic science base that regulators need to work with that could be applied to whatever products come out is well developed. That is what people would look to the Research Councils to do first and foremost. Of course, there are other aspects that Research Councils ought to be helping in in terms of feeding that science quickly into the knowledge pool of regulators and industry and also looking at the safety aspects of, say, health or practical applications of nanotechnology that are funded by Research Councils themselves. You are absolutely right, there are quite large gaps in our knowledge. At the moment regulators have to take risk assessments based on knowledge that is weaker than in other domains. We would point in particular to the fact—you have probably heard this already—that the mode of action of a nanoparticle that has a toxic effect or health hazard attached to it may be quite different from the toxicological action of a new medicine and, therefore, what we need to see is science emerging that is not linked to a particular way of thinking that is in classical toxicology. Some of the initial science that came through when the MRC started promoting the area was based around a few key hypotheses, that the mode of action was the opposite of stress, and we are now starting to see more hypothesis-free science coming out using expression arrays, proteomics, to look at the general state of health of cells without having to go into the experiment with a presumption about what precise effect you would have, but with a greater chance of picking up whatever effect is there. That is the sort of role the Research Councils should be concentrating on first and foremost to apply that generic toolkit.
Professor Fryer: There is also a question about science that is missing. We know really very little about physically how material gets from the gut through into the body. It is quite clear that materials must go through a nano state—it starts as a yoghurt up here and ends up in the bloodstream—but how that is done physiologically is not known in detail, so the

question of how any particle, be it a nanoparticle or not, would behave under those circumstances is not straightforward.

Q395 ***Lord Haskel:*** This is obviously a very important gap in knowledge as regards nanotechnology in food. What steps are you taking to fill this gap?
Dr Mulkeen: Could I say first of all what we have been doing since 2007 on nanotechnology generally and then pass on to colleagues to talk about food.

Q396 ***Lord Haskel:*** The knowledge about nanoparticles in the gut.
Dr Mulkeen: From the MRC's points of view we are happy generally with the progress we have made since we put out the highlight notice and started promoting application of this in this area more actively in March 2007, and we have updated that since. We are happy with the response to that. A weakness that I would concede is that the response has not included enough gut work. It is a highlight notice that we think we will be updating quite regularly over the next few years as the science moves on. Right now we need to push out a stronger message about gut physiology and also some of the tissues, such as the nervous system.

Q397 ***Chairman:*** How many research groups in the UK do you support who work on nanoparticle toxicology from the point of view of the gut?
Dr Mulkeen: There is one group which has given evidence to you, which is Jonathan Powell's group, which looks both at therapy and others. With the proposals that are coming through now using Omics approaches, they should be applicable to a number of tissues but they are not looking exclusively on the gut.

Q398 ***Chairman:*** So is the answer one?
Dr Mulkeen: The answer is one exclusively, but even there that group is working partly on using nanotechnology to improve delivery of iron through the gut as well addressing the safety concerns. The portfolio that we have is very dominated by respiratory exposures driven by the fear of carbon nanotubes having asbestos-like characteristics.

Q399 ***Lord Haskel:*** Of course, the effect of nanoparticles in the gut will be both long-term and short-term. Is there any work being done to look into the long-term chronic effects of nanoparticles?
Dr Mulkeen: As separate from the short-term effects? No. It is too early in the state of our knowledge to say that you could pursue one particular experimental line because there are some effects we are looking at chronically and some short-term. On areas such as inflammation, as experiments progress they could be unveiling either a short-term or long-term inflammatory damage process. Not specifically separate programmes on the chronic effects.

Q400 ***Lord Haskel:*** Do you have any plans for that?
Dr Mulkeen: What we would like to see is more gut work coming through the core generally of all sorts, a broad spectrum.

Q401 ***Lord Crickhowell:*** Forgive me, I am not a scientist and I know very little of the work of the Research Councils, but I must say the answers that we have received so far this morning leave me bewildered. Here you are talking about structures that coordinate and get research going in the right direction and, as has already been said, we have had evidence about very obvious gaps and urgent areas that need research, yet I do not get a sense that anything has been done or is being done to actually get the work heading in this direction. I am worried by the general air of, "Oh well, it's very early, it's all very difficult. We need to have more knowledge before we set off in a particular direction". Am I wrong in thinking that so far there is no real coordinated effort in this country—it appears to be working slightly better in some other countries—to get the research going in areas where there are obvious gaps?
Dr Mulkeen: Could I comment from what the MRC has done, which is not just about the gut, and then pass over to Amanda.

Q402 ***Lord Crickhowell:*** The gut is one area but there is a whole range of areas where there does not seem to be an effort to direct us into a field which is clearly going to be of crucial importance for regulatory effort and so on and where risk assessment at the moment is very difficult because we have not got the basic knowledge. Surely this is an area where the Research Councils ought to be able to coordinate and push things rather further than I get the impression you are able to do.
Dr Mulkeen: At the MRC we started promoting the area in March 2007. Since then we have committed an extra £3 million and at around the same time the Department of Health committed slightly over half a million. The first few proposals that came in were tied to a particular mechanism of action in the sense that they were narrower proposals but good quality science. We then took a look at what was coming through and decided we needed to broaden it out, encouraged a wider range of proposals and encouraged people to come in with applications that looked at nanoparticles in the context of the whole body rather than cells *in vivo*. That second step was successful as well and we have brought through some very good high quality proposals. In the summer we intend to put out a new statement to the community

of what we now think the deficiencies are and what the next step of gaps that we want to see addressed are and if the community is as responsive as it has been over the last 18 months we think we will get in good quality proposals there as well.

Q403 ***Lord Mitchell:*** Could I change the question just a little to all of you. One of the areas where I have been concerned is the area of alcohol and dangers to the unborn child of mothers who drink alcohol and the fact that alcohol flows across the placenta and is unable to be dealt with by the foetus. I am just wondering as far as nanoproducts are concerned whether this could be the same issue.
Dr Mulkeen: That it could pass into the foetus?

Q404 ***Lord Mitchell:*** Yes, because the foetus cannot process it.
Professor Fryer: The simple answer is I do not know but I suspect not because alcohol is a substantially smaller molecule than anything that we would be talking about in this context. If you are talking about species that are at the 100/200 nanometre scale, this is substantially bigger. My belief is that it is not possible, but I will find out.
Chairman: Perhaps you could let us have a follow-up note on that particular point.

Q405 ***Baroness O'Neill of Bengarve:*** The BBSRC has supported several public engagement projects in the field of nanotechnologies. How do Research Councils coordinate their work with other government agencies, including BIS and the Food Standards Agency? How do they ensure that the public engagement activities that they support are built on and are useful to other government departments that have an interest here?
Dr Collis: I would say that coordination operates across several levels. As mentioned previously, BBSRC and other Research Councils are members of the Nanotechnology Issues Dialogue Group where we sit alongside colleagues from Defra, FSA and BIS, and that provides a vehicle for exchanging information and developing joint activities. We also, within the RCUK arrangements, have a public engagement with a research group and through that group we work together to identify issues and methods of engagement and to maintain awareness we engage with key national players in the field. We have also worked specifically in collaboration with other Research Councils, so BBSRC and EPSRC worked in partnership in the Nanodialogues experiment. In other areas outside of nanotechnology we have worked with the MRC on stem cells and also on ageing research. With regard to those activities and activities in the nanotechnology area, we also have our Bioscience for Society Strategy Panel. Our thinking and our work is very much informed by that and we receive advice from that strategy panel. We also work with its counterpart in EPSRC, the Societal Issues Panel.

Q406 ***Baroness O'Neill of Bengarve:*** That is a lot of coordination. Do you have a sense of urgency about this or do you feel that this is something that we need to keep ticking over because the science is moving fairly slowly and there is nothing that will surprise the public or damage the adoption of new technologies by the food industry?
Dr Collis: I think that BBSRC has been active, and I will scope it out a bit to the broader nanotechnology area, since 2003 with the discussion meeting Atom by Atom, and that has moved through the provision of financial support for the NanoJuries project and then Nanodialogues. There has been a series of activities over the last few years which have been focused around the early identification of generic issues and upstream engagement. Of course, with regard to nanotechnology and food, through the Nanotechnology Issues Dialogue Group we have a forum where we can work with, say, the Food Standards Agency. They may have issues that they will take forward with consumer or citizens forums in relation to perhaps labelling and regulation. Equally, that will flow from the Ministerial Group on Nanotechnology with BIS. I would say that most of our activities currently have been focused on that upstream engagement, but it is important that those activities sit alongside and are informed by the activities that others may take forward perhaps more around regulatory issues, labelling, et cetera. That said, in other areas we have facilitated discussion between regulators when we have considered it appropriate as part of an upstream engagement activity.

Q407 ***Chairman:*** Do you have any way of measuring whether the work that you do in this area has any impact? How do you measure that?
Dr Collis: I would say that Bioscience for Society Strategy Panel, which is essentially a group that oversees BBSRC's public engagement work, provides a forum through which we can receive advice on how effective those activities have been.

Q408 ***Chairman:*** What has the advice been?
Dr Collis: The membership of that group, which spans food, environment and animal sciences as well as learned societies and industry, has indeed received reports from, say, the NanoJuries and Nanodialogues exercise and my understanding is they have considered those activities to be appropriate and they

are able to view the area from the perspective and knowledge of having seen developments in public engagement over a period of time and able to look at the issues around nanotechnology informed by the experience around GM and also informed by activities around stem cells, ageing and other areas.

Q409 ***Chairman:*** I must say I do not find that a very convincing answer that you know whether or not this is making a difference, for example, to public understanding or public attitudes. A report to a committee that says, "Yes, it's going okay", does not seem to me to be a very convincing answer.
Professor Fryer: When you physically do it and explain to an audience the implications and we are looking at once upon a time what would have been called core science, so creating nanoparticles that are not necessarily nanoemulsions, and you explain the implications of that, which is essentially food grade materials in food grade situations, my anecdotal experience is this is not seen as a dangerous issue. Whether that is simply the result of half a dozen conversations with the public, I do not know. Quite how you would gather that class of information, again, I am not sure.
Dr Collis: Can I make an additional comment. In looking at the NanoJuries, for example, one of the recommendations from the NanoJuries project was around greater openness in public funding and development of nanotechnologies. Perhaps, John, you could say something about the Grand Challenges in nanotechnology and health activity that EPSRC led on with regard to how advice has come in and been implemented.
Dr Wand: Yes, if that is okay.

Q410 ***Chairman:*** Yes, but could you be brief, please.
Dr Wand: I will try and do so. The cross-Council programme is working through a series of Grand Challenges looking at where nanotechnology can make a contribution to areas of societal importance. Last year we were focusing on healthcare and wanting to find out where we should be focusing our efforts in nanotechnology for healthcare. We had a series of advice streams feeding into that, naturally enough from scientists, medics and so forth, but also we carried out a public dialogue exercise where we contracted an external professional organisation to work with a series of focus groups to look at the emerging conclusions from the scientific studies and give us the public's take on where we should be focusing within nanotechnology for healthcare. That was one stream of advice which fed into our decision-making process and helped inform the actual areas that we ended up focusing down on. That was a first for certainly the UK Research Councils in terms of using a public dialogue process to then inform where we should be focusing our research endeavours. We have kept in contact with the members of the public who participated in that exercise, which was 80 all-told, so they are having updates as to what is going on, and the feedback from them is they felt that was a valuable exercise and they were actually influencing how public money was being spent. Of course, it is difficult to generalise beyond that. The other thing we have taken from the outputs from that public engagement exercise is to feed it back to the scientists who are generating research proposals and those have been featured in some of the research proposals we have funded as well.

Q411 ***Lord O'Neill of Clackmannan:*** Perhaps we could look at one of the areas that came up in your public engagement, namely the concerns about the funding of health and safety research. In 2007 the Council for Science and Technology expressed concern about this and did so in the context of what they regarded as the Government's over-reliance on the responsive mode funding. They felt that this was perhaps not the best way to do it. What is the view of the Research Councils on health and safety matters and the availability of funds given the response mode arrangement that you currently work in?
Dr Mulkeen: From March 2007 we moved beyond response mode within the MRC, which leads on the safety side. We put out a highlight notice, which means we communicate with the community around what we think is needed. We change that so that as one wave of research proposals comes through and gets funded we say what the next gap is. We have had a good response to that. The Research Board that assesses the proposals has also been very alert to the importance of the area. The success rate of a typical response mode application to the Research Council is in the range of 20–23 per cent. In this area we have funded nearly 40 per cent of the proposals that have come through. The Board is being proactive.

Q412 ***Lord O'Neill of Clackmannan:*** That was in nanotechnology?
Dr Mulkeen: No, that was in nanotoxicology, just on the safety side.

Q413 ***Lord O'Neill of Clackmannan:*** It was only on nanotoxicology. You say that the response rate has been good and you have spoken in percentages, but what does the percentage mean in real terms?
Dr Mulkeen: There are about six projects with about £3 million in total from the MRC side, and the Department of Health contributed a bit over half a million, and another three or four smaller projects on top of that.

Q414 ***Lord O'Neill of Clackmannan:*** So we are talking about nine projects in *in vivo* areas, is that correct?
Dr Mulkeen: The new ones. There was some preceding work in Edinburgh at the Centre for Inflammation Research and some in the Human Nutrition Centre in Cambridge, which you will have heard about.

Q415 ***Lord O'Neill of Clackmannan:*** That is the MRC's one, but what about the other Research Councils? Evidence from the EMERGNANO report indicates that there are still major gaps in the research into health effects of nanomaterials. How are the other Research Councils responding to these?
Dr Collis: From BBSRC's perspective, we recognise that with regard to human health the MRC leads and with regard to environmental toxicology leadership really comes from the NERC. That said, we recognise the importance of ensuring that underpinning basic biological science is integrated in the context of human and environmental toxicology as demonstrated through our co-funding through the environment and human health activity that was led by NERC and includes funding from the other Councils here. As I mentioned earlier, with regard to work on nanoscience of foods most of our work is currently around the use of the very latest detection technologies to understand better food materials and food processes.

Q416 ***Lord O'Neill of Clackmannan:*** You have told us that you recognise there is a challenge, but I think what we would like to know are specific examples of the amount of response there has been to this challenge. At the moment all you are telling us is you know that there is an issue, but you do not seem to know how big it is and you have not been able to tell us so far how many institutions are engaged in this area. Could you be a little more specific?
Dr Collis: In responding to that challenge we would work in partnership with MRC on human health and with NERC on environmental toxicology.

Q417 ***Lord O'Neill of Clackmannan:*** Do you think the responsive mode is the best way of doing it or do you think you should be more interventionist yourselves?
Dr Collis: The responsive mode ensures that the very best quality research is supported in this area. The application of the strategic steer on responsive mode, such as is operated by MRC, encourages the submission of applications to the Research Councils. In that respect, that strategic steer in increasing the volume of applications coming and funding the very best is a response to meet the research gaps here. Can I just add, if I may, my Lord Chairman, that perhaps one additional strategic intervention that we should look to make as a group is around research community networking and bringing together researchers working in the safety area, and it is our role to facilitate this, with those working in, say, engineering departments on the actual free nanoparticles themselves.

Q418 ***Chairman:*** Could I just pick up on this because I am getting more worried as we go along. We have heard from you and others that there are gaps in knowledge, you have responsive mode or calls for applications which yield pretty small numbers of responses, to be quite frank—six or nine responses from the whole scientific community seems to me to be pretty small—but I am not convinced yet, echoing perhaps what Lord Crickhowell said earlier, that you are actually trying to plug the gaps, that you have got a plan to plug the gaps in knowledge. Maybe you would say it is not your job, but if it is not your job be clear that it is not your job and, if you think it is your job, tell us how you are planning to plug the gaps.
Dr Mulkeen: On the numbers, as I said, the overall Safety Science community in the UK is quite small, a small number of centres of excellence.

Q419 ***Chairman:*** Can we just focus on the answer. Are you intending to plug the gaps?
Dr Mulkeen: Yes, but it will not necessarily take the form of a research programme with 200 small grants scattered across the UK. I think a small number of highly capable excellence centres is what we need and the funding stream is oriented towards that. While the numbers are small, a £3 million investment is significant and we would rather make a small number of large highly capable awards than to scatter the money thinly.

Q420 ***Lord Haskel:*** Will you be commissioning this or, again, is it a matter of challenge?
Dr Mulkeen: There are two different sorts of safety challenges that the Research Councils face. One is to strengthen the general fundamental science base. So far the response we have had to the first highlight notice and then the changed highlight notice asking for more *in vivo*, whole animal, whole organism, science has been very good. That mechanism has been adequate so far. If it started not to be adequate we might have to take more active steps. To give one example where we may need to take a more active step, a very eminent neuroscientist in the UK who was planning a substantial programme on the movement of particles within the nervous system has been poached recently by a German research initiative, not related to toxicology, and we will need to think about whether we can encourage some other

people from the neurosciences background to step up to the mark. By and large, for the basic science we are okay so far but we will take more active steps if needed. The other area is the degree to which particular lines of research that are oriented towards a new product, treatment or class of products being supported by the Research Councils engage with Safety Science at an early stage. For example, in many of the healthcare nanotechnology projects that MRC, BBSRC and others have supported the people leading those projects have a background in pharmaceuticals, they understand the safety issues, and while there may be gaps in everybody's knowledge about nanotoxicology worldwide they know how to make sure the particular thing they are developing gets state of the art treatment from a safety point of view. What Amanda was pointing out was that we are now reaching the stage in a wider area of Research Council funded projects that have been stepping up over the last few years where we need to move beyond simply looking at the people who have already got a strong healthcare nanotechnology background and as the standard of Safety Science steps up in the UK do much more active networking to reach out and, for example, to draw in the environmental toxicology work that NERC is developing which provides some quite relevant insights into the movement of particles out of the gut in lower organisms and so on. It is the state of science maturity that means we need to step up and take a different approach over the next few years compared with what we have been doing over the last year.

Q421 ***Lord Cunningham of Felling:*** Is there any overarching forum or dialogue in this area which brings together the private sector with academia and the Research Councils? If so, what is it?
Dr Wand: I suppose the most obvious forum is the Nanotechnology Stakeholders Forum which is chaired by Defra which has people able to come on an open invitation basis from academia, government departments, industry and non-governmental organisations. Typically, that meets every quarter and has 30-odd people round the table from 30-odd different organisations.

Q422 ***Lord Cunningham of Felling:*** Does it in any way try to identify gaps where government funds need to be directed, for example?
Dr Wand: It has not as yet, although there is nothing to stop it doing so, but as one stream of evidence it does feed into the Ministerial Group which, again, meets on a quarterly basis.

Q423 ***Lord Cunningham of Felling:*** So what does it do?
Dr Wand: At this stage it has been mainly taking information and evidence from what Government in particular and other organisations have been doing in the area around public engagement and health and safety issues.

Q424 ***Lord Cunningham of Felling:*** For example, say someone believed we needed to be doing more work in nanometrology characterisation or nanotoxicology, would they be issues which would emerge from this dialogue?
Dr Wand: There could well be issues which emerge from that dialogue which would then feed either into the Nanotechnology Research Coordination Group to take that forward in more detail or through the Ministerial Group depending on the nature of the issue which was identified.
Dr Collis: Those issues would also arise from, say, the EMERGNANO report which has been commissioned via the NRCG because that would be looking against the 18/19 research priorities to see how well research activity on the global level has delivered into those research priorities.

Q425 ***Lord Cunningham of Felling:*** Would this quarterly meeting discuss issues relating to EU/UK regulation of nanotechnologies?
Dr Wand: Again, in a broad sense, yes. We have people from the EU Member States who attend and make presentations to these meetings as well, so it does take a European perspective.

Q426 ***Lord Cunningham of Felling:*** The Research Councils have told us they believe that uncertainty about regulation may already be stifling research. Is that your view collectively or individually?
Dr Wand: I think at the basic level not. It may be stifling more applied research perhaps in terms of product development, but we do not see any evidence of it stifling very basic research.
Professor Fryer: There is a question about the adoption of technologies, particularly in the nanoemulsion, what is essentially an extension of conventional emulsion science, in that the question is what is the consequence of incorporating 100 nanometre emulsion droplets. To some extent, milk has had them for millions of years but the industry is nervous because the answers are not absolutely there. The implication is that if you make food grade materials with food grade equipment it will be food grade, but the question of whether there is something different that happens at this scale in a food sense and is eating an agglomerate of milk proteins the same as eating milk proteins, essentially the belief is there is not a problem but there is no certainty.

Q427 ***Baroness O'Neill of Bengarve:*** Is there an answer to the question whose responsibility is it to identify gaps in knowledge at this stage?
Dr Mulkeen: On the safety side?

Q428 ***Baroness O'Neill of Bengarve:*** On the safety side.
Dr Mulkeen: It needs a team approach. It needs bodies like the Defra run Coordination Group to fill the gaps that are about how to synthesise information to make good regulatory decisions, gaps in individual companies' abilities to make preliminary assessments of safety and gaps in the basic science that we are most responsible for. The coordination process from where we sit seems to be working well in terms of getting that dialogue going in the main sectors that we have been dealing with.

Q429 ***Lord Crickhowell:*** I am puzzled, I must admit. I was puzzled when I read the question that Lord Cunningham put to you as to why uncertainty over EU/UK regulation should stifle research and development in the area. I do not quite understand. There are large areas where we have already got established regulation—REACH on chemicals—which may be the core to a lot of the regulation that we are considering with nanomaterials and the requirement to ensure its safety. That is already there and up and running. Please explain to a simple-minded non-scientist why some uncertainty about the regulatory pattern should stifle research. I do not understand.
Dr Wand: I think it is a combination of regulation and public acceptability, and we are back to the case study of GMO. Does a company want to invest a lot of money in developing a product which will then not be acceptable in the marketplace either because of public opinion or regulation which may still be in the evolutionary stage? I do not know a lot about REACH but I understand there are questions about how far it will apply to nanomaterials and nanoparticles. There is uncertainty in the regulatory regime in detail and there is also uncertainty over the public acceptability side of nanotechnology and companies, therefore, want to take a cautious step forward before investing potentially large sums of money.
Lord Crickhowell: That may be a commercial judgment, which I understand, as to whether they take the research into the development phase and so on, and a lot of them are doing the research, we know they are, but I thought we were addressing here the work of the Research Councils and I cannot see why some doubts about the way the regulatory regime may go should hamper research of the kind that you are encouraging.

Q430 ***Baroness Neuberger:*** Can I just add to that because I think this is key. I do not understand it either. The thing that I would want to know is if there is the worry about this might go the way that the GM debate went, is there not all the more an obligation on the Research Councils to take this very seriously, either to do the research that reassures the public or to do the research that makes the public think, "Actually, it may be our suspicion was right". I just do not get the argument, that is the bit that is worrying me.
Dr Mulkeen: I misunderstood the question, I thought it was focused more on the industry uptake of what Research Councils do. In our sector, leaving safety aside and looking at nanotechnology applications in healthcare, certainly there are some companies that are more willing to take risks on innovative science than others, but, as you say, that was not the question. I cannot think of any area of MRC science relating to safety which has been in any way inhibited by uncertainty of the regulations.
Dr Collis: With regard to the research portfolio in the broad bio nanotechnology area, equally I do not feel that the uncertainty over regulation is stifling that basic research.

Q431 ***Chairman:*** You do not think it is?
Dr Collis: No. We are seeing our portfolio growing year-on-year, but a lot of our portfolio is set in the context of nanomedicine and new detection technologies.
Professor Fryer: Industry is more worried about the acceptability issue and whether these things will be food grade materials. They must be in some form nano when they are digested but the question is how they are digested.

Q432 ***Lord Crickhowell:*** All the more reason for research.
Professor Fryer: With my BBSRC Council hat, there is an industry/university club that has been built that the food industry are involved in and they are funding the sort of work into digestion/gut behaviour that we would hope for. It is not a very large programme. I have to be slightly careful because we have applied to it. It will be building this sort of understanding, I hope. We know surprisingly little about what happens between the mouth and the gut.

Q433 ***Lord Mitchell:*** I am always concerned about duplication going on everywhere in the scientific community and, therefore, the waste of resources that could lead to. I just wanted to ask you how the Research Councils within the UK coordinate with the EU and other international bodies. How do you coordinate research? How do you ensure that

research in the UK complements rather than competes with research abroad?
Dr Wand: I suppose one very significant way of doing that is through the OECD where Defra represents the UK. I think you have already had evidence on this, that there is this list of 14 nanoparticles that have been identified and countries have agreed to take the lead on looking at the health xenon and safety implications of those nanoparticles. The UK is leading on two of them—cerium oxide and zinc oxide. As an example of a cross-agency funding arrangement the work that is being funded is being funded by a combination of Defra, EPSRC and the Technology Strategy Board working in collaboration with the Nanotechnology Industries Association. It is trying to take a holistic view of the issue and feed back through OECD channels into other international partners looking at these particles and other particles as well, so there is a coordinated effort occurring worldwide through that set of channels.

Q434 ***Lord Cunningham of Felling:*** It is hardly worldwide because it would not include the People's Republic of China, would it?
Dr Wand: I think China is involved to some extent in some of those activities. I think it sees itself as a current player in the nanotechnology area.

Q435 ***Chairman:*** Could you perhaps follow that up to confirm whether China is involved in these activities?
Dr Wand: I could do that[20].

Q436 ***Earl of Selborne:*** On this subject of European Union research funding, could we ask the opinion of the Research Councils as to how effective the present framework programmes might be in this area and what chances there are in the next round, in the eighth round, of there being a contribution, particularly plugging some of the gaps that we have identified today.
Dr Mulkeen: I am not very familiar with the projects that the EU has funded in the UK to date. The number is small. Discussion on the next framework, it is too early to say. Across Europe there is a good level of information sharing. Whether the decisions are taken in the framework programme to target areas or whether it has the right level of specificity in the targeting, I am not sure.
Professor Fryer: There has been a very large EU programme on the molecular basis of allergenicity, for example, which is about take-up of nanoparticles, they might be molecules, and there is the beginning of a cross-European base in that area which I suspect will be the sort of science that we are going to need.
Dr Collis: I understand there are four or five large framework programme funded projects in the broad nano health and safety arena and we can provide details of those if that would be helpful.[21]

Q437 ***Chairman:*** How would you rate the UK's research effort in the area of health and safety effects of nanotechnologies compared with other European countries or, indeed, compared with other countries outside Europe? Are we in the Premier Division, in the Championship, whereabouts are we?
Dr Mulkeen: In Safety Science generally—

Q438 ***Chairman:*** Relating to nanotechnologies.
Dr Mulkeen: —the UK has got a strong base to build on. The number of projects is probably lower than in some other countries; the quality, I hope, is first rate. We should probably all take a look at the EMERGNANO report when it comes out and use that for some benchmarking over the next few months. That will be a more comprehensive set of information than we have had so far.

Q439 ***Chairman:*** At this particular stage you would not care to offer a view as to where we are in the international league table?
Dr Collis: Simply to say with regard to the largest number of studies in the broad health and safety area the US would definitely be number one.

Q440 ***Chairman:*** I would like to go back, if I may, before drawing this session to a close to ask you about these gaps which we are obviously concerned about. You did say earlier on in your collective response that you would take more active steps if needed to plug the gaps in knowledge. I wondered how you would decide when it was needed and what would trigger these more active steps.
Dr Mulkeen: On the safety side, I expect we will have to review and restate the call for proposals in the light of what is getting funded and work by the Defra/NRCG Coordination Group on a six monthly basis. Over the summer we will use EMERGNANO to add to what we have already identified, which as I mentioned earlier is that we are not getting in enough proposals around gut, we have not had the proposals in that we would like to see around movement of nanoparticles in the nervous system, but it may be that when we look at EMERGNANO there are other

[20] "The People's Republic of China is a participant in the Working Party on Nanotechnology of the Organisation for Economic Cooperation and Development (OECD)."

[21] "The EMERGNANO report, which was referred to in our evidence, is now in the public domain on the Defra website at http://randd.defra.gov.uk/Document.aspx?Document=CB0409—7911—FRP.pdf . The report covers 19 EU FP funded projects in the area of nano health and safety and has the benefit of placing these into a worldwide context of some 293 projects."

areas that we would want to highlight as well. I think we will be doing this every six months for the foreseeable future because, as you say, even if the end product of the research is to prove that there is a much lower risk than people thought, it is still a very, very worthwhile investment.

Q441 ***Lord O'Neill of Clackmannan:*** When does the six month review period start? Has it started yet or is it just an idea that you have got?
Dr Mulkeen: We reviewed it following discussions at NRCG just after Christmas. We have already had different sorts of proposals coming in after that. We will change it again this summer. Again, depending on what we learn about what other countries are finding and what we learn from the outcomes of the science, it is going to be an exceptionally fast moving field, so six or nine months. We will just have to keep our eyes and ears open and change the call to reflect whatever gaps come up.

Q442 ***Lord O'Neill of Clackmannan:*** Six months has become nine months, you did not know when it started and you do not know when the next one is. Do you not have a kind of diary, timetable or timeline that you will operate along?
Dr Mulkeen: Absolutely. There is a regular series of coordination meetings across the public sector. The reason I have to be vague is I can say that we will update it over the summer but I do not know when the next update or next change in direction will be necessary. I just know that given the sort of science we are dealing with lots of new calls for statements will be needed over the coming years. There is a very regular timetable of meetings.
Chairman: Thank you very much. I would like to draw this session to a close and thank all four of you for helping us to explore the issues that are on our minds. You will receive copies of the transcript for correction before it is finalised and published. Also, we have requested from you a couple of follow-up points so I look forward to receiving some further information from you. If you feel there are areas that we have not covered that we should have asked you about, we would also welcome any further comments that you might wish to generate spontaneously. Thank you very much indeed.

Supplementary memorandum by the Biotechnology and Biological Sciences Research Council (BBSRC)

Foetal Risk from Nanoparticles.

This is a frequently-asked question in the community, with very limited data. There is some unpublished data in rats showing that nanoparticles can cross from the mother to the foetus, and some data from smoke particle studies that also suggests that transfer is possible. There are probably a variety of routes of access, as with gut absorption, and different particles may behave in different ways.

The route to the foetus will probably be through the placenta. The placental membrane is designed to separate the foetus and mother's blood circulation whilst facilitating nutrient transport. The membrane is not a simple size-selector; many of the mechanisms by which nutrients and other molecules are transferred involve activity within the membrane. A recent review is Jones *et al* (2007). The involvement of the placenta in toxicology is discussed in detail by Myllynen *et al* (2005). Blackburn (2007) reviews transport of molecules to the foetus:

— small molecules (less than molecular weight 100 if water-soluble, ie sub-nm in size) can cross the membrane by simple diffusion; this is the mechanism by which alcohol can enter the foetus;

— larger molecules and structures enter through other mechanisms; for example, some very large molecules (such as immunoglobulin G, molecular weight 150,000, which confers immunity) enter by endo- and exo-cytosis; the molecule travels through the placental membrane in a vesicle; and

— some viruses can infect the foetus, but it is clear that the placenta provides a barrier; for example maternal-infant transmission rate of HIV is only 25 per cent in mothers who do not receive prophylaxis (Koi *et al*, 2006). Viruses obviously vary in size (10–300 nm).

It thus seems very unlikely that nanoparticles can enter the foetus through simple diffusion unless they are very small and simple molecules. The mechanism of transport will be different to that of alcohol. Much larger molecules, such as nanoparticles can enter via other mechanism, but will have to stimulate the membrane in the same way as immunoglobulin does. It seems unlikely that transport to the foetus can be completely prevented, but the concentration of any nanoparticle will be substantially less than in the mother.

References

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July 2009

TUESDAY 16 JUNE 2009

Present	Crickhowell, L.	Mitchell, L.
	Cunningham of Felling, L.	Neuberger, B.
	Krebs, L. (Chairman)	O'Neill of Clackmannan, L.
	Haskel, L.	O'Neill of Bengarve, B.
	Methuen, L.	Selborne, E.

Letter from Lloyd's Corporation

Lloyd's is the world's leading specialist insurance market, trusted to shoulder the risks of the world. The Corporation of Lloyd's operates a performance framework for firms in the market to ensure that underwriting, risk management and capital setting is robust. In this capacity we have established an Emerging Risks Team which monitors for potential new threats and assesses the possible impact on the insurance industry.

The rapid pace of development led us to publish a report, at the end of 2007, on the risks and opportunities associated with nanotechnologies. This was launched at a co-hosted seminar assembling an expert panel of insurers, academics and legal experts who presented their views to an audience of underwriters and risk managers. There are many interesting applications for nanotechnology and we understand the societal benefits that will be gained through pursuing this field. However, given the nature of our industry, we are also concerned over the potential health and safety risks that could make manufacturers of nano-enhance products future targets for litigation. There is a compensation culture spreading within Europe and Asia[1] which heightens our concerns.

According to the Project on Emerging Nanotechnologies the use of nanotechnologies in the Food industry the third largest sector to use nanotechnology enabled products, as of August 2008. Therefore it is a major industry in this growing field. Whilst far from clear whether insurance claims would arise, or if made whether they would be upheld, we believe it is important to consider now the extent of insurability of these products. The impact to insurers could manifest itself through several insurance products including:

- Product liability coverage that may pay out for having to recall a large number of products through health risks, perceived or actual;
- general liability coverage may be triggered if manufacturers were negligent in their duty of care to consumers, for example if the nano element of a product was shown to directly cause, or contribute to, a disease;
- general and environmental liability policies may also become exposed with respect to environmental disasters, for example if silver nano particles were to accumulate within the environment and either travel up the food chain or by killing bacteria and microbes essential to local or national ecology; and
- employer's liability policies, may cover employees who suffer disease or disability through their work in the nanotechnology industry if it were to be shown that the risk management of health risks of processes were to blame.

These risks predominantly relate to health risks that nanotechnology may pose when used in food containers, within food products themselves, or in the exposure of workers when creating the products. There is also the issue of full lifecycle management including how nano-materials behave after they have been disposed. For example, the 27th report by the Royal Commission on Environmental Pollution stated that "to date, adverse effects on populations or communities of organisms in situ have not been investigated and potential effects on ecosystem structure and processes have not been addressed." We understand that questions like this and many others cannot currently be answered. We are also aware of worrying research that suggests that some forms of nanotechnology may have adverse health implications.

One of our key concerns relates to the length of time it takes to establish health impacts in humans. This is important for insurers as, depending on policy terms, we can face the risk of claims for decades after the premium is paid. When setting the premium we have to estimate the level of risk and, with respect to nanotechnology, such estimates are inherently uncertain. The asbestosis cases of the 1990's, led to massive losses for the whole insurance industry. We believe that current spending on health impacts of nanotechnologies is materially smaller than the amount spent on developing products. While we recognise that

[1] "Directors in the dock"—Lloyd's 360 project report,

investment in developing new technologies is essential if the UK wishes to remain at the forefront of the technological economy, we must also protect ourselves from the potential pitfalls of producing the next product equivalent of asbestos insulation, leaded petrol or DDT pesticide.

As insurers it is our business to manage risk. However the quantum of risk must be well understood and limited in aggregate. Where this is not the case the risk can become uninsurable. We are aware of at least one US company that has excluded all aspects of nanotechnology; others are actively avoiding providing direct cover to this industry. There is a danger that some inherently safe nanotechnologies will be treated in the same way as others, such as carbon nano-tubes, which are causing much concern. To combat this we need to identify those specific nanotechnologies that could, or do, pose a significant or long term risk. These could be excluded from cover, or conversely cover could be restricted according to a published list of technologies understood to be generally safe. This would help insurers calculate premium rates that better reflect the risk and ultimately provide assurance against the societal cost of insurer insolvencies over the longer term.

We believe a clearer understanding can be achieved through coordinated research into the effects of nanotechnologies at a national or international level. The outcomes of such research should include standard, flexible and *auditable* risk frameworks that will protect employees and enable insurers to assess the robustness of companies' risk controls. There should be a requirement to demonstrate compliance with the framework before products are used in food. There should be requirement for companies and Research Councils to advise immediately there is material research evidence to suggest adverse health impacts and the level of materiality should be agreed by an independent body. To utilise a risk framework or perform a risk assessment, research would also have to identify the level of hazard and exposure mechanisms that each type of nanotechnology presents.

It is vital that products, especially food products, have adequate labelling when nano-technologies are used. In this way the consumer can make an informed choice on whether to purchase the product and this, we hope, will reduce liability costs in the future.

We believe the insurance industry is an important stakeholder in this debate and thank the House of Lords Science and Technology Committee for giving Lloyd's an opportunity to contribute.

Supporting information:

http://www.lloyds.com/emergingrisks/Lloyd's report on Nanotechnology: Recent developments, risks and opportunities.

http://www.safenano.org/NanoInsurancePerspective.aspx Nanotechnology: An insurer's perspective.

http://www.lloyds.com/News_Centre/360_risk_project/Research_and_reports.htm Directors in the dock: Is business facing a liability crisis?

http://www.nanotechproject.org/The Project on Emerging Nanotechnologies.

www.lighthillrisknetwork.org Website of Lighthill Risk Network sponsored by Lloyd's, Catlin, Guy Carpenter and Aon-Benfield.

http://www.rcep.org.uk/novelmaterials.htm Royal Commission on Environmental Pollution—Novel Materials in the Environment: The case of nanotechnology

13 March 2009

Memorandum by BSI British Standards

BSI British Standards welcomes this opportunity to respond to the Committee's call for written evidence.

Internationally agreed standards, from the International Organization for Standardization (ISO), the Codex Alimentarius Commission (CAC) and the Global Food Safety Initiative (GFSI) have become indispensible to ensure food security and food safety. For example, the ISO 22000 "family" of standards addresses issues such as the application of food safety, traceability in the feed and food chains, and audit and certification:

ISO 22000:2005 Food safety management systems—Requirements for any organization in the food chain;

ISO/TS 22003:2007 Food safety management systems—Requirements for bodies providing audit and certification of food safety management systems;

ISO 22005: 2007 Traceability in the feed and food chain—General principles and basic requirements for system design and implementation; and the planned

ISO 22006, Quality management systems—Guidelines for the application of ISO 9001 in crop production

However, whilst these and some 700 other standards developed by ISO/TC 34 "Food products" have proven extremely valuable in addressing many of the issues relevant to conventional food production, additional measures will be needed to support the introduction of new technology, in particular, nanotechnologies, into mainstream food manufacturing and packaging.

The recently published opinion on "Risk Assessment of Products of Nanotechnologies" by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) (see http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf) and the Scientific Opinion of the Scientific Committee of the European Food Standards Agency on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" (http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm) highlight the need for validated measurement and characterization methods, which standards can provide:

— "The methodology for both exposure estimations and hazard identification needs to be further developed, validated and standardized."

— "There is a need to establish reliable and standardized measurement techniques, to develop measurement strategies, and to implement screening/monitoring of nanoscale particles in sensitive work areas."

— "The main issues may be summarized as problems in replicating actual exposure conditions in laboratory tests and the lack of general availability of robust and specific measurement methods. Exposure assessment needs to consider each stage in the life-cycle."

— "In relation to the physico-chemical characterization of ENM (Engineered NanoMaterials), stability in FCM (Food Contact Materials), food and feed matrices, and analytical tools it is recommended to develop and validate routine methods to detect, characterize and quantify ENMs in FCM, food and feed matrices and in biological tissues";

Satisfying other recommendations of both committees will rely upon the availability of suitable and validated test and measurement methods developed through standardization:

— to determine the effects of size of ENMs on physico-chemical properties, compared to those of the dissolved chemical or micro/macroscale materials;

— to investigate the interaction and stability of ENMs in the presence of components in food and feed matrices, in the GI tract and biological tissues;

— to generate information on the amount and form (dispersed or aggregated) of ENMs content in food and feed, and the bioavailability of the nanoform following ingestion; and

— to determine migration of different ENMs from FCM into food and feed.

When using nanomaterials, an extensive characterization is necessary, including the nanomaterial as produced and the nanomaterials as used in test systems and the nanomaterial as present in final products.

An issue of specific importance are the properties of the nanomaterial as it is actually used in products and to which consumers may be exposed. For the risk assessment the latter characterization is of highest relevance.

Nanotechnology, defined as "the application of scientific knowledge to control and utilize matter at the nanoscale, where size related properties and phenomena can emerge" (definition by Committee ISO TC 229 "Nanotechnologies", resolution 28/2008, November 2008), presents unique opportunities but also, as highlighted above, unique challenges, and it is the latter that standardization typically addresses.

Where such challenges impact global markets, global consensus and harmonization are essential. Significant efforts are being made to develop and approve international standards that will help address the diverse challenges presented for the application of nanotechnology to food and food packaging. However, international agreement in this area will require active participation and cooperation of the various members of the international community, in particular the relevant National Standards Bodies with activities in the area.

The UK committee for standardization for nanotechnologies, NTI/1, was established in 2004 to develop voluntary, consensus based, anticipatory standards in this new and emerging field. Through its early establishment of NTI/1, the UK gained an "early mover" advantage by being able to propose and lead both the international (ISO/TC 229) and European (CEN/TC 352) standards committees in the area, an advantage it still holds. This has enabled the UK to exercise considerable influence over developments in these two committees, where the first published document in the ISO committee was the result of a UK proposal based on a UK document (PAS 71, "Nanoparticles vocabulary"), sponsored by the then-DTI. The UK is currently leading all of the approved, CEN led, work items in the CEN nanotechnologies committee and seven of some 30 approved work items in the ISO committee.

It is widely recognized that, irrespective of the application area, the effective and responsible development of nanotechnologies requires the construction of a comprehensive and effective foundation based on agreed ways of naming, describing and specifying things, measuring and testing things, and agreed protocols for hazard and risk assessment, risk mitigation, and risk communication. The UK national committee NTI/1 has already taken a lead in these areas by the publication of seven sector-specific, terminology and definition documents, and three guides: to safe handling and disposal of manufactured nanomaterials; to specifying nanomaterials; and to labelling of manufactured nanoparticles and products containing manufactured nanoparticles. The committee is also actively cooperating with its partners in the UK, Europe and internationally to identify how best to support stakeholders in whatever sectors they operate.

The chairman of NTI/1, in his role as chair of ISO/TC 229 and CEN/TC 352, has participated in two DG SANCO "safety for success dialogues" on the use of nanotechnologies in food and cosmetics, an International Risk Governance workshop on "Risk Governance Of Nanotechnology Applications In Food And Cosmetics" and participates in the OECD Working Party on Manufactured Nanomaterials. These various activities help keep the committee at the forefront of this important area.

NTI/1 has active representation from and close links to a wide variety of stakeholders, including industry, trade associations, research organizations, government departments and regulatory agencies, the Technology Strategy Board (TSB), Knowledge Transfer Networks, universities, and societal stakeholders (http://www.bsigroup.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/Introduction-to-Committee/). The food and drinks industry is represented through the membership of the Food and Drinks Federation, which plays an active role in the work of the committee. However, it has been difficult to engage with the Government's own regulatory body in the area, the Food Standards Agency, despite its nominal representation on the committee following a meeting with its chief executive at the beginning of 2007.

NTI/1 recommends a cautious approach to dealing with nanomaterials, and proposes that nanomaterials should be treated as hazardous, unless adequate scientific evidence is available to the contrary or to enable specific safety measures to be defined. Whilst this recommendation was prepared principally for industrial exposure scenarios, it is obvious that manufacturers should not allow their customers to be exposed to unknown risks. Therefore NTI/1 recommends that the cautious approach proposed in BSI's document PD 6699-2 "Guide to safe handling and disposal of manufactured nanomaterials" should be applied equally to all products of nanotechnology that are placed on the market.

To help address this area, NTI/1 has prepared plans for the development of a comprehensive suite of standards for hazard and risk assessment for nanotechnologies and nanomaterials, including exposure assessment in both occupational and non-occupational settings relevant to nanotechnologies, which would include food and food packaging. These documents would complement the guidance on safe handling and disposal of manufactured nanomaterials and the guidance on labelling, both published with support from DTI/DIUS at the end of 2007. However, at the moment there appears to be no appetite amongst government departments to maintain the UK's proactive leadership in the area, and the committee is concerned that its plans for a dynamic programme of work, initiated with the development and publication of nine documents at the end of 2007, will be thwarted, depriving UK industry and research of early guidance in this important area. In particular, NTI/1 believes it should be working closely with the TSB on the development of the hazard and risk suite of standards referred to above, and believes the TSB strategy for metrology and standardization in nanotechnologies should be aligned with NTI/1's objectives. Without such support the UK's pre-eminent position in standardization for nanotechnologies will be lost.

Technical standards, play a critical role in ensuring the safety, quality and reliability of products and processes, efficient production, and cost reduction through competition. They are equally valuable as a tool for promoting innovation and commercialization by the dissemination of good practice, validation of new measurement tools and methods, and verification of new processes and procedures. Conventionally such standardization activities would be supported by the industries benefiting from them. However, in new and emerging areas, such as nanotechnologies, where the industry is still small and fragmented, there is an unwillingness, or inability, to invest time, effort and money in standards development. Thus without an active commitment to standardization and metrology on behalf of the Government it is difficult to see how the UK can achieve its goal of creating wealth and a better quality of life, through high value products and processes based on nanoscale technologies.

About BSI British Standards

BSI British Standards is the UK's National Standards Body, recognized globally for its independence, integrity and innovation in the production of standards and information products that promote and share best practice. BSI works with businesses, consumers and government to represent UK interests and to make sure that British, European and international standards are useful, relevant and authoritative. For further information please visit www.bsigroup.com/britishstandards.

About BSI Group

BSI British Standards is part of BSI Group, a global independent business services organization that inspires confidence and delivers assurance to customers with standards-based solutions. Originating as the world's first national standards body, the Group has over 2,300 staff operating in over 120 countries through more than 50 global offices. The Group's key offerings are:

- The development and sale of private, national and international standards and supporting information
- Second and third-party management systems assessment and certification
- Product testing and certification of services and products
- Performance management software solutions
- Training services in support of standards implementation and business best practice.

For further information please visit www.bsigroup.com.

About ISO

ISO is a network of the national standards institutes of 159 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system.

ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.

Therefore, ISO enables a consensus to be reached on solutions that meet both the requirements of business and the broader needs of society.

About CEN

The European Committee for Standardization (CEN) is a business facilitator in Europe, removing trade barriers for European industry and consumers. Its mission is to foster the European economy in global trading, the welfare of European citizens and the environment. Through its services it provides a platform for the development of European Standards and other technical specifications.

CEN's 30 National Members work together to develop voluntary European Standards (ENs).

These standards have a unique status, since they also are national standards in each of its 30 Member countries. With one common standard in all these countries, and every conflicting national standard withdrawn, a product can reach a far wider market with much lower development and testing costs. ENs help build a European Internal Market for goods and services and to position Europe in the global economy. More than 60.000 technical experts as well as business federations, consumer and other societal interest organizations are involved in the CEN network that reaches over 480 million people.

March 2009

Examination of Witnesses

Witnesses: Mr Trevor Maynard, Lloyd's Corporation; Dr Peter Hatto, British Standards Institution; and Professor Richard Owen, University of Westminster, examined.

Q443 ***Chairman:*** I would like to welcome our three witnesses for this seventh public hearing of our inquiry into Nanotechnologies and Food and just to inform you that the proceedings are being webcast. I would also to draw attention to the information note available to members of the public which sets out the declared interests of the members of this Select Committee as they will not be repeated whilst we ask questions. I would like to start off by inviting our three witnesses to introduce themselves for the record and if you wish to make any brief introductory statement this is also an opportunity to do that, so perhaps I could kick off with Mr Trevor Maynard.
Mr Maynard: Thank you to you and your Committee on behalf of Lloyd's for being given the opportunity to take part in this evidence session. Lloyd's is the world's leading specialist insurance market-place covering some of the largest and most individual and complex risks in the world. If I could just take a moment to explain a little about Lloyd's because it is quite a complex place. It is not an insurance company, it is an insurance market-place where 86 syndicates compete amongst one another to provide insurance and reinsurance to companies and clients around the world. Together they make one of the largest insurance and reinsurance markets in the world. Each syndicate is made up of one or more members and historically they were individuals but now there are fewer than 800 individual members of Lloyd's who are actively participating and they make up only five per cent of the capital at Lloyd's. The remainder is provided by members backed by private and public shareholders, investment funds and specialist insurance investors. Each syndicate is managed by a managing agent and it is the responsibility of the managing agent to employ underwriting staff and manage the syndicate on the members' behalf. The managing agents are regulated by the Financial Services Authority. The Corporation of Lloyd's, where I work, oversees the activities of the market, which includes admitting new members, new managing agents, approving business plans and ensuring solvency. The Corporation itself does not carry out insurance business but we supervise the market's activities. We are also regulated by the Financial Services Authority. I am the Manager of Emerging Risks at Lloyd's Corporation.

Q444 ***Chairman:*** Thank you very much. Dr Peter Hatto?
Dr Hatto: Certainly I would like to thank yourself and the Committee for the opportunity to attend this hearing. I would like to make a brief statement but before I do that I would like to introduce myself as the Chair of the UK, the European and the International (that is the ISO) Standardization Committees for Nanotechnologies. Standards are not critical to life but they are critical to modern living. Standards are one of the most important tools used to take new technologies to the market-place. Standards transfer research findings into guidance documents thus providing a bridge that connects research to industry. This connectivity is critical to successful commercialisation. Standards are not part of the regulatory framework but can and do support regulation for example through the 'New Approach' Directives. They derive their legitimacy from the voluntary consensus-based approach used for their development and application. Standards are used because they provide a reliable and validated basis for best practice and to ensure inter-operability. Early participation in standards-making allows countries and organisations to help create and shape markets, as with the Global System for Mobile Communications (GSM) and can provide valuable technical and business intelligence. Whilst it might appear that standards will inhibit innovation, the existence of relevant standards frees innovators to concentrate on the essential essence of their innovation rather than being diverted by issues that are not core to the end product or service. Thus the development of anticipatory standards in new and emerging areas of technology provides a foundation for innovation not a barrier to it. This was highlighted in the Sainsbury Report *Race to the Top* where metrology and standards were seen as critical in the innovation ecosystem. In the area of nanotechnologies the UK has established itself at the forefront of standardisation activities and holds the chair and secretariat of both the ISO and CEN, that is the European committee for standardization technical committees. It produced the first internationally reviewed standard in the area of nanoparticle terminology and has developed terminologies for another six sectors of nanotechnologies together with guides to safe handling and disposal of nanoparticles, labelling of nanoparticles and specifying nanomaterials. It has recently embarked on the development of a guide to exposure assessment to nanomaterials and a guide for small to medium-sized enterprises to regulation and standards relevant to nanotechnology-based business. By continuing its dynamic leadership of standards-making for nanotechnologies the UK can retain a position at the cutting edge of technical and commercial developments in the area, despite a significantly lower national spend on nanotechnologies than its principal competitors such as the US, Germany and Japan. This leadership role

will help secure critical opportunities to compete effectively in an increasingly aggressive global market. The final point is that failure to continue to support this important activity will result in the UK losing the leading position which it has established over the last five years. Without having influence in the standards arena technology will be based on other countries' requirements and this will give them a competitive advantage which will be to the detriment of UK industry.

Professor Owen: Good morning everyone and likewise thank you very much for having the opportunity to talk with you all. I am a Professor of Risk Assessment in the University of Westminster. I am physically located at the Policy Studies Institute where I am a fellow. Before I moved back into academia I was head of the Environment and Human Health Programme at the Environment Agency where I led on nanotechnologies and regulation. I was until quite recently chair of the steering group for the OECD on risk assessment in nanotechnologies and I am the co-ordinator of the UK Environmental Nanoscience Initiative which is a programme looking at the environmental risks of nanomaterials. It is a science programme between the Natural Environment Research Council, Defra and the Environment Agency which was set up with them in 2006. I am particularly interested in risk governance of emerging technologies, an area that I am now taking forward at Westminster.

Q445 ***Chairman:*** Thank you very much. Perhaps I could kick off with a rather general question about how you perceive the barriers to risk assessment in relation to nanotechnologies and nanomaterials in the food sector. In particular, I would like to draw attention to one point that was made in the Lloyd's written submission calling for a 'standard, flexible and auditable risk framework'. I wonder if you could explain to us what that means and who would produce it, and also perhaps at the same time to ask all three of you, given that we have heard from a number of witnesses that there is considerable uncertainty in the underlying science, is it indeed possible, even if you had a framework, to risk assess products containing nanomaterials and, if not, what should we be doing at the moment? That is an envelope of questions that perhaps Mr Maynard would like to kick off with since I asked particularly about the Lloyd's submission.

Mr Maynard: Underwriting by its nature is a process of risk assessment and in fact financial quantification of the potential loss, so whenever our underwriters take on a risk they are risk assessing. The premium rates will depend ultimately on the risk characteristics of the process or product. At present, to my knowledge, there is no formal global list of products, food or otherwise, that use nanotechnology. There are informal databases such as the Woodrow Wilson Center database but they only include products which mention nanotechnology in their marketing so they are likely to miss examples and we do not know how many they miss. We believe that a list of products that use nanotechnologies should be set up and maintained by regulators or some independent third party that is respected. Quite who that is, in a sense, is probably for other people to decide but I think an organisation that is respected is critical. We think that such a list should include the companies involved in the full supply chain including those outside the UK or EU. It should have a precise definition of the nanomaterial, including its size (because different sized versions of the same material can have different properties), how the material is used in the process or product in detail, links to research on the properties of the material, a list of health or environmental concerns, and some sense of the uncertainty around that, so you get research published, perhaps one paper here or there that raises concerns, but the question we are interested in is how widespread is that concern felt, what is the uncertainty. We think that that sort of list would assist in the process of underwriting and risk assessment and it is critical to influence these emerging technologies before they become embedded in our society, so now is the time to influence this, I think.

Chairman: Are there other comments on this including on the question about the uncertainties of the science?

Q446 ***Lord Cunningham of Felling:*** Can I just ask a question. I assume from what you are saying that you think that such a register should be compulsory and legally binding?

Mr Maynard: Yes we do. I suppose I should come back and answer your question about 'flexible, standard and auditable' just to give some points around that. We would like it standardised where possible if we can get global or as international as possible agreement on these things, because Lloyd's operates obviously in a global framework. Flexibility is just recognising that the pace of change with nanotechnology is so fast that if you come up with regulations that are hard-coded then you will not be able to react to changes as they come along. Being auditable really allows underwriters to differentiate between risks and if they are audited in some sense then you can get a sense of the rigour with which the process has been followed, and even if you could give a grading that would be even better, to be honest, to give a risk assessment which would allow people to differentiate better-managed companies from worse-managed companies in the premium and then drive responsible innovation.

Professor Owen: I think that there are probably four specific areas that come to mind straightaway of which possibly the most pre-eminent is whether or not current risk assessment methods are fit for purpose. It is a little like taking your car for a MOT and the garage not quite knowing what to test. There are technical guidance documents that fit within the regulation but we are not sure whether they are fit for purpose. In fact, the European Food Safety Authority's view at the moment, or rather I should say the view of their Scientific Committee, is that risk assessment processes are still under development in respect to nanomaterials in food and feed. There is a big question about whether the current methods can demonstrate that these things are safe in current form. The second area or barrier is whether current regulations, for example for non-foods legislation, trigger substances to be risk assessed in nano form. Under REACH, with which I am quite familiar, which is the more general industrial chemicals regulation, the triggers are tonnage so if you manufacture above a tonne of material you have to provide a certain level of information and more at ten tonnes and so on. The question then—and this is something that the Royal Commission on Environmental Pollution picked up—is that the mass of a material is slightly irrelevant in dealing with nanoparticles; it is the surface area that is more important, so do these triggers cover nanomaterials? This also links to labelling which I will leave to Peter and others to say whether or not you are actually going to pick up a nanomaterial going through the regulatory process if it has no way of identifying it as a nanomaterial. The third area is whether or not there is sufficient scientific evidence, to pick up your point Lord Chairman, as to whether you can make a case for nano regulation or whether there is a nano effect, so do nanomaterials in food or otherwise present greater risks in terms of bio-availability, in terms of their inherent toxicity, in terms of interaction with other chemicals, natural or manmade, or biological systems, or do they have novel effects. At the moment there is just insufficient co-ordinated research and, perhaps as importantly, inadequate governance processes to ensure that that information is presented in a timely way. I am really picking up on what Trevor is saying as well, that we need to speed that process up. Finally, we have not to forget that risk assessment is not just a dry process of understanding hazard exposure, it is actually important to understand what we call the social framing of that process, what the public views are on that, and really more research needs to be done about what people think about nanotechnology in food, the risks and the benefits, because people do not think of risks in isolation, they look at a risk/benefit balance when they make those sorts of appraisal.

Q447 ***Lord Haskel:*** You have told us about why standards are important in innovation and in insurance. Why are standards and definitions important in the context of regulation and in the context of risk assessment as well?

Dr Hatto: There is an old adage which says if you cannot measure it you cannot make it. I think you can extend that to regulation and say if you cannot measure it and you cannot define it you certainly cannot regulate it, and what we are missing is universal agreement on definitions, and I will come back to that in a moment, and of course universal agreement and availability of protocols for measuring. In terms of definitions, forgive me Lord Chairman for making this statement but I think the title of this investigation suffers from the problem of definitions because it seems to me that although it is about nanomaterials, you are probably thinking more of what ISOTC229 (which is the technical committee of which I am chair) calls "nano-objects". The Royal Society and Royal Academy of Engineering study published in 2004 talked about nanomaterials and gave a broad generalised definition which includes both nano-objects, those are the materials with one, two or three dimensions in the nanoscale, but also nano structured materials. I think the main concern here is probably with nano-objects, with nanoparticles with three dimensions in the nanoscale (and quite what that means is open to question) with nano fibres with at least two dimensions in the nanoscale, probably not with nanoplates because they are not of that much interest in this particular area. It is clear that we need international agreement on what we are talking about when we use these terms. In terms of risk assessment, risk assessment needs to somehow consider hazards because without exposure (and risk is a combination of hazard and exposure) there is no risk, and we need to have some validated protocols to determine hazard, and at the moment we are somewhat lacking in that area. My own committee in ISO is developing some documentary standards for risk assessment based on some work done over the last few years by DuPont and Environmental Defense. We are developing some work in the area of control banding which is a risk assessment type of approach, but without these tools at our fingertips we are in a very difficult position. I think the biggest challenge is really on measurement and characterisation, how you measure things, what do those measurements mean. It is very easy to say that these nanoparticles are 100 nanometres in diameter, but how did you measure it, because the result you get is a function not only of the particles but also of the measurement technique, and there are enormous challenges in determining the physical and chemical properties of these materials. I am not sure if that is adequate.

Q448 ***Lord Haskel:*** We are of course concerned with nanoparticles in food and presumably the hazard there is that people will get poisoned by it or they will suffer chronic illness. How do you deal with that?
Dr Hatto: Presumably people will only get poisoned (a) if they are exposed and (b) if they are poisonous, and the question is whether they are poisonous. Simply because they are nanomaterials does not mean they are any more poisonous than the macroscale forms of the material. As you are probably aware, the OECD Working Party on Manufactured Nanomaterials is about to undertake a rather expensive, something like $45 million, sponsorship study into 14 representative nanomaterials. You will notice the definition has not come out there and that is rather because the Working Party on Manufactured Nanomaterials has kept their working definition of manufactured nanomaterials to themselves. There have been no detailed studies into the impact of these materials and there is a huge problem because a lot of the studies are done using in vitro techniques where you are exposing cells to nanomaterials and also in vivo studies and there is a lot of disconnect between the results from in vivo and in vitro studies, so which one do you take? Do you take the one that kills the cells or one that kills the organism? I think we would prefer to take the one that kills the organism but a lot of the chemical risk assessment and chemical toxicology testing is based on in vitro studies and of course the European Commission would like us to use only in vitro, but there is a recognition that it probably will not tell you what you want to know.

Q449 ***Lord Methuen:*** Is not one problem that you have chosen a nice round number of 100 but it could be 50 or it could be 250? Do you not have a problem there in actually defining what it is you want to define?
Dr Hatto: That is a major challenge and the ISO definition, if you like, is based on a definition of the nanoscale. We use the nanoscale in all of our definitions of nanomaterials. We have defined the nanoscale as the size range from approximately—and it is important to say approximately—one to 100 nanometres. The 'approximately' can be flexible but it has been introduced simply because if you were to stop at 100 then what about 101 and can you tell the difference between 100 and 101? It is recognised there might well be impacts of larger materials. In the area of nanotechnology we want to put some sort of limit otherwise we are going into the sunset almost. Why did we choose a lower limit when the Scientific Committee on Emerging and Newly Identified Health Risks did not? The reason we chose a lower limit was simply because if you do not have a lower limit on the nanoscale then atoms are nanoparticles, so clearly you want to think about materials that are not atomic-sized or molecules or essentially microscopic materials, and the way I think about nanotechnology is not unique properties of materials but unique challenges and anything in that size range has—
Chairman: You have made your point. Lord Selborne?

Q450 ***Earl of Selborne:*** My question is to Mr Hatto. In your opening remarks you referred to the United Kingdom being at the forefront of standardisation of nanotechnology but in the written evidence the BSI has told us that it has been difficult to engage with the Food Standards Agency and there is no appetite amongst government departments to maintain the United Kingdom's leadership in the field of standardisation and risk assessment. First of all, would it be correct to say from that that we have a position of leadership in spite of the Government and its agencies and what is it that you would like the Government to do to reform its ways?
Dr Hatto: I would not say that we have leadership in spite of the Government. We have leadership because of the support we have received up to now, but that support is dwindling, and I think the evidence did not say there is no appetite, it said there appears to be no appetite. I think that is an important difference because it is not possible to engage with all aspects of government. With regard to the Food Standards Agency we are not currently involved in standardisation in the area of nanotechnologies and food and if we were that would not be the responsibility of my committees. In ISO it would be the responsibility of TC34 which is food, but we would work closely with them to ensure that they harmonised the terms and definitions with us. The deputy chair and myself had a meeting with the Chief Executive Officer at the Food Standards Agency about two and a half years ago and we were given the strong impression that they wished to engage in this area, and in fact somebody was appointed to the committee but that individual has attended I think one meeting and has never to my knowledge submitted any comments on any of the documents that we have distributed for comment. Of course one can understand that there are more pressing issues in food than nanotechnology for that individual and for the Food Standards Agency but these issues are coming forward very rapidly. We believe that it is important because we are at the stage of developing the foundation of standardisation, the measurement and characterisation and terminology and so on that I think it would have been valuable to have had their input on. A similar situation applies to the MHRA, the Medicines and Healthcare Regulatory Agency, who were engaged in the committee early on but then they made a blanket decision to withdraw from all standardisation activities as far as I am aware

because there was a feeling that the regulatory authority should not be engaged in these sorts of activities, but without engaging with those parties, it is difficult to ensure that there is a complete connect between industry and the regulator (it would not be sensible to have a barrier between the two) and the people involved in the development.

Q451 ***Earl of Selborne:*** Standardisation can only be effective in this technology at the international level ultimately. OECD presumably would be the Holy Grail of trying to get standardisation on that level, not that you would not build by building blocks at the national and European level first, I assume?
Dr Hatto: I think it depends very much on what sort of standardisation you are talking about. If you are talking about toxicology testing I would certainly agree but of course nanotechnology is not only toxicology, it is a much broader area and a lot of our work is involved in developing protocols for measurement and characterisation of nanoparticles. This is going to be critical for toxicology of course because you need to understand the relationship between the physical and chemical properties of the materials that you are testing and the toxicological impact simply because of the huge variety of nanomaterials that we will have, unlike, let us say, a chemical which you might dissolve and then expose yourselves or your organisms to when you have an insoluble nanomaterial then the presentation of that material to the cells or to the organism—
Chairman: May we now move on to next question please and Lord O'Neill.

Q452 ***Lord O'Neill of Clackmannan:*** Mr Maynard, in your evidence you draw attention to the fact that the precautionary principle has been recommended in the EU but that the US and Japan prefer a lighter regulatory touch. Do you think that the precautionary principle should be applied to the use of nanotechnologies and nanomaterials in food?
Mr Maynard: We would define the precautionary principle to mean 'if an action could cause harm to the public or environment then in the presence of uncertainty the burden of proof falls on those proposing the action'. There are various definitions of it around but that would be the definition we would take. It is clear to us that consumers are particularly sensitive to the use of nanotechnology in food. Even from the submissions to this Committee that I have read on your website that has become very clear. It suggests to us that the public have an expectation that particular care will be taken by developers in this respect. There also appears to be a low understanding of nanotechnology by consumers, perhaps not surprisingly. They will therefore entrust larger organisations such as retailers, manufacturers and maybe even insurers to protect them from harm. If appropriate care is not taken and harm arises we have found that the views of society in general set the backdrop for legal cases and awards for damages certainly in the US with the jury system, and therefore if particular care is not taken it might lead to larger claims against insurance policies in due course. We are very much aware that nanotechnology might be transformative in the future and that there are many important global trends that will require innovative solutions to solve them, climate change for example, population growth, food shortage, water shortage, and we are not trying to stand in the way of this innovation, but if I could give some details on the cost of asbestos.

Q453 ***Chairman:*** Could you keep it succinct please.
Mr Maynard: Very succinct. The cost is estimated at $200 billion globally of which insurers have paid $120 billion. The annual cost to us is still 2 to 3 billion per annum and it is expected to last for another 15 years. It led to a number of insurance company insolvencies and it brought Lloyd's very close to insolvency itself, along with some other factors of which I am sure you are aware. Asbestos had only one exposure mechanism—inhalation—and was only one material. Nanomaterial is many materials and many possible exposure mechanisms, so I would say a precautionary approach in this case seems very sensible.

Q454 ***Lord O'Neill of Clackmannan:*** So you would not really favour the lighter touch regulation that perhaps—and I say perhaps because it is still in its infancy—the American system seems to involve? That may be because they are more litigious than we are and therefore have a quicker and easier recourse to the law. Given that you operate internationally, how do you assess the difference between the European approach and the American/Japanese model?
Mr Maynard: Certainly in the US for example we have suffered many lawsuits for many different liability claims and the culture there is different. In fact some of Lloyd's research is showing that the compensation culture is moving across from the US to the EU. In terms of the standards, anything around nanotechnology, the more definition you have the easier it is for us to tighten our policies and make sure we know what we are covering, so I would say, yes, we do support the precautionary principle in this case.

Q455 ***Chairman:*** Professor Owen, would you like to add anything on this?
Professor Owen: First of all, it is probably worth saying that you cannot generalise between the EU and the US too much because it is not a consistent invocation of the precautionary principle and the

precautionary principle can be invoked in many different ways, as Trevor has said. I would take the UN Rio Declaration which is "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent [in that case] environmental degradation", so the emphasis is on serious or irreversible damage. The precautionary principle is being implemented already for nanotechnology in two contexts that you may or may not be aware of. The first is in the case of high aspect ratio carbon nanotubes where some work published in Edinburgh showed that they had "asbestos-like" properties and since then the Environment Agency took the view that they should be classed as hazardous waste and the Health and Safety Executive, if I recall correctly, described them as substances of high concern. That was on the basis that high aspect ratio carbon nanotubes may have similar sorts of behaviour as asbestos and therefore have serious implications to health. There was still a lot of scientific uncertainty around that, the experiments had not been done through inhalation for example, but there was enough evidence there for action. The second which perhaps you will be less familiar with was the Government's response in 2005, which I was involved with to the Royal Society and Royal Academy of Engineering report in which the Royal Society and Royal Academy said that there should be no deliberate introduction of manufactured nanomaterials into the environment until more was known about their risks. The Government responded and agreed with that recommendation and made a recommendation to industry to minimise the introduction of nanomaterials in waste streams and to take on a voluntary stance of not introducing them deliberately into the environment. There are two situations here where there has already been the invocation of the precautionary principle to set the context for your work.

Q456 ***Lord Crickhowell:*** Can I probe a little about the likely reaction of the insurance market and its consequence. Lloyd's has stated that there are already certain insurance companies who have refused to provide insurance for aspects of nanotechnology. As you said Mr Maynard, Lloyd's is by far the largest specialist insurance market. More than 30 years ago I was managing director for a Lloyd's insurance broking firm and I would certainly have loved to have been able to place in front of underwriters the neat, tidy, comprehensive compulsory list that you described at the start of your evidence. However, as we have also heard, there has been insufficient co-ordinated research, there is a lack of agreement on definitions, and it is very unlikely, even if we have a list, that it will be quite as comprehensive and tidy as you say underwriters would like it to be. Bearing in mind the realities, how optimistic are you that an insurance market is likely to develop which will provide companies cover for the products as they introduce them, and, presumably, if it is the companies themselves introducing the products who are going to have to provide as much evidence as likely to appear in the lists, do you think a market is likely to emerge? If it does not, how much do you think it is going to inhibit the companies in developing and producing products?

Mr Maynard: I understand that lack of availability of insurance can be an impediment to innovation and in terms of how big an impediment, I think that would be for the companies themselves to comment on. In terms of will a market be there, Lloyd's and the Financial Services Authority both require companies to think about emerging risks when setting their capital, so there is, if you like, an understanding that these aggregations of risk have caused problems in the past, like asbestos, and there is a requirement to do scenario tests to think through how you might be affected in the future. The new Solvency II reserve and capital requirements also require companies to think about all possible emerging risks. The first point is that people do have to think about these issues carefully. If the claims exceed the premium then the capital is used to pay for the balance of the claim and we have a duty to protect the assets of our capital providers. Our investors expect us to have a good understanding of the risks we take on because if we get that wrong it is their money that is being spent. There are many unknowns with nanotechnology. We also see that there is a predicted rapid increase in the size of the market. In the absence of this list telling us what products nanotechnology are used in, you have an uncertainty of whether you are covering it or whether you are not covering it, so that is a significant issue. The key point of course is that we are there to provide insurance and so we wish to provide insurance, that is our role, and, where possible, that will be provided. However, there is always a danger that cover will be withdrawn or limited if the risks are too uncertain. The purpose of us submitting evidence to this inquiry is to say that insurers do very much care about this information. The more that is available the better we can quantify the risk and keep the market insurable for longer. As I have said, there are companies who have said on a limited basis for example, "We will not provide any employers' liability cover. Any company involved in nanotechnology, we are not going to cover them if they have made a decision to do that."

Q457 ***Lord Crickhowell:*** I suspect there is not much point in asking you to speculate about what is still a rather uncertain future, but there are already in the

market certain nanomaterials in packaging, in the coating of a refrigerator and so on, where the rules may be changing. Do you know if cover is being provided for those kinds of materials at present?
Mr Maynard: I would imagine it is. This is something, as I tried to explain before, I work at the Corporation, that it is very difficult for me to know but I would imagine it is.
Lord Crickhowell: I would say as a sufferer from the asbestosis cover I hope we are not talking in terms of nanotechnology in quite that sort of disaster area, but I thank you. I do not think we can really discover much more on what the markets will discover.

Q458 ***Baroness Neuberger:*** Pursuing that, Lloyd's has stated in its evidence that it is vital that products, especially food products, have adequate labelling when nanotechnologies are used. I would be very interested in knowing why you think it is necessary. I would like to add a supplementary straight away because Professor Owen said earlier that he thought it was essential that the products were labelled because otherwise how would anybody know that nanotechnology had been used in the production or that nano products were there. If you could both clarify that that would be helpful, if I understood you rightly and I may not have done.
Mr Maynard: In our experience, if customers have the opportunity to make an informed choice then this can cut down the risk of later litigation. Conversely, misleading or silent marketing can lead to claims. As I said before, consumer knowledge is low but they do seem to be concerned when they are explained about nanotechnology and they are resistant to it. Really what we would fear is in the absence of labelling a backlash from society that would then set up a framework for claims which might be viewed positively by certain juries for example in the US. We think that labelling combined with an appropriate explanation of these terms would reduce the risk.
Professor Owen: To give you an example, under the REACH legislation, which is for general industrial chemicals, the view is that if you are registering a nanomaterial before you put it on the market you need to provide the information on the properties of that material and if you have information on the hazard and exposure, but if you do not actually know it is a nanomaterial then it is going to be quite hard to do that. One might have a CAS number with a suffix for example to say that it is defined as a nanomaterial. In the absence of that, there is actually some guidance from BSI on the labelling of manufactured nanomaterials which is really worth having a look at. BSI have been very helpful in providing that sort of support to the community. I think there is some work going on in ISO in that area as well but it is fundamentally important to know that you have the material otherwise the Chemicals Agency in Helsinki for example will not be able to do anything further with that information.

Q459 ***Baroness Neuberger:*** I would agree and I also think there is a public interest argument for it which neither of you have made. I think, Mr Maynard, you have used the argument that actually it reduces the risk of litigation. I am not clear that it is a straightforward public interest argument you are using, Professor Owen, so could you just clarify?
Professor Owen: If you want to ensure that your nanomaterial does not fall through a regulatory gap, fall between two stools, you have to be able to identify it as a substance to be risk assessed in a nano form.

Q460 ***Baroness Neuberger:*** And that in the end comes to a public interest argument because of the risk assessment?
Professor Owen: Yes it does.

Q461 ***Lord Mitchell:*** I just want to go on to the subject of labelling. In another context in the alcohol industry I have fought to ensure that labels are on alcohol and it is a hard battle and they will obfuscate you with all sorts of things about voluntary codes and ideas, and the bottom line is it does not get there. I am sure the food industry is as well organised as the alcohol industry is and I am sure they will resist every single attempt to have compulsory labelling on their products. That is just a statement.
Professor Owen: I suspect that there is an argument to say is there a nano effect and should a bulk form of something be labelled in a different way to a nano form? The problem there is until we have got the evidence to show that, that case has not been made. There is a general issue here with emerging technologies which I hope is coming to light here which is it takes an order of decades for that information to be assembled for the methodologies to be proven to be fit for purpose and in the meantime you have got the diffusion of that technology into society and the use of it and that comes down fundamentally to issues of governance, about how that information is assembled to ensure that it is at the same pace as innovation, and that is where we have a fundamental Achilles heel in terms of procuring that evidence.

Q462 ***Baroness O'Neill of Bengarve:*** Mr Maynard, you spoke a moment ago about reducing litigation but also about the informed consent of consumers if it was labelled. Would it really be informed consent? Can you envisage a way of doing these labels so that people know what the nanomaterials included in their food are and what their significance is? It seems to me that this is rather far-fetched. Is it just that one can make a claim that liability has been transferred if

there is a label or do you really think there can be informed consent?
Mr Maynard: I suppose the alternative is worse, to not try and label is worse than to try, both from a societal point of view, a public interest point of view, but also from a litigation point of view. I think, as I said before, that people do expect great care to be taken with these things and using new technologies without fully understanding the health impacts is a difficult practice. I think people should be given the chance to know what is in their food. Yes, whether they can really be expected to understand the consequence of that is a very difficult question but I prefer to see us try.
Dr Hatto: Might I briefly comment on that because, as you are aware from Dr Owen's comment, BSI has produced a guidance document on labelling and that was developed with the support of the Food and Drinks Federation and a number of other organisations. Of course it is a voluntary guide and there is no obligation to use it. That guide has now been introduced into the European Committee for further development as a European guide, and the International Committee has also asked to participate in that, so there will be an international document coming out perhaps in the next one and a half to two years. It will still be a voluntary guide but it was developed following the Royal Society and Royal Academy of Engineering recommendation that labelling should be provided not only to inform but from the up-stream public engagement perspective, so very much from a public interest direction.

Q463 ***Lord Cunningham:*** Can I ask Dr Hatto: do we have at the industrial scale the ability to produce complete uniformity of nanoparticles?
Dr Hatto: May I respond by asking what you mean by complete uniformity of nanoparticles?

Q464 ***Lord Cunningham of Felling:*** 100 per cent of the material of exactly the same size?
Dr Hatto: Absolutely not, and in fact one of the shortcomings or one of the problems at the moment is that there are very, very few standard or certified reference materials which can be used to calibrate equipment, for example, and those that are available tend to be at the top end rather than the bottom end. I think the National Institution of Standards and Technology in the States, NIST, has produced some standard certified reference materials towards the lower end of the order of 20 nanometres and this is consistent and certified and so on, but, no, it is absolutely impossible to produce.

Q465 ***Lord Cunningham of Felling:*** So this begs the question then what is the label going to say about the nanomaterials, how can it be specific?
Dr Hatto: It can be specific as to the nature of the nanomaterials.

Q466 ***Lord Cunningham of Felling:*** But not about the size or the properties, presumably?
Dr Hatto: It could give information about the size range, of course because you do not get a fixed size you get a size range. Unless of course the information about any impact is known, then it clearly cannot say that but it certainly would enable people to know that there are nanoparticles, let us use a generic term, in there.

Q467 ***Chairman:*** It sounds a bit like the label "may contain nuts"—"may contain nanos".
Dr Hatto: May I just comment on that because in fact one of the people involved in the development of the guidance document appeared to have been responsible for the "may contain nuts" and he was adamant that it should not be "may contain nanos". Let us be clear that all food will contain nanoparticles now—not in the future but now, not deliberately introduced but they are there.

Q468 ***Lord Cunningham of Felling:*** When you say that you mean manufactured nanoparticles or naturally occurring ones or both?
Dr Hatto: Probably both.

Q469 ***Lord Crickhowell:*** Can I just ask Professor Owen a question. You twice referred to REACH and you, understandably, and I think rightly, suggested that the present one tonne limit and so on would need revision. In your experience within the Environment Agency and so on, would you comment further about the need for a fairly urgent review of REACH by the European Community and the difficulty that any such review, on past experience of the introduction of REACH, is going to take a very long time. Are we likely, do you think, to get changes in this very important area of regulation soon enough?
Professor Owen: The answer to that is no, quite frankly. Of course a lot of our legislation in the UK comes from Brussels and legislation such as REACH is fundamentally important and that bigger picture always has to be borne in mine. The view on REACH is that in principle the risk assessment framework is fit for purpose but the devil is in the detail in terms of implementation. I come back to the methods. All that sort of legislation is based on a risk assessment methodology and if you are not sure whether that risk assessment method is fit for purpose it is very difficult for manufacturers and importers to be able to do their job. In my view, it is for the OECD to expedite that process and to focus its attentions on providing guidance to be used in a harmonised way across the globe, both under REACH and other forms of legislation. If we are going to try and reduce that time-frame that might be one of the places that we might look to do that job.

Q470 ***Chairman:*** I would like to close by just going back to two points that the three of you raised earlier on and just try to clarify the points. One concerns the precautionary principle and we heard two definitions of the precautionary principle from Mr Maynard and Professor Owen, one about the burden of proof on the individuals or groups proposing the action, and the other one about uncertainty being no excuse for preventative measures if there is a serious threat. I just wondered how you would apply the precautionary principle in practice to the use of nanotechnologies in the broadest sense in the food sector?
Professor Owen: The precautionary principle in all its different forms boils down to one simple thing, which is that the absence of full scientific certainty is not an excuse to do nothing. What you do is not necessarily a moratorium or a ban; all it is saying is that you have to do something or you should do something, you should not just sit there and do nothing. What that forms takes can be various and it is worth saying that nanotechnology is not one nano, it is a variety of different things—manufactured, some in different forms—and so it is very difficult to generalise. I think it is worth saying that from the outset. Where we had carbon nanotubes there was a case in point there that we knew that high aspect ratio carbon nanotubes could have very dangerous and long-term damaging effects so by extrapolation one could say, yes high aspect ratio nanomaterials may be like asbestos, so you have to ask the question about whether or not serious or irreversible damage is likely to occur from that.
Mr Maynard: I have not got a great deal to add to that other than precaution should as a minimum I think include telling people what you are using, when and how, so at least transparency.

Q471 ***Chairman:*** Thank you and my final, final point, which was touched on in the discussion on labelling, we talked throughout this session on various occasions about the definition of nanotechnologies or nanoparticles and I just wondered if very succinctly Dr Hatto could give us what he thinks are the key aspects of the definition for the food sector in terms of our report, just in a few sentences.
Dr Hatto: Let me just slightly side step that, if I may.

Q472 ***Chairman:*** No, please do not side step it!
Dr Hatto: Okay, it is critical that we have definitions for all of these different aspects of nanotechnologies and there was a comment earlier about disagreement or no agreement on nanotechnologies, but let me just emphasise that the ISO committee of which I am a chair, and we had a very full week of meetings last week in Seattle, is currently working on developing international agreement on nanotechnology definitions, not a definition for nanotechnologies but definitions relevant to nanotechnologies, and we are working in sector specific areas. We have not yet dealt with the food industry but we are addressing medical health and personal care applications and the bio-nano interface.

Q473 ***Chairman:*** Sorry, just to cut to the quick, this means that your group does not yet have an agreed definition as applied to the food industry?
Dr Hatto: An agreed definition for what?

Q474 ***Chairman:*** Nanotechnologies, nanomaterials, nanoparticles?
Dr Hatto: We have agreed definitions for nanoparticles. We have not yet finalised a definition for nanomaterial but nanomaterial is relatively easy to deal with. The definition for nanoparticle will be relevant to any industry not just to the food industry.

Q475 ***Chairman:*** Can you give in a sentence what the definition of a nanoparticle is according to your organisation?
Dr Hatto: Yes, it is based on this term nanoscale and a nanoparticle is one of the nano-objects and it is a nano-object with three external dimensions within the nanoscale.

Q476 ***Chairman:*** But not a particular number, because we have heard 100 nanometres?
Dr Hatto: No, because the definition comes back to the nanoscale, so the nanoscale is the dimension defining terms from approximately one to 100 so if something is within the nanoscale it is within that range. A nanoparticle has three external dimensions within the nanoscale.
Chairman: Thank you very much. I would like to thank all three witnesses for sharing with us their thoughts on the questions we have put to you during this session. I would like to also remind you that the transcript will be sent to you for correction before it is published and also to invite you if you wish to send in any other additional points where you feel we have not given you a chance to clarify your thoughts, and of course those would be published in the written evidence alongside the transcript in due course. With that I would like to thank you all very much indeed.

TUESDAY 30 JUNE 2009

Present	Crickhowell, L	Neuberger, B
	Cunningham of Felling, L	O'Neill of Clackmannan, L
	Krebs, L (Chairman)	Selborne, E
	Mitchell, L	

Letter from the Royal Society of Chemistry

On behalf of the Royal Society of Chemistry [RSC] I am pleased to attach the formal submission to your current inquiry on *Nanotechnologies and Food*.

This RSC evidence follows the questions outlined by Sub-Committee I in its *Call for Evidence*.

However you might find helpful the following excerpts from our submission which seek to highlight the four key areas covered by our evidence. These are:

Classification of Nanoparticles in Food

Novel nanoparticles in food can be divided into soft materials (these are largely consumed) and hard surfaces (non-contact and contact applications such as processing equipment and packaging). Due to the nature of their applications, the impact on human biology is less significant for hard surface materials than soft materials; therefore the risks to human health are likely to be lower for hard surface materials.

Regulatory Framework

In the absence of legislation and an appropriate risk assessment framework, the food industry will be liable for any new hazard. Whilst small companies and academic institutions are researching the potential of this emerging technology, commercial realisation of new products and ingredients is not being carried through to market.

Potential Uses and Contributions

Nanotechnology has many potential contributions to make across the food supply chain. These include noncontact sensors in food processing and packaging, new functional materials, food formulation and improvements in diet, for example increasing the content and bioavailability of micronutrients of food. New materials based on nanotechnology, with increased strength, offer the potential to reduce packaging waste by allowing down gauging of the packaging and improved thermal transfer.

Public Engagement and Consumer Information

People are often suspicious of new technologies because they are concerned that corporate profits may come before public safety. Thus, with the introduction of any new technologies, there must be an early dialogue involving effective communication of the benefits as well as risks to the consumer and/or the environment. There must be a balance of providing the relevant information necessary for consumer choice, and bombarding the consumer with unnecessary detail. However, the balance must be in favour of information being made available to consumers. This information should be presented in a standardised form.

If you need any further detailed information may I invite you to contact my colleague Dr Farrah Bhatti.

You may be aware that the Society launched a major report on food in the House of Commons on 21 January 2009 entitled *The Vital Ingredient*. This was co-authored by Dr Bhatti. Apart from emailing this evidence to you I shall provide a hard copy together with a copy of the published report which I hope you might find useful for your files.
If you need to get in touch with me by all means please do so.

I hope this is helpful.

Dr Stephen Benn

The RSC welcomes the opportunity to contribute to the House of Lords Science and Technology Select Committee call for evidence on "Nanotechnologies and Food".

The RSC is the UK Professional Body for chemical scientists and an international Learned Society for advancing the chemical sciences. Supported by a network of over 46,000 members worldwide and an internationally acclaimed publishing business, our activities span education and training, conferences and science policy, and the promotion of the chemical sciences to the public.

If you would like further information or need anything in this document clarified, please do not hesitate to contact me.

Farrah Bhatti

State of the Science and its Current use in the Food Sector

1. The RSC has recently published a comprehensive report identifying the science, engineering and technological innovation that underpin food production. This report, *The Vital Ingredient,* covers the breadth of the food supply chain: Primary Agriculture, Manufacturing, Processing, Distribution, Retail, Consumer, and Waste. Nanotechnology is one of a number of existing and future opportunities for the chemical sciences to improve food sustainability and food security.

2. Hard copies of the report are available on request, alternatively it can be accessed online (www.rsc.org/thevitalingredient).

3. The RSC response will focus on the state of science, relating to nanotechnology, and its use in the food sector.

4. It is important to clarify exactly what is meant by nanotechnology and nanoparticles in relation to food. Nanomaterials have been broadly defined by the Royal Society and the Royal Academy of Engineering as having one dimension less than 100 nanometres. There are many examples of existing nanoparticles which are not new, eg viruses which range in size from 10–300 nm across. Manufactured nanoparticles to be added to food could involve manipulation of existing ingredients, or completely novel chemical structures. Manipulation of food at the nano-level is also not new; homogenisation of milk to prevent the natural separation of cream from the rest of the emulsion is a classic example of this.

5. Novel nanoparticles in food can be divided into soft materials (these are largely consumed) and hard surfaces (non-contact and contact applications such as processing equipment and packaging). Due to the nature of their applications, the impact on human biology is less significant for hard surface materials than soft materials; therefore the risks to human health are likely to be lower for hard surface materials.

6. In the absence of legislation and an appropriate risk assessment framework, the food industry will be liable for any new hazard. Whilst small companies and academic institutions are researching the potential of this emerging technology, commercial realisation of new products and ingredients is not being carried through to market.

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

7. Nanotechnology has many potential contributions to make across the food supply chain. These include noncontact sensors in food processing and packaging, new functional materials, food formulation and improvements in diet, for example increasing the content and bioavailability of micronutrients of food. New materials based on nanotechnology, with increased strength, offer the potential to reduce packaging waste by allowing down gauging of the packaging and improved thermal transfer.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

8. Nanotechnologies are currently being used in the treatment of aqueous effluent from the food industry. Microfiltration, ultrafiltration, nanofiltration and reverse osmosis membranes are all used for water treatment, depending on the size of the molecules to be removed or recovered. Some organisations are investigating the potential to reduce beverage turbidity arising from the presence of insoluble components, particularly those that might confer a functional benefit.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

9. Nanotechnology will provide the food industry with more capability and precision, which will in turn make processes more efficient and sustainable, both in manufacturing and in subsequent digestion. The need for mechanisms to control the delivery of functional ingredients within the body has focused on the development of nanostructures such as:

— the use of proteins to lower fat content in emulsion-based products with no detrimental end-product organoleptic effect;

— the use of acid-sensitive alginates that create a "full" sensation inside the stomach, slowing down gut passage rates;

— engineering taste sensations into high fat products or nutritional benefits;

— nano-filtration, already applied to the filtration of microorganisms from food;

— filtering out components such as lactose from milk and replacing it with another sugar, creating milk suitable for lactose-intolerant individuals; and

— encapsulation systems used to provide protection against environmental factors, controlled release and nutrient delivery.

10. The use of intelligent packaging systems and technologies for the improved control of food spoilage, hygiene and food safety is a key area for further development, the emphasis being on control rather than detection. For example, there has been considerable work on developing the use of time temperature indicators, but their uptake has been limited, since detection without remedy, produces more waste.

11. Nanotechnology has potential benefits by reducing deterioration. For example, packaging based on nanotechnology that absorbs oxygen will have significant benefits on the shelf-life and eating quality of certain foods. However, such approaches cannot be applied without fully considering the microbiological impact of reducing oxygen, which may include stimulation of growth or selection for wholly or facultative anaerobic pathogens such as *Clostridium botulinum.*

12. Nanoscale film on confectionery, based on oxides of silicon or titanium with antimicrobial properties could increase the life of much manufactured food. Currently the application of such materials to food with a short shelf-life is limited by the long contact time needed to achieve the desired antimicrobial effects. Additionally, the effect of such film may be limited to that part of the food that is in direct contact with it.

13. Nanolaminates for food packaging include edible films for fruit, vegetables, meat, and chocolate baked goods. Films that provide specific protection from moisture, lipids and gases can improve the textural properties of food, and serve as carriers of colours, flavours, antioxidants, nutrients, anti-browning agents, enzymes and antimicrobials.

14. Nanoparticles could be used in printing ink, changing the colour of the label to indicate the remaining shelf-life of a perishable food, possibly replacing (with regulatory agreement) the current "use-by date" labelling system.

15. These developments require significant technical, legal and consumer education issues to be considered before any new products enter the market.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

16. A sufficient supply of the omega-3 fatty acids is essential for a healthy diet. Since they cannot be metabolically synthesised by humans, they can be considered comparable to vitamins. Omega-3 fatty acids, or the triglycerides containing them, can be incorporated into food products; however they must be added close to the end of the manufacturing process because high temperatures and heavy metal ions cause rapid

oxidation. Another technique to protect these fats from oxidising in prepared foods is microencapsulation. This technology is already available; however current research into the formation of nanoemulsions provides further potential.[1]

17. Generally industrial research in nanomaterials is limited, although Leatherhead Food International and the Nano Knowledge Transfer Network are working with industrial consortia. There is a risk that UK developments in this area will lag behind other nations, due to fears of a repeat of the consumer resistance to other new technologies such as GM and irradiation.

What are the barriers to the development of new nano-products or processes in the food sector?

18. Barriers to the development of new nano-products or processes in the food sector include uncertainty surrounding issues of regulation, health and safety, the risks vs benefits of the new technological developments, and consumer acceptance.

Health and Safety

19. The RSC recommends looking at the following reports for information on issues of health and safety, risk assessment, and regulation:

- Food Standards Agency *Report of FSA regulatory review of the use of nanotechnologies in relation to food,* 2008[2]
- Royal Commission on Environmental Pollution report, *Novel Materials in the Environment: The case of Nanotechnology,* 2008[3]
- European Centre for Ecotoxicology and Toxicology of Chemicals workshop report *"Workshop on Testing Strategies to Establish the Safety of Nanomaterials"*, 2006[4]
- The European Food Safety Authority (EFSA) scientific opinion on *"The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety"*, 2009[5]

20. Furthermore, the OECD Working Party on Manufactured Nanomaterials, established in September 2006, is looking at international co-operation in health and environmental safety related aspects of manufactured nanomaterials.[6]

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

21. This aspect is not well regulated owing to inadequate funding, the burden of import regulation falling on some individual local authorities associated with major ports, lack of validated analytical methods, and gaps on horizon scanning for risks associated with imported nanotechnologies and nanomaterials.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

22. No comment.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

23. This depends on any gross differences in the toxicity of nano materials. As always the first step is to determine the intrinsic toxicology of the "parent" material itself and then look to see if reducing the particle size down to the nano scale changes the toxicological profile.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

24. EFSA is actively engaged in coordinating European risk assessment to feed into potential Commission regulation of nanotechnologies and nanomaterials.[7] The OECD is also working in this area.[8]

[1] Henry J V, Frith W J, Fryer P J, and Norton I T, *Kinetically Trapped Food Grade Nano-emulsions, Foods and Food Ingredients Journal,* 213, 192 (2008).
[2] http://www.food.gov.uk/gmfoods/novel/nano
[3] http://www.rcep.org.uk/novelmaterials.htm
[4] http://www.ecetoc.org/workshop-reports
[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm
[6] www.oecd.org/sti/nano
[7] http://www.efsa.europa. eu/EFSA/efsa_locale-1178620753812_1211902132298.htm
[8] www.oecd.org/sti/nano

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

25. The last major study into public attitudes towards nanotechnologies in the UK was carried out in 2004 by the market research company BMRB International:[9]

- The results of the opinion poll, carried out by BMRB for the Royal Society and Royal Academy of Engineering joint working group on nanotechnology, showed that 29 per cent of the public claim they have heard of nanotechnology, while only 19 per cent are able to give some definition of it. Of those who are able to offer a definition of nanotechnology, 68 per cent said it would make things better in the future.
- Participants drew a parallel with GM when considering the ethical implications of nanotechnology because of the perception that both involve changes at the most fundamental level to form something that does not occur in nature. Both GM and nanotechnology could be seen as "messing with nature" in a specific way by "manipulating the building blocks of nature". They expressed concerns about whether scientists are trying to "play God".
- Participants were very positive towards potential uses of nanotechnology in medicine, particularly in terms of earlier diagnosis and treatments. However, they also had concerns about the long-term potential side-effects of nanotechnology, and about its reliability.

26. Public opinion may have changed in the last five years, and it would be worthwhile to repeat this study. Indications from the USA are that the public are more accepting of nanotechnologies in the last two years. Consumers are more likely to embrace technology when they can see a clear benefit for them (as shown by the more positive attitude towards nanotechnology in medicine). Public attitude in the UK may have grown to be more positive in recent years if the benefits of nanotechnology in food (eg reduction of food waste, improved nutritional content of food, and cost of food) have become clearer.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

27. Feeding emerging scientific areas, such as nanotechnology, into the communication and engagement process should be done at an early stage, as exemplified by the nanodialogues (experiments in upstream public engagement), led by Demos, and part-funded by the government in 2005–07. As a result, EPSRC recently included a public dialogue on nanotechnology to help develop its funding call in this area.[10]

28. Failure of consumer acceptance can also be guarded against by well informed and robust regulation safeguarding consumers while promoting innovation. However, this will require funding for research into fit for purpose detection systems and deeper insights into the toxicology of engineered nano-products.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

29. People are often suspicious of new technologies because they are concerned that corporate profits may come before public safety. Thus, with the introduction of any new technologies, there must be an early dialogue involving effective communication of the benefits as well as risks to the consumer and/or the environment.

30. This was done effectively by Sainsbury and Safeway supermarkets when they started to sell Zeneca's GM processed tomatoes to their customers in 1996.[11] [12] The products were clearly labelled as GM and consumers were given a free choice as to whether or not to buy the GM tomato product. Consequently, consumers tried the new tinned tomato puree and sales started to grow.

31. The "climate" around GM changed primarily due to concerns that the USA would not segregate their GM soya and maize from their non-GM counterparts, thus removing choice from the consumer.[13]

32. One of the problems for companies promoting GM crops was that the consumer did not see the benefits and were not offered choice. This is in contrast to the use of GM in the pharmaceutical industry, where benefits to the public are much more obvious. Similarly, any situation which reduces consumer choice should be avoided.

[9] http://www.nanotec.org.uk/MR1.htm
[10] http://www.epsrc.ac.uk/Content/News/PublicDialogueonNanotechnologyforHealthcare.htm
[11] http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/tomato.html
[12] http://www.agbioforum.org/v4n1/v4n1a11-tait.htm#R3
[13] http://www.supra.ed.ac.uk/Publications/paper14.pdf

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

33. Consumers are often bombarded with large amounts of conflicting information about climate change, the environment, and new technologies in food production and waste disposal; and it is very difficult for them to make balanced judgements. There must be a balance of providing the relevant information necessary for consumer choice, and bombarding the consumer with unnecessary detail. However, the balance must be in favour of information being made available to consumers. This information should be presented in a standardised form. Emerging technologies will facilitate this, for example point of sale information in addition to that available on a food label could be made available via mobile telephones, barcode scanners, wifi devices and similar innovative information rich streaming facilities. Websites can provide much more detailed information particularly to shoppers using the internet.

13 March 2009

Memorandum by the Nanotechnology Industries Association

Background

The NIA, Nanotechnology Industries Association (NIA), is the market-independent, responsible voice for the industrial nanotechnologies supply chains; it supports the ongoing innovation and commercialisation of the next generation of technologies and promotes their safe and reliable advancement.

The NIA stands for science-and technology-based expertise in nanotechnologies, encompassing members companies that have successfully developed and commercialised nanotechnologies for over 25 years.

Through proactive collaborations with regulators on the national, European and international level, as well as engagement with other nanotechnology stakeholders, the NIA promotes a framework of shared principles for the safe, sustainable and socially supportive development and use of nanotechnologies, by securing a publically and regulatory supportive environment for the continuing advancement and establishment of nanotechnology innovation.

On the 15 December 2009, the House of Lords Science and Technology Select Committee appointed a sub-committee [Sub-Committee I], to investigate the use of nanotechnologies in the food sector.[14]

The Committee intends to focus on the following areas: food products, additives and supplements; food contact packaging; food manufacturing processes; animal feed; pesticides and fertilisers; and products that may come into contact with food, such as food containers and cooking utensils. The Committee will not be considering what happens to nanotechnologies and nanomaterials when they become waste products, or their potential impact on the environment.

On the 3 February 2009, the Sub-Committee launched an inquiry into the use of nanotechnologies and nanomaterials in the food sector, inviting the submission of evidence to the questions below.

State of the Science and its Current Use in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

- Nanotechnologies are enabling technologies, which help to improve existing products and enable the development of entirely new applications and products; the (potential) applications of nanotechnologies in the food sector include:
  - Improved barrier material in food & drinks packaging (ie enabling better/longer safe storage and transport of food & drink, preventing premature perishing of food & drink, enabling longer retention of flavours and gas content)
  - Smart packaging materials, which enable real-time indication of potential perishing of a food/drink (ie gas detector with colour indicators, etc.)
  - Anti-fouling and anti-stick coating on food/drink processing surfaces (ie enabling a reduction of water-and detergent-use in food/drink processing plants)
  - Anti-microbial surfaces reducing food contamination

[14] Follow this link to the House of Lords website, in order to find out more about the members of Sub-Committee I: http://www.parliament.uk/parliamentary_committees/lords_s_t_select/st1members.cfm.

- Nanomaterials are one product of nanotechnologies; the (potential) applications of nanomaterials in the food sector include:
  - Increased solubility compared to macroscale particles of the same substance (ie enabling increased flavour with lower levels of ingredient, such as salt)
  - Encapsulation of vitamins and other food additives (cf. nutraceuticals), preventing the premature degradation of the additive upon ingestion
  - Solubility modification of macroscale materials, enabling a change in bioavailability of beneficial substances
  - Improved functionality of ingredients enabling lower levels of additives giving cleaner labelling
  - Improved control of texture, taste and stability of processed foods

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

- A few sources of information on the current state of the market for nanotechnologies and nanomaterials in food & drink:
  - "Nanotechnology in Agriculture and Food" (Nanoforum report, 2006) [15]
  - "Nanotechnology in Agriculture and Food" (Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2006) [16]
  - "Study: Nanotechnology in Food and Food Processing Industry Worldwide 2006–2010–2015" (Helmut Kaiser Consultancy, 2006)[17]

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

- See above

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

- There are ongoing research and development activities conducted by University labs (part-funded by public funding, and part-funded by industry), in enterprises focussed on nanotechnology, or on food/drinks innovations, as well as in the labs of large multinational companies.

What are the barriers to the development of new nano-products or processes in the food sector?

- Public perception: Both large and small companies fear a consumer backlash, if the benefits of using nanotechnologies and nanomaterials in food, drinks and food processing cannot be communicated adequately.
- Regulatory threats & lack of guidance on potential approval hurdles: Enterprises and small companies, which are sometimes conducting contractual research for larger companies, fear that a backlash on the use of nanotechnologies in the food sector, or, indeed the introduction of a demanding and costly approval process will render their companies' core technologies non-viable.

Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?

- The use of nanotechnologies as an innovation to processing methodologies and tools, as well as the use of nanotechnology-enables smart packaging and food-safety screening detector and sensors does not create any new properties in the final food/drink product; therefore, risk assessments apply as before.

[15] *"Nanotechnology in Agriculture and Food" (Nanoforum report, 2006)* http://www.nanoforum.org/dateien/temp/nanotechnology%20in%20agriculture%20and%20food.pdf

[16] *"Nanotechnology in Agriculture and Food" (Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, 2006)* http://www.nanotechproject.org/news/archive/new_report_on_nanotechnology_in/

[17] *"Study: Nanotechnology in Food and Food Processing Industry Worldwide 2006-2010-2015" (Helmut Kaiser Consultancy, 2006):* http://www.hkc22.com/Nanofood.html

— Nanomaterials are currently not used in food & drink in Europe (NOTE: this does not include products available over the internet).

Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?

— "Nanotechnologies" should be excluded from this question (see above—ie "The use of nanotechnologies as an innovation to processing methodologies and tools, as well as the use of nanotechnology-enables smart packaging and food-safety screening detector and sensors does not create any new properties in the final food/drink product; therefore, risk assessments apply as before).

— For Nanomaterials:

  — Research funding is needed, but needs to be aligned with other, ongoing programmes of research into similar areas (cf. FP7 Programmes, other national initiatives, such as in Germany (see Fraunhofer Institute))

  — Research must be coordinated; test protocols must be agreed.

Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

— "Nanotechnologies" should be excluded from this question (see above).

— For Nanomaterials:

Yes. The current RA methodologies have been reviewed; they have been found to be generally adequate to cover RA on nanomaterials in the food sector, BUT agreement on the following desperately needed:

  — Test protocols

  — Sample handling

  — Dosimetry

  — Exposure scenarios

  — Exposure assessment

  — Testing of (commercially) relevant nanomaterials

— Research, conducted in the absence of the above agreements, will only increase confusion, mixed messages and will ultimately increase the possibility of a backlash.

Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?

  — The risks associated with engineered nanomaterials should not be different from those associated with naturally occurring nanomaterials (given that it is the transport mechanism of insoluble material that causes the biggest uncertainties).

  — HOWEVER, it needs to be clarified, if (and when) a naturally occurring nanomaterial becomes an engineered nanomaterial (ie do processing/manufacturing steps, such as harvesting/mining, isolating, purifying, etc., turn a naturally occurring nanomaterial into an engineered/manufactured materials).

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

  — On the 17 June 2009, the European Commission released a Review of the "Regulatory Aspects of Nanomaterials", which concluded that "current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework". This conclusion is true for products of the food sector, which have to adhere to the safety requirements laid out in the relevant directives (eg Novel Food Directive, Product Safety Directive).

— The European Commission highlighted that guidelines were needed, in order to clarify approval processes of (food) products containing nanomaterials (ie if/and how additional data requirements are triggered upon the use of nanomaterials in a product). The nanotechnology industries agree that guidance for implementation is required.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

— The NIA worked very closely with DEFRA on the UK's Voluntary Reporting Scheme; all industry submissions have been made by NIA Members, most of them through the NIA as an agent.

— DEFRA was never able to say, how many submission were expected to be received in two years, and the 10 submissions that had been received were openly called a "disappointment". However, DEFRA representatives have now repeatedly said that the low quantity of submissions seems to be "commercial reality".

— One major problem of voluntary reporting schemes is the high requirement of staff time to complete the onerous questionnaires, without any visible benefits.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

— The OECD is running two working parties on nanotechnologies:

— The Working Party of Manufactured Nanomaterials (WPMN) (established October 2005) is concerned with the safety aspects of nanomaterials; this WP has recently started a multinational Sponsorship Programme on the Safety Testing of Manufactured Nanomaterials: 14 internationally agreed, commercially relevant manufactured nanomaterials will be tested, and testing protocols developed.

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

— There is little understanding in the public domain of the use and benefits of either nanotechnologies or nanomaterials; the public is very vulnerable to science-fiction stories, without realising that our daily food (ie milk, tea, etc.) is based on natural nanomaterials.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

— Governments and industries are adamant not to allow nanotechnologies and nanomaterials become another "GMO" (ie public backlash against the technology), but the lessons learnt have let to little action so far: industrial companies are still concerned to be the first one to "stick the neck out" by publically engaging in the debate, and Governments have done little to run "generic" stakeholder engagement programmes, which do not highlight a particular company.

— The UK Government funded one of the most comprehensive reviews of public engagement in nanotechnologies,[18] without actually conducting public engagement itself. Now, that the review has recommended, how it should done, Government should step up and run public engagement programmes that are delivering balanced risk-benefit communications.

[18] The Nanotechnology Engagement Group (http://www.sciencewise-erc.org.uk/cms/nanotechnology-engagement-group-reports/)

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

— The public needs to be trusted to understand technical details, but they also need help to understand the concepts of (a) very low risk potential, and (b) very low exposures.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

— Consumers should be given an opportunity to understand the benefits of nanotechnologies and nanomaterials.

— Consumers need to be provided with information, but labelling is not necessarily the best way to provide balanced information—it often raises concern and causes confusion.

The NIA and its member companies thank you for the opportunity to provide these comments.

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies.

The NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an ongoing advancement and commercialization of nanotechnologies.

20 March 2009

Memorandum by Professor Richard A L Jones, University of Sheffield

1. *The emerging debate about nanotechnology and food*

The subject of applications of nanotechnologies in food is rising in media profile. This is being driven, on the one hand, by publications from promoters of nanotechnology pointing to substantial potential benefits and quoting very large projected future markets (see, for example, [1]), and on the other hand concern from NGO's and consumer organisations (most recently, Friends of the Earth, who published a report on the subject last year [2]). The debate is compromised, in my view, by a lack of clarity about the scope of the various technologies that are being lumped together as nanotechnology.

2. *What is nanotechnology?*

Most people's definitions are something along the lines of *"the purposeful creation of structures with length scales of 100 nm or less to achieve new effects by virtue of those length-scales"*. But when one attempts to apply this definition in practise one runs into difficulties, particularly for food. It is this ambiguity that lies behind the difference of opinion about how widespread the use of nanotechnology in foods is already. On the one hand, Friends of the Earth says they know of 104 nanofood products on the market already (and some analysts suggest the number may be more than 600). On the other hand, the CIAA (the Confederation of Food and Drink Industries of the EU) maintains that, while active research in the area is going on, no actual nanofood products are yet on the market. In fact, both parties are, in their different ways, right; the problem is the ambiguity of definition.

3. *The naturally nanostructured nature of most food*

The issue is that food is naturally nano-structured, so that too wide a definition ends up encompassing much of modern food science, and indeed, if you stretch it further, some aspects of traditional food processing. Consider the case of "nano-ice cream": the FoE report [2] states that "Nestlé and Unilever are reported to be developing a nano-emulsion based ice cream with a lower fat content that retains a fatty texture and flavour". Without knowing the details of this research, what one can be sure of is that it will involve essentially conventional food processing technology in order to control fat globule structure and size on the nanoscale. If the processing technology is conventional (and the economics of the food industry dictates that it must be), what makes this nanotechnology, if anything does, is the fact that analytical tools are available to observe the nanoscale structural changes that lead to the desirable properties. What makes this nanotechnology, then, is

simply knowledge. In the light of the new knowledge that new techniques give us, we could even argue that some traditional processes, which it now turns out involve manipulation of the structure on the nanoscale to achieve some desirable effects, would constitute nanotechnology if it was defined this widely. For example, traditional whey cheeses like ricotta are made by creating the conditions for the whey proteins to aggregate into protein nanoparticles. These subsequently aggregate to form the particulate gels that give the cheese its desirable texture. The distinction between "natural" food nanoparticles and structures and ones that have been deliberately engineered is potentially very problematic. For example, the recent European Food Standards Agency scientific opinion [3] concentrates on "*engineered nanomaterials",* but goes on to add that *"'Natural' nanoscale materials (eg micelles) will be considered if they have been deliberately used eg to encapsulate bioactive compounds or further engineered to retain their nanoscale properties. 'Natural' nanoscale components present as emulsions (eg in homogenized milk, mayonnaise, etc.) will not be considered."* This places the emphasis on whether the manipulation of the nanostructure has been done on purpose. Of course, in the hypothetical case that a particular nanostructure developed during processing did have potentially harmful effects, then the potential danger it might pose would not be affected by whether its introduction was intentional or not.

4. *Different types of nanotechnologies have quite different risk profiles*

It should be clear, then, that there isn't a single thing one can call "nanotechnology"—there are many different technologies, producing many different kinds of nano-materials. One makes materials and structures at the nanoscale in order to access new properties—and these new properties in principle could bring new risks. But there are a number of quite different classes of properties that going to the nanoscale unlocks, and it is this variety of different types of nanoscale behaviour that makes it impossible to precisely specify a size range that constitutes the nanoscale. Different properties are affected by size in different ways, and it is only a general sense that many such properties start to be dramatically affected below sizes of a few hundred nanometers that underlies the adoption of definitions such as that which defines 100 nm as the upper limit of the nanoscale. One class of properties is affected by the simple issue of the larger surface to volume ratio of small particles; this affects issues such as solubility and catalytic effectiveness. Another important class of properties arises from the interaction of the physical dimensions of a nano-object with the wavelength of some kind of radiation. This includes the well-known transparency of small dielectric particles such as nanoscale titanium dioxide and the colour changes of gold colloids, and the quantum confinement effects that arise in semiconductor nanoparticles (quantum dots). Finally there are a number of properties that arise due to the importance of Brownian motion and strong surface forces at the nanoscale, in particular the phenomenon of self-assembly, which underlies, for example, the formation of nanoscale surfactant micelles, and is of great importance in biological processes at the nanoscale.

In the same way that the new properties that arise at the nanoscale can have their origin in quite different physical phenomenon, so the new potential risk profiles of such materials will be very different, and it will be impossible to generalise across these categories. To give a few examples, cadmium selenide quantum dots, titanium dioxide nanoparticles, sheets of exfoliated clay, fullerenes like C60, casein micelles and phospholipid nanosomes will all have quite distinct profiles of risk and uncertainty and it is likely to be very misleading to generalise from any one of these to a wider class of nanomaterials.

5. *Engineered nanoparticles versus self-assembled nanostructures*

To begin to make sense of the different types of nanomaterial that might be present in food, there is one very useful distinction. This is between engineered nanoparticles and self-assembled nanostructures. Engineered nanoparticles are covalently bonded, and thus are persistent and generally rather robust, though they may have important surface properties such as catalysis, and they may be prone to aggregate. Examples of engineered nanoparticles include titanium dioxide nanoparticles and fullerenes.

In self-assembled nanostructures, though, molecules are held together by weak forces, such as hydrogen bonds and the hydrophobic interaction. The weakness of these forces renders them mutable and transient; examples include soap micelles, protein aggregates (for example the casein micelles formed in milk), liposomes and nanosomes and the microcapsules and nanocapsules made from biopolymers such as starch.

6. *Varieties of food nanotechnology*

Some potentially important areas of application of nanotechnology in food include the following:

— *Food science at the nanoscale*. This is about using a combination of fairly conventional food processing techniques supported by the use of nanoscale analytical techniques to achieve desirable properties. A major driver here will be the use of sophisticated food structuring to achieve palatable products with low fat contents.

— *Encapsulating ingredients and additives*. The encapsulation of flavours and aromas at the microscale to protect delicate molecules and enable their triggered or otherwise controlled release is already widespread, and it is possible that decreasing the lengthscale of these systems to the nanoscale might be advantageous in some cases. We are also likely to see a range of "nutriceutical" molecules come into more general use.

— *Water dispersible preparations of fat-soluble ingredients.* Many food ingredients are fat-soluble; as a way of incorporating these in food and drink without fat manufacturers have developed stable colloidal dispersions of these materials in water, with particle sizes in the range of hundreds of nanometers. For example, the substance lycopene, which is familiar as the molecule that makes tomatoes red and which is believed to offer substantial health benefits, is marketed in this form by the German company BASF.

7. *Nanotechnology in packaging and food contact materials*

Nanotechnology will also find applications in packaging and food contact materials. Again, there are some important distinctions.

— *Essentially passive nanostructures*. These will be typically used to control barrier properties (eg controlling gas diffusion for plastic beer bottles), and examples will be the use of exfoliated clay coatings and composites.

— *Nanomaterials which release active ingredients*. For example nanosilver may be incorporated in packaging materials for anti-microbial properties.

— *Active devices*—from sensors to detect spoilage, through to "intelligent packaging".

One issue is worth mentioning in this context. These ideas for incorporating nanotechnology in packaging all, in different ways, tend towards increased material complexity, which does go counter to some other trends, particularly the drive to minimise waste and make things recyclable.

8. *Clarity and shared understanding must underlie real dialogue*

What is important in this discussion is clarity—definitions are important. There are large discrepancies between estimates of how widespread food nanotechnology is in the marketplace now, and these discrepancies lead to unnecessary misunderstanding and distrust. Clarity about what we are talking about, and a recognition of the diversity of technologies we are talking about, can help remove this misunderstanding and give us a sound basis for public dialogue.

References

[1] *Nanotechnology in Agriculture and Food*, Nanoforum, May 2006

http://www.nanoforum.org/dateien/temp/nanotec%20hnology%20in%20agriculture%20and%20food.pdf

[2] *Out of the Laboratory and on to our Plates: Nanotechnology in Food & Agriculture,* Friends of the Earth, March 2008, http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf (accessed12/3/09)

[3] *The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety,* The EFSA Journal (2009) 958, 1–39

March 2009

Examination of Witnesses

Witnesses: Dr John Hoskins, Royal Society of Chemistry, Dr Steffi Friedrichs, Nanotechnology Industries Association; and Professor Richard Jones, University of Sheffield, examined.

Q477 ***Chairman:*** I would like to welcome the three witnesses and apologise that you are so far away from us. We are in rather a large room and we do not issue free binoculars, so I do hope that you have got your spectacles with you! I would like to welcome you to this eighth public hearing of the inquiry into nanotechnologies and food, to let you know that the proceedings are being webcast, and I would like to draw attention to the information note which is available to members of the public which sets out the declared interests of the members of this Sub-Committee of the Science and Technology Select Committee so we will not be repeating our declared interests during the questioning. Before we start I would like to invite each of the three witnesses in turn to introduce themselves, and if you wish to make any opening statement please feel free to do so. Professor Jones, perhaps you could kick off.

Professor Jones: I am Richard Jones. I am a physicist from the University of Sheffield and my professional interest is in the nanoscale properties of synthetic and biological macromolecules. Relevant here, I have done some work on food-related issues in collaboration with some food companies. From 2007 to 2009, in fact to the beginning of this month, I was the senior strategic adviser on nanotechnology to EPSRC, which is the research council which leads on the cross-council programme Nanoscience through Engineering to Application. I have also had a very strong interest in public engagement in the area of nanotechnology over the last five years and I chaired the Nanotechnology Engagement Group.

Dr Hoskins: I am John Hoskins and I am here as a representative of the Royal Society of Chemistry. Within that organisation I am a member of the Environment, Health and Safety Committee who have asked me to be here today and I am also a member of Toxicology Group as well. My particular expertise is in the toxicology of nanoparticulate materials. I should add that the Royal Society of Chemistry is particularly interested in this Committee because of our launch in this House in January of the paper *The Vital Ingredient* which concerned our interest in food.

Q478 ***Chairman:*** Thank you very much.

Dr Friedrichs: I am Steffi Friedrichs. I work for the Nanotechnology Industries Association. The industry association is globally the only one that is focusing on nanotechnology and industry. That is reflected in our membership in that we have members from the US and from Australia as well and from across Europe. There is still a large number of industries from the UK because that is where we were created in 2005, very much as an initiative by the industry itself in saying that we need a voice at a time when the UK was seen to be the most proactive country in debating nanotechnology challenges and opportunities in 2005. Last year, we moved over to Brussels and we have now opened and incorporated an office there but we retain our nanotechnology UK base as well.

Q479 ***Chairman:*** Thank you very much indeed. May I start off the questioning by putting to you a question that is very basic but has concerned us more and more as the inquiry has progressed, namely exactly how one defines what one means by nanotechnologies or nanomaterials particularly in the context of regulation. Professor Jones, I notice in your excellent submission you have quite a long discourse on different kinds of nanotechnologies and different kinds of properties of nanoparticles and I wonder if you could give us an introductory comment, and then I would invite the others to follow, on how you feel in the context of regulation nanotechnologies and nanoparticles should be defined.

Professor Jones: As my written evidence suggested, I think this is a very difficult issue which is at the heart of the problem that we face; the difference in definitions that people are using is at the root of the misunderstandings we see between different groups about to what extent nanotechnologies are already in the market when it comes to food. The first thing to stress, which I am sure many people have said to you already, is this issue of diversity. Nanoparticles, nanoscale materials cover a very wide range of different materials that really do not have a lot in common when it comes to toxicity, and certainly there is no sense in which one can say there is a set of common features that a particular set of nanoparticles has. The important distinction that I have tried to draw out in my evidence was the distinction between engineered nanoparticles, hard covalently bonded materials like titanium dioxide and nanoscale silica, which have an essential permanence about them (although they can actually of course aggregate and become less nanoscale in that way) from self-assembled nanostructures which really are assembled due to weak non-covalent bonds, things like nanosomes, liposomes, micelles and such like where component molecules come together in nanoscale assemblies through reversible non-covalent bonding. These can be expected to be much more mutable and in many cases will disperse as soon as they are eaten if they are in a food product. The other distinction that one can make is a distinction between synthetic nanoparticles and natural nanoparticles or natural nanostructures. It is

a feature of interest as well as a problem from the point of view of definition that food materials have a lot of natural nanostructures in them already. Some synthetic nanoparticles might be made away from the food processing location and put into food products as ingredients, but some nanostructures will arise due to the processing methods that are used in the manufacture of food. The point to make is that, in many cases, whether we can talk about food nanotechnology or not is essentially an epistemological issue, in the sense that many food processing methods produce nanoscale structures. To some extent you could argue that it becomes nanotechnology when you know that these structures are on the nanoscale, when they are purposefully introduced, and when you have analytical data to tell you that these nanoscale structures are indeed being created. One final point—it would be very tempting to think that we do not need to worry about those nanostructures that arise from traditional food processing methods or developments of those because they have been around a long time. That is a tempting conclusion that in many cases might be right but I think one does need to bear in mind the possibility that natural food processing will produce nanostructures that may have harmful effects. It is not necessarily the case to say that because things are natural that they are safe.

Q480 ***Chairman:*** Thank you very much. Would Dr Hoskins or Dr Friedrichs like to add anything?
Dr Hoskins: Not really. I think that sums it up very clearly.

Q481 ***Chairman:*** Dr Friedrichs?
Dr Friedrichs: I would like to comment very briefly and particularly thank you for mentioning that there needs to be clarification of nanotechnology and nanomaterials definition in the context of regulation, because the problem that we have is that the purpose, for which we are seeking a definition, is the one that always needs to be mentioned, when a definition is sought. Without that, definitions can be quite detrimental or entirely misleading when it comes to posting a definition without knowing what it is for. A definition for risk assessment needs to be very different from a definition for technology and innovation, for example. The problem that we have at the moment is that we are dealing with a number of different definitions on a number of different levels. We have had the International Standards Organisation working on a definition for a number of years now and they have come up with a working specification of nano objects and nanotechnology, not even mentioning nanomaterials. Obviously that is a technical definition, which is only going to go so far when it comes to using it for the regulatory context. Another aspect is that when we go into the public domain and talk about the definition, more and more things are coming into force. When you look at the reports published by NGOs and by consumer associations about the perceived presence of nanotechnologies in consumer products, they are quite often using different definitions from those the industry is using, and that is then seen as a very bad effect when industry is seen to say 'we do not have any nanotechnology in those products that you say include nanotechnology'. They are both saying the same thing; they are just not agreeing on the same definitions. My appeal would be to always disclose the definition that one is using for any discussion upfront so that any misunderstanding, particularly by the consumer and by the public, can then be avoided from the first moment on.

Q482 ***Chairman:*** Thank you. Perhaps I could just follow-up with a couple of points. In the Nanotechnologies Industries Association's submission you say: "The risks associated with engineered nanomaterials should not be different from those associated with naturally occurring nanomaterials." So it seems as though in that position you are disagreeing with the distinction that Professor Jones drew between engineered particles that are covalently bonded and naturally occurring particles that may be held together by weaker bondings and therefore are less stable. Is that a genuine disagreement or is that something which relates to the way it has been expressed?
Dr Friedrichs: I do not think it is a disagreement, Chairman, particularly not regarding the example you just gave because engineered nanomaterials and naturally occurring nanomaterials are by no means distinguished in the technical differences that you have just recalled in covalent bonding or weak or strong bonding. We have insoluble nanomaterials occurring in nature. We are inhaling fumes from combustion engines as anthropogenically created nanomaterials daily and organisms have learned to cope with those on a certain level, if not entirely. I do not think it is a disagreement at all.

Q483 ***Chairman:*** So from a regulatory perspective you would not want to consider naturally occurring nanoparticles automatically being distinct from engineered nanoparticles? You would want the regulations to look at both?
Dr Friedrichs: Of course the distinction needs to be made but what should then not be seen as an assumption upfront is that the engineered ones, the ones that are deliberately manufactured, as you quite often find, or intentionally manufactured as you quite often find in one of those definitions, that those are seen inherently as more toxic than the ones that we are inhaling daily either naturally occurring or

anthropogenically produced by industrial mechanisms.

Lord Crickhowell: I am not a scientist and every time we have this discussion I become more confused. I hear what you have been saying on what is a very complicated issue. I have in front of me the report of the Scientific Committee on Emerging and Newly Identified Health Risks. They have a paragraph on the same subject and when I finished reading it I was even more confused than when I started. I suspect that we as a Committee are not going to be able to simply say it is all very difficult and there are a lot of different factors to be taken into account. I think people will probably expect us to suggest a workable definition that people can at least discuss as a basis. Are any of our witnesses going to be able to put forward, are you going to be able to put forward a basic definition which is likely to stand up to scrutiny and examination and carry us forward? I think in the days when I was a minister, having heard all these expert views, I would have turned round to my officials and said, "Sit down and produce a workable draft, argue about it and let me know if that will stand up." Are we in a position to do that?

Q484 ***Chairman:*** Professor Jones, would you like to come back on that?

Professor Jones: Yes, this is the point at which I am rather glad I am a scientist and not a regulator. I think it is very difficult. You have heard the very simple idea that people have that we can just say it is 100 nanometres and below that is a problem and above that is not. That clearly will not wash. I think we need to consider both the nature of the ingredients and the degree to which nanoscale structure has been introduced with intentionality. I think you can clearly distinguish engineered nanoparticles, which are entities that you can make a relatively clear definition of. One should be looking at whether these have substantially new properties by virtue of their size. That is an important factor in determining whether it was something one ought to consider. In a sense, I am not volunteering to provide to you with that cast-iron definition, but I hope I have been able to illustrate some of the issues that you would need to take into account when one would make such a definition.

Q485 ***Chairman:*** Would any of the other witnesses care to propose a cast-iron definition or do you follow the lead of Professor Jones?

Dr Hoskins: I do not think we can offer cast-iron ones. The nature of the beast is that we are going to have to be fairly woolly about it. One of the important factors is that the materials as manufactured should maintain their nanoscale properties when in use. This would of course be a rider to any definition rather than a definition itself. If in use for example involves dilution, then of course you can get a breakdown of a number of covalently bonded nanostructures. I think that is going to be the way. You are going to have to keep to the very crude definition of compound or structures or whatever—less than 100 nanometres—and then add a number of riders depending upon function.

Q486 ***Chairman:*** You have just disagreed with Professor Jones who said the definition of below 100 nanometres will not wash.

Dr Hoskins: It will not as a definition in its own right, no.

Q487 ***Chairman:*** Did you wish to add anything Dr Friedrichs?

Dr Friedrichs: Just as a clarification in underlining that Richard and John did not contradict each other. Naming 100 nanometres as a really clear absolute cast-iron cut-off is clearly what is not going to wash. If we look at what John mentioned about retaining the nanoscale properties, when you look at nanomaterials you will find that most of them only show true nanoscale properties—i.e. not just a linear increase in surface area but really something happening on the nanometre scale that the material does not do at a larger scale; there is a step change of property—we observe almost all of those below 50 nanometres and most of those below 20 nanometres.

Q488 ***Earl of Selborne:*** The Nanotechnology Industries Association says in its submission to us that the current regulatory framework is adequate but that industry needs updated supportive guidelines to address uncertainties in the toxicology underpinning risk assessment. Could you give us your thoughts as to what such guidance should include and could you put that in the context of what guidance is currently given to companies to tell them whether a product falls under the Novel Foods Directive?

Dr Friedrichs: The call for guidance is one that is particularly necessary when you look at where nanotechnology innovation is done. It is done to a large extent where innovation is done in entirely new emerging technologies: by small companies. It is in particular the small companies that need guidance when it comes to developing products for which they need to know, when they are aiming for an exit strategy, either selling the products to a client, licensing the technology process, or in fact exiting by being bought by larger companies, how much the approval process of the final product is going to cost. Therefore you need guidance as to if there is any extra data required when a consumer product contains nanomaterials or is based on nanotechnology as opposed to not having done so before. That is all the guidance we are talking about. We need guidance when it comes to approving such products for the

market. For the food industries, we have in Europe, as we have with all other products, the Product Safety Directive which holds the manufacturer responsible for making sure that the product is absolutely safe. That is irrespective of the presence of nanomaterials or the use of nanotechnologies. The guidance that needs to be implemented and needs to be written at some point, sooner rather than later, is if the regulator thinks that they require additional data or additional research in order to maintain this approval process as it is. For food products on the market, particularly in Europe, that problem does not arise at the moment.

Q489 ***Earl of Selborne:*** If I could come back to your earlier observation that there should not be an automatic assumption that nano-engineered products are automatically likely to be more toxic. Is not the underlying issue that the risk assessment has to be determined because clearly nanoparticles have been in our food supply which humans have evolved to ingest whereas engineered nanoparticles may or may not be equally benign; we just do not know? Is there not therefore a precautionary element which has to be taken into account in the risk assessment?
Dr Friedrichs: Yes, there is, but our regulation and our risk assessments are fully capable of dealing with uncertainties.

Q490 ***Chairman:*** Just to pick you up on that. I am quoting from the EFSA opinion here which was published in February this year which says: "The adequacy of currently existing toxicological tests to detect all aspects of potential toxicity of engineered nanomaterials has yet to be established." Then it goes on to say: "Any individual risk assessment is likely to be subject to a high degree of uncertainty." That seems to be a much less concrete and definite assertion than the one you have just made, Dr Friedrichs.
Dr Friedrichs: That goes hand-in-hand with EFSA's recommendation for a case-by-case approach to risk assessment, so it is talking about the established risk assessment, the established tests and approval approaches. "Established" means that we have an agreement which is the same for all nanomaterials and for all nanotechnology when it comes to approving them in food products. We are not there yet. We do not even have any food products that have any nanomaterials in them. The emphasis is very much on the word "established" in that context. At the moment all we can do and the best we can do is a case-by-case approach. That is done to state-of-the-art and on a European level with full recognition of the precautionary principle.
Lord Mitchell: I would like to take a look at co-ordination of research. I wondered what co-ordination is going on between industry, academia and government on risk assessment? Secondly, what role should industry play in any national research strategy?

Q491 ***Chairman:*** Professor Jones, you would probably be best-placed to answer given that you have been advising EPSRC on such matters.
Professor Jones: Indeed. As I am sure you have heard, there are mechanisms for co-ordination of research through the Nanotechnology Research Co-ordination Group which is a forum for agencies like the research councils and the Technology Strategy Board.

Q492 ***Lord Mitchell:*** Is this UK or European?
Professor Jones: In the UK, yes. I think it is fair to say—and I am talking about the UK picture at the moment—that the research councils have various priority areas for the application of nanotechnology, so for example in the EPSRC programmes that have been developed there has been an emphasis on nanotechnology for medicine and nanotechnology for things like clean energy and environmental mediation, and so from the research councils' point of view their emphasis has been on making sure that the research on potential adverse effects as well as public engagement has been aligned to what their priorities are. It is not the case that the nanotechnology applications in food are a priority for the research councils, so there has not been a particularly strong push from the research councils to address specific issues arising from nanotechnology in food. The Technology Strategy Board is the body that is being tasked with co-ordinating research with industry and for putting together industry consortia to do research, both in bringing research to market and in dealing with toxicological and eco-toxicological issues. Their major instrument for promoting research on the toxicological side has been the Safe Nano Network which TSB has supported. I know that the NIA has been active—and Steffi can speak to this—in identifying the research needs of NIA members and feeding into TSB. I know that has had an impact for example on some of the OECD recommendations. The OECD is providing a kind of transnational medium for people to identify research priorities and the UK's TSB and NIA have been instrumental in making sure that the UK fulfils its share of the OECD research programme.

Q493 ***Lord Mitchell:*** I wonder if Dr Friedrichs has anything to add to that?
Dr Friedrichs: I believe you have already in your records mentioned a number of times the OECD effort where 14 representative nanomaterials have been agreed between industry and policy makers, ie regulators, on the international forum that the OECD represents. These are relevant and

representative nanomaterials in that they are commercially relevant, so we are not talking about creating esoteric nanomaterials that might never be used and never pose an exposure threat. These are nanomaterials that are made by industry, they are donated by industry into the co-ordinated research programme at the OECD, the so-called OECD sponsorship programme, and they have a large potential and sometimes even current commercial use. They are also representative in that once we have the 59 end points that are currently set under the sponsorship programme to be tested for all of these nanomaterials and various different forms thereof, we will have a matrix of data points that will hopefully, ultimately, give us an answer to the question of whether there are such things as intrinsic toxicological properties of nanomaterials or if there is nothing that any nanomaterial has in common with any other nanomaterial. It will also give us some indication as to how many high aspect ratio or soft and hard nanomaterials fall into this overall plot of where the toxicology of nanomaterials needs to be regarded.

Q494 ***Lord Mitchell:*** What efforts are being made to assess the risks from the introduction of nanoparticles into the food chain from unintended and accidental means? What should government be doing about this?

Professor Jones: I think it is fair to say that the effort in nanotoxicology in the UK has really been focused on the respiratory aspects of nanoparticles. This is a function of the way the decision was made to rely on responsive mode funding for nanotoxicology. That means to some extent we have the research that reflects what people in the UK are good at, which is respiratory toxicology. I cannot say that there has been a huge amount of research supported in the area of understanding the effects of direct ingestion of nanoparticles.

Q495 ***Baroness Neuberger:*** Dr Friedrichs, you have already said that almost all the development here is being done by small companies and the Royal Society of Chemistry has said that whilst it is small companies and academic institutions that are researching the potential of the emerging technologies, the commercial realisation of new products and ingredients is not being carried through to market. I think what we would be very interested in knowing probably first from Dr Hoskins and Dr Friedrichs but also from Professor Jones is what you think the main barriers are to the commercialisation of nanotech products in food, food packaging and agriculture.

Dr Hoskins: The big problem for large companies is probably fear: fear of the unknown and fear of litigation, unfortunately. Another problem which underpins this is the fact that legislation such as the European legislation REACH on the transfer of chemicals, and indeed the assessment of the safety of chemicals such as we get with IARC, the international agency in Lyons, will not accept that the nanostate is in fact any different from the bulk state, and therefore in spite of the fact that they continue to discuss the risk properties and hazard properties of a number of nanoparticulate materials they will not differentiate them from the bulk materials. A good example is titanium dioxide which we see of course in paints and everybody is comfortable with. People are less comfortable when they come to the nanoparticulate material because of the fact that, probably not in use but possibly in manufacture, there is a chance of people respiring this material, and work has shown (interestingly for a pharmaceutical company but not for a food company) that the particles are taken up by the nerves in the nose and transported directly into the brain through the blood/brain barrier which has a very substantial effect on the brain, at least in so far as one can interrogate mice. This may well be happening in people as well and it is this sort of scientific fact that is holding back the big companies because through the various Food Safety Acts and amendments to these they have a requirement to produce safe food, and if there is going to be a problem in its manufacture (and it is probably more likely in its manufacture than in its consumption) then they have to be extremely careful as to how they approach things because the penalties for them making a mistake and, if you like, unleashing a particular health problem are just too great for them to bear at the present time, so conservatism and fear is holding back the companies.

Q496 ***Baroness Neuberger:*** You are talking about reputational concern there because if the small companies are doing it they are presumably bearing the same degree of risk?

Dr Hoskins: The bottom line is that it is a question of share prices that are affected. There is another problem in that there is little doubt that the *vox pop* part of the media is in places trying to demonise the prefix 'nano'. "What have we got going into our foods?" It only wants a handful of journalists to start saying, "We have another GM problem," and then the big companies will rush away from the situation very quickly indeed.

Baroness Neuberger: We have had a sense of some of that from people that we have talked to and we certainly had a sense of that from people we were talking to in the US last week. I suppose what you are really saying is some of the small companies are keeping going because they are not as worried, it is not share price and reputation, but the big ones are fearful in a whole variety of ways. What is the barrier,

what is stopping the smaller companies anyway from realising it and bringing it to market?

Q497 ***Chairman:*** Dr Friedrichs, perhaps you would like to add a comment on that.
Dr Friedrichs: There is a necessity to consider the value chain here. No small company is going to produce a product and take it through the full value-adding steps of putting it into an existing product and taking it all the way to market. What the small companies do at the moment is contract research or they might have identified a particular new mechanism by which to improve a material by going on to the nanometre scale with production mechanisms. They need a business-to-business client in order to bring that to market, so when we are talking about the small companies you will not find them as the brand owners selling into the final market.

Q498 ***Baroness Neuberger:*** Just one very quick thing on this from all three of you perhaps is about the R&D in the UK both on the innovation and on the translation. Is that keeping pace with other countries? We had a slight sense when we were in the States that perhaps it is not but we do not know.
Professor Jones: Can I just add something about the barriers because I think there is something obvious but important to state. A big barrier to the uptake of nanotechnology in food is simply the fact that food is a ruthlessly low-margin business with very strong competitive pressures, so very sophisticated bits of science need to be justified. They will add production costs and they need to be justified by very tangible new benefits, so I think it is easy to see barriers in terms of fear of public reaction, but the pure commercial realities of producing the product may be just as important.

Q499 ***Lord Mitchell:*** If I can come back on that. Food may be low margin but it is very high volume.
Professor Jones: Absolutely.

Q500 ***Lord Mitchell:*** And research and development does not go by unit cost; it goes over the complete amount.
Professor Jones: But I am not talking about the research and development costs. I absolutely appreciate, yes, you can spread the research and development costs over a very big volume of products, but it is the additional costs in processing, rather than research, that I am talking about here. Very small additional costs in processing will make food companies rather reluctant to introduce new technologies unless they have a really tangible benefit that is going to come out from it.

Q501 ***Lord Cunningham of Felling:*** To take an obvious example in the food business—salt—presumably (and some people have argued this) salt on a nanoscale would mean that far less salt would need to be added in food processing and food products, presumably with a consequent saving on cost, and at the same time at the nanoscale we are told that the food would appear to taste exactly as before with much less quantity of salt in it. What is holding up that kind of development?
Dr Friedrichs: It is in combination with what Richard just explained, it is the scale-up as well. You will quite often find that for the small research and development lab, the small company that has developed a desk-top approach or maybe a prototyping approach, the scale-up is still one of the highest barriers to making very high volume nanomaterials. In combination with what was said it is the scale-up that one needs in order to commercialise these materials. That is exactly the answer to that.

Q502 ***Baroness Neuberger:*** Can I pick up that point about how we are doing in comparison with other countries because that would be quite useful to know.
Professor Jones: Do you mean in food specifically or in nanotechnology as a whole?

Q503 ***Baroness Neuberger:*** In food specifically and the innovation and translation bit
Professor Jones: My guess—and this is really just my impression—is that I would not have thought that we were particularly far behind. The food sector is a strong sector in the UK and it is supported by strong R&D. If one is thinking about the big multi-nationals, Unilever, Nestlé, Kraft, Danone, one of the biggest of those is based in the UK, and I think that drives a very substantial science base.

Q504 ***Lord Crickhowell:*** Dr Hoskins, reference to REACH takes one rather conveniently to my next question. The problem about REACH at the moment is that it deals with the bulk materials and clearly it is going to need revision if it is going to provide cover for what we are talking about. All our witnesses agree that it is likely that the revision of REACH is going to take a very long time; these things do. Its introduction took a pretty long time. The Royal Society of Chemistry state that imported food products containing nanotechnologies and nanomaterials are not well-regulated owing to inadequate funding, the burden of import regulation falling on local authorities with major ports, lack of validated analytical methods and gaps in horizon scanning for risks. Can you elaborate on this? Do you have evidence that this is happening? What basically that is saying is that if nanotechnology

products are being developed elsewhere in the world we are not very likely to know about it when they arrive in this country or Europe.
Dr Hoskins: This is a major problem. Since about half of our food is imported and there are major exporters in, shall we say, China or India, if they were to produce a material containing nanp-particulates we would not know about it, and since our food comes in through a relatively small number of places, the major ports, it is down to the local authorities in those ports to check the imports that are coming in. I discussed this with the Government Chemist, who are liable to be involved in validation, and the trouble is that while at some considerable expense one can analyse and determine the presence of nanoparticulate material, let us take an example and say something like nanoparticulate silver in food packaging, it is an expensive exercise and probably there is not the funding or the laboratories to whom the local authorities will have to go and these will not have a validated method to work to. In fact, only a few of them will have the equipment to do the sort of electron microscopy and plasma spectroscopy that is needed to determine both the presence and the nanostate of a material that comes in.

Q505 ***Chairman:*** Do you suspect that there is in imported food coming into this country containing engineered nanomaterial that is just not being detached? Is that your suspicion?
Dr Hoskins: I think we have to regard it as a distinct possibility but I do not know.

Q506 ***Chairman:*** I wonder whether Dr Friedrichs has anything to add to that.
Dr Friedrichs: I do not think I can add anything. I would very much doubt considering what we said before that a company would put expensive nanomaterials into a food product without wanting to cash in on the benefits claimed.

Q507 ***Lord O'Neill of Clackmannan:*** The FSA is considering a register of nano-derived foods and food contact materials. What would be your view on such a register? Do you think it should be voluntary or mandatory?
Dr Friedrichs: I was surprised to hear that because we are struggling with the very first topic you mentioned when we opened this hearing in that they would have to define what nanomaterials are and, in particular, when it is a mandatory requirement you would then have to set very strong strict cast-iron (as you called it before) rules of "you are in if you are under a certain threshold and you are out if you are not". Because of that, the current understanding and the verdict of all expert committees and the fact that we only have limited cases at the moment, I would strongly recommend that such a register ought to be a voluntary approach in which industry is worked with in order to be inclusive rather than exclusive because I think that would bring everybody a lot further. I would like to see a lot more on how that would be structured and what it would be based upon, in particular with regard to definition if it goes forward.

Q508 ***Lord O'Neill of Clackmannan:*** We do have an example already of Defra's voluntary scheme which is significant only in the low participation rates. Are these low participation rates by your members because of the difficulties of definition or are they reluctant to put their heads above the parapet?
Dr Friedrichs: The Defra voluntary reporting scheme is one of my pet topics. Defra launched it when I was new in the job and had appointed somebody to see it through who was as new to dealing with that sort of issue as I was. We worked together on that to the extent that we the NIA actually went to our member companies, sat down with them and completed the reporting form with them. I can tell you it is 12 pages of detailed questions. For a company that makes a living from having developed a new process of making nanomaterials for example, they might have a drawer of 27 different samples of nanomaterials, and since no weight threshold was given in the VRS reporting template,they were expected to fill in 12 pages of detailed questions for every one of those 27 nanomaterials. Naturally with one of those submissions taking of the order of three to five hours when you are a company of six people, you can close the shop if that is required of you. We went out and did it with the companies and helped them to do it. We actually had to rewrite the reporting format because it had been lost somewhere in the files. That was all fine. All of the industry submissions to the reporting scheme that Defra received have come from NIA members, as far as I know, some of them through us, some of them external to us. I know that Defra is now saying after having commissioned the Nanotechnology Knowledge Transfer Network, that it is bringing in another 1,100 companies in the UK and asking them to participate in the reporting scheme. From interviews with over 1000 companies, the KTN has received one more submission, so Defra is now officially saying in a number of fora that this is the commercial reality in the UK. I do not think claiming that this has been disappointing has any grounds. This is the commercial reality of those companies that are actually making nanomaterials in this country within the remit of allowing that they might have gram scales of proof of principle materials for which you cannot ask them to complete all of it. If Defra wants a specific

completion for a specific nanomaterial, they are welcome to come and find out more about it.

Q509 ***Lord O'Neill of Clackmannan:*** Am I right in thinking that you came into this process once the survey had been set up and you merely helped in the filling in of the forms? Is that right?
Dr Friedrichs: We commented on the survey itself. It underwent a six-month public consultation and some changes were made to it. One of our very strong recommendations based on how Australia and Germany had done reporting schemes before was to make it a tiered approach. Do not send out 12 pages of detailed questions, which is going to have a scary effect on everybody who opens the letter, but send out a simple letter saying what are companies making, how much of that, and what is done with it when it leaves your premises. Then, if Defra is interested in any of those submissions that come in, with an answer that you can make within five minutes, they could then go back and ask for more detail on those nanomaterials they are really interested in. Australia has been more successful in doing that tiered approach and asking very few very simple questions in the first place. That is what we recommended.

Q510 ***Lord O'Neill of Clackmannan:*** Just one last point, do I take it then that the difficulty with definition and the problems involved in completing the forms would make it such that to have nanomaterials included in food labelling information would be almost worthless because of the complexity and inability to have a consensual form of definition?
Dr Friedrichs: Labelling is an entirely different aspect. I would not want to answer the question on the basis of what we have said so far in a different context.

Q511 ***Chairman:*** That is surprising because if you started off by saying a register would be difficult to assemble because of the definition, it is surprising that you would not make the same comment about labelling.
Dr Friedrichs: The comment about definition stands, but everything else that we have said regarding the voluntary reporting scheme being voluntary or not and having a threshold is not something that is of foremost priority when you consider labelling.
Chairman: I understand. Lord Selborne?

Q512 ***Earl of Selborne:*** There have been a number of voluntary codes for the nanotechnology sector around the world, including one in this country in which I declare an involvement. Do these voluntary codes serve a purpose? Do they impart public confidence or do they help the nanotechnology industry?
Dr Friedrichs: Yes, I guess we were involved in that. What you have to appreciate is that the code that in particular Lord Selborne chaired and that we helped to set up was called in by the financial community in collaboration with the Royal Society. We worked on it to bring industry to the table. It does not only, and certainly not in the way that it is put, serve the industries. What it does is it cuts across the international market and it cuts across the supply chains, bearing in mind that current regulation and agreements are always done on products and on applications and there is no cut across between the regulations that apply to products and applications. This comes very much with the spirit of codes in mind that a code needs to be implemented in different areas of the market no matter if they are regionally restricted or supply chain restricted. To our members, who are working with the code, it definitely helped them to have an internal audit. It definitely helped to raise the profile. The first principle of this code is that it needs to be signed off by a board or by management, it has to be taken into consideration by all of them and they can all vouch for the fact that it has helped multinational companies to raise the profile of what they are doing in nanotechnology safety.

Q513 ***Earl of Selborne:*** Do you see voluntary codes as a step towards regulation or a substitute?
Dr Friedrichs: It is neither a substitute nor is it the first necessary step. It will always have a role alongside regulation, where it can grip, in particular between one regulatory region to another one where it can hold everybody to the same level of safety, if a company has plant and is commercialising products in more than one legislative area. It always has a role in parallel to regulation and it always should be kept within regulation where it is seen to.

Q514 ***Lord Cunningham of Felling:*** In view of what you have been saying, what new role, if any, do you think government should adopt in respect of the development of nanotechnologies, particularly in the area of food? Should the government be looking for a new regulatory framework? Should it take the view that existing regulatory arrangements are adequate or should it do something different?
Dr Friedrichs: I think what government should do in this particular context, particularly when we are looking at food—and let us just focus for a moment on food—is that we should learn from what went wrong on the GMO debate and step up when it comes to communication, working hand-in-hand with the people who can actually deliver the data and the sound science and technology-based facts and take the public away from speculation and from scare stories.
Chairman: That leads us neatly to a point which I think Baroness Neuberger would like to make.

Baroness Neuberger: You have absolutely made the point. What public engagement activities do you think industry should use? You have said they should step up to the plate and actually do it but what should the industry be doing and indeed, to follow Lord Cunningham's point, what also should government be doing in informing the public and communicating with the public on nanotechnologies and food? Do you think there is something that industry should do that is separate from what government should do? Should government should take some kind of lead?

Q515 ***Chairman:*** Perhaps, Professor Jones, since you have been involved in the EPSRC dialogue?
Professor Jones: I think this is hugely important. This comes down to trust. The public does not necessarily have trust in the food industry. It does not necessarily have trust in government either. So I think the role of government needs to be to provide a space where government, industry, NGOs, academia and other people with an interest can meet and discuss things in a way that makes them feel a little bit safe from the pitfalls of when public engagement goes wrong. For example, I think we have seen the problem so far of people in industry where nobody particularly wants to be the person to step forward first. So we need to make a place where industry can feel they are presenting a collective voice, and no individual company is going to be picked off. We need a place where scientists can contribute without thinking that the media is about to tear them apart in all the ways that the media does. Government's role is not necessarily to do this job itself but it is to facilitate a mechanism for doing it at one remove.

Q516 ***Baroness Neuberger:*** A sort of safe space kind of thing. The Royal Society was very complimentary about the EPSRC dialogue so that is presumably the kind of structure you are talking about?
Professor Jones: Exactly, yes, I think it is important that it is seen to be run not directly out of government but at one remove from that. One needs to worry about where funding for such an activity comes from so that people feel confident that the organisation that is doing this is above the fray.
Chairman: Thank you very much. I think I need to draw this session to a close now but I would like to thank all three of our witnesses for their answers to our questions as well as their written submissions. If there are any points on which you have not felt able to express the full richness of your views or if there are any points that we have not raised with you that you would like to draw to our attention, please do write in with further evidence and that material will, as with the written evidence, be published alongside the transcript of this session in due course. You will of course receive a copy of the transcript for correction before it becomes the final public version. Thank you very much indeed.

Examination of Witness

Witness: Dr David Carlander, European Food Safety Authority, examined.

Q517 ***Chairman:*** Thank you very much for joining us for this session. I should remind you that the session is a public session. It is the eighth hearing of our inquiry into nanotechnologies and food. The proceedings are webcast so it is available to the public at large. I also mentioned to the members of the audience who you cannot see but who are sitting here with us that the interests of the Committee members that have been declared are on the information slip available. Perhaps Dr Carlander, before we come to the first question I could ask you briefly to introduce yourself for the record.
Dr Carlander: My name is Dr David Carlander and I have been with EFSA for the last three years. Previous to my position in EFSA I was working for the Swedish Ministry of Agriculture as well as for the National Food Administration in Sweden. In EFSA I initiated my work here working for the GMO unit aiding in the risk assessment of genetically modified organisms. For the last two years I have been working with the Scientific Committee and Advisory Unit where I am co-ordinating EFSA's work on animal cloning and also on nanotechnology, the reason why we are having this conversation.

Q518 ***Chairman:*** Thank you very much. May I start off by referring to the EFSA scientific opinion on potential risks arising from nanoscience and nanotechnologies that was adopted on 10 February 2009. In the report you identify various research gaps and knowledge gaps in relation to risk assessment and I wondered what you see the priorities are for research and whether or not EFSA influences the Commission in its allocation of funds for filling these gaps?
Dr Carlander: As for the research priorities, as indicated in our opinion, they are not prioritised as such and for the time being EFSA has not made any firm priorities on the research needs. These were research gaps which we identified during the work on the opinion. As for co-operation with EFSA and DG Research, EFSA is regularly asked to provide our input into the future programmes on DG Research. That is a procedure we have in place already.

Q519 ***Chairman:*** So does that mean that if you were to identify priority areas through this scientific opinion those might well be taken up by the Commission in calls for research proposals?

Dr Carlander: Yes, I assume that would be the case. Coming back to the opinion, obviously it was asked for by DG Sanco at the European Commission but it has also been submitted to the European Commission as such. It also involved DG Research so they already should be aware of the recommendations that we provide in this opinion.
Chairman: Thank you. I would like to turn to Lord Selborne.

Q520 ***Earl of Selborne:*** Good morning, Dr Carlander. We were told by the UK Food Standards Agency that Silver Hydrosol was recently evaluated by EFSA in the context of establishing an EU list of authorised sources of vitamins and minerals for use in food supplements and that as there was insufficient information to complete the assessment this product is unlikely to be included in the eventual list. Is it possible therefore to risk assess products when there is such a high level of uncertainty about their toxicity and exposure and does this not make a product inherently a high risk one?
Dr Carlander: Thank you for the question. Silver Hydrosol is in a sense both a good and a bad example. In a way it is a good example in that it showed that the risk assessors, the EFSA experts, were not able to conclude on the data provided in the dossier. The risk assessors need the full data otherwise we cannot conclude on the risk assessment. Silver Hydrosol is a bad example because there were not enough data and we did not make an assessment and therefore, because we could not make an assessment of that product, there is in a sense a safety for the consumer that unsafe products should not be on the market. As for the uncertainties that exist, they were so clear in this case of Silver Hydrosol that some additional information would have been needed to perform the risk assessment. So already now in the system, the risk assessors, when they identified that there is not enough data to perform a risk assessment, they (as is usually the case for other products we assess) ask for more data or we may come to a statement that we cannot conclude on the safety. In a sense, you are absolutely right that if there is no data we cannot perform a risk assessment but in a sense such products would then not be risk assessed and therefore in the future would likely not be on the market.

Q521 ***Earl of Selborne:*** So were you not able to get any further data? Was it just not available?
Dr Carlander: For this product the data was just not available yet. It is possible in the future that the applicant will come back with a more complete dossier.

Q522 ***Lord Crickhowell:*** The trouble is that we keep getting evidence that there is a general lack of exposure data for humans and particularly a lack of research into the effects on the gut and therefore transmission through the blood system into the brain. We are told that really there is very little known about it. In that situation how is it possible that in the immediate future you are going to be able to obtain data or carry out a risk assessment on almost any product that is going into the human gut?
Dr Carlander: This would fall a little bit under the last response. We cannot do a risk assessment if we do not have the data and this may be very much resource demanding for companies that would like to place products on the market. To conform to the information there may be a need for substantial studies being done at this stage until we get more information available on how these nanomaterials are distributed throughout the body, where the toxicity is and their classification. We are coming back to the issue that without the information we cannot do the risk assessment.

Q523 ***Chairman:*** At the moment your approach is a case-by-case approach, as I understand it. Do you think that that is sustainable in the long run?
Dr Carlander: I am sorry, your voice did not come through. Could you just repeat that question?

Q524 ***Chairman:*** Yes. As I understand it, you would at the moment take a case-by-case approach to risk assessment. In the long run would you envisage carrying on with that or would you like to switch to some more systematic framework?
Dr Carlander: Well, as information develops and we can learn from experience how pathways would work and how these materials would work, I am sure that in the future we will be able to make a more facilitated risk assessment. The case-by-case approach is in a sense not very different from the current case-by-case assessment we have on most products and substances that we assess, so in a sense I would not say it is very much different but obviously the more that is being published and the more research is being performed, the more we will learn and we will eventually probably end up with a simplified risk assessment.

Q525 ***Lord O'Neill of Clackmannan:*** On this question of the risk assessment of products, what guidance do you think the Commission should be giving to companies in this area?
Dr Carlander: To start with, the EFSA being the risk assessor and the Commission being the risk manager, I would prefer to avoid speculating whether the Commission would provide some guidance, but I can mention that the Scientific Committee of EFSA in May last month endorsed a self-tasking facility, so we will set up a new working group on nanotechnologies. One of the tasks that we can ask this working group to address is to look more specifically into guidance and for guidance to be provided to companies. As a first

response I would like to say that in the opinion that we have produced we have a generic section on providing guidance for risk assessment that we provide as guidance for our risk assessors so our risk assessors should know what to look for specifically. Just from that guidance document it could also be deduced by companies what information would be needed. The opinion we produced was admittedly, as asked for by European Commission, an initial opinion, and we will go on working in this area and we may also provide more detailed guidance for companies, as we have done in other areas such as in GMO for example.

Q526 ***Lord O'Neill of Clackmannan:*** I am just not quite clear here. Are you telling us that the work that you undertake is independent of the Commission but were the Commission to give guidance they would have to refer to you as the source of information if not the source of opinion, would that be correct?
Dr Carlander: Yes, that would be correct. As an example I can just mention what is written in the proposal for the novel food regulation where there is also a proposed definition of nanomaterials. There is an article asking that the Commission should provide guidance to industry and to do so they should co-operate with the European Food Safety Authority, so obviously there is already in the regulations that we will provide specific advice to the European Commission.

Q527 ***Lord O'Neill of Clackmannan:*** But you have yet to be asked for it and until you are asked for it you are not prepared to tell us what kind of information or advice you would give them, is that correct?
Dr Carlander: Yes, in a way, because this new working group will starts its work when we have the new scientific committee. You may be aware that we have just changed our committees and the panels, and so they will start their work in July when they have the first plenary meeting. I do hope that this working group will initiate its work in August/September and then go on. They have a mandate for the next two years and then after that we will see where we will take it further.
Chairman: Perhaps I could now turn to Baroness Neuberger.

Q528 ***Baroness Neuberger:*** It is rather following on on some of the same lines. How would you define nanoparticles within legislation such as the Novel Food Directive; is that something you can tell us at the moment?
Dr Carlander: If I could tell you the answer to that I would be very much appreciated by the whole international world.

Q529 ***Baroness Neuberger:*** This is the impression we are beginning to get, yes.
Dr Carlander: It is very difficult to put it into perspective or put it in the correct context, and it is outside the remit of EFSA as being risk assessors. In our opinion we did not provide a definition, which you might have read, and it is up to the risk manager. There are different approaches that can be taken and I would not like to speculate too much where this would lead us, unfortunately.

Q530 ***Baroness Neuberger:*** Can I probe a little bit further, and I realise that there are some things you may not want to say, but in your opinion you state that "natural" nanoscale materials such as micelles will be considered as engineered nanomaterials if they have been deliberately used, such as to encapsulate bioactive compounds, or further engineered to retain their nanoscale properties. Would you suggest that that might be used within a definition?
Dr Carlander: Possibly. I would not know, but possibly.
Baroness Neuberger: Okay, that is as far as you can go. Thank you very much.

Q531 ***Earl of Selborne:*** EFSA has recommended that the Commission should gain an overview of the current products on the market containing nanoparticles. How would you suggest that the Commission sets about this and monitors their current and future use?
Dr Carlander: There are many ways that the Commission could do this but again being the risk assessment body of the European Commission that may be touching a little bit on how to manage potential risk, but it could involve Member States, surveillance teams, the various measures that the Commission can take together with the Member States. Also at the European Food Safety Authority we do not have a remit ourselves to sort of scan or have the competence to ask for this specific data which would be on the European market. It is more related to the risk manager, the Commission in this case.

Q532 ***Earl of Selborne:*** You are the risk assessor whereas the Commission are the risk manager. What as risk assessor would you require in order to ensure that the monitoring is effective for your purposes?
Dr Carlander: We would like to get a good understanding, and if we could use such information, especially for the exposure assessment, which is a difficult area. If the quality of this information could be so good that we could use it for our exposure assessment, that would be very appropriate, but I do not have a very detailed answer to this question unfortunately.

Q533 ***Chairman:*** Thank you. Could I ask you one very specific question and then a couple more general ones? The very specific question is whether in your risk assessment you deal with all kinds of food contact materials such as food packaging or chopping boards that have been impregnated with nano silver particles, or refrigerators that have a nano silver particle in their lining. Do you deal with all of these in terms of risk assessment?
Dr Carlander: We would deal with all the food contact materials that would fall under the European food contact materials legislation, and we would do the risk assessment based on a request or a mandate that we would receive from the European Commission. In that sense, yes, if we were to receive such a request we would do this risk assessment.

Q534 ***Chairman:*** My second point was about risk assessment itself. We were recently in the United States and we heard that the National Research Council there has published a report suggesting a new approach to risk assessment in relation particularly to nanotechnologies. Is this something that EFSA is aware of?
Dr Carlander: I am not fully aware what specific report you are referring to. Would it be on the toxicity pathways? I would be very happy to receive information about this report obviously.

Q535 ***Chairman:*** Yes. Maybe it is something we could follow up in writing afterwards, if you do not mind.
Dr Carlander: That would be very much appreciated[19].

Q536 ***Chairman:*** Then finally, just to clarify, could you briefly recount the relationship between the risk assessment that EFSA does and the research that is required to underpin that, and the work done by the national bodies within the Member States—bodies like AFSSA in France or the Food Safety Authority of Ireland or the Food Standards Agency in the UK?
Dr Carlander: Maybe just a broad reply to that. We have in EFSA our Advisory Forum where we have regular contacts with the Member States and the risk assessment bodies of the Member States, so that is one forum that we are using to share and discuss information specifically for nanotechnologies. The network is there, it exists, and it is being used.

Q537 ***Chairman:*** What about the sharing of research information, is that also through the same network?
Dr Carlander: Obviously it will depend on what stage the research is at. For scientific publications we would collect the information from everywhere we can; for information that has not yet been made publicly available the networks that we have built up within EFSA could also be used to share this information.
Chairman: Thank you. Lord Cunningham would like to ask a follow-up question.

Q538 ***Lord Cunningham of Felling:*** It is a fairly simple question I hope. Are you able to tell us what percentage of the total effort of the European Food Safety Authority at the moment is being directed towards nanotechnologies and food? Is it one per cent, five per cent, ten per cent or less than that?
Dr Carlander: It is a good question but unfortunately I am not aware. Staff-wise we have an internal taskforce on nanotechnologies with experts or staff in the various units that are involved in potential applications of nanotechnology such as in feed, food contact materials, nutrients and food additives. We have about ten to 15 people in this taskforce but when it comes to the budget unfortunately I do not know. I can of course provide the information[20].
Lord Cunningham of Felling: You can provide the information. Thank you.

Q539 ***Chairman:*** Thank you very much indeed, Dr Carlander, for answering our questions. I wish to draw this session to a close now and I would invite you, if there are any further points on which you would like to comment in writing, please feel free to do so. We have asked you about two specific points, one was the allocation of resources to nanotechnology within EFSA which you said you could supply us some information on.
Dr Carlander: Yes.

Q540 ***Chairman:*** Secondly, if we give you the information about this American report from the National Research Council you could let us know whether it is influencing the approach to risk assessment taken by EFSA. Those would be very helpful comments for us to receive. You will in due course receive the transcript of this session which will be available for you to correct before we make it public, and any written evidence you provide is also of course made public. I would like to close and thank you very much indeed for your time and for answering our questions.
Dr Carlander: Thank you very much.

[19] "This is refers to National Research Council's *Review of Federal Strategy for Nanotechnology-Related Environmental, Health* (ISBN-10: 0-309-11699-6, ISBN-13: 978-0-309-11699-2). The report is well structured and highlights important considerations for the development of a research strategy and indicates issues relevant to be developed to for a risk assessment of nanomaterials. The report is an assessment of the strategy applied in the US, which may not be fully relevant in a European context."

[20] "Depending on how the calculations are performed different estimates can be made. For the development of the Scientific Committee March 2009 opinion we had 15 types of meetings with 2–10 experts over the period 2007–09"

TUESDAY 7 JULY 2009

Present	Crickhowell, L	Mitchell, L
	Cunningham of Felling, L	O'Neill of Bengarve, B
	Haskel, L	Selborne, E (Chairman)
	Methuen, L	

Examination of Witnesses

Witnesses: Rt Hon Lord Drayson, a Member of the House, Minister of State and Government Spokesperson, Department for Business, Innovation and Skills and Ministry of Defence, and Mr Ian Dalton, Head of the International Chemicals and Nanotechnologies Team, Department for Environment, Food and Rural Affairs, examined

Q541 ***Chairman:*** Welcome Minister and Mr Dalton, we are delighted that you have been able to join us. This is our ninth public hearing of our inquiry into nanotechnologies and food. May I just remind those present that we are being webcast? There is an information note available to the public and we welcome the members of the public who have joined us. This sets out the declared interests of members. May I therefore now invite you Minister for the record to introduce yourself and Mr Dalton and then perhaps, if you would like to make an introductory statement, please do so?
Lord Drayson: Thank you. I am Minister for Science and Innovation within the Government. In that role I also chair the Ministerial Group for Nanotechnology and therefore have responsibility for this matter within the Government.
Mr Dalton: I am Ian Dalton. I am Head of the International Chemicals and Nanotechnologies Team within Defra. Just to give my apologies, John Roberts, who gave evidence last time to the Committee actually had an appointment he could not get out of, so I have taken over for today.

Q542 ***Chairman:*** So you can help us with the Defra side of affairs in so far as they do not come under Lord Drayson's sphere.
Mr Dalton: Yes.

Q543 ***Chairman:*** Would you like to make any opening statement or shall we go straight into the questions?
Lord Drayson: May I just very briefly say how, as Minister for Science and Innovation, nanotechnologies are high on my agenda. I recognise this is an issue of some concern and is a matter which we take very seriously. The main mechanism for the way in which we are managing the issue is through the Ministerial Group for Nanotechnology.

Q544 ***Chairman:*** When do the Government plan to publish their national strategy for nanotechnologies? In an earlier session in March we were told that the ministerial group would meet towards the end of April when they would agree the way ahead for the next steps of the strategy, potentially including a consultative process. How will the Government coordinate this national strategy across Government and indeed to what extent will they be leading the strategy?
Lord Drayson: Our plan has now been agreed across the Government and the various departments which have an interest in this matter and it has been agreed that we will work towards a consultation process this year, leading to publication of the strategy early next year. The process by which we do that is by means of consultation with all of the various stakeholders both from scientific communities, from industry and from those interested parties, for example consumer groups, to provide us with the information to be able to put together a coordinated strategy encompassing matters of concern and publish that early next year.

Q545 ***Chairman:*** So that would be some time in 2010?
Lord Drayson: That is correct.

Q546 ***Chairman:*** So far as there is coordination of the research, would that be led by your Department or by the research councils?
Lord Drayson: There are several groups which feed into the overall responsibility for this issue, the ministerial group chaired by myself. For example, there is a coordination group for officials, there is a research coordination group and, in a growing example of the way in which the research councils work together, there is a coordination group for research from the research councils, all of which feed into this process to enable us to form the strategy. It requires us to do a thorough analysis of the issues, the state of play of those issues today, the view relating to the potential concerns that there may be with regard to consumer products using nanotechnology and to give a clear sense of the coordination of the implementation plans across Government. Therefore RCUK, Research Councils UK, is an important

group for the coordination of that research from the research councils.

Q547 ***Lord Haskel:*** In 2006 the Centre for Business Relationships, Accountability, Sustainability & Society at Cardiff University published a review of the regulations on nanotechnology. Have the Government now responded to this?
Lord Drayson: We have not responded specifically to the BRASS report because we believed that our response to those issues was satisfactorily encompassed within the response to and our view on REACH, the overarching review of regulation relating to chemicals as a whole. Our conclusion on that is that there is a strong case for the science of nanomaterials to be regarded as needing further work within the overall regulations for chemicals. We believe that our response, through the European Commission, through arguing the case for the development of further regulation, is best done under REACH. We believe that the response to the BRASS report had been covered in that overall response relating to REACH.

Q548 ***Lord Haskel:*** As I understand it, there were some special concerns about nanotechnology in this report. Will you be addressing those special concerns?
Lord Drayson: Yes, we will. We recognise that the science of nanotechnology is moving quickly. The particular challenge of understanding, for example, the nature of the body's immune response to particles of size 100 down to one nanometre requires significant research. We regard the current REACH regulations, for example, which set out a framework based upon the one-tonne threshold for regulation, as not being adequate in the case of nanomaterials. We believe that the case has been made for there to be development of legislation and regulation in this area and that is what we are pursuing through European channels.

Q549 ***Lord Haskel:*** Do you expect the European Parliament to make special amendments to REACH to treat nanomaterials differently to the bulk forms of REACH?
Lord Drayson: Yes, we do. That is the drive of our argument. We feel that the one-tonne limit is not satisfactory for these materials. This is a loophole which needs to be closed.

Q550 ***Lord Haskel:*** Do you have a timescale for this? When do you think that this will happen?
Lord Drayson: Given the nature of the European process, it would be unwise for me to commit myself to a timescale but I can tell you that this is something which we regard as being important. We regard the scientific understanding to be such that this one-tonne limit is no longer effective, given the way in which the science has moved on.

Q551 ***Lord Crickhowell:*** You have been very positive about the two main issues I was going to raise. I once had to chair a Committee in an earlier incarnation on an inquiry into REACH and perhaps the one lesson we learned there was that it all took a very long time. The trouble about the timescale is that it seems to me likely that it will be several years before anything is likely to emerge from Europe to cover this point. Is that not cause for anxiety?
Lord Drayson: It is a track record in this area and the speed of regulation which leads us to have a strong sense of the importance of establishing a regulatory framework which keeps up with the movement of the technology and the science. This is a challenge in many areas of science and technology but it is particularly of concern in this area where I believe that in this country we have learned some important lessons from GM foods. There are some parallels in the way in which this is an underlying technology where the potential benefits and risks of the technology are just emerging. Therefore, where we do identify loopholes in the regulation because of the way in which this technology does not effectively get covered under the one-tonne limit, we need to move quickly and this is the argument we will be taking within Europe, but I accept your concerns.

Q552 ***Lord Cunningham of Felling:*** How are the Government ensuring that health and safety research into nanotechnologies is coordinated across Government and within the research councils and, as importantly, that the research into the scientific knowledge base required by regulators for risk assessment is funded?
Lord Drayson: This is an area which requires us to have a light touch but where, as Science Minister, I should be grateful for feedback and guidance from this Committee. The reason I say that is because the principles under which we carry out scientific research in this country, the peer review process under Haldane, where it is not for ministers to direct where research takes place or which specific research projects should be funded, is a process which I think we all recognise works extremely effectively. Where there are areas for directed research to take place, we have used a light touch, through the encouragement of research coordination groups, where again it is the scientific community itself, through the NRCG, making decisions, making recommendations about cross-cutting research, but where we are not as a government directing that research. As I am sure the Committee is aware, there have as yet been no clear safety concerns which have been raised through the application of nanotechnology, of nanomaterials, but

we must not be complacent. We do believe the nature of research being directed to explore specific issues needs to come from the research community. The research community itself is best placed to raise those concerns, the best place to identify those research projects, for example in areas of immunology. Although the Royal Commission argued for a more coordinated approach to the direction of research, this is not something we are pursuing at present.

Q553 ***Lord Cunningham of Felling:*** We will come back to concerns in a little while. Can we safely assume that, as the person who chairs the Ministerial Group for Nanotechnology, it is actually your responsibility ultimately to see that all these things are carried forward?
Lord Drayson: Absolutely; it certainly is.

Q554 ***Lord Cunningham of Felling:*** In that case, how will you ensure that the knowledge base we have just been talking about is ready and robust enough to be effective by the time products start appearing on the market, say in a three- or five-year timescale? How will you make sure that happens?
Lord Drayson: As part of the process we are going through at the moment, in the run-up to the publication of our strategy, we are reviewing what has gone on. We have not been standing still; a lot of work has gone on over the last two years and one example of that is the way in which we will be reviewing the voluntary reporting by companies in the use of nanotechnologies and asking ourselves whether or not voluntary reporting is working well enough, whether we need to move to a more assertive requirement on companies to do so. The point of the strategy is to make sure that we get the balance right between not putting regulatory barriers in the way of the development of this technology, which potentially has very significant benefits, for example in health, but being sufficiently on top of any potential indications of risk that require us to do the underpinning research to understand how the body deals with these nanoparticles in a different way to the way it deals with more conventional particles and the whole area of toxicity for example.

Q555 ***Lord Cunningham of Felling:*** The Committee understands that the nanotechnology research coordinating group has been preparing a new research strategy for nanotechnologies. Is that correct?
Lord Drayson: That is correct.

Q556 ***Lord Cunningham of Felling:*** Is this group effective?
Lord Drayson: Yes. I would say that we are seeing that cross-cutting research coordination across the research councils is of growing effectiveness and this is a good example of that, because we can see how, in a number of important areas, and nanotechnology is one of those areas, it is an interdisciplinary approach, both in terms of research proposals but also in terms of understanding how research that may be taking place in physical science can be coordinated with research in medical science. I do not have any sense that this is not working well: quite the opposite.

Q557 ***Lord Cunningham of Felling:*** Who is responsible within Government for ensuring that the gaps in scientific knowledge, identified in this strategy I have just referred to, will be filled? Where it appears from the strategy that work that should be done is not being done, who will take responsibility for ensuring that it will in future be done?
Lord Drayson: The responsibility flows from the individual research councils, coordinated through RCUK, the coordination group is providing advice to me as the Science Minister and therefore it is my responsibility as Science Minister to ensure, based upon the advice from this group, that the knowledge base and any potential gaps are filled.

Q558 ***Lord Cunningham of Felling:*** Is the Food Standards Agency responsible in any way for taking initiatives on commissioning relevant research needed for their regulatory role?
Lord Drayson: Yes. In terms of the more applied research responsibility of Defra, in terms of leading that research and the Food Standards Agency providing input to that, perhaps Mr Dalton would like to comment.
Mr Dalton: The FSA obviously have their regulations in place which govern—

Q559 ***Lord Cunningham of Felling:*** Yes, but if I might put the question another way, if the FSA sees that it does not have relevant research needed to underpin its regulatory role, will it take the initiative in commissioning such research?
Mr Dalton: Yes. Sandy Lawrie from the FSA is here and, speaking on his behalf, I think that is the case, yes.

Q560 ***Lord Cunningham of Felling:*** In all of this, where gaps may appear or the need for new work arises or becomes apparent, who can make authoritative, budgetary allocations or changes in budgetary allocations to ensure that the work is properly funded?
Lord Drayson: There are two aspects to this research. In terms of the underpinning research, the decision is taken by the research councils through the peer review process but based upon their cross-cutting coordination group. If the FSA, for example, felt that there was a gap in fundamental research which needed to be filled to enable them to develop an

effective regulatory framework, then that is something which would be taken into account by research councils and therefore the responsibility for the allocation of their funding made by the research councils and based upon that input.

Q561 ***Lord Crickhowell:*** I understand very well what you are saying about light touch and Haldane. I think you are anticipating a future inquiry of the main Committee on this very subject. I hope you will forgive me if I repeat a question which I put at what we thought was a very unsatisfactory meeting that we had with representatives of the research councils. I said " . . . I must say the answers that we have received so far this morning leave me bewildered. Here you are talking about structures that coordinate and get research going in the right direction and, as has already been said, we have had evidence about very obvious gaps and urgent areas that need research, yet I do not get a sense that anything has been done or is being done to actually get the work heading in this direction. I am worried by the general air of, 'Oh well, it's very early, it's all very difficult. We need to have more knowledge before we set off in a particular direction'". Am I wrong in thinking that so far there is no real coordinated effort in this country? It appears to be working slightly better in some other countries. It may be that the evidence we received from the research councils was at fault in coming to that conclusion but that was the conclusion of the Committee when we concluded our meeting with them a long time later.
Lord Drayson: I will take the Committee's views on this very seriously and will take up the points that you make. I recognise that this area of technology is moving at a speed which is leading to people's concerns. Thankfully there have been no safety issues raised at present but there is a sense that the technology is being used in products and that there are gaps in our knowledge. It is therefore very important that underpinning research is done and if the Committee feels that the coordination which is taking place within the research councils is not sufficiently effective, that is something which I will address.
Lord Crickhowell: The one area which at virtually every session we have had has come up as an urgent area which needs research is the effect of prolonged presence of artificially manufactured nanotechnologies in the gut and effectively nothing has been done in that field. Some work has been done on the lung. There does appear to be an urgent need to go into certain areas like that and all the evidence we have received is that nothing has happened so far.

Q562 ***Chairman:*** We were taking evidence in Washington DC a couple of weeks ago and, although Lord Crickhowell said just then that some countries appear to be doing better, quite frankly I do not think we felt the United States was one of them because they had the same problem which we feel the FSA will be facing soon. In order to perform their regulatory role they will need some fundamental science which appears to have been commissioned neither here in the UK, nor possibly at the EU level, nor in North America. I do feel, as you will feel from the tenor of our questioning, that the technologists, the food industry, are moving faster than the fundamental research, which often happens in emerging technologies. Perhaps it is something the research councils, who did not appear to have a very coordinated approach to this to our mind, although we perhaps should reserve judgment for the moment, would need to give some strong leadership on in determining these priorities for fundamental research.
Lord Drayson: We accept that concern as being valid. We recognise that this science of the interaction of nanomaterials with the body, and in particular with the gut, is not well understood and more research needs to be done. The way in which we can most effectively ensure that we establish a sound scientific basis for that research does depend upon the academic community coming forward with appropriate research proposals which are then judged through the normal process for funding. We are also aware that existing regulation and legislation do put an absolute requirement onto food companies to ensure that the food products that they develop and market are safe whatever the materials that are used within them. Nonetheless, the long-term toxicological effects of nanomaterials, for example on the gut, need to be better understood and it is themes like this which I expect to become clear through this work which is taking place now and which is to be incorporated in the strategy document alongside the work which is being done on public engagement around this issue. It is important for us not only to be actively working on the underpinning science of understanding nanomaterials, but it is also very important to be engaging with the general public and consumer groups in particular relating to the perceived risks and potential benefits of those technologies such that the technology and its adoption does not get ahead of the public's confidence in it.

Q563 ***Lord Mitchell:*** One of the things which became apparent to us both in the UK and in the United States was that leading food companies and also other companies involved in cosmetics and sunscreen and the like seemed to be in some degree of denial or certainly secrecy regarding what they were doing. We found them very unwilling to share their thoughts with us as to what was happening in this

direction. I just wondered whether this climate of secrecy is helpful to what we are trying to explore.
Lord Drayson: I do not believe that it is helpful. We have put in place a voluntary reporting system. If I am right, I believe we have had 12 responses to that. I have to say that the response from industry has been disappointing and unless industry is more open about this issue then we will have to look at more assertive means to encourage industry to be so. The industry in this case needs to learn some of the lessons which were learned relating to GM foods. This Government have absolutely learned those lessons. The way in which this House, for example, has worked very hard to establish an effective regulatory framework around stem cell research has been because there has been a really effective public engagement, openness, debate of the issues. That cannot take place if companies are not providing clarity about the work that is being done and potential applications and we take this very seriously indeed.

Q564 ***Chairman:*** One of the problems perhaps with research councils, I know they do not use it exclusively, is that they are used to the responsive mode of funding but, if a gap is developing, would direct funding be used as the more appropriate model?
Lord Drayson: It may be. Because of the sensitivity around this issue of directed funding from Government, the danger of the scientific community being seen to be told what to research by the Government, we really do need to move carefully in this area with feedback from this Committee as to the right balance, what the Committee would feel, in terms of a light touch but an effective approach in more directed funding. To be effective, funding really does need this direction, it needs to get down to the level of specific areas of research and it would not be effective for the Government to be talking in general terms; we are identifying the specific gaps in understanding. The Committee has already mentioned issues relating to interaction with the gut for example, which therefore raises the question as to how we can most effectively encourage the research community to focus those areas of research where there are identified gaps without it being seen as being directed by ministers.

Q565 ***Lord Methuen:*** How is work on health and safety issues coordinated with similar research being undertaken in the EU and in the wider international community?
Lord Drayson: The responsibility for health and safety issues was brought into the coordination of these areas through, for example, ministerial responsibility at the ministerial group, then, in terms of the nanotech issues discussion group including officials with responsibility for health and safety making their contribution within that, down into the coordination through research councils. So the health and safety issues are brought through these mechanisms into the work and will be incorporated into the review which is taking place, leading to the publication of the strategy document next year.

Q566 ***Lord Methuen:*** What about the international aspects?
Lord Drayson: All aspects of getting a firm grip of the state of play are the responsibility of the stakeholders, for example the Department of Health, Defra and so forth putting their recommendations and their views into the international context. I believe that there is a fair argument to say that the United Kingdom is a leader in both consideration of these issues and putting these issues into a wider context of maintaining and developing public confidence in a new technology. I believe that the UK has learned some important lessons in dealing with some of the challenging ethical issues which have come out of science and I think that we are pretty effective now in doing that within the UK but it is the responsibility of those stakeholder groups, when making that contribution, to do so in the context of views from other countries, particularly the United States and Europe.

Q567 ***Lord Methuen:*** The EFSA, the European Food Standards Agency, is obviously concerned.
Lord Drayson: Yes.

Q568 ***Baroness O'Neill of Bengarve:*** I want to ask a question about capacity. We were told by Dr Andrew Wadge, the Chief Scientist from the FSA, of concerns about the capacity of toxicologists to cope with this research, namely numbers and an ageing cohort. Are you seeking to address this issue?
Lord Drayson: Yes. Capacity of scientists and engineers in research is a broad issue of concern. One of the key themes which I have within my areas of responsibility is developing the concept of skills activism within the research base. By that I mean getting a clear audit of where there are gaps in particular skills and expertise needed for national priorities. You mentioned toxicologists. In a review which we are carrying out at the moment for the life sciences industry we have noted the lack of clinical pharmacologists, for example. We have had a model within higher education of the Government having a very hands-off approach to decisions taken by universities and colleges relating to the provision of courses in particular areas; effectively the market is determined through the interest of students as to whether or not those courses are provided. We are now carrying out this audit and we are looking at this. What is clear from this is that this is leading to a mismatch in terms of both the types of skills and

expertise which are required for industry—in this particular case toxicologists—and the provision of courses. We are looking actively now at how we can most effectively influence students to participate in those courses for which there are skills gaps, where there are clear needs, therefore career paths within industry, which are needed for national priorities and research. I hope that we are able to come forward with some new policies addressing this issue over this year.

Q569 ***Baroness O'Neill of Bengarve:*** When you say "influence", is it envisaged as a way of raising students' consciousness and inviting them to change their choices or is it a move away from a demand-led competition for research studentships and for master's level courses?

Lord Drayson: This is an area where we are at a very early stage in thinking about this. I do believe that this summer in particular, in part because of the global economic downturn, a greater shift is now taking place in the relative attractiveness of different career options than we have seen for some time. We have certainly seen, for example, a huge positive influx of science graduates going into teaching. We have said for a long time that we need science teachers having qualifications in the particular sciences they teach and we are seeing that a number of people are coming back to teaching. We believe that there are opportunities to make a shift here in research towards encouraging people who are qualified in these areas, who have maybe left the research sphere, to come back to it. However, what we need to do is to think about how we are allocating our national resources and directing those resources most effectively to affect the motivations of the people. We need to think about all aspects, whether that is the knowledge and increasing the visibility of these courses or increasing the understanding of the gaps and therefore the career opportunity, but also other factors, for example issues relating to student loans, looking at the whole package of what affects the motivations of people to choose courses.

Q570 ***Lord Crickhowell:*** The Government's 2009 Budget announced that £106 million of savings would be delivered by the research councils within the science and research budget to be re-invested within that budget to support key areas of economic potential. Will this reallocation into resources have any impact on the budget for health and safety research into nanotechnologies? Will any work be cut back or postponed in this area?

Lord Drayson: It is very important for it to be clearly understood that this is not about cuts; this is about an expectation from the Government of all departments, and within those departments, my department and therefore the research councils, to improve efficiency in what they do. Very positively, I believe, the efficiency which can be achieved has been ring-fenced within the research budget and will be spent on research. So these efficiencies which I do believe can be achieved—I have seen for myself the way in which we are moving to shared services across the research councils, co-location of those shared services in Swindon—are leading to cost savings and those cost savings are being re-invested in research rather than administrative support. I believe, again not ministers but research councils should decide where those research monies, the £106 million you mentioned, are invested in research, through the peer review process, through the independence of Haldane. The way in which they are doing that is to identify cross-cutting research themes and that is for them to decide and that is wholly appropriate. I do not see this leading to any cuts in funding for health research in this area as you describe.

Q571 ***Lord Crickhowell:*** I am sure when I was a minister I used to give answers like that and say we are going to get it all out of savings and there will be no cuts. Forgive my slight scepticism based on the experience of successive governments. It is surely going to produce pressures and I come back: are you quite confident that, in this area where we have already identified shortcomings in knowledge which makes risk assessment extremely difficult, we are not going to see such failings as damage the programme that we identify as important?

Lord Drayson: One of the really pleasant aspects of being Science Minister in this Government is that this Government have shown by the decisions they have taken now for 11 years that they believe in the absolute importance and value of scientific research. We have more than doubled the science research budget and we have maintained the science ring-fence. What could be a stronger sign that we are serious than that the Prime Minister, Lord Mandelson and I have all made clear that we are maintaining investment in science despite the downturn, we are maintaining the science ring-fence but I do believe, having been a practitioner in science myself in industry, that scientific research and the management of scientific research can achieve efficiencies in the way in which it is organised and managed like anything else. It is right, for example, for the MRC to think about whether or not all of its staff should be located in central London in a very expensive building or whether it could be more effectively done if a number of those staff were to be moved and relocated in Swindon. The savings which are generated being freed up and re-invested in the research is a very positive aspect of our policy and it is one which I believe the research community supports provided they understand that is exactly what we are doing.

Q572 ***Lord Methuen:*** To what extent are the Government looking into the potential of nanotechnologies to help with wider societal issues such as obesity? Are there any plans to support research into the potential benefits of nanotechnologies in food in this area?
Lord Drayson: The understanding of the use of nanotechnologies, so, for example, nano-encapsulation of foods to modify the way in which they are taken up by the body and therefore it having a role in effect in managing such challenges as obesity, is at a very early stage. This is an area where significant research is being undertaken by the food companies themselves. The important role for research in this area is to address the underpinning understanding of the way in which the body processes nanomaterials and whether or not there are different mechanisms for the processing of those materials when presented to the body in the nanosize. I believe it is too early to say whether or not there is a realistic prospect in the medium term of this technology being applied to address obesity.

Q573 ***Lord Methuen:*** This comes back to targeted delivery by micro-encapsulation.
Lord Drayson: Targeted delivery both of functional foods and medicines is a well-established field but it is understood how, for example, the presentation of particles has an adjuvant effect on the skin. That adjuvant effect is better understood in terms of the interaction with the immune system in the epidermis than it is understood in the gut. Therefore, before getting to the point where we can realistically understand the potential benefits of nanotechnology to be used to address obesity—a very important health challenge—we have to get a better understanding of the underlying mechanisms and the way the body processes nanomaterials through the gut and whether or not that leads to any specific immune response. That should be the right focus now for our research, to get a handle on that in parallel with the work which is taking place within the food companies, the development of these technologies to see their potential in novel foods.

Q574 ***Lord Methuen:*** It worried me that you implied in one of your earlier answers that you were waiting for the universities to come forward to propose research. I think you should be more proactive in encouraging this research.
Lord Drayson: We see a real role for the FSA here. If the FSA have a concern and they do not feel that there is enough understanding of this research to enable them to provide effective regulatory framework, this is something which provides us with the opportunity to put that into the assessments, decisions which are made by the research councils in judging the research projects. Research into this area is taking place at the moment funded by the research councils. If it would be helpful to the Committee, I can ask our research councils to provide a summary of the research projects which are being undertaken at the moment, but I do think the Committee has identified a very important area of the need for further research relating to interaction with the gut.

Q575 ***Chairman:*** If the FSA do have these concerns to which you refer, it is quite probable, given the international nature of the food industry, that these concerns will be shared with other health and safety agencies in Europe—France, Germany and the like. To what extent are Government confident that we are able to coordinate the research programmes not just of the European Food Safety Authority, which after all is not really a regulatory body, but of its other like-minded agencies in Europe, which clearly would be the right way to approach these issues?
Lord Drayson: As I am sure the Committee is aware, a significant proportion of research which is funded by the research communities is of proposals which are international collaborations or research groups across both Europe and with the United States. That is something which we encourage. We have certainly seen the effectiveness of that, for example in stem cell research and development of the memorandum of research understanding with the State of California. However, it is not perfect and I do believe that ensuring there is better coordination internationally of the understanding of research priorities is an area where more work needs to be done. We need to put more effort into this because, as we have already discussed, the science is moving quickly in this area, the possibility of application of the science to products needing to be marketed requires us to move more quickly, hence the need for this strategy which we will be publishing early next year.

Q576 ***Lord Haskel:*** While this work is going on, and in the expectation that there might be some significant benefits to health from nanotechnology, have the Government given any thought to supporting the commercialisation of these technologies?
Lord Drayson: The Government are very active in the general sphere of encouraging a culture within our universities which supports the transfer of technology from the laboratory into commercialisation and we have made huge progress on this over the last 10 or 11 years. For me, working as a science entrepreneur 10 or 15 years ago, the attitude now is extremely supportive. I believe that the role of the Technology Strategy Board has been

very effective; again independent of ministers, private sector input to the decisions relating to which technology platforms are supported. The feedback which I have had recently in doing the review of the commercialisation of science has led to the conclusion that the UK has a stronger set of early-stage science-based enterprises and projects now than it has ever had, that the quality of management that we now see is stronger than it has ever been. We now have a number of serial science entrepreneurs who are re-investing their talent and expertise. The problem which has been identified has been the lack of money; there has been a lack particularly of venture capital which is dogging the ability of these projects to be developed in the current economic environment. We have addressed that. The Government have recently announced a new £1 billion venture capital fund specifically targeting areas of growth such as technology such as this, where the Government are acting as a cornerstone investor, providing £150 million, investing *pari passu* on the same terms as the private sector and we anticipate that fund will be able to start investing in companies working in these high growth areas at the end of this year.

Q577 ***Lord Haskel:*** I am not aware that any of the Technology Strategy Board platforms actually incorporate nanotechnology. Hopefully they may well do in the future. Of course technology transfer plays an important role but are the Government going to do anything about translation research or offer any incentives to food companies to use these products?

Lord Drayson: You are correct that there is not a specific nanotechnology-related technology platform. In part the nature of this technology is so broad in its scope that it is actually quite difficult to identify an all-encompassing technology platform. What is likely to happen is that certain themes within the application of nanotechnology into particular industrial sectors—you mentioned food—will in time identify the underpinning technologies. Remember that the Technology Strategy Board's role is, once it is understood what the underpinning technologies are likely to be, to do a review to assess whether or not it is likely that the United Kingdom is well placed to commercialise and exploit that and then to put targeted investment into those areas. It does not seem at present that we are at the stage to be able to identify those areas. Nanotechnology is moving fast but it is not clear what are likely to be those underlying platforms. This is something which the Technology Strategy Board monitors carefully.

Q578 ***Lord Haskel:*** So it is really too early for Government to define some sort of commercial strategy to commercialise these technologies.

Lord Drayson: That is one of the answers which I expect to come out of this process which will be reporting with the strategy document at the beginning of next year. If that is identified, then that gives the Technology Strategy Board something very clear to latch onto.

Q579 ***Lord Crickhowell:*** May I ask a question which goes rather wider than just nanotechnology? I was very interested when you said we were doing better than we have done in the past about getting the link-up between the university world and industry. I worked extremely hard when I was Secretary of State for Wales, based on what I learned in California and my old college, Trinity Cambridge, which was probably more successful at that stage than anyone, to try to get the same kind of development going in Cardiff and in Wales. You said that there was a lack of venture capital. The one thing that one found in California almost without fail was that the venture capitalists sat themselves down next to the universities because they realised that the opportunities were swinging out of them because of the ability of people in the university world in California to move in and out of the university industry, backwards and forwards, and make a lot of money out of it. I am sorry this does go wider than technology. Why is it that venture capitalists are not actually involving themselves in this world and what are you trying to do to make them realise that. Based on your own experience, you are a man who is perhaps better qualified than almost anyone to tell them.

Lord Drayson: The single biggest problem that we have had in the United Kingdom, that Europe has had, is the difference between the United States venture capital industry and in particular the West Coast, the Sand-Hill-Road-type investors, people like Kleiner Perkins and so forth, is that because of the success of the waves of technology investments which took place which led to the building of Silicon Valley, the West Coast investments funds have been able to achieve scale typically of $1 billion or more per fund. It has not been possible hitherto for the United Kingdom or European funds to match that size. What that has meant has been that where an investor is making an investment of $1 billion, where a rule of thumb is that you would invest no more than let us say 10 per cent of that fund in an individual company, a $1 billion fund enables you to make follow-on investments as the company develops of sufficient size to create a real world leader. On the other hand, in Europe, where we have had funds of the order of £50 to £100 million or so maximum size, 10 per cent of those funds is a much smaller amount of money, which has meant that in the United Kingdom and in Europe venture capitalists have only been able to go so far with their investment in a

company and they have then come up against that barrier and the company has had to be sold or has had to find alternative forms of finance. Our analysis, as the Government has determined, is not only to address short-term problems relating to venture capital at the moment in the UK, where venture capital funds are limiting their investments to companies in which they are already an investor, but to address this for the long term too and that we need to create a fund of equal size. This is why this is a real first for the UK, this innovation investment fund which we launched last Monday of £150 million cornerstone investment by the Government which will then be followed on with investment from the European Investment Bank and then pension funds to create a £1 billion venture capital fund, a ten-year fund which will have sufficient size to address this long-term equity gap issue. The feedback which I have had both from investors in the United States as well as investors here in Europe is that the Government has, in addressing this fundamental issue, removed the major barrier. This is an important step forward which consolidates the progress which we have already made in this country relating to the science, the commercialisation of science and the management expertise. If I might just finish this very long answer to your question, one of the things that venture capitalists in the United States in Silicon Valley have been telling me is that they have been coming to the United Kingdom to identify managers and scientists to take back to California because they recognise the science and the expertise is here. I hope that this new fund addresses that brain drain and we can attract people from the United States and people to stay here and be funded.

Lord Crickhowell: It was a very interesting answer.

Chairman: We are verging on another very interesting report we should do. Indeed the main Select Committee is looking at its priorities; perhaps it should take due note of that. Can we get back to nanomaterials now?

Q580 ***Baroness O'Neill of Bengarve:*** You have already referred a couple of times to Defra's voluntary reporting scheme and this question may be for both you and Mr Dalton. Why do you think that the voluntary reporting scheme for nanomaterials has not been taken up at a very high level? Why is the take-up low?

Lord Drayson: I will ask Mr Dalton to comment on this from the Defra point of view because this is a joint project.

Mr Dalton: It is worth just putting the voluntary reporting scheme into the context in which it was launched. The first principle at the launch was not to get complete coverage of all industry which was dealing with nanomaterials but instead it was to get some information back around what difficulties companies were experiencing, what research priorities might need to be addressed, things like that. The intention was never to get 100 per cent coverage. With that in mind, we actually asked for information that was quite technical; there was quite a lot of work involved, if you wanted to report to the scheme. That hampered take-up quite a lot but the intention was not to get 100 per cent take-up.

Q581 ***Baroness O'Neill of Bengarve:*** Would Defra see the scheme developing? Would it want to encourage participation? Might it even make the scheme into a mandatory one?

Mr Dalton: This has already been touched on by the Minister. We are now reviewing the options around how we take the reporting scheme forward. There are some decisions to be made around the level of information you might want to ask for again in any revised reporting scheme. If you were to simplify it then you would get a much larger uptake and working in partnership with industry you might get nearer to 100 per cent coverage simply through a voluntary scheme, if you revised the kind of data you wanted to ask for. The option of course does lie to make a mandatory reporting scheme something we could take forward. As we develop the options, then ministers will take the final decision on that.

Q582 ***Baroness O'Neill of Bengarve:*** What do you want the scheme to achieve?

Lord Drayson: A perfect scheme would be one which had full support and engagement of industry on a voluntary basis and provided us with sufficient information on what the individual companies were doing to enable us to feel we had a firm handle on the development and potential application of these technologies in future products. The response to date has been disappointing, that we have only received 13 responses from a request to something like 40 companies. The request to the companies, as Mr Dalton says, was detailed and I can understand why companies may have felt there was a considerable burden on them. However, I would argue very strongly to the industry association that it is very important and in the interests of the company concerned for public confidence to be maintained. These are issues of some complexity and therefore require quite considerable information from the companies concerned and we do need to see a better response in future. Officials are reviewing the information which has come back to us. We will take into account the feedback from the industry association and listen to the industry association and the companies as to whether or not moving to a simpler request for data makes sense. I have to say really quite clearly that I do expect industry to respond effectively. It is not good enough to see this level of response.

Q583 ***Baroness O'Neill of Bengarve:*** Do you envisage the scheme developing in a way that might be relevant to creating a register of nano-derived foods and nanofood contact materials?
Lord Drayson: Possibly. We need to maintain an open mind as to whether or not we move to some form of mandatory reporting. Given that this is an area which is moving quickly, in those circumstances it is best if you have a voluntary relationship of real effectiveness between Government and industry where you have good communication from industry as to the area of development and research that they are undertaking rather than moving to a mandatory scheme or some form of regulation. I want to stress that we do need to see a better response in future.

Q584 ***Baroness O'Neill of Bengarve:*** I note that it would be ideal to have a voluntary and effective scheme, but in a context where evidence we have been given is that industry is often quite coy about work that it is undertaking in this area because they have not taken on board lessons which Government have taken on board about being open about these things, do you think that the likelihood is that a voluntary scheme can be made to achieve what you wish to achieve?
Lord Drayson: No. I have to be direct with the Committee; I do not think that it is likely based on the evidence to date. I am open-minded. I hope I can be surprised, but I am determined, as Science and Innovation Minister, to ensure that the different industries that we have and we rely upon to be successful in the country learn from each other. There are huge lessons to learn from the way in which these different issues raised by science have been taken on board by industry and there are some common themes which we have learned. The most important one is that the more open an industry and science is with the general public, the greater the confidence of the general public because the general public is able to assess for itself the relative risks and benefits and Parliament is able to put in place light-touch effective regulation which maintains the public's confidence. We are determined to ensure those lessons are learned.

Q585 ***Lord Crickhowell:*** Staying in the same broad area, the Government's response to the RCEP's report on *Novel Materials* states that the Government will review their existing structures and mechanisms for sharing information and for stakeholder engagement with a view to finding light-touch ways of encouraging researchers and companies to provide early evidence of developments without compromising their commercial advantage. What are the existing structures in place to do this? Do the Government have early ideas on how they might be improved?
Lord Drayson: The discussion that we have just had really focuses on this. It is around getting a clear sense from our review which is taking place this year as to whether or not we are going to be able to generate sufficient confidence from our existing regime, say for example the voluntary reporting regime. If we are not going to have sufficient confidence, then to put in place such mechanisms as will provide us with the confidence to move to the next stage in terms of clear regulatory framework and public engagement and confidence in this issue. We are very clearly focused this year on gathering the information from the various stakeholders to come to a conclusion which would then be part of the recommendations coming out of the strategy document early next year.

Q586 ***Lord Crickhowell:*** Is there a central database for health and safety data on nanotechnologies in the UK, where companies and academic institutions can deposit their work and share information on health and safety issues?
Lord Drayson: I am not aware of a central database. I will write to the Committee, but I am not aware of such a database being in place.

Q587 ***Lord Cunningham of Felling:*** In this ministerial commitment to openness and dialogue, the Government committed themselves in January of this year to developing a programme of dialogue around nanotechnology developments. Can you bring us up to date with how that programme is coming along?
Lord Drayson: Yes, that dialogue is part of the wider initiative that we have, *Science and Society,* and a number of programmes which we have put in place to improve both the understanding and engagement of science with the general public and to ensure that there is a clear understanding within the science community effectively of the duty of the science community as we see it, particularly where funded by the taxpayer, to engage with the general public. For example, a practical example of how we are doing this, ministers have written to HEFCE asking HEFCE, in the development of the new research assessment framework, to take into account the effectiveness of individual scientific researchers and university departments in the public engagement that they carry out as part of the overall assessment of the excellence of their research. What we want to see is the development of a new generation of scientists in this country who welcome engagement, communication of the work that they do as scientists, issues such as this. This is a theme which we have been very actively developing this year. In the general sense the *Science: [So what? So everything]* campaign, which was launched by the Prime Minister and myself earlier this year, was specifically aimed at not targeting the scientific community but targeting the

general public. We are clear that the scientists have huge support from the general public, but science has been seen too much as something which is done apart from the general public, done by a scientific elite. We need to develop further scientific literacy within this country and, whether it is nanotechnology or stem cell research or GM foods, these are underpinning strengths which we need to develop. I believe the activities which we are undertaking in *Science and Society* are delivering that. We are seeing real progress in this.

Q588 ***Lord Cunningham of Felling:*** Is it intended that there will be upstream widespread dialogue with the public about nanotechnologies and food? Has that already begun or is it planned?
Lord Drayson: It is expected. It is what I expect from the input, the work that has been taking place, the consultation that is going on. We have taken on board, for example, the comments which were made at the end of last year in the *Which* report relating to nanomaterials. We have learned how effective public engagement on issues in other areas of science has enabled positive assessment in the minds of the general public in terms of the risks and benefits and disengagement, particularly with the community of scientific journalists in this country, is also important to ensure that the lessons that were learned the hard way from GM foods are applied here in the case of nanotechnology.

Q589 ***Lord Cunningham of Felling:*** Is it right to conclude that in your role as chairman of the ministerial group you are also responsible for taking this project forward?
Lord Drayson: Yes; I am responsible for the whole area of science communication with a seat in the Cabinet and as chairman also of the Cabinet Committee for Science and Innovation which was established in October last year to ensure that there is a cross-departmental coordination of science, science underpinning good government policy. That committee has been effective in ensuring that we develop clear use of policy based around well-founded science, for example the way in which independent scientific expertise is used by departments, used by ministers to inform public debate and develop it into good policy.

Q590 ***Lord Cunningham of Felling:*** When the Government responded to the Royal Commission on Environmental Pollution report on novel materials, they said they were commissioning a pilot initiative, I am quoting here, "to provide public access to a balanced source of information on nanotechnologies". Can you tell us about that? Is there a website? How is it being taken forward?
Lord Drayson: Yes, we are developing a website exactly for the purposes of developing the engagement of the general public. I do believe that development of websites, although helpful, is not sufficient. We need to stimulate open discussion and debate about issues relating to developments in science, for example nanotechnology, and the way in which the development of that debate that has happened relating to stem cell research, for example, which took place whilst the regulatory framework was being debated within Parliament, showed the importance of that debate having taken place ahead of the development of the framework. We can expect that there will be a developing regulatory framework for nanotechnology as the research comes into place, as we can see from this review which is taking place this year, which is going to lead to the provision of the strategy document next year. We are putting in place therefore consideration of mechanisms for stimulating that public dialogue in parallel with that. What the Committee can expect, what comes out of that strategy document, is not just recommendations relating to regulation, relating to research, but also a plan for public engagement in those issues in parallel with it.

Q591 ***Lord Cunningham of Felling:*** Is it the case that all government departments, across Government are totally committed to this strategy?
Lord Drayson: The departments which are most relevant to this strategy, my Department, Business, Innovation and Skills, Defra, Department of Health and the DWP with its responsibility for health and safety, absolutely are. I have seen good engagement from ministers in this. In terms of the wider engagement in science, both from my own position as Minister for Science and Innovation but also the way in which science has been increasingly discussed over recent months in the context of a vision for this country's future, it gives me confidence that there is an understanding and buy-in to this across Government. That is the sense I have.

Q592 ***Lord Cunningham of Felling:*** We have heard from several witnesses, indeed you have referred to it yourself on a couple of occasions this morning, about the paucity of information, the lack of information and announcements coming to the public about nanotechnologies in the food sector. You also made some comments about what you said was the unsatisfactory response to the voluntary reporting project. What more can the Government do? What thought have you given to this, other than making it compulsory to encourage the better flow of information to the public from the private sector?
Lord Drayson: One important role that the Government can fulfil is to explain how lessons which have been learned in one industrial sector give a sense

for other industrial sectors and the development of a body of corporate knowledge around the most effective way to handle emerging scientific issues and the ethical considerations which come out of them. There is a real role for the Government in doing that. The way in which that can be most effectively done is firstly to make sure within the Government that there is good coordination between ministers and between civil servants of good practice. We have established the Science and Innovation Cabinet Committee to do that. In the case of nanotechnology we have the research coordination groups; we have the nanotech issues discussion groups. I do feel we have the mechanisms to do that. Then it is about us having an open but pretty robust dialogue frankly with the various industry groups and encouraging them to be as open as possible within the constraints of commercial confidentiality. I believe that we are making some progress on that. I do not think we have made enough progress in the area of nanotechnology and we will be pressing industry to respond more and to go further.

Q593 ***Chairman:*** We would all recognise that in previous exercises in public engagement on emerging technologies the absolutely essential requirement is, and there will be uncertainties, uncertainties both as to the benefits and the risks, that there has to be openness, there has to be transparency, there has to be accountability. One thing which is clearly not happening at the moment, for reasons which are perhaps understandable, is that those food companies who are most likely to run with this particular emerging technology are not at all keen to put their head above the parapet. This, on the face of it, appears to be a recipe for disaster in terms of public engagement and confidence.

Lord Drayson: Absolutely right. I have mentioned GM foods at length; animal rights extremism is another example of where initially CEOs of pharmaceutical and biotechnology companies did not wish to put their heads above the parapet and discuss the issue. That was a mistake and it took a recognition that it was only by chief executives of those companies being prepared to explain and discuss openly why it was regrettably necessary to undertake animal research to ensure that medicines were safe and it was also a legal requirement to do so, that we started to have the environment which enabled politics to work effectively. These are important lessons which have been hard won in science in this country. I am determined, as Science Minister, to ensure that those lessons are applied to emerging issues such as this one.

Chairman: Thank you very much. Minister, we have come to the end of our questions. You have been very generous with your time with us and the session has been most helpful. May I thank you and your colleague Mr Dalton for helping the Committee. You will of course see the transcript and have an opportunity for corrections and if there are any other points or supplementary data, for example you said to Lord Crickhowell that you might just check on the central database for health and safety data, if any such information could be made available to the Committee, we should be most grateful. Thank you again very much for your help today. We are most grateful.

Supplementary letter from the Minister for Science and Innovation, Department for Business Innovation & Skills

In follow up to the evidence that I gave to the House of Lords Science and Technology Sub-Committee on 7 July 2009 you asked me to investigate the existence of a central database for health and safety information. Having consulted with colleagues from the Health and Safety Executive I can now confirm that whilst there is no central UK database as described, the OECD's Working Party on Manufactured Nanomaterials has developed a database of global research conducted into the safety of manufactured nanomaterials. The recently-launched database provides a comprehensive inventory of information on international research projects and aims to support the evidence base, highlight knowledge gaps and facilitate a joined-up approach to further research. Additionally, the monitoring and safety of nanotechnology products is something that we are considering as part of our evidence gathering to inform the UK Strategy for Nanotechnologies.

I hope that this information is useful in your inquiries.

31 August 2009

TUESDAY 7 JULY 2009

Present	Crickhowell, L	Mitchell, L
	Cunningham of Felling, L	O'Neill of Bengarve, B
	Haskel, L	Selborne, E (Chairman)
	Methuen, L	

Examination of Witness

Witness: Dr Nicholas Deliyanakis, DG Research, European Commission, examined.

Q594 ***Chairman:*** Good afternoon, welcome and thank you very much for giving evidence to this House of Lords Select Committee on Science and Technology. As you know, we are conducting an inquiry, and have been for some weeks now, on nanotechnologies and food. We do have members of the public here also who are sitting in on our evidence session but you will probably not be able to see them. May I start by asking whether you could tell us what role DG Research plays in funding health and safety research in the field of nanotechnologies in comparison with national research councils and government agencies? How much of the research budget for nanotechnologies is devoted to health and safety research?

Dr Deliyanakis: The European Commission as well as the national funding bodies, for example in the UK the Health and Safety Executive, do fund research into the safety of nanomaterials in general. The Commission, through its framework programmes for research, has so far dedicated around €40 million to this research in the last two years alone with a further €10 million this year. Before that, in previous framework programmes, we invested something like €28 million in this research. Other international bodies also carry out a great deal of research into the safety of nanomaterials. Compared with the overall budget for nanotechnology research, in the case of the framework programmes, of the order of five per cent is spent on safety research, but I hasten to add that a comparison would not be appropriate. It would not be appropriate, because of course safety considerations are of current concern, whereas the rest of the research into nanotechnology focuses inevitably on the future, on things like applications in health, energy and the environment. So we are looking at different timescales. Moreover, the generic research into nanotechnology does include safety and that component is not included in the figures.

Q595 ***Chairman:*** Could you just perhaps tell us a bit about your own role within DG Research?

Dr Deliyanakis: I am a member of the unit for nanotechnology in DG Research and my role is as the Secretary of the Commission's inter-service group for nanotechnology. In the Commission we have a so-called action plan for nanotechnology, which covers all the issues from research to safety to ethics and of course it is implemented with the help of Member States, other bodies and the many different DGs in the Commission. My role is to help coordinate this, as well as to follow some of the research projects.

Q596 ***Lord Mitchell:*** Good afternoon, as it will be in Brussels. We want to talk about coordination in research. How is research within the EU on nanotechnologies coordinated between the Member States? Secondly, what coordination takes place between the EU and other countries outside the EU with international organisations such as OECD?

Dr Deliyanakis: It is coordinated in many different ways. Let me first say something about coordination of research in general. The research that the Commission funds is coordinated formally through the so-called programme committees, where Member States are represented. Moreover, within the Commission it is coordinated through the so-called inter-service consultation. Both interested DGs and interested Member States can bring their opinions and they are part of the decision-making process. Turning to the research on the safety of nanotechnology, that is coordinated in additional ways, additional to these two mechanisms I mentioned. One of them is, as you say, the OECD, which has a working party on manufactured nanomaterials and, very briefly, this defines goals in several areas of safety from toxicity to exposure and so on. The delegations to the OECD then sponsor this work, in other words they undertake part of the work. The Commission participates very actively in that working party, so in practice we have in the shape of that working party a good coordination mechanism for the research into safety. Moreover it is one of the mechanisms which allow us to take the results of research projects and bring them to bear on regulation[1]. There is international cooperation. The Commission does engage very actively in that also. I have already mentioned the work within OECD and that of course is international, as it includes not only European Member States; we also collaborate on research projects, for example with the US, and we have had so-called coordinated calls, whereby a

[1] "That is, the technical implementation of regulation, through the development and validation of test methods for instance."

number of projects are selected with joint funding from the two sides, the European and US sides for example. This is an additional international cooperation mechanism in the field of research on safety. Finally, we also cooperate in terms of regulation through a regulatory dialogue. For example, we have funded a project which concluded this year and which looked at the differences between the approaches to the regulation of nanomaterials in the US and the EU.

Q597 ***Lord Methuen:*** How are funding priorities for nanotechnologies research determined within the EU? What input do European Community organisations such as DG Sanco and EFSA and national bodies such as the UK research councils, have into this process?
Dr Deliyanakis: I have already mentioned two formal mechanisms, one within the Commission and one involving the Member States through programme committees. Now there are also many informal but very important mechanisms for such input. In the case of nanotechnology research, as well as research into the safety of nanotechnology, we work very closely with the so-called European technology platforms. They bring together representatives from industry and academia and they come up in each case, in each area of research, with a so-called strategic research agenda. Many of these platforms address safety, so we take their input when we develop the topics for the research on safety. Within the Commission we have the inter-service group for nanotechnology, of which I am the Secretary, and what we do within that group is to assess the needs with regard to regulation, that is the technical needs with regard to the implementation of regulation, and then address them with appropriate research topics that come up in the successive work programmes of the framework programme. Once that is done, we get proposals and in the fullness of time fund them and get the results from the projects. There is an internal mechanism for taking the interests of regulators like DG SANCO and EFSA into account and there is also a number of external mechanisms, both formal and informal, which again cooperate very actively in the case of the research into the safety of nanotechnology.

Q598 ***Lord Methuen:*** How does the Director General Research ensure that the regulatory needs of the Commission and the national bodies are taken into account in this process?
Dr Deliyanakis: Our colleagues in the "regulatory" DGs, that is DG Sanco[2] and DG Enterprise and Industry interact with national regulators. I am not an expert in the regulatory side so I cannot go into the details, but what I can say is that through the mechanisms I described it is fair to say that the needs of all regulators are taken into account. That does not mean that we have covered all the uncertainties by funding research projects; there are still gaps and the current research projects have not answered all the questions. However, we do have the mechanisms in place, and of course in principle the funding as well, to pursue whichever questions remain open on the technical front. That is my personal role in the whole edifice of European nanotechnology.

Q599 ***Lord Crickhowell:*** A major regulatory measure is REACH for the control of chemicals. We have received a lot of evidence that there is an urgent need to revise REACH in order to cover the nanotechnology possibilities and problems effectively. Are you involved in linking up with REACH to ensure that job is done effectively?
Dr Deliyanakis: Yes, we are very closely involved both with the national regulators and with ECHA, which is the agency which implements REACH, and this is done primarily with the help of our colleagues who work on regulation. The current position of the Commission, as you probably know, is that in principle regulations like REACH, but not only REACH, are sufficient in principle to cover risks of nanomaterials. Incidentally, let me say that REACH does not cover chemicals as such, it covers substances, therefore it is partly for this reason that we say that REACH covers it. A normal, very frequent objection is: yes, you cover chemicals in the bulk form but you have nothing to say about chemicals in the nano form and that is not entirely correct because of course there is scope, even under the present provisions, to deal with nanomaterials separately from their corresponding bulk forms. That said, we do not rule out changes or adaptations in the existing regulations. Here I speak very much as a non-expert, but I mention it only for completeness and I think you will hear more about that from my colleagues in the Commission. Suffice to say that we do have plans both to monitor the implementation of REACH as regards the regulation at the level of nanomaterials, and to present the results in 2011 and if necessary to revise it[3] as well. Partly the reason why we are funding the research into the safety of nanomaterials is to be in a position technically to supplement the regulations we have or support regulatory changes. Here I must say once again that I speak very much as a non-expert in my capacity as the Secretary of the Commission's inter-service group. It is my job to have an overview and I am trying to present this overview now. I hope you will hear more about that from my colleagues who are experts on the regulatory side.

[2] "The Directorate General for Health and Consumers."

[3] "That is, not only REACH, but the regulatory framework in general."

Q600 ***Lord Haskel:*** You have told us all about the work which has been done about health and safety and about the technology platforms and indeed you mentioned some gaps. When we talk to the industry and when we talk to researchers here, we are repeatedly told that there are major gaps in the scientific knowledge required for the risk assessment of nanotechnologies in the food sector to satisfy the requirement that food is safe. What are you doing to ensure that it is these knowledge gaps, these gaps in knowledge which are being filled before EFSA is required to risk assess new products?
Dr Deliyanakis: What we are trying to do is to focus our research on the gaps. As I explained, we talk to all the stakeholders within the Commission and outside to identify the gaps and then what we do is to focus our research topics on the safety of nanotechnology on these gaps. I have to admit that so far the Commission has not funded any projects which look specifically at the safety of nanotechnology in food[4]. Of course it goes without saying that this is one of the areas that we will look at. However a lot of the research that we have already funded is relevant because of course we looked at the toxicity of certain common nanomaterials and to some extent the route of introduction is immaterial. I am not saying that we do not need research specifically on the safety of nanofoods. What I am saying is that some of the research results we already have are relevant. The general answer is that we look very carefully at where the gaps are, and for that we have a number of scientific committees outside the Commission; and then we focus our research funding specifically to address the gaps. The other thing I can say is that we are encouraging our different projects, the different research teams in the projects that we fund, to cooperate not only within their own projects but within what we call a cluster, in other words to compare results and to see where the gaps are, to see how efforts can be consolidated. For this effort we have funded a so-called coordination action called NanoImpactNet with more than 20 partners, including several in the United Kingdom, which tries to bring together all the work, both the EC-funded work and the national work on the safety of nanotechnology.

Q601 ***Lord Haskel:*** All I can say is that from the people that we have seen and the food companies that we have seen they do not seem to be aware of the efforts you are making and it is obviously very important that they are aware, otherwise they are not going to make much progress.
Dr Deliyanakis: This is a very good point. It is also an aspect of the approach to nanotechnology that the Commission is trying to address, albeit partially, and it is a general question of outreach and engagement with society. I do take the point that not all of our activities, be that in research or efforts to ensure the safety of nanotechnology, are presented in the best possible way; that is certainly one of the challenges. Suffice it to say, as I explained earlier, that we are very much aware of what has to be done in the area of research into safety and we are doing all we can, using the framework programme as a tool, to address the gaps, and engage both with the technical stakeholders and with what we might call the societal stakeholders. Of course it is very much work in progress. I think it would be fair to say that we have achieved a lot in the different aspects of the nanotechnology policy but in each one of these areas, safety, outreach, regulation, more remains to be done. Speaking personally as a Commission official engaged primarily in research, all I can say is that we are doing our best with the funding available to us to address this need. There are of course questions that only the legislators can address, with regard to what should ultimately be allowed and what the overall policy should be, but what we are trying to do as Commission staff is to ensure that we have an integrated policy and that we implement it as effectively as possible.

Q602 ***Lord Cunningham of Felling:*** Does the Directorate-General have a wide-ranging dialogue with the private sector and the academic world on these issues?
Dr Deliyanakis: I did not quite understand the question. Is there dialogue with the private sector?

Q603 ***Lord Cunningham of Felling:*** Correct.
Dr Deliyanakis: Yes, there is a lot of dialogue with the private sector now. I have already mentioned the European technology platforms. This is one of the many mechanisms we have to engage in dialogue, in this case with industry. In this dialogue and in the context of nanotechnology, what we are trying to do is to develop nanotechnology both effectively and safely. In other words we want to take a pragmatic approach, we want to develop nanotechnology, come up with new ideas and make sure that these ideas are implemented in the shape of projects. On the other hand we want to do so safely, hence the funding into safety research. We do not want to do only one thing or only the other. As far as I am concerned, our interlocutors in industry are very much behind the research programme and, incidentally, in our safety projects we often have research partners from industry. Now, looking at private partners more generally, again there are many other dialogues, other mechanisms that we use. For example, in the context of ethics and safety we talk to NGOs and in the context of international cooperation we talk both to governmental and private partners. This is all I can say about that.

[4] "Although such research may well have been a part of some funded projects in the theme of FP7 dealing with food and biotechnology."

Q604 ***Lord Cunningham of Felling:*** Can the Committee conclude that you have a similar dialogue with universities and research institutes on nanotechnology?
Dr Deliyanakis: Absolutely; that is absolutely correct. We have a strong dialogue with academia as well as industry. I mentioned a number of advisory mechanisms: one of them is an expert advisory group which advises the Commission on nanotechnology issues. There, both industry and academia are represented. Then of course we have a very effective and formal mechanism in the shape of the projects that we fund and that we follow. That is, incidentally, the added value of having the Commission spending considerable human resources in following projects directly, instead of just defining some research policy and then allowing projects to be funded without any follow-up. People like me talk directly to the researchers, both academic and industrial, who are engaged in a project; and in addition to the formal mechanisms, we very much try to follow their concerns and their ideas in formulating both our generic policy and our specific priorities for research. The other thing of course is that we are trying to bring academia closer to industry in REACH and in many other ways.

Q605 ***Lord Cunningham of Felling:*** That leads me to my final question, which you have just touched on briefly. When these dialogues with industry, the private sector and the academic world show gaps in funding in the nanotechnology area, maybe for detection or nanotoxicology or nanometrology, what role does the Directorate have in ensuring that those funding gaps are addressed?
Dr Deliyanakis: That is done primarily in the case of nanotechnology safety through the inter-service group for nanotechnology which I mentioned. Every research topic is discussed for roughly a year up to the time of publication. So every year there are many opportunities both formal and informal for the regulators, for example, to bring their needs together for the choice of topics. In research on safety as well as research in general, it is inevitable that one has to make hard choices because of course in general the framework programme funding accounts for something like five per cent of the national public funding, so we have to prioritise in safety as well as in research in nanotechnology and research in general. That said, we do have an impressive and growing portfolio of projects on safety research, even before we begin to look at the research on safety which is done within larger and more generic nanotechnology projects. Of course it is very important to bear in mind that the national funding bodies have to play a large role, not only in research funding in general, but research in the safety of nanomaterials. I mentioned the coordination mechanism. I would also mention in passing that there is a project on food safety which is funded in the UK, I believe by the Health and Safety Executive and possibly another body but certainly funded at the UK national level. Of course we try to coordinate all this work, as we are doing in other areas of research.

Q606 ***Chairman:*** Thank you. That brings us to the end of questions that we would like to put to you. Is there anything else that you would like to add? Anything that you would like to put on the record but we have not given you an opportunity to do so?
Dr Deliyanakis: Thank you for this opportunity. I do not have any factual information to add. What I would say is that the nanotechnology policy is very diverse. It includes innovation, research, training, infrastructure, regulation and safety. What we try to do is approach it in what I call an integrated responsible and safe way. In my evidence I have not been able of course to give you a precise picture of our whole approach, but I think I have been able to make it clear that we are all working together between the Commission and the Member States, to ensure that on the one hand nanotechnology applications are realised, and on the other hand that it is done safely. Thank you.
Chairman: Thank you Dr Deliyanakis. You have given us a lot of assistance this morning. We are most grateful to you for having joined us in this videolink. Thank you.

TUESDAY 14 JULY 2009

Present	Crickhowell, L	Methuen, L
	Cunningham of Felling, L	Neuberger, B
	Haskel, L	O'Neill of Bengarve, L
	Krebs, L (Chairman)	O'Neill of Clackmannan, L
	May of Oxford, L	

Examination of Witnesses

Witnesses: Gillian Merron, a Member of the House of Commons, Minister of State for Public Health, Dr Clair Baynton, Head of Novel Foods, Additives and Supplements, and Dr Sandy Lawrie, Head of Novel and GM Food Safety, Food Standards Agency, examined.

Q607 ***Chairman:*** Minister, thank you very much for coming to see us this morning and also thank you very much for indicating that you might be willing to stay on a little bit longer than the planned time of finish at 11.40 up to about noon if we need to continue with a few questions. I would like to welcome you and Dr Baynton and Dr Lawrie from the Food Standards Agency. As you will be aware, the proceedings are being webcast and for the members of the audience sitting behind you I would like to refer to the information note which sets out the declared interests of the members of the Select Committee so we will not be repeating those during the questioning. Before we come to the questions, I would like to invite the Minister, and the others indeed, to say a few words of introduction that you might wish to say and to introduce yourselves for the record. I would like to hand over to the Minister.
Gillian Merron: Thank very much, Chairman, and perhaps if you will allow me as well as introducing my colleagues to make a very brief statement which sets out how I see this very important issue. Can I start by saying thank you for inviting me. I am very happy to help the Committee and if there are any matters that we perhaps do not deal with as well as you might like then I am very happy to ensure that we provide further information. I understand that I am your final witness so I will do my best to wind up proceedings well for you. Of course, as the Committee is aware, I am the Health Minister responsible for the Food Standards Agency which is why I am before you. As many of the members of the Committee are also aware, I am not a scientist so I am delighted to be joined by Dr Baynton and Dr Lawrie who are scientists, which will assist me greatly. I am also very aware that around the table we have many experts in all fields, including of course the Food Standards Agency. Perhaps if I can just make a few points which for myself as a relatively new minister I have realised on this issue. We have a very fascinating new area of technology before us and it also strikes me that it is very much work in progress. I think it is probably difficult for the average consumer, in which I put myself as well, to grasp the range of possibilities, not least of all because there are very few practical examples on the market. From my point of view we are keeping very much an open mind about the future benefits of the use of nanotechnologies and nanoparticles in relation to food. I also feel that we are very much at a development stage. It is difficult to assess how much of this will come to fruition. When I ask myself what do we need to do, it strikes me that we need to ensure that benefits are not lost if there is not an appropriate and proportionate regulatory system. That is what we need and it will allow those products to come on to the market in a way that gives the consumer full confidence that the new products are safe as well as of benefit to them. So obviously a robust approach to safety assessment is crucial. There are gaps in the underlying science that need to be filled if the risk assessors are to do a proper job and ask the right questions and draw very valid conclusions from the data. I feel there is a lot of work still to do. In conclusion, I am very keen that we explore the possibilities in respect of food but there are two things that are uppermost in my mind. One is safety and second of course is the interests of the consumer, and I hope that will help the Committee to understand where I hope we will go in respect of nanotechnology and food.

Q608 ***Chairman:*** Thank you very much indeed. I do not know whether Dr Baynton or Dr Lawrie would like to add anything or simply to introduce themselves for the record.
Dr Baynton: I am Clair Baynton from the Food Standards Agency. I head the Novel Foods, Additives and Supplements Division. My division has a co-ordinating role for nanotechnology across the Food Standards Agency.
Dr Lawrie: I am Sandy Lawrie and I also work in the Food Standards Agency and I head the part that deals specifically with novel foods, which of course includes this general area of nanotechnology.

Q609 ***Chairman:*** Thank you very much. Perhaps I could kick off. One of the things that we have spent quite a lot of time discussing and hearing evidence about is a very basic question and that is what is the definition of a nanomaterial as applied to food. We are aware that the European Commission has been revising the Novel Foods Regulation and has come up with a definition of nanomaterials which therefore under their definition those materials should undergo pre-market safety assessment. However, the Food Standards Agency told us that it has reservations about the proposed definition. We would be interested to hear what are the concerns and what should be included in the definition of nanotechnology. Obviously this is fundamental to any discussion about safety assessment, about regulation, or consumer information.
Gillian Merron: It is crucial indeed and the main problem is workability. First of all, what we look for in a definition obviously is clarity and enforceability. I think it is on those two that it falls down. My view is that the definition is better on cosmetics than it is on food and an interesting one to look at. If we are asking food operators to comply then we have to give them something to comply with that they understand and where they do not find themselves accidentally falling foul of compliance. So scientifically the view of the European Parliament was useful but not so in workability. Perhaps to quote very specifically, the definition includes criteria such as the "of the order of 100 nanometres". Well, for operators and for enforcement I think that will create some blurring. Similarly with materials with larger dimensions, of the order of 100 nanometres, are to be included "if they retain properties characteristic of the nanoscale". The truth is that in the debate we do not know enough to say what is characteristic. So that is why the UK did abstain and we feel that to move forward what we need is much greater consultation and deliberation by stakeholders because it has not only got to be relevant but it has also got to be testable, it has got to be enforceable. Those are the reasons for our concerns.

Q610 ***Chairman:*** Would in fact the UK position go as far as the position we heard from the Food and Drug Administration in the States that they would rather not have a precise definition at all because I think, in their view, any definition that you try to come up with would leave loopholes or possibly provide ambiguities?
Gillian Merron: I am a bit of an optimist so I would hope that that we could find the right definition. For me the important thing is that we must test it with stakeholders. I think that perhaps not enough of that was considered. If we did not have a definition my question would be how do we enforce that? How do we work with that? Perhaps I could ask Dr Lawrie to comment.
Dr Lawrie: I think in this debate it is important to recognise that we do not rely on this new definition in order to say that new nanomaterials fall within the scope of the novel foods regulation and therefore need to go through the whole requirements of pre-market application, evaluation and then formal authorisation. You will see from our previous regulatory review we felt that there was very good coverage of nanomaterials that might be introduced for food use through existing regulation, none of which mentioned nanotechnology or nanomaterials already, so the inclusion of a new definition in the novel foods regulation provides welcome clarity in saying yes, clearly these materials fall within the scope, but I would argue that even if you do not have a definition in that legislation you are still covering virtually all the cases you can imagine.

Q611 ***Chairman:*** So how do you decide then whether to include it for pre-market approval or not?
Dr Lawrie: The scope of the regulation on novel foods talks about whether it is a new material. Taking as a crazy example adding carbon nanotubes as an ingredient, plainly that is a new ingredient that has not been used in food before and it is a novel ingredient falling within the scope. At the other end you have a familiar material which is engineered in a way to make it nanoscale and that is covered under our existing regulation as an example of a novel process applied to an existing ingredient but which changes its properties. So we have a definition based (a) on novelty and (b) on changes in properties, particularly biological properties, which seems to cover all the areas of concern. A regulatory definition would be useful to provide clarity for people who say yes, but there might be a loophole, but it is not the only reason why nanomaterials added to food would have to undergo a pre-market assessment.
Chairman: Thank you. May I turn to Baroness Neuberger.

Q612 ***Baroness Neuberger:*** It is really a follow-on in a way. The BSI told us that it had been very difficult to engage with the FSA on issues of standardisation for nanotechnologies—part of what we have been talking about—and then I quote: "There appears to be no appetite amongst government departments to maintain the UK's proactive leadership in this area". I think what we would like to know is what the FSA is actually doing about that, how it is working with other organisations and whether it wants and, if so, how to ensure that international definitions and standards are appropriate to its role as regulator?
Gillian Merron: It may be helpful if I were to clarify this. It is a difficulty because the BSI Committee does not focus on food, it is not specific, and so the role of

the FSA is more of a watching brief. I hope that gives a bit of context. Also in terms of the Government and the BSI our main interface is through Defra and there is a representative from Defra who routinely does attend the BSI Committee and the chair of the BSI Committee contributes to the work of one of a number of cross-government groups that we have in nanotechnology, the Research Co-ordination Group, in respect of measurement and also standardisation of nanomaterials. What I would say is that the work of the various standardisation bodies nationally, at EU and at international level, is useful in providing a baseline. As is rightly said, that follows on from the previous discussion that we have just had. I do not know that I would share the view there is no appetite amongst government departments.

Q613 ***Baroness Neuberger:*** I am not wholly surprised to hear you say that.
Gillian Merron: No, I would not share that view. I find it difficult to take that because that Committee does not specifically deal with food. Perhaps if the Committee were to bear that in mind that would be of use to us. I am sure we will go on to this but there are a number of cross-government committees and actually of course one of them that I will certainly be involved with is the Ministerial Group. We have a whole range of cross-government groups so it is not just the FSA.

Q614 ***Lord Methuen:*** Do you think the EFSA will be able to keep pace with the demands for safety testing of all new nanotechnologies that enter the market in food, food supplements, food additives, packaging and perhaps agricultural products?
Gillian Merron: The first point is that it is very difficult to predict what the flow will be and what the number of new nanomaterials in industry will be coming forward. What I can say is the more general issue of the EFSA matching its resources to the demands upon it is not specific to nanotechnology. What they do do, and I would expect them to do, is extend their resources by extending capacity by using external contracts, for example for technical support with Member States, and I would expect them to do the same.

Q615 ***Lord Methuen:*** Is the FSA concerned with that? Do they provide additional support?
Gillian Merron: Would you like to comment, Dr Baynton.
Dr Baynton: Yes, the FSA has a number of scientific experts that are members of the various scientific panels in EFSA. One of the officials of the Food Standards Agency was involved in the discussions on the EFSA opinion that was published earlier this year, so we do play a very key role within the EFSA scientific panels.

Q616 ***Lord Methuen:*** Does the FSA have enough resources or would it need additional resources if a lot of these things come forward?
Dr Baynton: I think that is something that—
Gillian Merron: That will be a question for the Minister, will it not!
Dr Baynton: Sorry.
Gillian Merron: I was not taking it away from you. I think the main thing is it is difficult to predict what demands it will put on the EFSA and of course we are not the only Member State.

Q617 ***Chairman:*** Just as a follow-up to that, one of the things that we have heard from a number of sources is that the products on the market at the moment using nanotechnology are largely food supplements. There are quite a significant number of food supplements that are on the market that use nanotechnology to encapsulate for example vitamins or minerals. I know there are now new regulations that cover food supplements but I wonder if you could explain to us whether the nano-engineered food supplements have been through some approval process before they are put on the market.
Gillian Merron: That question is for you.
Dr Baynton: We are aware obviously of the nano Q10 that I think we have referred to before and a colloidal silver product. I know that EFSA has been looking at colloidal silver and has recently given an opinion on that, but I am not aware that EFSA has given an opinion on the nano Q10 product, so I am not aware that that specific product has undergone a safety assessment in relation to use of nanomaterials.

Q618 ***Lord May of Oxford:*** I particularly worry about this area because I start with the possibly incorrect prejudice that much of the food supplement market is a hark back to the quackery of the 19th century, not to say the 13th century, so I do not have much confidence in the kind of science they are likely to apply in thinking about it. Do you think that is unfair?
Gillian Merron: I think it is radical. I think it is plainly spoken!
Dr Lawrie: If I could just comment particularly on the nano Q10 product. This is a new formulation of an existing product. Co-enzyme Q10 has been around for a while and is used indeed in supplements. It is a type of material which is not well-absorbed in the body so it is a class of compound which the pharmaceutical industry is very familiar with in dealing with these problems. So there is constant striving to get more reliable absorption of these types of compound and some vitamins are like that as well. This nano formulation, using the technical term, is a kind of micelle formulation. Micelles themselves are not new and they have been used in formulating both food ingredients and pharmaceuticals for many

decades, and I think the co-enzyme Q10 product has been researched in quite some detail by the company. In fact, I know that the German authorities have looked at it and consider that because it is simply an extension of old technology it does not actually hit the criteria for the novel foods requirements but they have also concluded that Q10 has not behaved differently, so I think we can be relatively confident in that particular case that the product has been looked at in some detail.

Q619 ***Chairman:*** But if we go from the specific to the general for us my question was under the regulation of food supplements is there any specific reference to nanotechnology?
Dr Baynton: No, there is not.

Q620 ***Chairman:*** What we have been told by some witnesses is that food supplements, whether or not they do any good, may be harmless in a normal form but because in a nano- encapsulated form the exposure may be increased because of the vastly increased surface area they could indeed become toxic. That is a possible risk and I guess you would acknowledge that too. Should not the regulations then specifically ask the question: are these food supplements manufactured with nanoparticles or nanotechnologies which could alter their potential risk to human health?
Dr Lawrie: I think that is an example of a more general question about the reformulation of any kind of biologically active material. In the case of vitamins and minerals, we now have a positive list which will come into force in a few months' time across Europe in terms of what substances can be added. Unlike pharmaceuticals though we do not regulate individual formulations of those substances and the argument that you quite rightly make that by making a nano formulation you could alter the bioavailability or the fate of the substance within the gut or whatever is certainly true, and you can make exactly the same argument for any other reformulation also. The question then would be whether nano is so different in terms of the differences it might be introduce that we need to have special control for nano formulations but we can leave the industry to self-regulate for other kinds of reformulation. We would be interested to hear whether the Committee has a view on this.

Q621 ***Chairman:*** Just to try and bottom this out, the current position of the regulations and the list that you mentioned of minerals and vitamins is that there would be no specific reference to whether or not they are nano-engineered?
Gillian Merron: Correct, yes.

Q622 ***Chairman:*** So whose judgment is it to decide whether or not they need to be looked at in a particular way because you have acknowledged that the nano engineering of them could alter their properties? Are they covered by novel foods?
Dr Lawrie: I was going to answer in those terms. In fact we looked at the formulation of co-enzyme Q10 as a food supplement potentially under the novel foods regulation before concluding that in fact in that particular case it did not hit the definition of a change which changed the biological properties of the material, but certainly other formulations could be looked at and if it is a new process or if it is a new type of formulation it could fall within the scope of novel foods.

Q623 ***Baroness Neuberger:*** I am finding this a little bit confusing so let me give you a non-scientist's version of what I am hearing and you will be able to correct me if I have got it wrong. On the one hand, the fact that there are nano-sized manufactured ingredients in food does not, because the definition does not require it, trigger any special attention. On the other hand, the fact that there are such elements in food as an ingredient may produce novel reactivity. So how can it be grandfathered in on the basis of the other larger particles being known to be safe if there is a different reactivity?
Dr Lawrie: The whole point of the novel foods regulation is to catch new ways that foods have been processed that change their properties, and if there was a formulation of a supplement which did change its properties in a remarkable way, as you have suggested, it seems to me that would clearly fall within the scope of the novel foods regulation and therefore require the product to the assessed and authorised before it could be used.

Q624 ***Baroness Neuberger:*** So you would get evidence of a form in this product, we are not using any novel ingredient but we are using it at a novel size, and it does or does not have different reactivity?
Dr Lawrie: That is right because the regulation covers novel processes as well as novel ingredients.

Q625 ***Chairman:*** And the same argument would apply to food supplements as well as to other foods, would it?
Dr Lawrie: Yes.
Dr Baynton: Yes.

Q626 ***Chairman:*** There is of course a flaw in that argument because we have heard on numerous occasions that the science that is required to assess the risks associated with re-engineering things at the nanoscale is incomplete, so it is all very well to say we

simply look and see if the properties have changed and the potential toxicity has changed as a result of nano engineering but if the science is not there to answer that question how does the regulator implement the regulations?
Dr Lawrie: A very good point. This leads on to the question about the gaps in our understanding and how we could be filling those.

Q627 ***Baroness O'Neill of Bengarve:*** We received evidence from BIS (only they were DIUS then) in Annex 4 of their submission, that the Science and Innovation Network in Germany refers to the potential risks associated with the use of synthetically amorphous silica as a food additive in nano form if new gel-based production processes are used, and notes that they may require new safety assessment. Preliminary results from a German group at the University of Düsseldorf have shown that there is the potential for amorphous silica to be toxic to gut epithelial cells once it is nanosized (the tests were actually done on 14 nanometre sized particles). Is this a matter of concern for the FSA? Is it considering new safety assessments?
Gillian Merron: I think it would be fair to say that it is certainly of interest and the document that was provided by DIUS, as it was, does correctly say that the new manufacturing process would require a new safety assessment, and I would certainly agree with that. It is a bit early to say is the honest answer to the question because it is not clear whether the product that we are talking about is commercially available and whether it is the type of silica that will be used in the food industry. I do know that EFSA is doing a review of all existing food additives so questions in this area will obviously be addressed when the silica is re-evaluated. Just one final point. It is possible to speed up the review of silica if necessary if new information says that there is a potential risk from an existing product, but, in truth, it is just a bit early to give much more of a comment than that.

Q628 ***Chairman:*** We were informed in the United States that amorphous silica is widely used as an anti-caking agent in food manufacture. I wondered if that is the case in Europe as well.
Dr Lawrie: Certainly silica as a food additive is widely used in general. There is a type of silica called fumed silica which typically contains these very small particles which I think is different to the process that the Germans are talking about, but again it is another type of silica manufacture that does result undoubtedly in nanoparticles. The extent of the use of fumed silica is something which the industry has not yet been able to confirm with us. There are people saying it is used and others saying that we do not use it, it is an historical quirk. Certainly the substance has existed for many decades. As I say, that is different to the process that the Germans are talking about.

Q629 ***Chairman:*** Do we know that it has properties that are different from the properties of this one that could have adverse affects on the gut?
Dr Lawrie: I do not know the answer to that.

Q630 ***Chairman:*** You do not know?
Gillian Merron: We would be very happy to write to the Committee on that point.
Chairman: Could we follow that up? Thank you.

Q631 ***Baroness O'Neill of Bengarve:*** Another example given in evidence by Dr Jonathan Powell at the MRC Centre for Human Nutrition Research stated that titanium dioxide particles with an average diameter of 200 nanometres were added to food as a whitening agent. That of course is outside the 100 nanometre limit but it is within the range at which titanium dioxide particles show novel properties associated with the nanoscale. How is the FSA to ensure that examples like this where there is confusion over whether a product might contain nanomaterials that the regulations can apply?
Dr Lawrie: It always strikes me as rather odd that people talk about nanoscale titanium dioxide being used as a food colour because the whole point of nanoscale titanium dioxide, as used in sunscreens, is that it is transparent. Titanium dioxide is used as a food colour to give an intense whiteness to foods. For example some candies, if you suck the colour off a Smartie you are left with a white colour underneath which is essentially titanium dioxide. The idea of using nanoscale titanium dioxide for its colouring purposes seems to me to be perverse. Having said that, any material which is used in particulate form will contain a range of particle sizes, so you may find a substance with an average particle size of 2,000 nanometres, say, but if you look at the spread of particle size there could be some particles which are very small and some that are much larger as well. So that could be a source I guess of a small proportion of the titanium oxide being in nanoform, but certainly the addition of nano titanium dioxide as a food colour itself would seem to be counterproductive.

Q632 ***Baroness O'Neill of Bengarve:*** So does that lead you to think that any definition should be very cautious in looking at everything below a size considerably greater than 100 nanometres or does it lead you to think that a definition in terms of particle size may be a dead end?
Dr Lawrie: It is one of the complications. Everybody talks very clearly about this 100 nanometre boundary and plainly it is not as simple as that. If you are going to have a regulatory definition which is based on that

size you would have to say what proportion of particles would have to fall above or below that threshold in order for clarity to be there. We were talking about the definition in the legislation earlier, if I could just add that it is recognised that this is, as we have said on a number of occasions, an emerging area and the definition perhaps will need to be updated as we find out more about what should or should not be included. Within the proposal which is going forward for novel foods that will be possible using a very easy committee-based procedure to change that particular aspect of the definition so that it is recognised as a moving target at the moment.

Q633 ***Chairman:*** Could I just be clear on this. So the view of the FSA would be that although each of us in this room on average is eating, according to Dr Powell, five milligrammes per day of these engineered titanium dioxide particles, you could say with confidence that that poses no safety risk, and part of your argument is that many of the particles (not all) are larger than 100 nanometres?
Dr Lawrie: I do not know that we can be sure what the source of this titanium dioxide is. As I understand it, this is not based on the analysis of food, it is based on what ends up in the gut, so the titanium dioxide could be coming from other environmental sources other than food. In terms of the risk assessment, I know that titanium dioxide in the form it is used as a food colour has been assessed for safety, albeit some years ago, but as we mentioned earlier these safety assessments are currently being updated and colours are at the top of the list, and titanium dioxide would be covered there. Titanium dioxide in the form that is used as a colourant is regarded as safe based on a whole range of data at the time and that may include any small proportion of the material which is in nanoscale.

Q634 ***Baroness Neuberger:*** I want to go back to the reply that you gave, Dr Lawrie, on this question about silica and that fact that you cannot get a straight reply, it seemed to me from what you were saying, from the food industry as to whether or not this particular form of silica, not the amorphous silica but the fumed silica, is actually being used and, if so, to what extent and at what scale. I think it would be quite interesting to press you a little further on that and find out what you really think is happening because one of the things that we found both in the States and in a visit that we made in this country is that there is some reluctance on the part of the food industry to be really clear about what is happening and what the size is of what they are using. We certainly heard an example in the States of a cosmetic company that started talking about using nano-sized material and then changed its advertising.
Gillian Merron: Just to make a general point, I know we are likely to discuss this point but for me the issue of transparency is crucial and I think without it consumers will rightly wonder what is being hidden and therefore it will come back to bite the industry. A lot of the FSA's work is to try and press that point home. Perhaps on the science I could refer to Dr Lawrie.
Dr Lawrie: I think you are right. If it would help the Committee we can redouble our efforts in trying to find out from the industry more about the nature of the silica that is used.
Baroness Neuberger: That would be very helpful.

Q635 ***Lord May of Oxford:*** As a preamble to my question I would just like to say that when I was Chief Scientist I found myself many, many times saying that government handles very well, with very competent people, things which are well within the domain of known science. Regulating that you have conscientious people and generally people of science are all you need. The problems of public perception and sometimes the problems of actual, real worries—which are two different things but they are both real—come when you are at or beyond the frontiers of things that you confidently know and where you really need to be getting the very best people. You need to be freely admitting what you do not understand. I already find a little disconcerting the preliminary discussion we had about exactly getting a definition. I think you have to have a definition and that definition has to include an acknowledgement of the difficulty in having a definition and recognition that it is not precise. That brings me to my question, which is Lord Drayson told us that it is the responsibility of the FSA to commission relevant research for its regulatory role with respect to nanotechnologies. Other people have told us that there is quite a lot of uncertainty that cannot be qualified just in size because what you are really interested in is the way surface-to-volume ratio can change the properties, and that cannot necessarily be given one clear size, and it can change properties so that things get out of the gut into other places where they are not meant to be. Finally to come to my question, what steps is the FSA taking to fill the knowledge gaps or to clearly define the areas of uncertainty that are required for them to make a meaningful risk assessment of nanotechnologies in the food sector?
Gillian Merron: There are two specific areas of work being commissioned by the FSA. Then I will go back to the more general point about the role of the FSA. The first one is on the fate of nanomaterials in the gut, which obviously relates back to our earlier discussion. That will be a two-year plan for a piece of research. The proposals have been received and they are currently being assessed and the intention is that will

start at the beginning of next year. The second area is that the FSA is looking into contributing to a new EU project which will be three years beginning next year, January 2010, which will examine the methods of measuring nanomaterials in food, again the kind of thing we have just been speaking about. It does strike me that this is an area where we do need that research to support the risk assessment and to work around the points that were correctly made by Lord May about people's sensitivities in the absence of information. In general terms perhaps I can say to the Committee that the FSA is of course part of the Nanotechnology Research Co-ordination Group co-ordinated by Defra and that group has defined a number of research requirements and they are very much based on the gaps relevant to risk assessment. I know that the Committee has heard from other witnesses that the main mechanism for commissioning relevant research has been via the research councils and I also know that the Committee is aware that there are some projects which have been commissioned already in respect of nanoparticles in the gut either by the UK research councils or at EU level. Lord Drayson is right to point out government departments such as the FSA which do have a role in funding that relevant research.

Q636 ***Lord May of Oxford:*** To what extent do you very deliberately go out not just to solicit expert opinion but to take account of dissident opinion and mavericks and so on to make sure that you engage in the full spectrum of possible concerns? What is your mechanism for doing that?
Gillian Merron: Could I just clarify, is that more in respect of people's general concerns or scientific?

Q637 ***Lord May of Oxford:*** It is spelt out fairly clearly in the Protocols for Science Advice and Policy-Making actually. My personal experience has been that too often it is a cosy group of people.
Dr Baynton: The Agency at the moment is considering its science and evidence strategy from 2010 to 2015 which will underpin our new Strategic Plan which will cover that five-year period. We have been working in consultation with stakeholders looking at the type of research that we should fund over the next five years. Our Strategic Plan at the moment refers to new and emerging technologies and obviously that would include nanotechnology. Clearly this is a particular area of research where we would want to consider funding more work. Obviously we have to consider that against competing priorities for FSA resources and other research areas within the Agency. We are certainly at the moment working with stakeholders and working within the Agency and with our General Advisory Committee on Science and considering where our future research funding should be focused.

Q638 ***Lord May of Oxford:*** And how is this folded in with the European Commission and the regulatory agencies in the other European countries?
Dr Baynton: I do not have a very detailed knowledge of how the funding works, certainly with the European Commission, but we are looking to fund a specific piece of work, as the Minister described, looking at detection methods in relation to nanomaterials. Obviously, we are aware of different research requirements for different areas that the European Commission is focusing on and would look to contribute to funding some of those initiatives. There is this one project that we are hoping to fund which will be on the detection of nanomaterials.
Gillian Merron: If it would be helpful we can provide further details to the Committee.
Chairman: That would be helpful, thank you very much.

Q639 ***Lord Crickhowell:*** I am finding these answers interesting because up until now we have been left with something of a black hole. When we saw the research councils they were extremely vague about what was happening and of course we have the general difficulty that scientists like pure research and may not like to be directed into particular areas of research and so on, a subject which I think the wider Science and Technology Committee may be looking at quite soon. For the first time I have really been hearing about specific research projects being selected and financed by an organisation. What is the scale? I have no idea of the scale of the FSA research budget. How big a part do you play in actually getting specific research where it is needed? Can you really fund the research yourselves, for example in this great hole about the gut?
Dr Baynton: The Agency has a budget of about £22 million per year that we spend on research. I did not quite understand your question about the project on the gut.

Q640 ***Lord Crickhowell:*** We have been identified again and again, and indeed I think the Minister referred to it right at the start, that there is a great hole at the moment because there has not been any real research into the gut issue. I am really probing as to whether this is something where you can perhaps get specific research projects underway out of your own research budget and through your own push?
Gillian Merron: That was the first research project that I referred to where we have already indicated an intention by the FSA to commission, all being well, starting at the beginning of next year and that is very much about nanomaterials in the gut.

Q641 ***Chairman:*** One question that is related to that is that we have been concerned about is the capacity to carry out that research in the UK. We have become

aware of one research group in Cambridge that does work on nanoparticles in the gut. How many applications did you receive when you sent out your call for this work?
Dr Lawrie: I am not sure that we are at liberty for confidentiality reasons to say but we have had more than one. We had a number of applications to look at from different groups and what we have to do obviously is assess the quality of those applications. We have stressed that this is the kind of work which not just one man and his dog could carry out, it needed input from various different specialisms, and we were looking particularly for collaborative approaches which would allow the measurement and toxicology and so on all to be dealt with as part of a larger consortium. We are in the process of evaluating research proposals at the moment and we should be able to make a decision in the next couple of months on which one of those might be successful.
Gillian Merron: Again anything we can legitimately and helpfully provide to the Committee we will do. So we can perhaps take that away and see what we can offer.

Q642 ***Lord May of Oxford:*** What is the secret element of the number of proposals? I thought you said you are not at liberty to say the number of proposals.
Dr Lawrie: I am not sure.

Q643 ***Lord May of Oxford:*** Why not? I find that bizarre.
Gillian Merron: Please do not find that bizarre. I was just enquiring of officials about what we could say. That is why I suggested perhaps you will let me take that away. Whatever I can freely give to you of course I will.
Chairman: Normally the research councils for instance would not be secretive about how many proposals there have been.

Q644 ***Lord May of Oxford:*** And it is frankly in contradiction with the guidelines in the Protocols on Science Advice and Policy-Making.
Gillian Merron: We can come back to you on that point.
Dr Lawrie: I did not want to speak out of turn.

Q645 ***Lord May of Oxford:*** It resonates with all my worries.
Gillian Merron: Dr Lawrie was approaching it through the best of intentions but whatever we can helpfully provide you will have.
Dr Baynton: I am not sure about the timetable for commissioning that piece of work but certainly once it has been commissioned we can update the Committee on the successful applicant and the project in more detail. We normally place that sort of information on our website once the project has been commissioned.

Q646 ***Lord O'Neill of Clackmannan:*** How do you advertise for this research? Does it go in the *European Bulletin* or is it something where self-starters come along and say, "We want some money?" How is it done?
Dr Baynton: The Agency publishes what are called research requirement documents that outline the research that we are considering funding, but we also invite expressions of interest. If people feel that they have a particular interest and they feel it is something that the Agency might be interested in then certainly we very much welcome that as well as part of our horizon scanning for future research.

Q647 ***Lord Crickhowell:*** Minister, have any further developments been made on proposals for an EC register for nanotechnologies and would this register cover all instances of nanotechnologies or just those related to food?
Gillian Merron: I can only respond in terms of food but we are not aware that there are plans from the Commission to do this. Our view is that it would be useful to have an inventory. We need to clarify what is or is not on the market and so if it is not going to happen at an EU level then we do want to do it at a UK level. The FSA is going to be working on this in the next few months and talking with stakeholders about it, but I think it is important that we do have this before others who have more vested interests do so, so I am keen that we get on with this area of work.

Q648 ***Lord Crickhowell:*** The first question I want to ask is what is the role of such a register? Is it a source of public information about marketed products or is it principally an aid to regulation giving the FSA advance information about what is coming on to the market? It seems rather important that we know exactly what the register should be for.
Dr Baynton: I think it is something that we would like to discuss with stakeholders about how useful that particular register would be. I think really we will decide after we have had those types of discussions with stakeholders whether it is meaningful to have a list of products for consumers and whether consumers would find that helpful. I think it is important we talk to stakeholders about this before we make any final decisions.

Q649 ***Lord Crickhowell:*** The stakeholders may have very different views and consumers may take a very different view from the industry, which takes me neatly to my second question. Lord Drayson last week with reference to a voluntary reporting scheme run by Defra said that unless industry participation improved there was a case for making the reporting scheme mandatory and that he did not believe that voluntary schemes would necessarily be effective.

What is your view about that issue as it refers to the register that we are talking about here?

Gillian Merron: My preference is to start with voluntary. I very much recognise the problem with the Defra scheme. Some of the feedback I have had on that was that it was onerous in terms of what was required, so I do think that if we are to have a voluntary scheme we do have to make it possible to participate. Again relating back to an earlier conversation, industry was, I understand, rather reluctant to take part, they did not want to share information, so I think also we must not rely solely on industry to provide that information. Going back to our earlier discussion, we have to work with industry to make them realise that it is in their interests. Thirdly, it must not be too onerous. I would hope that we could learn from the fact that the Defra scheme did not work and perhaps find a better way to do it. I think our general preference is always to start with voluntary before deciding to go into mandatory.

Q650 ***Lord Crickhowell:*** So the third question is how do you get them to share health and safety testing data, in order obviously to avoid duplication of effort and to help develop standard testing methods? We detected a considerable reluctance by companies to share their data, for obvious commercial reasons, but if you are going to have a register are they not going to have to share some data with you?

Dr Lawrie: These are exactly the sort of questions which mean we should not rush into designing something off the top of our heads. We need to talk to people and say would it be possible and what would the difficulties be with this approach or that approach and also to be clear at the outset about what the purpose of the register is. The purpose of the Defra scheme was to try and assemble detailed information on a number of nanomaterials, recognising perhaps that they would not get them all because not everybody would participate, but to give a body of knowledge about the safety testing that had been carried out on these nanomaterials. The purpose of the register for food might be quite different. I sense that it is the lack of public information that is one of the major drivers for it. Perhaps once we have got a clearer idea of the range of so-called nanomaterials, bearing in mind that we then have to go down the road of what we define as a nanomaterial—are we concerned about water and oil emulsion as much as we are about silver nanoparticles for example—and once we have a clear idea of the size and scope of it and purpose then we can design the mechanism for it.

Q651 ***Lord O'Neill of Clackmannan:*** You have already spoken about involvement in EFSA but if you are going to secure the harmonisation of regulation, who would you consider to be the most appropriate international bodies or large national bodies for this and who would you envisage working with to secure harmonisation of regulation?

Gillian Merron: I think Lord O'Neill's question raises an interesting question which I thought of when I was preparing for the Committee which is the question of EU versus broader, and where the most effective route is. I am sure that the Committee will wish to take a view on that and I will be very interested in their view. To relate to the specific question, in terms of international harmonisation it would be through Codex Alimentarius a body which, as the Committee will know, is between the Food and Agriculture Organization and the World Health Organization. They have recently convened an expert consultation on the issue of the impact of nanotechnologies on food and we are awaiting the report which should be published shortly. There is also work being carried out through the Organisation for Economic Co-operation and Development. It is not directly related to food but it will help the safety experts to develop risk assessments that perhaps we can apply to a range of products. It is probably worth saying also that there have not been moves really at an international level to harmonise regulations for nanotechnologies and nanomaterials although there is work underway to try and secure a common understanding before making judgments about harmonisation. I think again that is a bit like the discussion about an inventory. We have to think very carefully about what we want to achieve and through what means because if there is to be harmonisation I want it to have some value.

Q652 ***Lord Crickhowell:*** I am just interested in the answer and so far virtually nothing has been said about the European Community. I would be interested to know how the regulatory efforts of the FSA fit into the European Community regulatory system and of course REACH has an impact on this. I am not quite clear how that relates to novel foods and so on but surely if we are actually getting co-ordinated effort, the European Community must play a fairly big part?

Gillian Merron: I think that was my point right at the very beginning. We spoke earlier in the Committee about the role of the European Union and I know Dr Lawrie can add something to these comments. There is a question about harmonisation of regulation and at which level it should be and what is its effectiveness. The reality is we probably can achieve things quicker through the EU than we can wider and what matters is, as I say, what effect we want to achieve. I know Dr Lawrie would like to add to that.

Dr Lawrie: It is perhaps because in the food area we automatically assume when we are talking about regulation that we are talking about European regulation. 98 plus per cent of food law applying in this country is European legislation so it is essentially a European activity. When we think of international we

think of going to the next stage beyond what we have through Brussels. The Commission itself has drawn up its own plans for taking nanotechnology forward in food and in other areas. I think as part of our initial written evidence from the Agency to the Committee we provided you with a copy of the top ten actions which the Commission was keen to take forward, so there is activity there, both within novel foods, as we have mentioned, with the regulation of food additives and food contact materials and so on. Everything in Europe is moving to take better care of nanotechnology and nanomaterials already. I do not know if that helps to answer the question.

Q653 ***Chairman:*** The last part of Lord Crickhowell's question concerned REACH. We are interested to know how important the REACH regulations are in relation to food safety.
Dr Lawrie: Typically they do not apply at all. We can give you chapter and verse on that but the materials used for food production are excluded from the scope of REACH and so for example if you have a food additive, and that is the only reason a substance is produced it may not crop up under REACH at all, as I understand it. We can check back on that.

Q654 ***Chairman:*** Can you please provide us with a follow-up note?
Dr Lawrie: I will do that. Obviously many substances will be multi-purpose and will be included under REACH as well as under food legislation.

Q655 ***Lord Cunningham of Felling:*** Can we now turn to how information about engineered nanoparticles in food might be conveyed to the public, with labelling as an example. We understand that the Novel Foods Regulation is proposed to be changed in respect of a requirement to label food that contains engineered nanoparticles. Is that correct?
Gillian Merron: The suggestion was not taken up as a common position in respect of blanket labelling if that is the reference.

Q656 ***Lord Cunningham of Felling:*** We understand that there are proposed changes to the Regulation to include the addition of a requirement to label foods that contain engineered nanomaterials. Is that correct?
Gillian Merron: Do you want to comment first of all on the European thing and we can go on to the detail.
Dr Lawrie: Under the novel foods regulation there is a requirement to consider the labelling of each product that comes through case-by-case and since that is what the regulation allows, and in fact requires, we think there should not be a blanket requirement for a particular category of ingredient to be labelled in a particular way under that regulation. That takes away any flexibility there might be for perhaps tailoring the way a particular ingredient is labelled. It provides only one aspect of control when there might be other nanomaterials which for one reason or another are regulated elsewhere and do not fall under the novel food regulation and these provisions here would not apply to them. If there is a requirement for labelling nanomaterials in food, it should be across the whole board not just for those which happen to come through the novel foods regulation.

Q657 ***Lord Cunningham of Felling:*** It should be across the board?
Dr Lawrie: If there were to be one, it would be better.

Q658 ***Lord Cunningham of Felling:*** Is there to be one or not? I am afraid you have lost me with all of that.
Gillian Merron: The simple answer is that there was a proposal from the Parliament for blanket labelling and, as I say, this was not accepted as the common position for reasons that I am sure you will now want to ask us about.

Q659 ***Lord Cunningham of Felling:*** Why is this not desirable?
Gillian Merron: The issue is blanket labelling. The regulation already requires that labelling is on a case-by-case basis. Perhaps I can use the opportunity to make a general point about consumers. I think that we have to be sensitive to consumers. We need to keep away from the worries of something is not natural; something is being done to us; we do not understand it. For me if blanket labelling of what something contains does not tell me something that is going to assist me to make a sensible decision then it may simply mislead me. That is why I think blanket labelling is not helpful and that is why I think it should be case-by-case. What I would say to the Committee is the FSA has a programme of citizens forums where it is consulting directly consumers and it is going to include nanotechnologies, in other words asking people what is it that they would like to know, what would be helpful, what would give them that insight to make a proper choice. Rather than go for blanket labelling we should be saying what do we need so that people know what is in their food so that they can make a right decision, and blanket labelling for me misses that point.

Q660 ***Lord Cunningham of Felling:*** I think what you are saying to us, Minister, is that some engineered nanoparticles in food may require information on the label and some may not.
Gillian Merron: It may or may not, absolutely.

Q661 ***Lord Cunningham of Felling:*** How will the public have any confidence in a system which tells them that some foods have engineered nanoparticles in them whereas in other cases the public are not told?
Gillian Merron: First of all, I am not approaching it from a position of not telling people. I think my position is that we do not know what is going to be helpful. All I am interested in is establishing what is going to be helpful. If it is helpful that for whatever reason everybody is told everything then there will be a way of doing that, but I do not think we are at that stage at the moment.

Q662 ***Lord Cunningham of Felling:*** It is a fairly simple question though is it not: does this material contain engineered nanomaterial or not?
Gillian Merron: Let me put it this way: you could indeed put that on every label but will it serve the purpose?

Q663 ***Lord Cunningham of Felling:*** When this consultation, which I think we are all reassured to hear is already in process, concludes, and if the overwhelming conclusion and the dialogue with the public is that the public believe that in every case the presence of engineered nanoparticulate material in foodstuffs should be conveyed to them through labelling, will that be the outcome? Will the Government accept that?
Gillian Merron: The words that I am about to use are we need to get it to be balanced, we need it to be proportionate and we need it to be informative. I think we have got to make a decision on any special labelling. I know that the FSA has already provided in written evidence to this Committee the report that was issued in March of this year which was an evidence review about public attitudes to emerging food technologies, but what I would like to convey to this Committee is my understanding—and I know only too well as a Member of Parliament—of the sensitivities that are around emerging food technologies, but I do think that we have to find a way of making that known in a way that is understood and sensible and, as I said in my opening statement, so that people get the benefits. I think there is a lot of interest in getting the benefit of nanotechnology and food without frightening people. I am sure you are with me.

Q664 ***Lord Cunningham of Felling:*** Having spent 40 years of my political life supporting the civil nuclear industry I am certainly not in favour of frightening people, and having dealt with BSE and variant CJD and for that matter GM foods, I am certainly not in favour of frightening people.
Gillian Merron: You have got the scars!

Q665 ***Lord Cunningham of Felling:*** So I absolutely accept that no-one sensible in this Committee or anywhere else wants to scare people. I know there are some people outside of this Committee who adopt those tactics but that is not what we are here for. A few questions earlier, Minister, you said to the Committee that you thought transparency was absolutely essential in all of this. If that is the underlying principle in approaching engineered nano particulate matter in food then the case for ensuring that in every case the public are told seems pretty conclusive.
Gillian Merron: I am just thinking back to what the fundamental principle about food labelling is. It is that consumers have sufficient information to make informed choices about what they eat. Information must by law be clear and not misleading and there is a limit to how much information can go on a food label. I think we have got quite a solid basis. Perhaps I should say what I am not doing. I am not seeking to withhold information; I am seeking to ensure that we have the right amount of information in the right form that consumers want and will be able to use. I am not trying to circumvent the provision of information. Perhaps I can give that assurance. I just find myself in a position where it is a bit early to give greater detail on that without seeing evidence.
Chairman: It also refers back to the very start of our discussion about what the definition of nanotechnologies is. If you are going to have blanket labelling, do you include things that are traditionally used ingredients that have been re-engineered on a nanoscale? Dr Lawrie told us those would not necessarily come under the novel foods regulation. They may or may not depending on whether the properties change, so it does open up a very broad question about the definition. Rather than dwelling on that perhaps I could move on to Baroness Neuberger.

Q666 ***Baroness Neuberger:*** You have already referred, Minister, to the report showing that the FSA has been looking at some of the public views about all of that. Could you tell us whether the FSA has mechanisms through which the public's ethical and social views on new technologies in the food technology sector can actually be taken into account in policy-making? That is very much following up what Lord Cunningham said that if the public has a strong view about this how do we translate that into policy?
Gillian Merron: Bearing in mind the scars on the back of Lord Cunningham and many others, as has already been referred to, I am very keen that we do take account of any ethical and social factors, indeed any factors, whether that is misinformation or fear. It

would be stupid not to, I think, is the simple way to put it. Just to reiterate to the Committee, we are running citizens forums through the Agency with ten to 12 participants reflecting the make-up of the local area, which are scheduled to meet up to three times a year, to give the kind of evidence through that nationwide programme that we will need. I am going to be very interested in what they are saying because, as I say, I am keen that we do not lose the benefits but that we get the benefits in a way that people will value. There are a lot of people who would welcome the reduction of fat, sugar and salt without loss of taste, to put it simply, and they want to be reassured that it is safe. That, as well as protecting consumer interests, is uppermost in my mind. Yes, there is a measure and it is through the citizens forums, and as a Minister I will be particularly interested in what those citizens forums come up with.

Q667 ***Baroness Neuberger:*** That will be in some way translated into policy? You may not take everything they say but there will a policy element in that?
Gillian Merron: Yes, and we are working with the British Market Research Bureau to put this work together.
Chairman: We have talked quite a lot about transparency, I do not know whether Lord Cunningham would like to pick that up again briefly.

Q668 ***Lord Cunningham of Felling:*** Yes, if I may, Chairman. What is the Government going to do or what does the Government have in mind to secure transparency among companies in the food sector with regard to their activities and work with engineered nanomaterials?
Gillian Merron: Following on from our earlier discussions, I do think that if we establish an inventory, that will help us. We have had the discussion about the difficulties of the previous Defra-led inventory, so I am well aware of that. I think it is a mechanism that does allow companies to give factual information. The truth is that consumers' fear is often about lack of information. I know that very well. I think one way of encouraging transparency—and it may be the Committee's deliberations might invite me to consider others—would be through that inventory. We also note that this is a very sensitive area for food companies. They are reluctant, and the Committee will have seen that for itself, and they are worried about all sorts of things, including damaging their commercial position, but the reality is with their consumers that openness will reap them some rewards. I feel that we have to continue through the Agency to not just stress the value but actually explain and cajole and persuade them of what the value of openness is. In fact in emerging food technologies, in my view, there is no other way because if they withhold they will be in battle with the consumers and I do not think companies would welcome that, so more work is necessary, but I do completely accept that this is a tough one.

Q669 ***Lord Cunningham of Felling:*** Is it safe for us to conclude then that the Government will exert pressure on food companies to be transparent and open in their activities?
Gillian Merron: Lord Cunningham, we will act always in the most appropriate way to get the result that we wish to have. Voluntary is always better. I always like it when people see the light more. It is my preference. I am new to the area so I will be seeing how far we are getting in getting them to see the light. As I say, perhaps this Committee's investigation may be able to produce some ideas also for me. I think the thing that the Committee needs to hear from me is my wish to see greater transparency from the companies.

Q670 ***Lord May of Oxford:*** I think it is fair to say that some of our conversations with the industry have been along the lines of, "Well, they have not noticed yet and let's hope they do not notice as long as we keep quiet about it." It poses a challenge for the lightly-lightly way of doing things.
Gillian Merron: If I might say this is the value of an investigation by committees such as this because it does highlight the need for that work.

Q671 ***Lord O'Neill of Clackmannan:*** If we could maybe take things back a wee bit. We are assuming that the foods are on the market, but before they get to the market we have had concerns expressed by witnesses about the lack of clarity in terms of the requirements of data which need to be provided in order to secure the permission under, for example, registering of products with nanomaterials as novel. What are you doing about that, if anything?
Gillian Merron: I will invite Dr Baynton and Dr Lawrie to comment, but I understand that we have not had enquiries yet of the FSA on data. There are regular meetings between the FSA and companies. Companies should be referring themselves to the EFSA, which sets out the questions that they need to answer. It is also the case that the European Commission, as the Committee probably knows, has acknowledged the need for more formal guidance and the EFSA will be producing this. Perhaps on a further point, companies should be aware that, in introducing any new substance or a substance which has been produced by a novel process, it is very likely to require clearance under the novel foods regulations, and if those regulations are to be revised in future to include a special category in respect of nanomaterials, then of course the FSA would be publicising that in its formal guidance. Certainly I would be interested if there were evidence of a lack of

industry guidance because of course that would not be appropriate. Perhaps I could ask Dr Lawrie or Dr Baynton to add to that.
Dr Baynton: Just to reiterate what the Minister has said, we already work very closely with the industry in relation to the novel food regulation. We work with companies when they are producing their dossiers for assessment under the novel food regulation. Obviously there will be guidance at a European level from EFSA and we are aware that the Commission is very keen for EFSA to produce that guidance. Equally, we would be happy to continue our discussions with companies and advise them accordingly on applications for the use of nanomaterials or nanoparticles in food. We would want to maintain the current good dialogue that we have under the novel food regulation for future applications in this area.

Q672 ***Lord Crickhowell:*** The Committee has heard concerns over the difficulties surrounding the detection and regulation of nanomaterials in imported food. Who is responsible for ensuring that there are appropriate techniques for monitoring imported food products?
Gillian Merron: The first point of course is that local authorities and port health authorities are the ones with the powers to check on the importation of food, and that includes taking samples for laboratory analysis. They may seek advice from the FSA about what laboratory tests are appropriate for each situation and the FSA has that general role to ensure that the enforcement bodies have all the tools that are necessary at their disposal. That includes the development and validation of appropriate test methods. The Nanotechnology Research Co-ordination Group is working at looking on how they can even better support this area and the FSA is also looking at contributing funds to a new EU project which will investigate the methods for measuring nanomaterials in food. Perhaps the overall point is that we do have to look to the future to ensure that we have the right technology available in order that we can properly detect and regulate as is required in imported foods.

Q673 ***Chairman:*** Could I follow up and ask would a typical trading standards officer or port health authority inspector have at his or her disposal the techniques to detect whether or not there are nanomaterials in imported food as we speak today?
Gillian Merron: Not at present but they will do.

Q674 ***Chairman:*** So there could be food coming in at the moment which is not being analysed because the techniques are not there?
Dr Baynton: Possibly, yes. We are not aware obviously of many products on the UK market but—

Q675 ***Chairman:*** There could be.
Dr Baynton: —coming from outside, yes.

Q676 ***Lord Crickhowell:*** It is obviously very early days, but are the trading standards officers and port health authority officers being told that this is an area that they are going to have to look at and should be looking at perhaps even now to some extent? I was once a director of a large port company and I would be a little sceptical that many port health authority officials actually have nanotechnologies high on their agenda about food coming in from, say, China or Brazil or some other part of the world.
Gillian Merron: I would agree, that is true, and that is the result of being at a very early stage. I can assure the Committee that we will have in process the necessary alert to those said authorities. I think this is a function of the stage at which we are.

Q677 ***Lord Methuen:*** The Food and Drink Federation has commented on the need for transparency along the food chain so that manufacturers are informed by their ingredient and packaging suppliers about the use of nanotechnology in any products that they are purchasing. What are the current requirements for reporting along the food chain?
Gillian Merron: Well, business-to-business sales are not covered by the same food labelling legislation, as I am sure the Committee is aware, that applies to consumer sales. However, businesses are required to pass on information that will make sure that the final food that is presented to consumers is in full compliance with the law. It is of course open to businesses to enter into a contract which is over and above what is required to make sure they get the disclosure of information in the way that they want it. For me the real issue is ultimately with the consumer. Does the consumer have all the information required? The law does require that whatever the supply chain that will have to be the ultimate provision, but, as I say, it is not absolutely required along the way as long as the outcome is correct. That may be a matter for example that the Food and Drink Federation may wish to work on with its members, as well as others if that is an area of concern to them.

Q678 ***Lord Methuen:*** Does it not concern you? It strikes me as slightly vague that the supplier could be not really informing the producers.
Gillian Merron: It would concern me if the consumer product at the end was not in compliance with the law, yes, and it may be that by definition one has to do that but, yes, of course compliance with the law is absolute. That compliance is not required business-to-business but, as I say, businesses may require that, and going back to our discussion on transparency, as the technology develops I think there will be

movement. It is probably not something they are considering at present.

Q679 ***Lord May of Oxford:*** This is possibly a step too far but how is the Government thinking about the possible inadvertent contamination of foods with nanoparticles in ways which were not intended?
Gillian Merron: The most likely source of contamination of food is from their use with food contact materials. We are not aware that we have got any food packaging materials in the UK containing nanoparticles at this stage and it is difficult to generalise on the likelihood.

Q680 ***Lord May of Oxford:*** I am thinking of food processing places where other uses of nanoparticles are being made. In the nature of some of them they are going to get out into the atmosphere, as it were.
Gillian Merron: My point was it is difficult to generalise on the likelihood that nanoparticles can migrate from packaging to food. It depends on the type and composition of the materials used.

Q681 ***Lord May of Oxford:*** I just wondered if it was something that was being considered?
Gillian Merron: It is something of interest and I am going turn to my scientist colleagues.
Dr Baynton: The Food Standards Agency is very aware of the potential for incidents to occur along the food chain. We have horizon-scanning activities to try and identify where there might be potential problems in the future. This is perhaps something that we do need to consider.

Q682 ***Lord Methuen:*** Could this not be fungicides and pesticides which are used in warehouses and other food storage places?
Dr Baynton: That could be one mechanism. I think that is something that we need to consider as part of thinking about incident prevention and prevention of contamination of food supplies with those types of chemicals.

Q683 ***Chairman:*** My recollection from my time at the FSA is that contamination is normally picked up by local authority inspectors. This goes back to the earlier question of whether the local authority inspectors have the techniques in their current tool kit to detect contamination if contamination were occurring. I think the information we heard earlier is that they probably do not at the moment, but you are working with them to build up the armoury of techniques, so if something happened at the moment in the way that Lord May referred to, and inadvertent contamination of a foodstuff with a nanomaterial did occur, am I right in believing that the trading standards officers would not have the technical armoury to find that out so it could be happening and we would not know?
Gillian Merron: That is true.

Q684 ***Chairman:*** We have used up more time than we were originally intending to, but I do appreciate very much, Minister, that you have been willing to answer our questions so fully and frankly and to engage with us, and also your colleagues from the Food Standards Agency. There have been a number of points on which you have agreed to follow-up in writing so we very much appreciate that and look forward to receiving those comments. Of course there will be a written transcript of this session which will be sent to you for checking before it becomes the published record. Any subsidiary evidence that you give us will also be part of the public record of our inquiry. As you said, this is our last oral evidence session, so thank you very much for rounding off our sessions with witnesses and we now set to work to complete the draft report which we hope to finalise during the autumn.
Gillian Merron: Thank you very much and I look forward to seeing the report. I think it will be of great assistance to us. Thank you.

Letter from the Minister of State for Public Health, Department of Health

Thank you for inviting me to appear in front of your Committee today, which I found very valuable. I hope the Committee also found it useful.

At the hearing, I promised to write to the Committee on the following points:

(a) the current use of fumed silica as a food additive and its relationship to the type of silica that was used in the German research;

(b) the number of research proposals that the FSA has received in relation to the fate of nanomaterials in the gut;

(c) how Food SA's food research relates to EU research programmes in similar areas; and

(d) the applicability of REACH to substances that are used in food.

I will send you this information by summer recess, with the exception of point "a" above which my officials tell me requires further investigation and liaison with industry. I have instructed the Food Standards Agency to respond to you directly on this point by the end of July 2009.

I hope that this is acceptable.

14 July 2009

Supplementary Letter from the Minister of State for Public Health, Department of Health

In my letter of 14 July I promised to provide the Sub-Committee with additional information on four points. My responses on three of these are set out below. I have asked the Food Standards Agency (FSA) to respond by the end of July on the remaining point, concerning nanoscale silica.

1. The Number of Research Proposals that the FSA has Received in Relation to the Fate of Nanomaterials in the Gut

The FSA has advised me that they are currently in the process of evaluating the proposals that have been submitted in response to its published requirement for research into the fate of nanomaterials in the gut. Considering the stage the FSA are at, revealing the number of proposals submitted at this stage could jeopardise any negotiations with applicants prior to placing of the research contract. However, the Agency will, of course, be happy to provide the Committee with this information once the commissioning process is complete.

2. How the FSA's Food Research Relates to EU Research Programmes in Similar Areas

The Food Standards Agency engages actively with the EU research programmes to help ensure that FSA and UK priorities are reflected in the EU programmes, and to ensure we are able to identify and benefit from opportunities for collaborative approaches.

The FSA is joint UK lead, with Defra, on the Management Committee responsible for the theme "Food, Agriculture & Fisheries, and Biotechnology" in the current EU research programme, FP7, which has the greatest overlap with Agency research priorities—one of its three sub-themes, on food health and well-being, has very close parallels with the Agency's principal objectives of food safety and healthy eating. The Agency also takes part in the UK's cross-government EU research networks with other Departments and Research Councils, to ensure it is informed on and can influence other themes which have elements of interest to the Agency, including the themes on: Environment; Health; Nanosciences, nanotechnologies, materials & new production technologies; and Social Sciences & Humanities.

The Agency's own research programmes take account of relevant research in Europe and the wider international context, and we can provide co-funding for European projects where these align with our priorities. The FSA co-funded five projects in FP6 (which ran from 2002–06) and to date has agreed co-funding for two projects in FP7—with co-funding under discussion for a number of further FP7 projects, including one on detection of nanomaterials in food. The Agency also collaborates in other ways with EU projects of interest, for example by participating in stakeholder, expert or advisory groups set up by EU projects to provide forums to exchange information and expertise between projects and interested parties. The Agency is also a partner in the FP6 "ERANET" project SAFEFOODERA, which aims to co-ordinate national research in food safety across some 19 European countries, and which has issued two successful jointly-funded research calls. Progress in co-funding in Agency research is reported annually in the FSA Chief Scientist's Annual reports.

The Agency also takes part in the UK programme of support to UK organisations to engage with EU research programmes, through promoting and facilitating opportunities to participate and to benefit from the results.

3. The Applicability of REACH to Substances that are used in Food

FSA officials have consulted with Defra on the application of REACH (Regulation (EC) 1907/2006, which governs the registration, evaluation, authorisation and restriction of chemicals) to nanomaterials used in food. Article 2 of the Regulation sets out a number of exemptions and, according to Article 2(5)(b), substances are excluded from the requirements for registration, evaluation and authorisation "to the extent that they are used … in food and feedingstuffs". In this context "food" refers to ingredients, flavourings, additives etc, as well as food consumed as such.

The REACH legislation could, in theory, be used to place restrictions on substances used in food. However, this seems unlikely in practice as the exemption mentioned above means that no information on relevant uses will have been collected and assessed.

The exemption for substances used in food does not extend to substances used in food packaging.

I hope this is helpful. Please let me know if you would like any further information.

21 July 2009

Further supplementary memorandum from the Minister of State for Public Health, Department of Health

Your letter also invited further information on five points. Points 3 and 5 were answered in Gillian Merron's letter of 21 July, which also addressed point 2 but from the broader perspective of the relationship between FSA and EU funded research (Q638 in the transcript). The specific work that is being considered for funding by the FSA is part of a 4 million euro project (Nanolyse) that is being led by the RIKILT Institute of Food Safety (The Netherlands), and is aimed at developing analytical methods for detection and characterisation of nanoparticles in food. The project aims to fulfil a major current need for validated detection/characterisation technologies that will enable quality control and safety assurance of the food products that are developed using nanotechnology-derived materials. The project is being undertaken by a consortium of research centres that includes the Food and Environment Research Agency in York. FSA has been asked to provide "top-up" funding for FERA's part of the work.

In relation to point 1, FSA officials have not yet been able to find any more information about the characteristics of silica that is used as a food additive and it is therefore not possible to comment on the relevance of the German work on amorphous silica. FSA Officials will continue to search for more information and report back shortly on progress. Point 4 concerns the European Commission's plans for an EU inventory. This was originally included in the list of "top ten actions" that the Commission drew up at the end of 2008. However, they have taken no action to date and officials understand from their Commission contacts that nothing is currently planned, at least in the food area. I hope this resolves the apparent inconsistency.

5 August 2009

Written Evidence

Memorandum by Campden BRI

1. Our Organisation

1.1 Campden BRI is the world's largest, independent, membership-based, research and technology organisation serving the food and drinks sectors. The organisation has over 1,700 member companies in more than 60 countries. Over the last three years, we have received funding from defra and EPSRC to identify applications and potential barriers to the uptake of nanotechnologies in the food sector. This has been, and continues to be achieved, through a series of meetings with industry and through email alerts to industry on developments in nanotechnologies that may have relevance to food applications. The mailing list for emails consists of 1,100 industry contacts.

1.2 The meetings have been composed of presentations from companies providing nanotechnology-based products such as coatings, manufacturers of foods, ingredients and agro-chemicals, academics carrying out research on nano-science or consumer attitudes, and representatives of Government departments. Our response to the call from the House of Lords is based on those presentations and information and enquiries from our members in response to those meetings and the email alerts.

1.3 Our response begins by looking at "Other Issues" not specifically identified in the call as we believe these set the scene for our response.

2. "Other Issues"

2.1 Questions from industry indicate a difficulty in understanding the meaning of the term "nanotechnologies". Some companies know that they experience equipment wear and that this leads to particles, at the nanoscale of 1-100 nm, in the product. Some processes used in the manufacture of foods produce particles that exist at the nanoscale for only short time periods and do not exist at that scale in the final product. Other processes, such as vapour deposition used in the manufacture of packaging, may create particles that are short-lived at the nano-scale or create films that are at the nano-scale in the final package. Conventional food processing operations, such as emulsification, may also create nano-structures. There is confusion as to whether these products are to be considered as "nano-products". There is also concern that sales of such products, which have been produced by methods available for many years, would be damaged if legislation were introduced that required them to be labelled as "containing manufactured nanoparticles".

2.2 Difficulties arise because nanotechnology has been given a specific size category but novel properties may be achieved outside this range and conventional processes, used for many years, may produce particles within that range.

2.3 Existing legalisation requires food to be safe irrespective of the method of manufacture or size of particles that it contains.

2.4 Defining nanotechnologies as producing materials with novel properties restricts some of the difficulties in understanding what the term means but it does not altogether eliminate the problem. For example, a beer bottle has been available that includes a layer containing clay particles at the nanoscale. The bottle extends the shelf life of the beer by restricting oxygen ingress. This would appear to be a novel property of the bottle material but not necessarily of the individual particles. Our comments below relate to nanotechnologies as procedures or equipment that create particles that have novel properties.

3. State of the Science and its Current use in the Food Sector

What are the main potential applications and benefits?

3.1 Applications for which the industry would like to see nanotechnology deliver solutions include: extended shelf life to reduce waste; improved quality such as flavour; alternative utilisation of food waste such as energy generation; sensing of contaminants (microorganisms, allergens); improved packaging to increase shelf life and reduce waste; alternative methods of creating desired mouth feel and taste of products with reduced fat, sugar, and salt composition. Nanotechnologies are believed to have the potential to offer solutions.

What is the current state of the market?

3.2 There have been at least eight reports written about the applications of nanotechnologies in the agri-food sector and at least one computer-based inventory of consumer products containing nanoparticles is available (Woodrow Wilson Inventory). Whether all of the applications or products are created using nanotechnologies is often unclear.

3.3 Silver is a known anti-microbial and applications to food supplements, food containers and food cutting boards are cited in the Woodrow Wilson inventory. None of these materials have been identified in the UK market although some clothing containing silver has been available. The inventory also cites canola oil and a tea as food products containing particles. The canola oil claims to use micelles to restrict the transfer of cholesterol into the blood stream. The tea is promoted as releasing increased selenium due to a ball milling operation reducing the size of the tea during manufacture. Micellation and ball milling have been known for many years.

3.4 Probably the most widely cited application of nanotechnology in the drinks sector is the beer bottle incorporating a layer of nano-clay, although other bottles based on vapour deposition of silicon oxides have also been reported.

3.5 Despite our efforts, we have not identified any food products or food packaging materials on the UK market that contain particles that have been deliberately engineered at the nano-scale using new and novel technologies. Understanding of food structure is developing through measurements and modelling at the nano-scale.

What are the barriers to the development of new nano-products or processes in the food sector?

3.6 Discussions at our meetings have indicated that the greatest barriers are cost (some barrier materials for packaging could be created for greater shelf life but the increased cost would not be justified); technical difficulty (nanoparticles can be difficult to manufacture and control); and health and safety concerns. A significant barrier is consumer attitude and the industry concern over that attitude. There is considerable worry that nanotechnology could suffer from adverse public opinion in a similar way to developments in biotechnology and that conventional food processing methods, which involve control of nano-structures in foods, would be associated with the newer developments in nanotechnology.

4. Summarising Comments

4.1 Despite there being definitions of "nanotechnologies" from many recognised sources, there is still uncertainty about the meaning of the word. It is unclear whether any process that produces particles at the nano-scale should be considered as "nanotechnology". Even if the meaning is extended to include a reference to novel properties, there could still be concern that nano-scale particles, irrespective of how they were created, could have an adverse effect on health. There are many developments in food and packaging manufacture that could provide benefits to consumers and nanotechnologies offer one of the routes to achieving those goals.

March 2009

Memorandum by Cargill

Cargill is an international producer and marketer of food, agricultural, financial and industrial products and services. Founded in 1865, the privately held company employs 160,000 people in 67 countries. Cargill helps customers succeed through collaboration and innovation, and is committed to applying its global knowledge and experience to help meet economic, environmental and social challenges wherever it does business. For more information, visit www.cargill.co.

Nanotechnology in Cargill

Materials of nano dimension have been present in the food chain for a long time. Our comments to this inquiry will be focussed on the deliberate fabrication of "nanoscale" materials, potentially of value because of their novel physico-chemical properties, or the novel processes by which these are fabricated and incorporated into products. It is of vital importance to Cargill that the regulatory definitions of nanotechnology only encompass new, deliberately fabricated materials. Any broader scope could inadvertently and significantly impact existing global food and feed supply chains.

The recent developments in material science that have made possible the study and control of matter at atomic and molecular scale, nano-technology, have resulted in the introduction of over 300 new products intentionally derived from this technology in non-food areas (eg cosmetics, coatings) and in some cases in the food and agricultural sectors. A recent review (see Woodrow Wilson Int Center) has identified that in the food sector, these products cover:

- *Forms*: nanoparticles, nano-emulsions, nano-catalyst, liquid crystals, nano-fluids, nano-crystals.
- *Functions*: inc. solubility/uptake, stability, flavor release/enhancement, colour release, packaging-antimicrobials.
- *Needs*: nutrition, improved immune system, flavor, fun, individualization, stability, safety.
- *Products*: oils, supplement, chocolate, beverages, gum, ice cream, dressing, fillings.

Cargill is well aware of these opportunities and believes that nanotechnology-based materials may offer valuable benefits to the food chain such as measurement sensors to enhance safety and quality.

However, after spending considerable time analysing the subject within the company, we have concluded that the potential safety risks, the emerging regulatory environment and the level of consumer acceptance of products incorporating nanotechnology are not generally well understood. In particular the investigation of the health, safety, and environmental aspects of these novel substances has not matched investment in nanotechnology research and development.

Consequently there are many gaps in understanding the effects of nanotechnology-enabled products on health and on the environment and particularly how their use in the food chain may expose our employees, customers and consumers to these materials. It is our understanding from the peer-reviewed science that the extremely small size of nano-particles permits possible transfer, after inhalation or ingestion, into and through human tissue by new and unknown routes. This potential toxicological hazard is difficult to measure and assess, and represents a significant risk until detailed studies have been carried out. This uncertainty about toxicological risk is a significant gap in determining safety legislation on which proper controls should be based. We support investigation into these issues.

Furthermore consumer surveys on nanotechnology, including specific applications in foods, indicate that the public has a low level of understanding of nanotechnology.

Experience has shown that the successful introduction of a new technology, especially one with potential health, safety and environmental impacts, requires a clear science-based regulatory regime, overseen by credible governmental authorities, and that the technology providers engage the public and other stakeholders to convince them of the advantages of the technology. None of these steps has been taken for nanotechnology

As a result, Cargill will not incorporate intentionally-engineered nano-materials into its products for the foreseeable future until these shortcomings are remedied.

This position does not mean that we will not maintain our interest in nanotechnology, especially where materials can be fabricated into devices and wholly enclosing nano-materials and where no human exposures need result. We will continue to assess these "non contact" uses in terms of their benefit to process control and product quality.

14 August 2009

Memorandum by the ESRC Centre for Business Relationships, Accountability, Sustainability and Society (BRASS)

Respondent Profile

The ESRC funded Centre for Business Relationships, Accountability, Sustainability and Society (BRASS) at Cardiff University is a major research centre dedicated to providing a critical view on all aspects of business relationships that affect issues surrounding sustainability, accountability and their interaction with different components of society. The comments provided in the response are based on the report "An Overview of the Framework of Current Regulation Affecting the Development and Marketing of Nanomaterials", written by the respondents for the Office of Science and Innovation in December 2006. The report is located at: http://www.berr.gov.uk/files/file36167.pdf.

Currently, BRASS is conducting research for the Department for the Environment, Food and Rural Affairs on the application of corporate social responsibility by the nanotechnologies industries in the context of safeguarding the environment and human health.

Introduction

BRASS welcomes this opportunity to contribute to the invitation to submit written evidence on the use of nanotechnologies in the food sector. In view of our previous work, and given our role as social science researchers, we have restricted our responses to the questions relating to the regulatory framework and to public engagement.

Regulatory Framework

Q. 1 *Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?*

In principle, current uses of nanotechnologies and nanomaterials will fall within the scope of a range of existing regulatory provisions. There is no nano-specific legislation, either in the UK or EU. The regulation of nanomaterials is therefore question of whether, and to what extent, legislative provisions designed to manage risks from *bulk*-scale materials also cover potential risks from materials at nano-scale. Given that current uses of nanotechnologies tend to involve the nano-scale versions of materials already subject to regulatory control, there are usually obvious regulatory regimes into which nanomaterials will fall. Nanomaterials may be caught within the remit of a wide range of existing legislative provisions, in areas such as consumer protection, occupational health and safety, and environmental protection.

There are instances, however, in which regulatory gaps can arise (see BRASS, 2006). First, nanomaterials may fall outside the remit of existing provisions because, even at bulk-scale, those materials are unregulated. Secondly, the content of existing legislation may, in some instance, be ill-suited to nanomaterials. Thirdly, the particular implementation of those provisions may fail to account for the properties or behaviour of nanomaterials. Existing legislative provisions were never designed with nanomaterials in mind (RCEP, 2007). It is unsurprising, therefore, that their capacity to afford adequate protection may be limited.

The limitations of current legislation are brought into sharp focus by considering their application to food products. The greatest potential difficulty arises in relation to the Novel Foods Regulation (EC) No. 258/97. Pre-market approval is required for novel foods and novel food ingredients, but not for those that are deemed by a national food assessment body (FSA) to be *substantially equivalent* to comparable traditional foods. Substantial equivalence between new and existing foods is determined by a range of factors, such as their composition, nutritional value and intended use; although there is no explicit provision in the Regulation that *particle size* or the unique *properties* of novel foods should be taken into account. This creates the possibility that novel foods or food ingredients containing nanomaterials will be deemed to be substantially equivalent to their existing bulk-scale counterparts, and thereby escape the need for pre-market approval, even though they may pose a greater risk to human health.

The European Commission has recently presented proposals for a new, amended Regulation on Novel Foods (COM (2007) 872). One of the proposed Recitals seeks to clarify whether foods comprising nanomaterials are "novel" and therefore subject to market entry control. "Novel food", the Commission suggests, should include "foods modified by new production processes, such as nanotechnology and nanoscience". The fact that amendments such as this are under consideration is encouraging. Some caution, however, should be expressed in respect of its *technology*-based approach to regulation. A *product*-based approach—in which the novelty of nano-foods is determined on a case-by-case basis according to their individual properties, functions and hazards—remains preferable, not least because process distinctions are not well recognised in the world trade treaties such as GATT.

Generally, food additives legislation (adopted under the framework of the food additives Directive 89/107/EEC, eg Directives 94/35/EC on sweeteners for use in foodstuffs, 94/36/EC on colours for use in foodstuffs, 95/2/EC on food additives other than colours and sweeteners, and 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners) is sufficiently broad to encompass the use of nanomaterials. Some aspects of that legislation, however, may be problematic. Directive 95/2/EC, for example, prohibits the use of certain additives in quantities above prescribed maximum levels. Although these maximum levels might be suitable for additives composed of bulk-scale materials, they are not necessarily so for materials at nano-scale. Legislation in this area tends to overlook particle size as a determining factor in the toxicity of substances. The new food additives Regulation (EC) No. 1333/2008 addresses this issue (see Article 12). We welcome this initiative as it presents an obvious solution to track developments in the use of nanomaterials as food additives.

Although the food additives Directive (89/107/EEC) does not set out specific criteria for the assessment of nanomaterials, it contains a number of "safety net" provisions which require that foods are continually observed and re-evaluated in light of changing conditions of use or new scientific information. Umbrella safety legislation (such as the General Food Regulation (EC) No. 178/2002 and the (UK) General Product Safety

Regulations 2005) provide an additional layer of regulation, prohibiting the placing of unsafe foods or products on the market. The capacity of these provisions to afford adequate protection against potential harm from nanomaterials, however, will ultimately depend on whether there are suitable procedures for the identification, characterisation and assessment of risks. These procedures are still lacking. Moreover there are questions about how far a general food safety law might actually deter risk taking conduct.

Q.3 *Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?*

The capacity of current regulations adequately to control the *present*, let alone the next, generation of nanotechnologies and nanomaterials is limited. As applications of nanotechnologies and nanomaterials develop, and become increasingly *dis*similar to conventional (regulated) technologies and materials, gaps in current legislation will only grow to be more pronounced. Before the capacity of regulations to address future applications of nanotechnologies can be properly examined, it is necessary to gain a clear idea of what those future applications actually entail. Whilst we do not consider it necessary to impose overarching nano-specific legislation (giving effect to a moratorium, for example), current regulations will, in our opinion, need to be amended to account for more sophisticated nano-based products and processes. Moreover these will need to be adapted to cover not merely foodstuffs but also packaging and materials used in food preparation.

Public Engagement

Q.1 *What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?*

Broadly speaking, the available evidence on public awareness in countries such as the USA and UK shows that awareness of the existence of nanotechnology in general has changed little from a low level a few years ago (Currall, King et al. 2006; Kahan, Slovic et al. 2007; Scheufele, Corley et al. 2007). For example, in 2006, 42 per cent of Americans surveyed had not heard of nanotechnology (Peter D. Hart Research Associates 2006), with this actually increasing to 49 per cent in 2008 (Peter D. Hart Research Associates 2008). However, research on attitudes towards specific potential applications of nanotechnologies demonstrates that there may be significant concern about food applications, particularly where nanoingredients are actually present within foods rather than simply used within packaging materials. A survey for the Woodrow Wilson Institute indicates that only 7 per cent of Americans would buy nanofood now, with 29 per cent not wanting to buy it at all, and 62 per cent wanting more information on risks and benefits, vs 12 per cent, 73 per cent and 13 per cent for food containers (Peter D. Hart Research Associates 2007). Evidence from research in Switzerland suggests that people may be hesitant to buy foods which either contain nano-additives or use packaging which contains nanomaterials or nanostructures (Siegrist, Cousin et al. 2007). This research also indicates that trust in institutions is a key factor in determining perceptions of such technologies. Survey data from Germany also indicates that mistrust of regulators and industry could be particularly significant with respect to nanofoods, as low trust of these groups is correlated with high rates of rejection of the use of nanoadditives in food (Halliday 2007). Further, research from recent public engagement events in the UK indicates that, in general, the public are perhaps more concerned about the extent of scientific uncertainty surrounding risk, rather than about the nature of risks that have to date been identified (Gavelin, Wilson et al. 2007, 39).

Q.2 *How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?*

Other evidence indicates that whether the public trusts or mistrusts the ability of regulators and industry to handle risks and uncertainties is based on experiences of previous technology controversies (eg Macoubrie 2006, 235–6; (Pidgeon, Harthorn et al. 2009), and on whether these controversies have been amplified by a lack of transparency from industry and regulators, both about risk and about scientific uncertainty. Although the assumptions behind public engagement activities have shifted in large part away from "deficit" models of public information about science, some commentators have observed that these models risk being replaced by a "trust deficit" model. For these commentators, unless the purpose and practice of engagement is altered, its purpose risks becoming merely about convincing the public, envisaged as "end-user consumers", of the potential future benefits of a technology (eg Kearnes and Wynne 2007). To counter these effects, the aim of future public engagement exercises on nanotechnology must focus on transparent discussion of scientific uncertainty over both benefits *and* risks. Unfortunately, to date the food industry has manifested a low degree of transparency regarding the presence of nanomaterials in food and food packaging (Schelke 2006). In certain areas such as flavourings, competitive forces may militate against greater openness.

Q.3 *What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?*

There is evidence from research done on public attitudes to GM foods to suggest that demonstration of technological benefits alone is not enough to persuade people to consume modified food (Cox, Koster et al. 2004). There is reason to suspect that similar attitudes may be evident in relation to "nanofoods". Trying to win public trust by stressing potential benefits may therefore be ineffective, as well as reproducing "deficit" models of engagement in new forms. It has also been argued that new technologies (with GM as a prime example) act as condensation points for the expression of broader public concerns, about eg the wider social responsibilities of industry (Kearnes, Grove-White et al. 2006, 300–301). Given that mistrust, in a UK context, is strongly correlated with experiences of controversies over BSE and GM, the importance in the future of the relationship between factors like mistrust and how both risks *and* uncertainties are communicated is difficult to overemphasise.

Q.4 *Should consumers be provided with information on the use of nanotechnologies and nano-materials in food products?*

Concerns which are sometimes expressed over exposure to risk turn out, on further investigation, to be about the *imposition* of risk, ie about the social context through which risk is distributed. Recent research shows that, as well as demanding information about the state of scientific uncertainty, publics are concerned with the management of consent to bear risk, and the moral issues which underlie issues of consent (Shrader-Frechette 2007). How marketing is used as a conduit for product information features again and again in recent consumer research as an object of concern (eg Federal Institute for Risk Assessment (Germany) 2006, Which? 2008, 10). Labelling and other marketing information provides a vital means of allowing people to make decisions about consenting to bear risk and uncertainty, and thus may be a key factor (amongst others) to establishing the social legitimacy of some uses of nanotechnologies.

Conclusion

In general terms we would stress that the Regulatory framework is not water-tight. It is capable of adaptive management since food is generally well regulated and those engaged in food production have strong incentives to ensure that food is safe. While work is already underway at a European level as a beginning of this process, progress to date has been slow. In part this is because of the difficulty of regulating in the absence of agreed definitions, metrics, processes of characterisation etc. However, this should not be used as an excuse to delay regulatory reform.

As for public engagement, this is not easy as a formal exercise amidst a low level of recognition of nanomaterials. However, there are strong messages demonstrating the importance of a continuing form of dialogue with the public and processes of transparent dealings. Without this, distrust of nanotechnologies and their regulation might quickly develop.

March 2009

Memorandum by the European Commission Directorate-General for Health and Consumers (DG SANCO)

Nanotechnologies and Food

1. *Could you provide the Committee with a brief update on the activities to update legislation relevant to the use of nanotechnologies in food, additives and food packaging, and the timetable for future activities?*

Brief update on the novel foods, food additives and food contact materials:

Novel foods: Under current novel food legislation (Regulation (EC) 258/97) all foodstuffs obtained through new production processes giving rise to significant changes, need an EU authorisation before getting market access. In the draft EU Regulation revision this legislation, it is explicitly proposed that food ingredients, which contain or consist of engineered nanomaterial will require an EU authorisation preceded by an evaluation by the European Food Safety Authority (EFSA) before getting market access. As regards the legislative process, the Council reached a "political agreement" on 22 May 2009 and the second reading will start under the Swedish Presidency in view of the final adoption of the text.

Food additives: The Community legislation on food additives requires a safety evaluation and pre-market approval of each new additive which is to be placed on the market and used in the Community. The new Regulation 1333/2008 on food additives, which was adopted in December 2008, clarifies that when for a food additive there is a change in particle size, for example through nanotechnology, a new evaluation would be

required from EFSA. Under such circumstances, the food additives in the nanoscale is considered a new additive and therefore needs a new entry into the Community list before it can be placed on the market (Article 12).

Food contact materials: General safety requirements for food contact materials are set out in a Framework Regulation which also empowers the Commission to adopt material specific requirements. For plastics, cellophane and active intelligent packaging harmonised Community requirements exist. These requirements foresee a pre-market approval of substances used in their manufacture. Current authorisations cover substances in bulk form but not in nano-form. In case a business operator using authorised substances has new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health he has to immediately inform the Commission, who shall ask EFSA to review the assessment. The use of an authorised substance in nano-form is regarded as an information which would trigger a review by EFSA. All other materials which are not covered by specific Community requirements are subject to specific national provisions.

2. *How does the Commission intend to define "nanotechnologies" and "nanomaterials" in the context of regulating their use in the food sector?*

The discussion on how to define "nanotechnologies" and "nanomaterials" is an on-going process in the Commission where also discussions at international level are taken into account. The Commission agrees on the need to develop a definition, preferably at global level, to serve as a basis also for EU regulation and implementing measures and instruments.

In the draft novel food Regulation, currently in the co-decision procedure, a draft definition of "engineered nanomaterials" has been introduced at the request of the EP. It has been supported both by the EP and the Council. According to this proposal, the proposed definition can be adapted, if necessary, taking into account new scientific and technical developments. Once such definition is adopted, it may be applied in other fields of food legislation, if necessary.

3. *What efforts are being made to harmonize the use of definitions for nanotechnology across food, food additives and food packaging legislation?*

Concerning food additives legislation, a definition of nanomaterials is not included in the new Regulation (EC) No 1333/2008. Independently from a nanomaterial definition, any significant change in particle size, including in the nanoscale, compared to the conventional food additive, would mean that the "new" food additive is not covered by the previous safety evaluation and would need a new authorisation preceded by a new EFSA evaluation. Similar provisions exist for food packaging legislation.

If and when definitions on "nanotechnologies" or "nanomaterials" are agreed in the Community, these could be also used in the area of food additives and food packaging.

4. *What advice does the Commission give to the industry on whether or not new products come under the novel food or other relevant regulations, and what guidance is provided specifically on the risk assessment of foods containing nanotechnologies?*

In the first instance the Member States should give advice to industry on whether a given product falls under the novel food or other relevant regulation. In addition, in the area of novel food and food additives, the Commission may decide under comitology on the legal status of a substance.

The Commission has requested EFSA to provide guidance on how the risk assessment of foods containing engineered nanomaterials should be carried out and what data is required for such an assessment. EFSA's Scientific Committee adopted the first opinion on nanotechnologies in food and feed on 11 February 2009 which was a general opinion on the approach to be taken when assessing nanomaterials.

In July 2009, the Commission has asked the EFSA to produce a detailed guidance document that addresses the practical needs of the safety assessment of applications of nanoscience and nanotechnologies to food (food additives, enzymes, flavourings, food contact materials, novel foods), feed and pesticides.

The Commission has requested that the guidance document should spell out requirements directly usable in the elaboration of applications. These requirements should specify the data and the information that the applicant should provide to describe the relevant mechanisms of action and demonstrate the safety of these food and feed applications. Furthermore this guidance should cover both the case when engineered nanomaterials are added by the manufacturer and when the nanomaterials result from the production process.

5. *How does the Commission co-ordinate its work on nanotechnologies, both within the Commission and with Member States? How is health and safety research co-ordinated, and what input does DG Sanco have into this process?*

In order to ensure internal co-ordination on nanotechnology policy and action, the Commission has established a permanent Inter-service Group where all the General-Directorates which have research or policy/regulatory responsibilities for nanotechnology are represented. The Group meets regularly in order to review developments and on-going activities, co-ordinate positions and decide how to organise collaboration on more specific initiatives. Meetings at Director-level take place when necessary in order to take policy decisions. Commission services activities are framed by a Nanotechnology Action Plan adopted by the Commission (Collège) itself.

Co-ordination with the Member States takes place, as far as necessary, in a sectoral manner, within the existing committees and working groups established within the framework of the various regulatory instruments. In addition, ad-hoc meetings are organised to discuss horizontal issues of common interest. An example is the meeting organised by Directorate General Health and Consumers on 17 March 2008 in order to discuss collaboration on risk assessment with the experts of the Member States.

Health and Safety research on nanotechnology is co-ordinated both through the Inter-service Group mentioned above, which may discuss research priorities, and via the usual inter-service consultation procedures which apply to all steps of definition and execution of research programmes, including in particular the establishment of themes for specific calls and the choice of projects. The different General Directorates, including DG Health and Consumers, provide their input at the occasion of the relevant inter-service consultations.

6. *How does DG Sanco ensure that health and safety research supports the regulatory needs of the Commission and Member States?*

As said above, the different DGs, including DG Health and Consumers, provide their input at the occasion of the relevant inter-service consultations. As a rule, discussions are initiated before the launch of the formal inter-service consultation in the context of the Inter-service Group. This ensures that the regulatory needs of DGs, including DG Health and Consumers, are taken into account when calls for proposals for research projects are launched.

7. *There have been several research gaps which have been identified in relation to health and safety testing of nanofoods for example work on the gut, the behaviour of nanoparticles within a food matrix, or the long-term health effects of nanoparticles in food. What work has been done across the European Union to close these gaps?*

EFSA adopted its scientific opinion on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" on 10 February 2009 and published it on 5 March 2009, which documents such gaps and identifies research priorities. One project presently under negotiation under the Framework Programme for Research and Technological Development managed by Directorate General Research and the NanoGenoTox Joint Action recently approved under the Health and Consumers Programme managed by SANCO should respectively address some aspects of the issue. More research on understanding the interactions between nanomaterials and living organisms–and of nanoparticles in the gut, in particular–is clearly needed and is being flagged as a priority for funding at EU level, in EU Member States, and internationally (please also see below).

8. *How will the recommendations from the EFSA's Scientific Opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety be taken forward?*

EFSA concluded that the use of nanomaterials in food will be assessed on a case-by-case basis. This approach is already in place for the authorisation of food additives, novel foods and plastic food contact materials. Guidance documents on risk assessment are being reviewed for food additives and for food contact materials and will also address nanotechnology aspects.

As mentioned earlier, the Commission will be asking for further advice from EFSA on data to be submitted for case-by-case risk assessment also in other sectors.

EFSA has made on research recommendations especially as regards shortcomings of risk assessment in relation to toxicokinetics, toxicity, exposure assessment and analytical methods. DG Health and Consumers supports that these recommendations will be addressed in new calls for research proposals managed by DG Research. Already in the end of 2008 DG Research launched a call relating to analytical methods. The decision on which projects will be supported is on-going.

9. *What contribution might nanotechnologies make to wider food policy issues, such as sustainable farming and healthy eating? Does the Commission have any initiatives to encourage such developments in nanotechnologies?*

Analysts expect nanoscience and the nanotechnologies to make a number of valuable contributions to "wider food policy issues, such as sustainable farming and healthy eating." First, nanoscience empowered by observational and analytical tools such as Atomic Force Microscopes (AFMs) and Transmission Electron Microscopes (TEMs) and nanotechnology-enabled labs-on-a-chip advances our understanding of the behaviour of food as it is manufactured and in storage, of the assimilation and digestion of food in the body, of food intolerances, of individual dietary needs, etc. Addressing these issues, nanoscience and the nanotechnologies offer means to extract better essential nutrients, to monitor the production of food more accurately, to increase the safety of the food chain–in particular thanks to sensors, to make foods more digestible, to reduce or eliminate their allergenicity, to cater to individual dietary needs, etc.

Nanoscience and the nanotechnologies also exhibit great potential regarding filtration and water purification.

10. *The EFSA opinion recommended that the Commission should monitor the current and potential future uses of nanotechnologies in food—what measures are currently in place to allow the Commission to monitor the use of nanotechnologies in the food sector?*

In the area of Community competence pre-market approval is required before a new product is place on the market. Food business operators have the responsibility to comply with the law. For example, if a food additive is produced in the nanoscale it is considered as a new food additive which needs a new EFSA evaluation and authorisation. The enforcement of the Community legislation and the control are the competence of the Member States. In non-harmonised areas the Commission is investigating with food business operators and Member States the use of nanotechnologies in the food sector. However, as there are currently no validated and internationally recognised methods to detect nanomaterials in food, the possibility for the Member States to control imported foods or foods sold on the internal market is limited. Research programmes are underway to address analysis of nanomaterials in food.

11. *The Food Standards Agency informed us that the commission will begin work on an EU inventory of nanomaterials in 2009. Can you tell us what progress has been made with the inventory, and how "nano" will be defined? Will it be a voluntary or mandatory register?*

In the light of the debate in the EP on the Commission's Communication on regulatory aspects of nanomaterials, the Commission announced that it will present a report in 2011 providing general information on the types and uses of nanomaterials, including safety aspects. The forthcoming report will be based on results from different sources, including research projects, regulatory reporting (eg REACH, Regulation on Classification, Labelling and Packaging) and scientific literature.

12. *The Draft Report on Regulatory Aspects of Nanomaterials by the European Parliament Committee on the Environment, Public Health and Food Safety calls for a clear regulatory framework on nanomaterials that fully addresses the nature of potential safety problems relating to nanomaterials. Do you think that this is necessary?*

In its response to the EP resolution of 24 April 2009 on regulatory aspects of nanomaterials, the Commission indicated its intention to review relevant legislation and instruments of implementation, and report on this in 2011; regulatory change will be proposed where necessary.

13. *Does the Commission feel that the control of imported foods containing nanoparticles is adequate across Member States? How are imported foods assessed and monitored by the Commission?*

In application of the subsidiarity principle, the enforcement and control of foods is the responsibility of the Member States. Through the Rapid Alert System on Food and Feed, findings can be communicated to all Member States. For example the Finnish border control officers stopped on different occasions, a product that contained vitamin C in nanoform and a product that contained nanosilver, both on the basis of the non-compliance with the novel foods legislation. DG Health and Consumers has started a dialogue with the Member States at technical level on how Member States control nanomaterials in food.

14. *Does the Commission have any plans to engage with the public on this issue, or to conduct research on public perceptions of the use of nanotechnologies in the food sector? Is there any co-ordination of activities in this area between Member States?*

Involvement of citizens remains a priority for the Commission. It will pay particular attention to this aspect in the follow-up to the Commission's first Nanotechnology Action Plan, and look into mechanisms to bring the outcome of national initiatives to the European level, where issues require a follow-up at the European level.

22 October 2009

Memorandum by the Food Additive and Ingredient Association

Introduction

The Food Additive and Ingredient Association (FAIA) represents the UK suppliers of Food Additives and Ingredients—details of our association are appended to this Submission as an Annex.

We have been monitoring the development of nanotechnology for several years and as an innovative industry we support its use. We believe that, as for all new technologies, there should be a robust safety assessment covering both human health and environmental issues. It is our understanding that the existing regulatory system can be used to ensure this.

The use of nanotechnology in the food additive area is extremely limited at the present time and is mainly in the research phase. Consumer acceptance is essential if it is to develop further and this will only be achieved if there is an open debate between all parties.

State of the Science and its Current use in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

For food additives and ingredients the technology offers benefits in the method of delivery. It will enable improved coatings and encapsulating techniques.

In the area of packaging it can control gases and moisture thus reducing spoilage. This will enable higher quality products to be produced and reduce wastage.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

We are not aware of any food ingredient or additive deliberately produced using this technology on the UK market at the present time. There are a small number of ingredients which contain some nano size particles as a result of the standard production method, these have been on sale for many years and we have not considered them here.

We are aware of developments in the specialist supplement area where by the technology can be used to aid absorption and to deliver products without adverse taste effects.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

Like all scientific developments—nanotechnology will evolve over the years. The research is however often company based and when at an early stage subject to confidentiality and that FAIA would not have access to theses details.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

As in the previous question FAIA would not have access to this type of information.

What are the barriers to the development of new nano-products or processes in the food sector?

As stated in the introduction Consumer acceptance and hence use of the technology by the retailers and food manufacturers is essential. In the past beneficial technologies have been lost to industry due to their rejection by the consumer. The consumer needs to understand the technology and appreciate the advantages it can bring to them.

In addition the burdens placed on industry in bringing products to market need to be taken into account. Whilst it has to be a prerequisite of sale that the safety of these products be demonstrated, a lengthy and complex approval system will prevent all but the large manufacturers from entering the market.

Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector? In which areas does our understanding need to be developed?

In recent months there have been a number of reports published on this issue including those of the SCENIHR (Scientific Committee on Emerging and Newly identified Health Risks) and the IRGC (International Risk Governance Council). These set out the areas of potential uncertainty but do not always provide guidance or offer solutions.

Very recently the European Food Safety Authority (EFSA) has a published its opinion, which recognises that the established international approach to risk assessment can be used but that there are many uncertainties which require additional research and may require case by case considerations.

One area which has to be satisfactorily addressed is the Health and Safety aspects for workers handling nanoparticles.

Is research funding into the health and safety implications of nanotechnologies and nanomaterials in the food sector sufficient? Are current funding mechanisms fit for purpose?

Can current risk assessment frameworks within the food sector adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

The aforementioned reports do make some recommendations in this area but further work is required.

Are the risks associated with the presence of naturally occurring nanomaterials in food products any different to those relating to manufactured nanomaterials? Should both types of nanomaterials be treated the same for regulatory purposes?

Where naturally occurring nanoparticles are used in additive preparations they have already been assessed as part of the standard approval procedure. These are not considered by industry to be the products of nanotechnology and should be treated in a different manner.

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

As new legislation is enacted Nanotechnology is one of the factors considered and the EU regulatory program is extremely comprehensive.

Imported products also have to meet the EU requirements irrespective of their country of origin however we are unable to comment on the enforcement of this legislation with respect to imports.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

The Food Additive and Ingredients business takes its responsibilities in this area extremely seriously. In addition the General Food Law (EU Regulation 178/2002) requires Food Business operators to ensure that all food products placed on the market are safe.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

FAIA is of the opinion that the EU Regulatory framework is able to adapt to encompass new developments. In addition the existing Novel foods and packaging regulations are believed to already cover these products.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

We understand that there is an ongoing dialogue between the major players in this area.

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

We believe public awareness to be very low, even in non food areas where there are products on the market that confer consumer benefits such as sun screens.

There are a number of initiatives in this area, such as that undertaken by the Responsible Nano Forum but this is an important issue which requires greater emphasis.

How effective have the Government, industry and other stakeholders been in engaging and informing the public on these issues? How can the public best be engaged in future?

FAIA is not aware of any specific Government Initiative in this area. Any public debate has been driven by NGO's. A more comprehensive program is needed but this can only take place when products are available—see comments below.

The Association believes it is essential for Government to take the lead on a proactive public communication programme. The application of new scientific developments to public benefit has on previous occasions (such as Genetic Modification) been misrepresented by, or been the subject of biased reporting in, certain segments of the popular press and broadcast media. We strongly believe that clear messages from Government must be delivered to prevent such a hijacking of the popular press by the anti-science lobby on this occasion.

What lessons can be learned from public engagement activities that have taken place during the development of other new technologies?

The Consumer needs to relate the technology to products which confer a direct benefit to them and until such foodstuffs are available on the market it will be difficult to engage in a productive dialogue.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

Consumers should be provided with information about a product which is clear and factual. It should add to their understanding of the product to be purchased and should not be misleading.

11 March 2009

Memorandum by Dr Chris Groves, ESRC Centre for Business Relationships, Accountability, Sustainability and Society

1. *What is the public perception of nanotechnologies and food?*

It should be noted, first of all, that available evidence tends to suggest that awareness of the existence of nanotechnology in general has changed little from a low level a few years ago. For example, in 2006, 42 per cent of Americans surveyed had not heard of nanotechnology (Peter D. Hart Research Associates 2006), with this actually increasing to 49 per cent in 2008 (Peter D. Hart Research Associates 2008). As a result, evidence

of public concerns about different applications of nanotechnologies has generally only been available from deliberative exercises which include extensive briefing sessions to get participants "up to speed" with current and potential future developments. As a result of such exercises, there is evidence that participants often express significant concern about food applications, particularly where nanomaterials are actually present within foods rather than simply used within packaging materials. A survey for the Woodrow Wilson Institute indicates that only 7 per cent of Americans would buy nanofood now, with 29 per cent not wanting to buy it at all, and 62 per cent wanting more information on risks and benefits, vs 12 per cent, 73 per cent and 13 per cent for food containers (Peter D. Hart Research Associates 2007). Evidence from research in Switzerland suggests that people may be hesitant to buy foods which either contain nano-additives or use packaging which contains nanomaterials or nanostructures (Siegrist, Cousin *et al.* 2007). But research has also indicated that it is not so much "technologies" that are the subject of trust or mistrust, as the institutions whose are seen as having the responsibility to ensure that technologies are applied in ways which produce benefits and avoid risks. Survey data from Germany also indicates that mistrust of regulators and industry could be particularly significant with respect to nanofoods, as low trust of these groups is correlated with high rates of rejection of the use of nano-additives in food (Halliday 2007).

2. *What do you think should be the aim of public engagement? Is the aim of public engagement activities to encourage the dissemination of information and inform debate on the issue, or to help guide research agendas, and inform public policy?*

While dissemination of information is a vital need, in relation to emerging technologies it is vital to avoid projecting propositions about either risks or benefits of prospective technological applications as surrounded with certainty. The extent of uncertainties around both the EHS implications of specific applications and their social implications should also form a central theme of public engagement. Whatever forms public engagement activities take, they should, as far as possible, avoid positioning the public as merely a passive recipient of information (whether said information concerns actual/potential hazards or benefits). Research suggests that the often ambivalent responses of publics in deliberative exercises circle around what they suspect that scientists, business and regulators do not know and perhaps cannot know about the applications of nanotechnology. With this in mind, engagement needs to focus on how to build consensus around the purposes for which technologies can and should be used, and how much uncertainty (including, but not limited to, known and determinate risks) society is collectively prepared to bear in pursuit of these ends. This implies that engagement needs to have some degree of input into shaping research agendas and regulatory policy, even extending to passing judgement on the social legitimacy or otherwise of a given application.

3. *Submissions from Which? and others note the need for more government research on what the public think about the issues surrounding nanotechnologies and food, and for more effective consumer engagement specifically focused on food. Is the Government doing enough to understand public attitudes to food and engage the public on the issues surrounding nanotechnologies and food?*

In the UK, the issues surrounding nanotechnologies and food have to date been the subject of one of the "Nanodialogue" events (funded mainly through OSI's Sciencewise scheme, organised by Demos and the University of Lancaster), which produced a report in 2007. More research is undoubtedly needed, but this also needs to be framed within a more systematic and long-term vision for the purpose of public engagement (see responses to Qs 4 and 6 below).

4. *The Responsible Nanocode initiative has suggested the establishment of a permanent "Nano Commission" style organisation to engage stakeholders and advise government on issues. Do you support this suggestion?*

No. First of all, there are questions to be asked about such an organisation's remit, and whether it makes sense to, once again, attribute a specious unity to "nano". In operating, such a body would have to respect the vast degree of differentiation between different nanotechnologies and their applications. This is reflected in the different issues which affect businesses who operate within distinct industry sectors. There will be different potential benefits, risks and social concerns to consider for different sectors. Consequently, it would at least be necessary to organise different working groups under the aegis of such a Commission. Further, research has suggested issues of trust, risk and uncertainty, and social purposes are key to understanding how publics assess technological applications—these are not unique to nanotechnologies. With synthetic biology already been touted as "the next nanotechnology", it would make more sense to talk of an organisation whose remit was identified as eg "Emerging Technologies" or "Responsible Innovation, which would seek to situate broader processes of technological development in the context of multi-stakeholder debates over social priorities.

5. *Is it primarily the responsibility of Government to run public engagement activities? What public engagement work do you think industry should be undertaking, given that the BRASS Centre has noted that the industry have been criticised over the lack of transparency regarding the presence of nanomaterials in food and food packaging?*

While the Government will inevitably have an important coordinating, and to some extent, financing role to play, it is necessary for industry to assist in organising engagement programmes and events in conjunction with public and academic partners. There is no reason to expect that individual businesses that are not already involved in systematic proactive public engagement (mostly in the pharma sector, but also in some cases in the chemical industry, eg BASF) to undertake extensive activities. For smaller companies, costs are prohibitive and expertise lacking; for larger consumer-facing companies, such activities are often located "downstream" in the product development process. Instead, the setting up of sector-specific collaborative bodies should be undertaken (Leatherhead Food is, for example, already involved in such efforts for the food sector). Such efforts may assist with overcoming the barriers to communication which have been evident in the food sector, but also elsewhere. Such bodies would have an important role to play in eg engaging business in considering the benefits of wider stakeholder engagement.

6. *What are the ways, practices or mechanisms to integrate public views into research strategies to allow public opinion and concerns to inform future research priorities and directions? The EPSRC recently conducted some engagement activities concerning nanotechnologies and healthcare. Do you think that this is an example of good practice?*

In terms of its methodology and approach the EPSRC exercise appears to have benefited from some of the lessons presented in the NEG's report from 2007 (with the extent of uncertainty about benefits and risks being at the forefront of the debates. However, it is not clear from the report available from the EPSRC website (http://www.epsrc.ac.uk/ResearchFunding/Programmes/Nano/RC/ReportPublicDialogueNanotechHealthcare.htm) how far participants were informed about the purpose of the engagement exercise and what influence their participation might have on future research. Nonetheless, the specific application and case-study based approach used here provides a useful example of how such studies may be undertaken. More broadly, while individual exercises may represent examples of bad or good practice, it is arguably necessary to support whatever deliberative exercises are undertaken with a clear vision and commitment to systematic and iterative dialogue, with the possibility of allowing its focus to evolve as potential applications become more concrete. If planned and undertaken under (for example) the aegis of something like a "Commission for Responsible Innovation", such a longer term process might look to move from providing input on research priorities (with EHS and socio-economic research included alongside physical/life science work), to assessing the design of individual applications, to providing guidance on what (if any) limits should be drawn around technological development based on specific concerns (eg over the limits to privacy).

7. *What are the best ways/practices mechanisms to integrate public views and concerns into policymaking (upstream dialogue) to ensure that public opinion and concerns inform the regulatory framework?*

See response to (6) above.

8. *Do you think that products made using nanotechnologies or containing nanomaterials should be labelled at the point of sale, and do you think that this will be useful to consumers?*

Labelling may have a role in allowing customers to make informed choices about the products they purchase, and may be seen as part of a response to moral issues which surround the marketing of products where uncertainties surround the possibility of harmful effects. However, reliance on labelling alone as a means of providing information to consumers is highly problematic, as it shifts questions about the social acceptability or legitimacy of a product very far downstream. Current public awareness of nanotechnologies is at low enough a level that such a measure would arguably not give consumers much useful information. It is far more important that industry and regulators should pursue openness and transparency through other avenues. If such a strategy is pursued, it should be undertaken only with coordinated information support, eg a website (funded perhaps by the EU) which outlines the state of the art with respect to EHS assessments of given ingredients, with transparency about the current limits to knowledge (with the URL provided prominently on the label). The objections made by cosmetics companies to the usefulness of labelling are in this respect quite valid. There is, for example, a distinction to be made between eg products which contain fullerenes and ones which contain nanoscale TiO_2, but simply requiring all such products to carry a "nano" label would go against the need to reflect the variousness of nanomaterials. Labelling has a vital role in setting the conditions for informed consent, but it must be located carefully within an overall strategy which has better upstream engagement for its basis.

9. *The Government has stated in its response to the Royal Commission of Environment Pollution's report on Novel Materials that it has now commissioned a pilot initiative "to provide public access to a balanced source of information on nanotechnologies, including research, products and regulation". The pilot will be based around an interactive website. Do you think this would be useful? What additional information should be provided to consumers this way?*

Yes (see response to Q.8 above). Part of the "balance" any such resource should manifest would have to include, as mentioned previously, discussion of the current limits to knowledge. This would mean that the website would have to be viewed as an aid to reflection about nanotechnologies (and technologies) more widely, rather than simply being about "what nanotechnologies are", what they "will" do to shape the future, and "what risks there are". It would have to be viewed as a resource for opening up and supporting critical reflection, rather than a sort of nano FAQ. For example, to support such an approach, it would also arguably be necessary to provide resources to illustrate how far, in other areas of our lives, we deal with difficult-to-assess risks and open uncertainties (to encourage people to think about why, for example, they are happy to own and use a mobile phone despite continuing EHS uncertainties).

10. *The FSA is currently considering developing a register of nano-derived foods and food contact materials. Do you think such a register would be justifiable and helpful? Do you think it should be voluntary or mandatory?*

Such a register would be useful, but only if (i) due consideration is given to how it can best be developed as part of an integrated approach from government both to the dissemination of information and consultation, and (ii) thought is given to how such a register can be supported to ensure wide compliance. In other words, neither asking for submissions, nor requiring them, can by itself be a solution. It would arguably be necessary, for example, to accompany such an initiative with new institutional arrangements of the kind mentioned above in response to Qs 4, 5 and 6 above, in order to secure both public and industry assent. The nature of the register itself would also need careful consideration: would it simply be a database of products and manufacturers, or would it also provide information on characterisation of materials, the extent of relevant toxicology, and so on? The more information that is required, the more costly compliance would be, which would of course disincentivise both larger and smaller companies from pursuing food nanotechnologies. Any new regulatory measures therefore need to be accompanied by reflection on how best compliance can be supported (with eg incentives of access to expert advice, or even grants to aid compliance activities or seed money for collaborative research between companies or between companies and academia). Should an adequately supported scheme be made possible, then incentivised voluntary compliance followed by mandatory compliance after a suitable period (eg two years) might be appropriate.

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June 2009

Memorandum by the Dr Hadwen Trust for Humane Research

Introduction

The following comments on nanotechnologies and food are submitted by the Dr Hadwen Trust for Humane Research.

The Dr Hadwen Trust is the UK's leading medical research charity that funds and promotes exclusively non-animal techniques to replace animal experiments. Our vital work benefits humans with the development of more relevant and reliable science whilst also benefiting laboratory animals. We believe that excellence in medical research and testing can and should be pursued without animal experiments. Our organisation has 38 years' experience of funding high-quality, peer-reviewed and innovative research aimed both at advancing medical progress and replacing procedures on animals.

We very much appreciate the opportunity to comment on this paper, and believe that as a research organisation dedicated to replacing animal tests (as well as the use of animals for other experimental purposes), our specific scientific expertise in the fields of toxicology and human health are relevant to this topic.

We hope that our comments will be considered useful and constructive.

Dr Hadwen Trust Comments

1. The current uncertainties for risk assessment of nanotechnologies and their possible applications in the food and feed area, as well as in other areas of use, arise due to the presently limiting information in characterisation, detection and toxicology data. This view was also echoed in the recent scientific opinion produced by the European Food Safety Authority on the potential risks arising from nanoscience and nanotechnologies on food and feed safety.[1] We are also aware of the lack of knowledge surrounding the current usage of engineered nanomaterials (ENM) and therefore exposure to such products is an area requiring immediate attention.

2. Whilst recognising that the currently used risk-assessment paradigm is applicable for ENM our concerns regarding proposed guidance for risk assessment of ENM in food and feed area centre around the acceptance of conventional toxicity testing methods to be used in identification of ENM hazards. We are of the opinion that additional issues specific to ENM need to be addressed due to the different properties displayed by ENM when compared to the bulk-form material,[2] as well as the differences likely to arise when storage and production methods are different, and this will require use of new test methods as well as new criteria by which the validity of such methods should be assessed. We also believe that assessment of ENM should be based on a case-by-case approach and that current testing strategies are not adequate for ENM and do not represent the most scientifically robust methods to employ. As with the cosmetics sector, it will be extremely difficult in the food and feed industry to characterise ENM and current guidelines do not specifically address ENM. Until methods are in place to properly determine the behaviour of ENM in living organisms and make careful and informed risk assessments, it is hard to see how regulators or companies are in a position to assert that ENM in food or feed products are safe.

3. We feel that it is more appropriate in the case of nanomaterials for companies to take a precautionary approach by avoiding exposing workers, consumers or the environment to these forms of substances. We do not believe clear commercial and societal drives to produce and market the many new and exciting nano-containing applications should overtake the fundamental requisite to protect human and environmental health and safety.

4. In a recent scientific opinion produced by the European Food Safety Authority on the potential risks arising from nanoscience and nanotechnologies on food and feed safety they concluded that engineered nanomaterials should be assessed on a case-by-case basis. It was also concluded that current toxicological methods may need methodological modifications which may include observing additional toxic effects and endpoints as well as developing, improving and validating *in silico* and *in vitro* test methodologies.[3] We wholly agree with the recommendations into furthering the currently limited knowledge and understanding of ENM behaviour and toxicokinetics through *in silico* and *in vitro* methodologies, as suggested by EFSA. However, we do not support the assumption that *in vivo* studies can be modified so that they accurately predict effects of EMN on human health or the environment for reasons set out below.

For these reasons the Dr Hadwen Trust recommends that for non-essential, non-medical applications (including cosmetic and household products, sporting equipment, textiles, food, feed and paints), ENM manufacture and use is prohibited immediately until relevant non-animal and nano-specific safety testing and risk assessment protocols are in place.

5. In a recent publication by the Royal Commission on Environmental Pollution it was acknowledged that "…the scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available at this point in time".[4] In accordance with this the Dr Hadwen Trust further believes that animal testing of nanomaterials is scientifically highly questionable. We would prefer to see an acknowledgement that, in concordance with the mention that some specified *in vitro* methods are not yet validated, existing animal tests are also not validated for this application (indeed, in some cases, existing animal tests have not been formally validated to modern standards for any application), and greater emphasis to be placed on the development, validation and use of non-animal test methods.

[1] EFSA (2009) The potential risks arising from Nanoscience and Nanotechnologies on Food and Feed Safety. Scientific opinion of the Scientific Committee.
[2] SCENIHR (June 2007) The appropriateness of the risk assessment methodology in accordance with technical guidance documents for new and existing substances for assessing the risks of nanomaterials.
[3] EFSA (2009) The potential risks arising from Nanoscience and Nanotechnologies on Food and Feed Safety. Scientific opinion of the Scientific Committee.
[4] Royal Commission on Environmental Pollution (2008) Novel materials in the environment: the case of nanotechnology.

6. Animal tests have limited value because of their inherent uncertainties.[5] These include the difficulties of extrapolating test data between species, genders and breeds of animals including humans (due to anatomical, physiological, biochemical, metabolic and pharmacological differences). There are major uncertainties in interpreting information from high-dose animal tests with single chemicals in ways that are relevant to low-dose human exposures to chemical cocktails. There are also problems with mimicking human routes of exposure in animal tests, and with scaling up from small animals with a short lifespan to larger humans who may be exposed to chemicals over decades. Even for data-rich chemicals, these uncertainties often delay rather than facilitiate regulatory decision-making, prolonging risks of damage to human health and the environment.

7. With a new field such as nanomaterials, the full range of potential toxicities is not known. Using standard animal toxicity tests, which are little more than "black box" methods, would risk overlooking novel unwanted effects. Human cell-based assays, in contrast, would allow the study and elucidation of a range of molecular and cellular mechanisms of toxicity. For example, human cell culture assays can be used to monitor the oxidative stress responses of cells exposed to nanoparticles.

8. There are a number of non-animal techniques currently being developed that represent a potential for nanomaterial safety testing. For example, perfusable 3D cell-matrix chambers for testing nanoparticle permeability and transport through tissues;[6] and the HμREL device,[7] which allows the toxicity of nanomaterials to be tested on several cell types in a multi-chambered microchip with a microfluidic channel, represent promising *in vitro* methods.

9. Human cell culture techniques have provided useful information on specific cellular responses to nanomaterials by measuring chemical responses[8] or responses at the DNA level using biomarkers and genomic techniques.[9] The feasibility of analysing *in vitro* nanomaterial activity in a general, systemic fashion has also been demonstrated using a multidimensional profiling approach with multiple cell types and assays reflecting different aspects of cellular physiology.[10] The data are then clustered using computational methods to identify nanomaterials with similar patterns of biological activity across a broad sampling of cellular contexts, as opposed to sampling from a single assay. This approach yields robust and detailed structure-activity relationships. Additionally, interesting alternative tests are already being developed by EU-funded Joint Research Centre projects such as Nanotox, which involves human cell culture techniques.

We hope that the House of Lords Select Committee will recommend that funding be made available for further research intended to result in creation of nano-specific non-animal test methods that have a clear regulatory applicability. Sadly, it appears to be the case that some potentially useful research in this field is not sufficiently targeted to meet genuine regulatory needs, and we would suggest that regulators or researchers with knowledge of the regulatory environment are required partners in any publicly funded research intended to produce new test methods.

10. In summary, human-relevant non-animal assays offer several advantages: using human cells or sub-cellular components they avoid species differences, and high-throughput systems allow the very rapid and cost-effective testing of multiple chemicals and multiple toxic endpoints, including novel ones. A moratorium should be introduced on all non-essential uses of ENM. This will ensure the protection both of human health and environmental safety, as well as fulfilling citizens' wishes to maintain high animal welfare standards[11] and prohibit unnecessary laboratory animal use, especially with inhumane and misleading methods.

March 2009

Memorandum by Professor Geoffrey Hunt, St Mary's University College, London

Certificant of the Institute of Risk Management, Professional Fellow of the Institute of Nanotechnology. Currently engaged in two FP7 (EU) nanotechnology projects, and in BSI/CEN nanotechnology standardisation initiatives. Co-author of book: *Nanotechnology: Risk, Ethics & Law*, Earthscan, London, 2006, 2008.

[5] Langley, G (2004) Chemical Safety and Animal Testing: A Regulatory Smokescreen? BUAV report, 35pp. Report available from the Dr Hadwen Trust.
[6] Ng, C and Pun, SH (2007) A perfusable 3D cell-matrix tissue culture chamber for in situ evaluation of nanoparticle vehicle penetration and transport. Biotechnology and Bioengineering 99:1490–1501.
[7] www.hurelcorp.com
[8] Lin W, Huang Y, Zhou X, Ma Y (2006) In vitro toxicity of silica nanoparticles in human lung cancer cells. Toxicology and Applied Pharmacology 3, 252–259.
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[10] Shaw SY, Westly EC, Pittet MJ et al (2008) Perturbational profiling of nanomaterial biologic activity. PNAS 105, 7387–7392.
[11] http://ec.europa.eu/environment/chemicals/lab_animals/pdf/results_ citizens.pd

Submitted on an Individual Basis

As a specialist in risk and ethics I would simply like to point out the following:

At the nanoscale, technological innovation for applications faces unprecedented complexity and uncertainties which impinge on all aspects of the nanotechnological research and development. This set of technologies has the power to transform our industry, play a part in overcoming our severe environmental issues and create new opportunities for recession-busting investment. It must be supported.

However, the real opportunities are in strong lightweight materials, industrial catalysts, energy, insulation, electronics and the like. There are gains to be had in nanomaterials for storage of food, but nanotechnology for food and drinks additives are a very low priority and too risky at our current state of knowledge. These should be the last to develop once we have gained understanding of nanoscale interactivity in other areas of theory and applications development.

To give some examples. It is not clear ….

(1) that nanoscale ceramics in PET (plastic) bottles, now widely in use, do not leach into the drink and if they do what the long term consequences would be for consumer health;

(2) whether nanoscale additives such as Silver, useful as anti-pathogenic agents, are not cumulatively toxic to humans; and

(3) whether the ability of some nanoparticles to pass through the protective biological barriers such as the blood-brain barrier, the retinal barrier and the fetal (placental) barrier does not pose cumulative risks for human health.

There are countless other questions that currently have no clear answer, but many "nano" food-related products are already on the market without the innovative risk assessment which is appropriate for a new technology with unknown risks, and without any requirement for the labelling which the public would expect.

In this situation it is incumbent on the UK government to ensure that the food industry acts in accordance with the Precautionary Principle, which it has signed up to (Commission of the European Communities, Brussels, 2.2.2000, COM [2000] 1 final Communication from the Commission on the precautionary principle. Attached [not printed].) It is not impossible that any future mass tort may rebound on the UK government.

12 May 2009

Memorandum by the Institute of Food Science and Technology

Introduction

1. IFST, the professional qualifying body of food scientists and technologists, has concerned itself with nanotechnology for many years and has produced a comprehensive Information Statement.[12]

2. IFST supports the use of nanotechnology where it is/will be beneficial to consumers in terms of product safety, quality and economics; these benefits may derive directly from food products themselves or from indirect food applications such as those indicated in more detail below.

3. Where application of nanotechnologies results in changes to existing products or processes, and it may be anticipated that new risks to human health or the environment may arise, IFST believes there will be a need for an adequate safety assessment, on a case-by-case basis.

4. IFST believes that it is possible to adapt the existing regulatory system to deal with new scientific evidence on engineered nanoparticles as necessary.

5. Nanoscience and nanotechnology are about understanding and engineering materials at the molecular or atomic level, and generally concern materials with one or more dimensions that are 10–100 nanometres or less. In this size range, the behaviour of materials begins to change. Some foods already contain natural nanoparticles but this submission will focus on engineered nanomaterials (ENMs).

6. Making materials smaller does not just lead to an increase in compactness, preciseness, or refinement of their structure and properties; it may lead to significant changes in properties. Due to its small size, high surface-to-mass ratio and surface reactivity, an ENM may have changed physico-chemical characteristics as compared to the dissolved and micro/macroscale forms of the same substance. These changed characteristics may have an important bearing both for potential beneficial food-related uses by permitting applications that might not otherwise be possible but, conversely, may also pose potential health and environmental risks.

[12] Nanotechnology (2006): http://www.ifst.org/uploadedfiles/cms/store/ATTACHMENTS/Nanotechnology.pdf

7. Any new technology has risks. Policy should go beyond just benefit/risk analysis. Where the potential benefits are significant, it should identify the hazards and encourage research and measures to eliminate unacceptable risks.

State of the Science and its Current use in the Food Sector

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

8. Many traditional methods of processing or cooking foods work through modifying naturally-occurring nanostructures within foods, or generating new nanostructures through tried and tested processes. Studies of nanoscience of food materials will lead to better understanding of such processes, better selection of raw materials and rational improvement in the processing of food materials.

9. The potential use of ENMs in food-related applications include: direct use of ENM ingredients and food additives; nano-encapsulation of flavours or other ingredients to give improved quality; improved emulsions and emulsion delivery systems; new, highly-selective filtration and separation techniques; use of packaging materials containing ENMs to provide improved product protection from external degradation factors and enable significant weight reduction; ENM cleaning materials: ENM food contact surfaces: development of new sensors for diagnostic use and to provide consumers with "real time" information about individual food products. These uses could potentially lead to the design of foods to address obesity, target chronic diseases, provide improved bioavailability of nutrients in foods, better food stability, reduced waste and improved food hygiene and food safety.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

10. In the absence of a universal definition of "nanomaterials", it is not possible to give a definitive answer to this question. Not only is the definition related to particle size but it must also be considered in relation to the proportion of a product's size distribution that has to fall below, say, 100nm in order for the product to be considered as "nano-containing". We will restrict our comments to those techniques and applications where the particle size has been deliberately engineered to possess properties and functional behaviour that differ from its conventional counterpart. We will not consider, therefore, the natural occurrence of nano-sized particles such as in protein, fat or sugar molecules/micelles, or the presence of a very small tail of nano-sized particles in the size distribution derived during conventional processing techniques such as emulsifying and milling.

11. IFST is not directly involved in the manufacturing or sale of food products but we believe that there are only a very limited number of food products currently on the market that contain ENM. We understand that the use of packaging such as plastic bottles is increasing, as is the use of nano-separation/nano-filtration. Although there are several databases claiming to list products that contain nanoparticles, we would urge caution over the use and interpretation of these. There are also products where the "marketing platform" claims "nano" in various forms but, when examined more closely, many of these claims do not withstand scientific scrutiny.

12. Amongst the small number of products on the UK/EU market that can be regarded as "genuine nano" are a laminated plastic bottle which incorporates clay nanoparticles as a gas barrier; a food supplement using a nano-encapsulated ingredient; a number of calcium/magnesium mineral ingredients and a form of silicon dioxide in which a proportion falls into the nanoscale and which has long been used as an "anti-caking agent" to facilitate the handling of powder mixes. We are aware of developments in oil-in-water and water-in-oil emulsions comprising micelles, into which ingredients such as fish oils can be encapsulated (to avoid unpleasant taste/smell); we understand a "light" oil (water in nano-emulsified droplets of oil) is also available, but not as yet in the UK.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

13. IFST is not aware of near-commercial developments other than those covered by the principles of the applications outlined above. Potentially, nano-sensors can be envisaged that would permit improved monitoring and quality control throughout the supply chain, eg temperature control and other external adverse influences. Targeted delivery of fertilisers, crop pesticides and veterinary medicines will also be increasingly feasible.

What is the current state of nanotechnologies research and development in the UK and how does it compare to research being carried out in other countries?

14. Whilst much nanoscience and nanotechnology research is not specifically food-related, it may nevertheless result in applications relevant to food. In the UK, the Institute of Food Research (IFR) is in the forefront, together with the Universities of Leeds and Nottingham.

15. Many major food companies are monitoring or researching the potential benefits of nanoscience in food. Much of their work is covered by commercial confidentiality; some are more willing to discuss this aspect of their research than others, so it is difficult to assess their precise level of interest and activity. Kraft Foods started the first nanotechnology laboratory in 1999 and its "Nanotek" consortium, involving 15 universities worldwide and national research laboratories was established in 2000. Both Unilever and Nestle are known to have research topics involving potential uses of nanotechnology. The food department at Rutgers University in New York appointed what is believed to be the first professor of food nanotechnology. However, it is generally recognised that leaders in the field are USA followed by Japan and China. The USA's 21st Century Nanotechnology Research and Development Act, passed in 2003, allocated approximately $3.7 billion from 2005–08, compared to an expenditure of $750 million in 2003. In Europe, current funding for R&D in nanotechnology is believed to be around €1 billion, much of which is funded through national and regional programmes.

16. In the UK, following the joint Royal Society and Royal Academy of Engineering Report[13] a Research Co-ordination Group was set up to focus research on regulatory gaps and needs, and to promote dialogue with international organisations. Funding for research was to come from current allocation to government departments and research councils. The reports of the group would be peer reviewed and placed in the public domain. In March, 2008, a UK government statement by the Group was published[14] and Periodic Reports of this Group have appeared on the Defra website.[15]

17. Defra's Government initiative on Micro—and Nano-Technology Manufacturing offered £45 million in support of commercial applications between 2003–09. FSA is funding two research projects to assess safety implications of ENMs used in food packaging and as food ingredients or additives.

What are the barriers to the development of new nano-products or processes in the food sector?

18. This question falls more to those responsible for commercialisation of any developments but IFST can identify a number of key issues. Consumer acceptability of nanotechnology products will be essential. There is a long history of distrust by consumers when new technologies are applied to food and food processing (well before BSE and GM, c.f. objections to pasteurisation and irradiation). This distrust is increased when the technology is difficult to understand and/or the benefits to them, as consumers, are not immediately apparent. It is further magnified when the science and technology is the subject of alarmist and unbalanced media coverage.

19. Conversely, IFST would highlight the "hype" promulgated by certain sectors that makes it difficult to distinguish between genuine nanotechnology applications and over-the-top advertising and which, understandably, therefore breeds a degree of cynicism among consumers (*see para 11*). IFST strongly advocates greater transparency and openness between all stakeholders so that all parties are better informed about the technologies, their applications and, most importantly, their benefits and potential risks. In the case of the latter, it will be essential to be fully open and transparent.

20. We are aware of the regulatory hurdles faced by a business in bringing any genuinely novel product to the EU market, the immense direct costs involved to develop and progress a submission and the indirect commercial costs incurred by the lengthy timescales involved. Notwithstanding (and fully recognising) the paramount need to establish consumer safety, these hurdles must be addressed if nanoscience and nanotechnology are to play their part in a competitive economy.

[13] The Royal Society and Royal Academy of Engineering (2004); Nanoscience and nanotechnologies: opportunities and uncertainties. http://www.royalsoc.ac.uk/
[14] www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf
[15] www.defra.gov.uk/environment/nanotech/index.htm

Health and Safety

What is the current state of scientific knowledge about the risks posed to consumers by the use of nanotechnologies and nanomaterials? In which areas does understanding need to be developed?

21. We should always be alert to the potential risks associated with the applications of technologies, especially new ones, and balance these against tangible benefits that the technology will bring. However, any target of zero risk is a false goal; there is no such thing in any aspect of life.

22. It cannot be generically assumed that a given ENM is safe based on previous risk assessments carried out on the corresponding macro—or micro—substance. Individual ENMs need to be risk assessed, on a case-by-case basis, as if they were novel substances. This will require more knowledge to characterise the ENM, more toxicological data and knowledge of usage levels and likely exposure from possible applications and products. While current toxicity-testing approaches used for conventional materials are a suitable starting point, their adequacy to detect all aspects of potential toxicity of ENMs has yet to be established. Toxicity-testing methods may need methodological modifications.

23. SCENIHR[16] and EFSA[17] both describe the uncertainties regarding toxicology and potential new risks associated with nanoscale materials. In view of the recently-revised framework of EU legislation on additives, flavourings etc and the ongoing review of the Novel Foods Regulation, it will be essential for clear guidance to be available to all parties on how these uncertainties are to be addressed if/when innovative products are to be evaluated prior to launch.

Can current risk assessment frameworks adequately assess the risks of exposure to nanotechnologies and nanomaterials for consumers? If not, what amendments are necessary?

24. The recently-published SCENIHR Report and EFSA Opinion address this question.

Are risks associated with the presence of naturally-occurring nanomaterials any different to those relating to manufactured nanomaterials? Should both be treated the same for regulatory purposes?

25. IFST has restricted this commentary to techniques and applications where the particle size has been deliberately engineered to possess properties and functional behaviour that differ from its conventional counterpart. We do not consider as "nanotechnology", therefore, natural occurrence of nano-sized particles such as in protein, fat or sugar molecules/micelles, or the presence of a small tail of nano-sized particles in the size distribution derived from conventional processing techniques.

26. *We suggest that there are 3 types of nanomaterials: (i) naturally-occurring, (ii) adventitiously present in conventional materials and (iii) deliberately engineered to confer novel properties (and, hence, might pose different risks). We consider it is impossible to regulate/legislate for naturally-occurring materials such as are present in milk and very difficult to legislate where the nanoscale material is adventitious; we question how such presence would be defined/identified/quantified or legal constraints be enforced?*

Regulatory Framework

Is the regulatory framework for nanotechnologies and nanomaterials fit for purpose? How well are imported food products containing nanotechnologies and nanomaterials regulated?

27. The regulatory framework for nanotechnology was fully evaluated by both FSA[18] (food applications) and the European Commission[19,20] (all applications). Both concluded that there were no major gaps but identified shortfalls in the toxicological knowledge on which risk assessments would be based.

28. We generally concur with the findings of both FSA and the Commission, but have a number of additional points which we describe below.

[16] SCENIHR: Risk assessment of products of nanotechnologies, 19 January 2009: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf

[17] EFSA: Scientific Opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. The EFSA Journal (2009) 958, 1-39. Available at: http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/sc_op_ej958_nano_en,0.pdf?ssbinary=true

[18] FSA Review of Potential Implications of Nanotechnologies for Regulations and Risk Assessment in relation to Food (2008): http://www.food.gov.uk/multimedia/pdfs/nanoregreviewreport.pdf

[19] COM(2008) 366: Commission Communication: Regulatory Aspects of Nanomaterials: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0366:FIN:EN:PDF

[20] SEC(2008) 2036: Regulatory Aspects of Nanomaterials: Summary of legislation in relation to health, safety and environment aspects of nanomaterials, regulatory research needs and related measures: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2036:FIN:EN:PDF

29. It is currently very difficult, if not impossible, to detect, measure or quantify ENMs in food matrices but we are aware of work at NPL in this area. Although most agree that the existing regulatory structure is applicable, without an appropriate enforcement regime underpinned with sampling and robust quantitative analysis, written regulations are of limited value *per se*. It remains an open question how legal constraints on the use of individual ENMs would be enforced (eg against imports) and, in particular, whether any such enforcement regime that would, in all probability, have to be based on paper traceability would satisfy consumers as to its rigour (c.f. GMO legislation).

30. Numerous Regulations and Directives provide a comprehensive regulatory framework but, in view of the identified deficiencies in the toxicological science on which they depend, need to be supported by appropriate guidance on their application to nanotechnologies and ENMs if they are to remain fit for purpose. Although most potential food-related uses of nanotechnologies are covered by some form of prior-approval process, the legislation is potentially deficient in apparently failing to distinguish ENMs of food-approved materials and permitting their use, based on safety guidelines and evaluations produced for macroparticles. In the absence of specific requirements for ENMs to be formally cleared as novel ingredients, food additives or food contact materials, or to indicate their presence on food labels, replacement of already-permitted macroscopic materials with ENMs of the same chemical composition (albeit limited to date) appears to have been considered as a simple formulation change.

31. The safety of *novel foods and food ingredients* is currently regulated by the EU Novel Foods Regulation 258/97. However, current mechanisms may not be wholly appropriate for ENMs, particularly where the parent material already has an established history of food use. However, Regulation 258/97 is being revised and the ongoing trialogue between the EC, EP and COREPER is seeking mutually-acceptable wording to bring ENMs specifically into the revised Regulation. It will then be essential to update Recommendation 97/618/EC, which provides the framework under which the scientific safety assessment is performed, to provide suitable guidance to the risk assessors to take into account the extent of prior knowledge of the individual materials and any uncertainties around their toxicology at the nanoscale.

32. ENMs intended for direct *food additive use* should be considered under the framework of Regulations (EC) No 1331/2008 and 1333/2008 and be assessed either as novel additives or, where the macro-material is already approved, through amendments to appropriate purity criteria. Under the general provisions of the Regulations, safety of any new additive must be assessed by EFSA. However, it is not obligatory for the Commission to seek EFSA's opinion if amendments to the purity criteria or specification of an existing approved material are sought and the changes are not liable to have an effect on human health. Recognised deficiencies in current knowledge on the toxicology of nanomaterials may expose this as a potential loophole.

33. Where ENMs are being used in *packaging and other food contact materials* (FCM), this appears to rely on clearance given to the use of the macroscopic material. The potential risk involved in the use of such materials will be negligible if it can be shown that minimal leaching of ENMs into relevant foods will occur. Although appropriate migration tests will have been done for FCM containing macroscopic additives within the existing regulatory framework, it is not clear whether additional tests have been carried out, related specifically to the use of ENMs.

34. The use of ENMs in food contact materials should be assessed within Regulation 1935/2004. This applies to all materials which are intended to come into contact with foodstuffs such as all types of packaging, bottles (plastic and glass), cutlery, domestic appliances and even adhesives and inks for printing labels. It provides for the establishment of a positive list of authorised substances, within specific legislation for each type of food contact material, and requires that new substances for food contact use must be authorised, following consideration by EFSA in respect of their potential toxicity. This Regulation will be of particular importance if/when nanotechnology food processing surfaces are introduced more widely. Furthermore, this Regulation also establishes requirements relating to the traceability of food contact materials from production to sale.

How effective is voluntary self-regulation either in the UK or EU or at an international level? What is the take up by companies working in the food sector?

35. Defra has operated a voluntary notification scheme but we understand uptake was limited.

Will current regulations be able adequately to control the next generation of nanotechnologies and nanomaterials?

36. Subject to the comments above, IFST considers the regulatory framework to be adequate but needing updated supportive guidelines to address uncertain toxicology underpinning risk assessment.

Is there any inter-governmental co-operation on regulations and standards? What lessons can be learned from regulatory systems in other countries?

37. The European Commission Seventh Framework Programme has adopted the "Nanosciences and Nanotechnologies: An Action Plan for Europe". This defines a series of interconnected actions for the immediate implementation of a safe, integrated and responsible strategy. Whilst not inter-governmental, BSI developed several Publicly Available Specifications and Guidance Documents which we understand to be under consideration for wider, international adoption by CEN.

Public Engagement and Consumer Information

What is the current level of public awareness of nanotechnologies, and the issues surrounding the use of nanotechnologies and nanomaterials in the food sector? What is the public perception of the use of such technologies and materials?

38. The Royal Society and RAE Report commented that the general public had begun to voice concerns about possible long-term side effects associated with nanotechnology and stated the importance that, before nanoparticles are used in foods and food-related materials, the relevant safety information is available within the public domain. The report further commented that without a considered approach, there is a risk that potential benefits of nanotechnology might be lost if, as with genetic engineering, consumers feel the technology is being imposed without warning, adequate perceived need or understanding of potential risks and benefits, and appropriate mechanisms for its control.

39. The Department of Innovation, Universities and Skills (DIUS) funded two "public engagement" activities, Nanodialogues and Nanotechnology Engagement Group[21,22] The Second UK Government Research Report[23] "Characterising the Potential Risk posed by Engineered Nanoparticles" (December, 2007) claimed that "The UK is ahead of other countries in engaging the public in nanoscience. Few such initiatives have taken place elsewhere".

40. In 2008, the German Federal Institute for Risk Assessment[24] stated: "As confirmed by BfR surveys, consumers expect nanotechnologies to simplify their daily lives. They mostly think of cleaning products, impregnating agents and functional textiles. By contrast, they are more sceptical about nanoparticles in food."

41. We note that the same lobby groups which stirred up unwarranted public concerns about the safety of foods and ingredients derived from GM crops are attempting to do the same for nanotechnology.

Should consumers be provided with information on the use of nanotechnologies and nanomaterials in food products?

42. IFST strongly advocates greater transparency and openness between all stakeholders so that all parties are better informed about the technologies, their applications and, most importantly, their benefits and potential risks. In the latter case, it will be essential to be fully open and transparent.

43. Current food labelling legislation specifically requires the names of ingredients to indicate details of their physical condition or any treatment which they have undergone, where omission of such information could mislead a purchaser. Whilst interpretation of this requirement is necessarily subjective, it could be argued that the name of an ingredient used in ENM form should be qualified accordingly. The key legal counter-argument would be whether the absence of such information could mislead a purchaser; IFST recognises that views on this will be highly polarised.

44. Similarly, legislation requires food additives to be identified either by name or designated E-number. In some cases, the E-number is sub-divided according to the origin and final form of the additive. This scheme has the potential, if required for consumer information, to be extended to encompass nanoscale additives.

Additional References not Quoted Above

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[21] www.bbsrc.ac.uk/society/dialogue/activities/nanodialogues_report.pdf
[22] http://www.involve.org.uk/assets/Publications/Democratic-Technologies.pdf
[23] www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport07.pdf
[24] German Federal Institute for Risk Assessment (2008): Nanotechnology in the focus of consumer health protection. http://www.bfr.bund.de/cd/27077

UK Government (2007); Second Research Report "Characterising the Potential Risks posed by Engineered Nanoparticles" www.dius.gov.uk/policy/documents/statement-nanotechnologies.pdf

March 2009

Memorandum by the Institute of Nanotechnology

Please see also the attached report from the observatoryNANO project, written by IoN staff. [Not printed]

STATE OF THE SCIENCE AND ITS CURRENT USE IN THE FOOD SECTOR

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

Includes processes to encapsulate chemical compounds within foodstuffs (such as vitamins, minerals, flavours, aromas) and protect them from degradation before consumption (eg moisture, oxygen) or allow them to be absorbed better by the gastro-intestinal tract. Such processes include nano emulsions, liposomes, solid lipid nanoparticles. This has the benefit of adding nutritional value to processed foods. Other advances are in packaging where nanocomposite materials can increase gas barrier properties thus helping maintain the desired environment of the packaged foodstuff (eg prevent fizzy drinks going flat, reduce the rate of food spoilage). For food production, coatings of nanostructured materials can help prevent microbial build-up and fouling of machinery.

What is the current state of the market for, and the use of, food products and food production processes involving nanotechnologies or nanomaterials, either abroad or in the UK?

Packaging materials containing nanoclays are being used by a number of companies, including Miller Brewing, for bottles, coatings on paperboard, and films. Such materials are manufactured by companies such as Bayer (Durethan), Honeywell (Aegis), and Nanocor (Imperm). There are a number of companies manufacturing delivery systems for nutrients such as Aquanova (based in Germany—most of the others are outside the EU). Several companies within the EU manufacture nanostructured coatings and filtration systems that could have applications in the food processing industry, including ItN Nanovation, SuSoS AG, Few Chemicals GmbH, Sarastro GmbH, NanoGate and Aquamarijn Micro Filtration bv.

What might the "next-generation" of nanotechnologies and nanomaterials look like? How might they be applied in the food sector, and when might they enter the market?

There is much research into next generation biodegradable polymers for packaging purposes. The rationale is to use materials that would normally be regarded as waste (eg stalks from cereal plants), process the cellulose into nanostructured material and combine with other materials such as nanoclays to provide a robust composite that can be composted at the end of its useful life. For foodstuffs we will see evermore ingenious emulsion technologies, allowing multiple nutrients/minerals to be stably incorporated in different foodstuffs according to their solubility, and we will see lower fat, lower salt and lower sugar processed foods, that from the consumer's perspective will still taste the same. These could be expected on the market within the next 10–15 years.

What is the current state of research and development in the UK regarding nanotechnologies and nanomaterials which have or may have an application within the food sector? How does it compare to research and development in other countries?

With the exception of Unilever and Leatherhead Food International, most industrial research on nanotechnology applications in agrifood takes place outside the UK, eg Germany (Bayer, BASF, Evonik). The hubs of academic research are Netherlands (Wageningen, NIZO) and US (Uni Mass, Rutgers, Rensselaer, Georgia Tech). In the UK we've have excellent polymer (eg University of Sheffield) and sensor research (eg University of Strathclyde) for food applications.

What are the barriers to the development of new nano-products or processes in the food sector?

For food additives, the main barrier is consumer acceptance. The reality is that we all rely (at least partly) on processed foodstuffs. Nanotechnology applications can help increase shelf-life of these (while reducing the use of preservatives) and increase nutritional value.

March 2009

Memorandum by the London Centre for Nanotechnology

REPORT WRITTEN BY DR THIERRY BONTOUX

Introduction

This white paper is the response of the London Centre for Nanotechnology (LCN) to the Call for Evidence sent by the sub-committee chaired by Lord Krebs and appointed by the House of Lords Science and Technology Committee on Nanotechnology and Food. The purpose of this paper is to demonstrate that nanotechnology is not new in food processing. It will also list new products used in food production and describe some of the major applications of nanotechnology in packaging.

General Background

The London Centre for Nanotechnology is a UK-based, multidisciplinary research centre bridging the physical and biomedical sciences. It has a management structure that allows for a clear focus on exploitation and commercialisation. It brings together two world-leading institutions in nanotechnology, namely University College London and Imperial College London, in a unique operating model that accesses the combined skills of multiple departments, including medicine, chemistry, physics, electrical and electronic engineering, biochemical engineering, materials and earth sciences, and two leading business centres.

The LCN building in Bloomsbury, opened officially in November 2006, is the only nanotechnology focussed building at the heart of a major metropolis. The facility comprises investments of £14 million for the building and £7 million for equipment and provides a complete range of interdisciplinary tools for bio—and non-bio nanotechnology, including senior staff with clinical expertise. A £2.4 million grant from EPSRC enabled the procurement of a scanning transmission electron microscope—the first of its kind in the UK and one of few in the world—now installed on the Imperial College site in South Kensington.

Operating funds come from a range of private and public sector sources, including the UK research councils, the EU, private companies such as STS/Sumitomo, and charities such as the Wolfson and Gatsby trusts. Nonetheless, UK government remains the most important funding source, and the LCN has been able to win large numbers of contracts, with values ranging between several thousand and several million pounds. For example, the LCN won a Science and Innovation award (£5.6M) to develop new nanometrology capabilities—key for the engineering and quality assurance needed for nanotechnology to achieve its commercial promise—on behalf of the UK.

LCN is organised around three application themes:

— Information Technology: The computing and communications needs of society continue to grow and have become increasingly complex. Approaches based on current technology are limited and a variety of new methods are being sought by LCN staff to circumvent these limitations, applying nanotechnology-driven paradigms such as quantum computing and spintronics.

— Healthcare: Society's need for healthcare continues to grow. Expenditure on healthcare in Europe is typically the largest item on a nation's balance sheet. LCN is uniquely placed; it has access to a vast bio-medical expertise, enabling new paradigms in healthcare. Under development are specialised sensors and novel cancer-diagnosis systems, as well as new insights into cellular biophysics and novel research techniques.

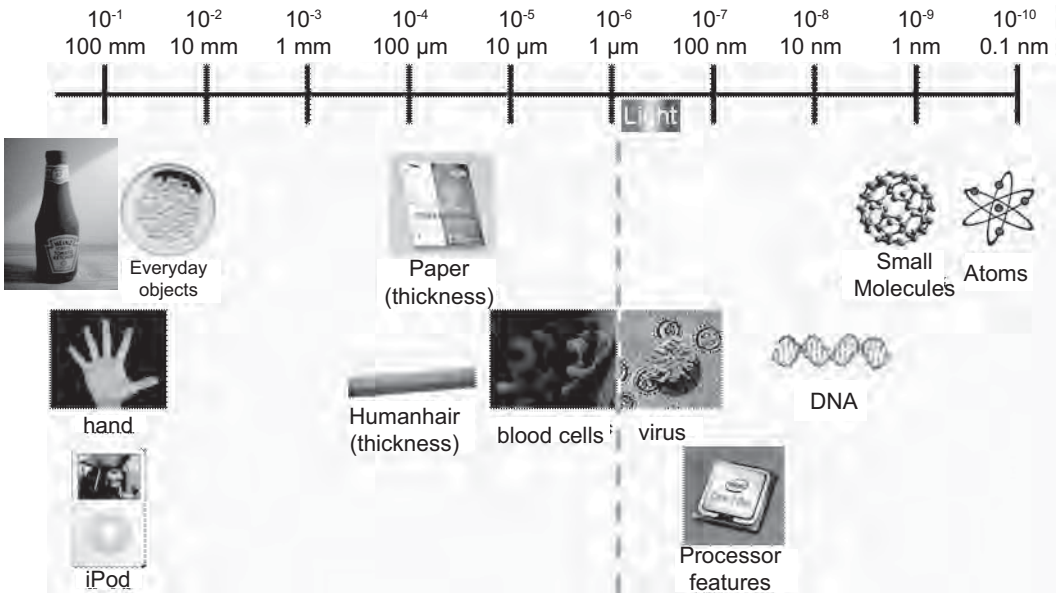
— Planet Care: Climate change is probably the single largest threat to society in the 21st century. The LCN uses its expertise ranging from biology to chemistry and materials science to conduct research in novel photovoltaics, new approaches to exploring current energy supplies, new materials for the nuclear industry and to store efficient hydrogen storage at room temperature.

State of the Science and its Current use in the Food Sector

What is Nanotechnology

Figure 1

HOW SMALL IS SMALL (COURTESY OF DR G CHARRAS—LCN)

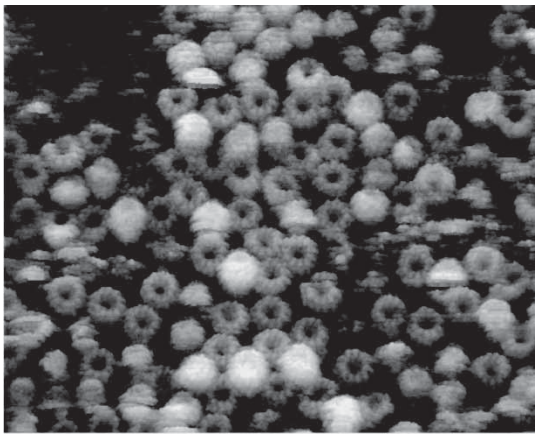


There is often a misunderstanding about what nanotechnology is. The general idea is that nanotechnology refers to novel engineered "nano" structures that never existed before in nature. Because it has only recently been branded as a science of its own, it generates both fear and fascination. We should consider how commercial IT brands use the term "nano" as a synonym of positive progress and how, on the opposite side, the cosmetic and the food industries often fear to speak about it. The commercial fascination is easily symbolized by the "IPod Nano", and a simple search on Internet will show many products using "nano" to brand high-tech electronics. The fear of nanotechnology can hardly be better described than with respect to the food industry. The public has lost trust in the regulatory authorities in general as well as in the food industry. It is fortified in its opinion by rare but dramatic events such as the baby powder milk poisoning last year in China.

Even if these two different perceptions of nanotechnology seem widely divergent, they have one thing in common: they see nanotechnology as a new science providing completely new products to the market, and it is human nature to consider that what is new is frightening. Activists try to mobilise public opinion against novel technology while the food industry conceals its use of nanotechnology to avoid alarming its clients. A rational approach that goes beyond stereotypical perceptions is needed to deal with the real meaning of nano-science and technology. In particular, nanotechnology does not necessarily imply nano-engineered particles.

Figure 2

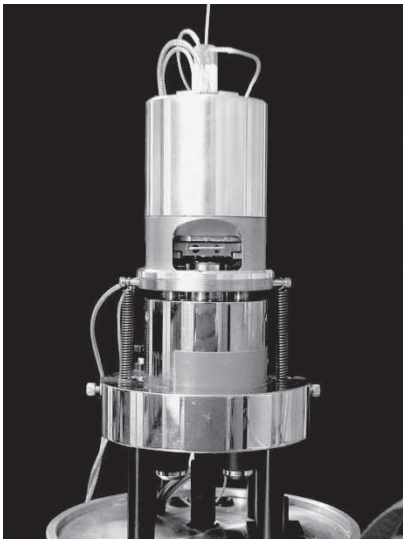
MOLECULAR ATPASE TURBINES VISUALISED AT THE NANSCALE
COURTESY STAHLBERG, H. ET AL.



We start by considering what "Small" is. Figure 1 compares the different scales of usual objects and links them to the nano-scale. There is a clear borderline between macro/micro scale and "nano" objects. This demarcation is the wavelength of visible light. Until the 1980s, scientists used either optical or electron microscopes to obtain direct images of the small-scale world. The latter microscopes could only produce images of small structures, usually in vacuum and generally destroying them in the process. The optical microscope however could lead to "in vivo" studies but could not "see" structures smaller than the wavelength of the light used to illuminate the samples. This is the origin of the 1μm boundary between traditional and nanoscale science. This limit was only overcome with the invention of the Scanning Tunnelling Microscope (STM) in the 1980s. The STM gave scientists and engineers the means to observe conductive surfaces at the atomic scale. They started to manipulate atoms one by one and develop "micro" electronics that soon became "nano" electronics. However, the main disadvantage of the STM is that it uses an induced current between the scanned surface and its "optics". The later invention of the Atomic Force Microscope (AFM) really made the difference and launched nanotechnology in the form we know it today. It allows us to "see" objects smaller than a micron without damage. It uses a pin to probe the surface of samples in a similar way as a blind person can "see" or read using his hands. The AFM found many applications in electronics and in biology. It gave birth to the modern understanding of biological nanostructures, enabling us to see cells and sub-cellular structures with unprecedented resolution (Figure 2).

Figure 3

HOME-BUILT AFM AT THE LCN
COURTESY BART HOOGENBOOM

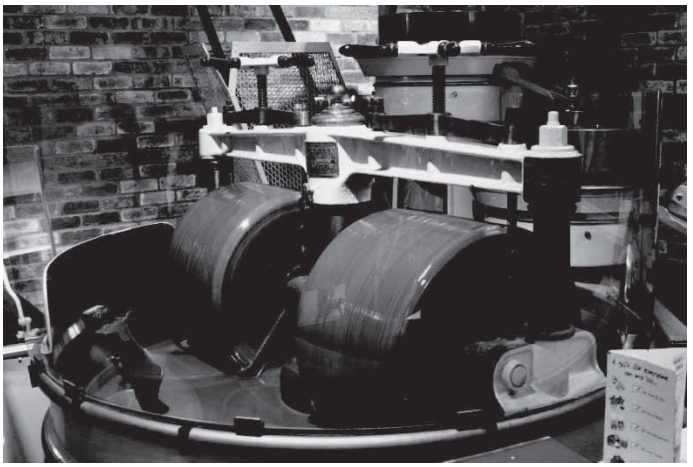


Today, there are many other types of equipment used to study nano structures, but none has had an impact comparable to that of the AFM. They all have in common that they are used across disciplines, in nanoelectronics, in chemistry and biology. Nanotechnology is not one branch of science, but a platform technology that gathers tools enabling scientists to study and manipulate objects below the 1μm optical limit. There is thus not one nanotechnology but a full range of nanotechnologies, comparable to the extremely broad meaning of the concept "engineering".

It has been rather common to associate electronics, genetics, and cell biology with nanotechnology, because during the last few years it has led to incredible developments in those fields. However, well before the word nanotechnology was even invented, there were other disciplines such as Chemistry, Biochemistry, Virology and Condensed Matter Physics (physics of solids and liquids) that had already dealt with nanoscale structures but were not capable of directly and easily seeing the objects they studied. In other words the concept of nanotechnology is new in everyone's minds but the studies and its applications are as old as modern science.

Figure 4

A CHOCOLATE MELANGER—PROBABLY ONE OF THE OLDEST NANOTOOL IN FOOD PROCESSING.
COURTESY SANJAY ACHARYA



One illustration can be found in what most of us consider as basic and very traditional food: chocolate. The recipe to achieve the transformation of cocoa seeds into chocolate is certainly one of the oldest processes based on nanotechnology. It aims to create small crystals of cocoa of only one specific type and whose building blocks measure approximately 6.5 nanometres across. The online encyclopaedia Wikipedia describes the process in the following way[1]:

> "*Making chocolate considered 'good' is about forming as many type V crystals as possible. This provides the best appearance and texture and creates the most stable crystals so the texture and appearance will not degrade over time. To accomplish this, the temperature is carefully manipulated during the crystallization.*
>
> *Generally, the chocolate is first heated to 45 °C (115 °F) to melt all six forms of crystals. Next, the chocolate is cooled to about 27 °C (80 °F), which will allow crystal types IV and V to form. At this temperature, the chocolate is agitated to create many small crystal 'seeds' which will serve as nuclei to create small crystals in the chocolate. The chocolate is then heated to about 31 °C (88 °F) to eliminate any type IV crystals, leaving just type V. After this point, any excessive heating of the chocolate will destroy the temper and this process will have to be repeated. However, there are other methods of chocolate tempering used. The most common variant is introducing already tempered, solid 'seed' chocolate.*
>
> *Two classic ways of manually tempering chocolate are:*
>
> — *Working the molten chocolate on a heat-absorbing surface, such as a stone slab, until thickening indicates the presence of sufficient crystal 'seeds'; the chocolate is then gently warmed to working temperature.*
>
> — *Stirring solid chocolate into molten chocolate to 'inoculate' the liquid chocolate with crystals (this method uses the already formed crystal of the solid chocolate to 'seed' the molten chocolate).*"

We chose to give this example only to demonstrate that nanotechnology is not novel as such and that nanostructures are not necessarily as dangerous or frightening as some members of the public believe. On the other hand, not all food engineering based on nanotechnology is necessarily as safe as manufacturing chocolate. The next chapter will look into the actual use of nanotechnology in food production.

Nanotechnology in our foods today

To underline that nanotechnology does not refer to only one specific type of technology, we shall use "nanotechnologies" from now on instead of "nanotechnology". Nanotechnologies can be found in the food manufacturing processes at different levels:

— Nanotechnologies can be incorporated into the food itself to create specific properties.

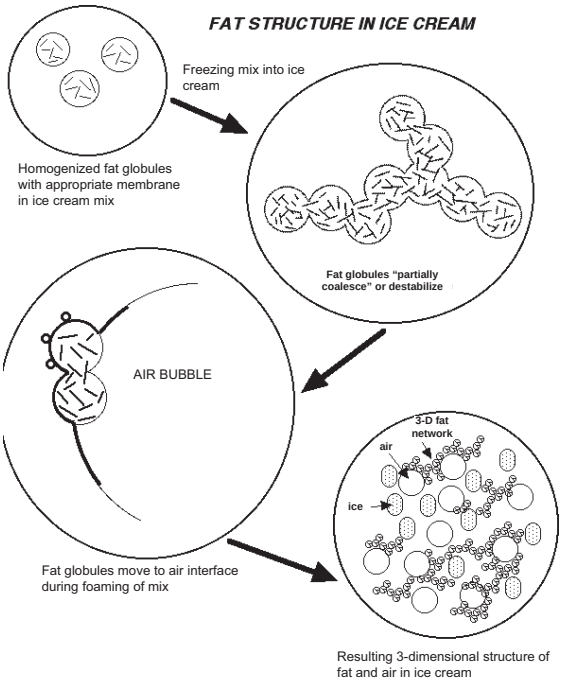
— Nanotechnologies can be used in packaging: several examples of such products are already available on the market.

— Nanotechnologies can be used to develop new materials and methods to manipulate and process foods, but this will not be treated in this report.

Nanotechnologies in foods

Figure 5

FAT STRUCTURE IN ICE-CEAM COURTESY OF PROFESSOR H. DOUGLAS GOFF—UNIVERSITY OF GUELPH



The first important point is that nanotechnologies have been used in food manufacturing for a long time without being named as such. One example is the addition of emulsifier to traditional manufacturing processes. For instance, to cut costs and meet consumer requirements, the food industry needs to reduce the quantity of fat and cream in the manufacturing processes of dairy product. Ice-creams need to be made with less cream, and since water is much less expensive than cream, the simple idea is to replace cream by water. However, ice creams made from water alone have never been considered as "delicatessen"; even sorbets need cream for unctuousness. This is where nanotechnologies come into action, even though ice-creams are not identified as nanofoods. Emulsifiers, such as lecithin, are used to mix products that previously needed cream to thicken.

Ice-cream is a complex nanostructure. It is at the same time a foam and an emulsion: it can be simplified as an emulsion of frozen water and air meshed into a foam of fat. The introduction of emulsifiers has had many positive effects on the structure and the conservation of the frozen dairy product. Emulsifiers are added to ice creams to replace the milk proteins found in cream, to actually reduce the stability of the fat emulsion, by

placing proteins on the fat globules surface, leading to thinner membranes more prone to coalescence during whipping. When the mix is subjected to the whipping action of the barrel freezer, the fat emulsion begins to partially break down and the fat globules begin to flocculate or destabilise[ii]. The air bubbles which are being beaten into the mix are stabilised by this partially coalesced fat. If emulsifiers were not added, the fat globules would resist this coalescing, the air bubbles would not be properly stabilized and the ice cream would not have the same smooth texture.

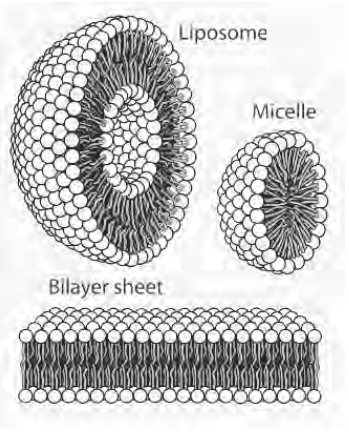
Beside the bulk introduction of chemical in the manufacturing process, there is intense research on the nanostructures of traditional food, to understand and optimise the stability of the product while further reducing their costs. Today's ice-creams are barely made with cream but nearly exclusively with water, thanks to chemical/nano-engineering. The same principle applies wherever emulsifiers are used. In general, nanoscale studies can contribute to the creation of better and cheaper food. Think of chocolate mousses that remain stable in time, even after days opened or kept outside of a refrigerator. We should also mention a famous brand of chocolate sweets which "do not melt in the hand but only in the mouth", and tomato ketchup sauces that, although being made only from natural ingredients, can stay fresh for up to 8 weeks once opened, and for several months if unopened. Any normal tomato purée would encounter phase dissociation only hours after processing. The only way to preserve those sauces for such a long time is by engineering their inner structures at a molecular level (ie nanoscale). Here again, the understanding of what happens at the nanometre scale is key to conservation and enhancement of gustative properties. Although being simple and basic foods, they all are the result of chemical and molecular engineering and, therefore could all be considered as "nanofoods".

Nanotechnologies can also be used to protect and deliver essential nutrients. Food processing relies on techniques that potentially degrade nutrients such as vitamins. They need to be protected from heat and acidity. Encapsulation is a reliable way to do so, also enabling faster absorption by the organism. It is used in two types of manufacturing: food enrichment[iii] and food supplements. Encapsulation concerns vitamins, preservatives and enzymes, but there are many new candidates for encapsulation, sometimes thousands of times smaller than living cells. For instance, Omega-3 additives are enclosed in nano-capsules of 30–40 nm to enhance their absorption by the organism and thus their effectiveness. The Woodrow Wilson International Center[iv] for Scholars maintains a list of products available to the general public and openly advertised as containing nanostructure or issued from nanotechnology. It shows that while food manufacturers have a certain reluctance to speak about nanotechnology, the sport food supplement industry is much more open about it.

In both cases, encapsulation presents many benefits for the industry and possibly for the general public. Nanocapsules can be incorporated in food to deliver nutrients while being rapidly assimilated by the body because of their size. The nutrient properties of food are better preserved because they are undamaged by the digestive process. The NovaSOL technology from the German ingredients firm Aquanova[v] is used to encapsulate vitamins A, D, E, K, ß-carotene, ascorbic acid, Omega3 fatty acid, lipoic acid, and lutein. The NovaSOL technology involves encapsulation of the ingredients in artificial micellae which measure just 30 nm, imitating the absorption process of nutrients by the human organism. Using the same technology, Aquanova has also found a way to extend the use of the preservatives sorbic and benzoic acid in foods with a high pH using its NovaSOL nanotechnology. Sorbic and benzoic acid are commonly used as preservatives, but until now their usefulness has been limited to the more acidic end of the pH scale, since performance decreases above pH4 and above pH6 they are almost totally ineffective. In the case of sorbic and benzoic acid, encapsulation enables pH-independent performance through the whole acidity scale. Thus, whereas in the past the preservatives were only suitable for use in sour-tasting products, they can now be used to protect against microbial spoilage in milder tasting products as well.

Figure 6

SCHEMATICS OF MICELLAE
COURTESY OF WIKIPEDIA



Another example of an encapsulated supplement is Driphorm®[vi], a dry powder form of fish oil produced by Nu-Mega. This Australian-based company advertises numerous other potential applications for their patented encapsulation technology:

- Infant nutrition—infant formulas and moist solid preparations.
- Bread and bakery products.
- Cereals—muesli bars, breakfast products.
- Dairy—frozen confection, yoghurts, fromage frais, milk.
- Supplements—capsules, dietary products.
- Beverages and juices.
- Animal Feeds.
- Fruit.

Nu-Mega recommends encapsulation because nano-size dispersions, emulsions and filled micellae are not subject to sedimentation, resulting in better product life span and storage. As their size is much smaller than the wavelength of light, they can be incorporated in clear and transparent foods without causing clouding.

Aquanova and Nu-Mega are no exceptions. The European industry is very active in this field. Groups like Nestlé, DANONE, Kraft, BASF, Bayer, Associated British Foods invest millions in research linked to nanotechnology[vii]. It is likely that the result of such research and investment will be used throughout the food production chain. In fact, there is already evidence of such practices in the usage of Transglutaminase (TGase). TGase is an enzyme that acts as a catalyst to promote cross-linking between proteins. It has a significant impact on properties of proteins such as: ability to gel, thermal stability and water holding capacity; thereby improving the functional characteristics of foods such as elasticity, binding ability, mouth feel, flavour, texture, and so on. This enzyme is very often used in non-dairy products and mousses, foams and jellies in association with Na-caseinate.

The number of examples of nanotechnologies used for food processing could be extended over several pages. Most of them would concern modifications of molecular and protein properties, and some are obviously linked to nanoengineering, like Nanocapsules. It is not the purpose of this report to give an exhaustive list of the application of nanotechnologies. However, we have demonstrated that nanotechnology in food is not science-fiction but a reality, and that there is not one type of nanotechnology applicable to the food industry, but several different approaches derived from traditional physics, molecular chemistry and biology.

Nanotechnology & Packaging

Food packaging has three aims:

- To contain.
- To protect.

— To inform—this will not be treated here because it is not directly linked with foods and toxicology.

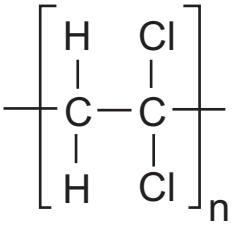
There is no such thing as simple packaging today. Traditional materials such as paper and wood disappeared long ago to be replaced by more convenient materials such as plastics. The same is happening again now, but less visibly due to the similarity in appearance of the new materials with plain plastics.

Contain & Protect

The primary purpose of packaging has always been to contain raw or processed food. This has not changed today, but the search for profitability and mass production has led to the development of increasingly sophisticated technology. This involves lighter, stronger, and smarter materials that are cheaper to produce. For instance, new materials can now provide longer shelf life by improving the barrier function of food packaging, reducing gas and moisture exchange and limiting exposure to UV light. Although those new materials look like many of their predecessors, most of them are the direct consequence of "nanotechnology" studies. Thousands of examples could be listed here.

Figure 7

MOLECULE OF PVC



The first evidence we shall give is used by everyone and is considered as a must-have in any kitchen: the Cling Films. Although the original film was invented by accident in 1953, long before the term "nanotechnology" existed, what makes them so popular is a direct consequence of a nanoscale phenomenon.

Cling films are made of polyvinylidene chloride (PVC). It forms a remarkable barrier against water, oxygen and aromas. It has superior chemical resistance to alkalis and acids, and is insoluble in oil and organic solvents. It has very low moisture retention and is impervious to mould, bacteria, and insects. Therefore, it has been widely used in all food industries for packaging and is most commonly employed in wrapping films of 100µm thickness. Non-PVC alternatives are now being sold, because of the risk transfer of plasticisers from PVC into food. It is indeed problematic for PVC to achieve full polymerization of the material, which could contain remnants of the vinyl chloride monomer. To achieve the full polymerisation and to develop new and better materials, engineers need to understand the dynamic of polymerisation, which involves studies at a molecular scale. In July, 2004 the composition of Cling films was changed to Low Density Polyethylene (LDPE). SC Johnson® claimed that this change was the result of an initiative to look for more sustainable and environmentally acceptable plastic. The new film does not contain chlorine. However, LDPE does not possess the same qualities as barrier to oxygen, aroma, and flavour molecules that vinylidene chloride copolymers do, making the new product a lower quality plastic wrap, as it is not as useful in protecting from spoilage or flavour loss.

In daily household practice, the films are interesting for their physical properties that originate from nanoscale behaviours, although most people never realise it. The "clinging" property is not due to any coating or glue sprayed onto the film, but to the molecular attraction between two layers of films. The chains of polymers try to bind together between layers when wrapped one against the other. The second interesting property of such films is their ability to block oxygen from reaching the foods. The chains of polymers form a mesh within the material, tight enough to block the way to molecules of gas. Hence, when optimising the manufacturing and changing the composition of the films, engineers have studied the nanoscale properties and structures of the chains of polymers, using the nanotechnology platform, although being recognised as chemistry by the public.

Durethan® films are another example of a material using nanotechnology and openly advertised as such. These films are manufactured by Bayer and have nano silicate platelets incorporated into a polyamide (PA) matrix. Contrary to the PVC films, the PA films are not as impervious to oxygen but are less hazardous to human health than PVCs. They tend to be preferred for industrial applications for this reason. Silicates are simple nanoscale clay structures, the same particles used in toothpaste or gum and gel manufacturing. The Nanoparticles of clay interact in various ways with the plastic film. They act as nuclei for crystallisation of the

polymer and improve the microstructure of the film. They also form a labyrinth of nano layers that O_2 molecules have to go through before reaching the foods packed inside. The molecules are forced to make long detours and their penetration is thus slowed down.

Similar usage of clay nanoparticles has been developed by Nanocor to create plastic bottles that do not interact with alcohol stored in beer. This new plastic development resulted in extending the shelf life of the packed beers up to six months by minimising the loss of carbon dioxide and impeding the penetration of oxygen into the beverage.

Mitsubishi Gas Chemical (MGC) and Honeywell Specialty Polymers both are using Nanocor's nanoclays in nylons as barrier layers in multi-layer PET bottles and films for food packaging. MGC's MXD6 nylon nanocomposite, called Imperm N, is commercially used in Europe in multi-layer PET bottles for beer and other alcoholic beverages[viii]. It is also being used for small carbonated soft-drink bottles, such as for Perrier® carbonated water.

Honeywell aimed its Aegis nylon 6 nanocomposites initially at PET beer bottles. In late 2003, a version containing an oxygen scavenger made a commercial splash with the introduction of the 1.6-liter Hite Pitcher beer bottle from Hite Brewery Co. in South Korea. Aegis is the barrier layer in this three-layer structure, which is said to provide a 26-week shelf life[ix].

Honeywell aims at using other Aegis nano-composites grades (without oxygen scavenger) as replacements for EVOH[25] in films and pouches. Such grades are reportedly lower in cost than EVOH, provide a better barrier, and also have better puncture resistance and good clarity. (Because of their size, nano-particles do not interfere with light transmission.)

To conclude this list of actual application of nano-composites designed for food packaging, we mention DuPont De Nemours, which has released a new additive to plastic films "DuPont Light Stabilizer 210" aiming to reduce damaged by UV radiation in transparent packaging[x]. It contains titanium dioxide with better properties than benzophenone and benzotriazole. In addition titanium dioxide is not prone to migration according to the manufacturer.

[25] Ethylene Vinyl Alcohol, commonly abbreviated EVOH, is a formal copolymer of ethylene and vinyl alcohol.

Nano-based materials have also been introduced for antimicrobial purposes. There are several products on the market nano-engineered to prevent bacteria to develop. They range from refrigerators sold by LG, Daewoo and Samsung, to kitchenware (made for example by Nano Care Technology Ltd), but also including containers like Camelbak® or baby cups made by Baby Dream®. This is only a short list and the nomenclature could be extended far beyond the few brands we have listed here. They all incorporate nanocrystals specifically identified for their antibacterial properties. There are four main different type of substances used:

— Silver: Silver ions and silver compounds show a toxic effect on some bacteria, viruses, algae and fungi, this effect is shared with heavy metals like lead or mercury, but without the high toxicity to humans that are normally associated with these other materials. Silver has been used since antiquity in medicine to cure wounds without any side effects; silver compounds were used to prevent infections during World War I, before the advent of antibiotics. Silver nitrate solution was a standard of care but was largely replaced by silver sulfadiazine cream (SSD Cream)[xi]. SSD creams became the "standard" of care for the antibacterial and antibiotic treatment of serious burns until the late 1990s[xii]. Silver can be found today in the form of nanocrystals with sizes ranging from 15nm to 100nm, with no evidence of toxicity for human being. Silver Nanoparticles are heavily used in food packaging and storage containers today.

— Silicon Dioxide: it is most commonly known as sand or quartz. In its nano form, fumed silica has a very strong thickening effect. Its primary particle size is 5—50 nm. The particles are non-porous and have a surface of 50—600 m^2/g. Density 2.2 g/cm^3. Inhaling finely divided crystalline silica dust (or fumed silica) in very small quantities over time can lead to silicosis, bronchitis or (much more rarely) cancer, as the dust becomes lodged in the lungs and continuously irritates them, reducing lung capacities (silica does not dissolve over time). However this is more a side effect of inhaling dust into the lungs rather than a direct effect of silicate dioxide chemical and physical properties. Such particle sizes are naturally present in the environment and if not inhaled, pure silicon dioxide is inert and harmless. Pure silicon dioxide produces no fumes and is insoluble *in vivo*. It is indigestible, with zero nutritional value and zero toxicity. When silica is ingested orally, it passes unchanged through the gastrointestinal tract, exiting in the faeces, leaving no trace behind.

— Titanium Dioxide: has widely been used as a white pigment for paint, but recently found new applications in nanoengineering. Titanium Dioxide is being used for its antibacterial properties and as a UV protector in cosmetics and in food packaging. Generally considered non-toxic, nanoparticles have sizes ranging from 20 nm to 200 nm. However, several researchers reported evidence that it led to deterioration of health in some animals[xiii]. The European Chemistry Industry Council and the America Chemistry Council (groups funded by the chemical industry) initiated toxicology studies. The studies exposed rats, mice and hamsters to pigment-grade TiO_2 (PG-TiO_2, 0, 10, 50 and 250 mg m^{-3}) or ultrafine TiO_2 (UF-TiO_2, 0, 0.5, 2 and 10 mg m^{-3}) for 90 days and the lung burdens and tissue responses were evaluated at the end of the exposure period and for up to one year after exposure. They show very different results between species, always linked to exposure of high doses of TiO_2 absorbed either by inhalation or absorption through food, but never in a way that could lead to a conclusion regarding usage of TiO_2 in food processing[xiv].

— Zinc and Zinc Oxide: Zinc is a nutrient that is critical to human health, but it is also an active chemical component that needs to be correctly dosed. Excessive absorption of Zinc can lead to poisoning and death, but this is also the case with many other types of nutrients. Furthermore, in the case of Zinc and Zinc Oxide, it is not the size of the particles that will influence the toxicity of the Zinc when absorbed. Zinc dissolves easily into the gastric acid and becomes Zinc chloride.

Conclusion

In this report we have provided evidence that nanotechnologies have traditionally been used in the preparation of food, albeit under different names such as "colloid chemistry" and "materials science", Nanotechnology does not necessarily mean nano-engineering, and many of the chemical modifications made to proteins in food should also be considered as nanotechnology. At the same time, it is true that nano-engineering approaches are introducing novel food additives and adding functionality to food packaging. Regulatory and legislative bodies should be aware of the full range of these applications when debating the use of nanotechnology in food.

About Dr Thierry Bontoux

French born and living in the UK since 2006, Thierry Bontoux has an industrial background, having held positions in France and the UK at senior level. His role at the LCN is to develop the connections and relations of the institute with industry. He has a scientific background with a PhD in laser engineering from the University of Osaka (Japan). During his PhD, he studied the simulation of light propagation equations in refractive media and the bi-stability of light in media with non-linear refractive indexes. Dr Bontoux moved to the UK in 2006 to join AeroMobile Ltd, a start-up company based in Crawley (West Sussex), to become director of administration and procurement. He joined the London Centre for Nanotechnology in early 2009.

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March 2009

Memorandum by nanoTox Inc.

TESTIMONY OF CHRISTOPHER J GINTZ ON BEHALF OF NANOTOX INC. BEFORE THE SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY—THE UNITED KINGDOM'S HOUSE OF LORDS—NANOTECHNOLOGIES AND FOOD SUBCOMMITTEE ON 24 JUNE 2009

By invitation from the British Government—British Embassy, Washington, DC

BIOGRAPHY OF MR CHRISTOPHER J GINTZ

Christopher J Gintz is a lifelong inventor involved in the formation of companies in the computer, information processing and science technology business. In 2003 he co-founded NanoHoldings LLC, a Company that raised $30 million for investment in the commercialization of nanotechnology from leading nanotech research centers such as Rice and Cambridge Universities. From 2005–09 years he helped form and served as Chief Technology Officer for 14 nano-specific technology companies spanning a wide range of civilian and military uses. Innovative technologies under development include materials with improved mechanical strengthening properties and replacements for earth metals that are increasingly depleted. In March 2009 he joined nanoTox Inc. as a strategic advisor for the advocacy of a private company- government partnership to study the toxicological properties of nanomaterials. He is the co-inventor of the notebook computer and has been responsible for the development of many electronics and energy technologies requiring complex understanding of the interaction between users and the environment. He holds a Bachelor of Arts degree in Sociology and Bachelor of Science Degree in Computer Science with advanced studies in statistics, chemistry and technology commercialization.

INTRODUCTION

The global economic crisis has significantly altered American national investment priorities. Science investment leading to accelerated technology commercialization is now a significant national priority. The size of this financial investment in American science is unprecedented. The country has not seen an equivalent commitment to the mobilization of scientific effort since the creation of the space program in the 1960's. Foremost on the administration's priority list dovetailing with its economic plans is the creation of an alternative energy policy that simultaneously reduces America's carbon footprint and increases its commitment to technology by creating high paying nanotech jobs. This agenda cannot advance without the successful commercialization of nanotech. The Economic Recovery Act is comprised of both a commitment to an investment in fundamental science and a renewed commitment to responsible regulation of technology making environmental, health and safety a national priority. Scientific investment and discovery in this area is global in scope with the American investment dwarfed by the financial commitments of America's trading partners in the United Kingdom, the European Community, Russia, China, Korea, Japan and Singapore.

This commitment is shown by the scope of the effort that is underway to study the complex interaction between these new technologies, people and the environment. Never before in mankind's history have we had the opportunity to study the potential health consequences of a material as it is being developed. Regulatory efforts heretofore have been reactive and usually after some debilitating health, safety or environmental problem emerged. This is not true for drug development however, where clinical trials assessing the potential health consequences are a major element of the regulatory environment. Stakeholders' interests in the

nanotech debate are meant to be inclusive. There is a general agreement by all concerned stakeholders that the specific studies of nano/biological interactions are important.

The following list of American governmental agencies involved in this process is not meant to be exhaustive but is indicative of the range of scientific and regulatory frameworks in which American business operates. However, a host of Federal agencies including the National Science Foundation, the Department of Energy, the National Institute of Health, the Food and Drug Administration, the Environmental Protection Agency and the National Institute of Occupational Safety and Health all have a stake in the development of nanotechnology. They have convened working groups consisting of domain experts covering the spectrum of interested stake holders including science experts, academic researchers, industrial partners, consumers and regulators to study the complex interaction of these materials and their interface with macro systems.

For example, in May 2009 the United States Food and Drug Administration convened its Second National Workshop at the Greentech/Nanotech Conference in Houston, Texas to define and access reference nanoscale particulates by their chemical composition, surface characteristics, size, and electrical characteristics to determine their behavior when interacting with biological systems. Future health and safety studies contemplated include but are not limited to an evaluation of their potential toxicity when handled and processed by workers and their subsequent disposal at the end of their life cycle.

nanoTox Inc. business and technical personnel are involved in participating from the inception in these workshops acting as an advocate for the safe and responsible handling of materials through the entire scientific, business development and materials production supply chain. In addition, nanoTox scientists are engaged with the emergence of food nanotechnology and during the last three years have published chapters in the most recent textbooks in the specialized area of gastrointestinal toxicology. Although it is funded by private investors it seeks to act in the role as a coordinating body bridging private industry concerns for factual scientific inquiry with the government's regulatory information requirements. It is formed out of the belief that all stakeholders are interested in verifiable scientific proof as a basis for responsible and balanced governmental regulation. nanoTox Inc. believes that periodic, on-going assessments are needed and that continuous monitoring of industrial processes is necessary to protect workers, consumers, and the environment. These assessments will help jump start the nanotech industry by creating a scientifically proven data base on which insurers can depend so that nanotech companies can accelerate product development in the marketplace thereby stimulating the economy.

nanoTox's initial deliverables include using both *in vivo* strategies (acute and subchronic toxicity studies focused on different exposure routes) and *in vitro* strategies (development of in vitro engineered human tissues, epidermis, bronchial and intestinal epitheliums.) These studies are intended to identify the potential impact of manufactured nano scale particles on human health.

Food Safety

Insuring the safety of the food supply is a global concern. People's concerns are well founded. During the past five years there have been significant health concerns about global pandemics with health scares involving the meat supply (mad cow's disease, swine flu, bird flu), bacterial outbreaks caused by improper inspection and handling of vegetables and peanuts, and deliberately tainted food stuffs such as the melanomin contamination in baby formula and milk supplies in China. Each health scare has been created by its own unique circumstances costing the world economy billions of dollars and created a general uneasiness among the populace about the safety of its food supply. As a result, the American agricultural industry has called for additional inspection and regulation to govern food safety. The *Wall Street Journal* reported on 18 June 2009 that the Congress has drafted legislation specifically for this purpose.

Since it is the Select Committee of the Science and Technology Committee of the House of Lords specific interest to investigate the specific use of nanotechnology in food, my comments will now specifically address the use of nanotechnologies and nanomaterials in food products, dietary supplements and food packaging. I will separate my comments between the food chain and the cosmetics chain.

Nano stakeholders have formed several mechanisms for the orderly dissemination of factual information about nanotechnology and both its interaction in the food chain and cosmetics. Two qualified sources of information are www.goodnanoguide.org/tiki-index.php and the International Risk Governance Council: "The Appropriate risk governance strategies for nanotechnology applications in food and cosmetics" see www.irgc.org/img/pdf/irgc_Pbnanofood_web.pdf.

Most experts agree that the negative implications for nanoscale materials in the food chain and cosmetics are *unlikely* but cannot be excluded, especially particles smaller than 20 nanometers.

According to the IRGC:

> ". . . There are problems at all phases of risk governance in nanotechnology. These include accepted and approved definition of what does and does not constitute a nanomaterial. Almost no hard data regarding nanoparticles in the contents of materials in specific products and very little scientific knowledge of the risks associated with nano scale ingredients or the products that contain them. As a result, the general public with a limited knowledge of nanotechnology is being influenced by alarmists writing communications, which are based on societal culture rather than any scientific basis. Consequently concerns about health issues and risks are growing even though there is no substantive evidence to justify these concerns."

State of the Science

As proof of this assertion, a literature search on the Internet finds only three references to food products and nanoscale particles. *Science News* reported on 27 May 2007 that the number of consumer products including food and food packaging using nanotechnology has doubled from 212 to 475 since the *Project on Emerging Nanotechnologies* launched the world's first online inventory of manufacturer-identified nanotech goods in March 2006. Clothing and cosmetics top the inventory . . ." See http://www.nanotechproject.org/consumerprodcuts. One can conclude from this search that given the billions of dollars spent on groceries, the size of the market for nanoparticle foodstuffs at this point in time is nearly non-existent.

Active research agendas on nanotechnology food and food packaging are also limited. There is no coordinated research effort on the study or use of nanotechnologies in food and food packaging. Only two scientists have a published research agenda in the field of nanotechnology and food. Dr Frans Kampers, a Dutch scientist at the Wageningen University and Research Center and Dr Rod Hill at the University of Idaho were symposium presenters on the subject (See *Science News*, 18 February 2009 "Could Nanotechnology Make an Average Donut into Health Food?" www.ScienceDaily.com/releases/2009/02/090214162746.htm) at the American Association for the Advancement of Science annual meeting entitled "From Donuts to Drugs: Nano-Biotechnology Evolution or Revolution." Dr Kampers alleged ". . . that European food companies already use nanotechnology in consumer products but few volunteer the information to consumers." Dr Kampers research agenda focuses on applications, products, processes, and sensors useful in food safety, food quality monitoring and in packaging."

Dr Kampers stated "European food scientists use nanotechnology to create structures in food that can deliver nutrients to specific locations in the body for the most beneficial effects." What are the nutrients and where is the scientific proof to back up these allegations? This is one investigator speculating in a symposium about what *may* happen not what is factually happening at this time. The main barriers to developing nanoscale nutrients are the cost and benefits associated with their development. We believe that those are anticipated developments are and not currently actively under development.

The nanotech packaging industry is in its infancy. There are nine references regarding nanoparticles and food storage in the *Products on Emerging Nanotechnologies* database. This is hardly an unmanageable group of products to access. They span the gamut from devices for actual food storage (plastic storage bags containing silver particles), beer bottles containing nanoparticles to keep gas from dissipating (nanoclays), plastic wrap (containing zinc oxide acting as an ultraviolet catalyst), baby bottles and salad bowls (silver nano particles to fight bacteria), aluminum foil (nanoscale carbon linings for better heat adsorption) and nano starch (improved adhesion in sealing bags) and refrigeration solutions including (nanoparticles in insulation) and odor adsorption. If there were a gap in the nanotechnology regulatory environment, it would involve the packaging industry. This application area represents a potential regulatory gap and perhaps merits further scrutiny because the food stored in some methods comes in direct contact with nanoparticles that subsequently contact biological systems.

Specific examples of the debate about cosmetics usually encompass a discussion of TiO_2 (titanium dioxide) base sunscreens. These sunscreens contain engineered nanoparticles but there is no current mechanism to distinguish "nano forms" from "other forms" of titanium dioxide. Here is a case where TiO2 sunscreens are considered existing materials not "new or novel" materials. This application area, like food packaging perhaps merits further scrutiny because nanoparticles are directly coming in contact directly with biological systems.

Answers to Specific Inquiries

(1) Most of the specific research in America on food and packaging is conducted at leading academic research universities in the form of non-Good Laboratory Practices (GLP) studies with poor documentation/reproducibility. These researchers have problems getting the necessary funding.

(2) The main barriers to developing these technologies are: (a) fear of consumer rejection of nano products and (b) the regulation of technology.

Health and Safety

The health and safety risks associated with nanoparticles in food and food packaging in the United States are unknown at this time. The two issues must be handled separately. The field is wide open since there has been no risk assessment performed in either area. Specific to the food supply we believe strongly that the United States Food and Drug Administration has the primary responsibility for monitoring all developments in food safety including food additives and nanotechnology. This is equivalent in Europe to the European Food Safety Authority (EFSA) and in the United Kingdom, the Food Safety Board. We would encourage the FDA's participation in international rule making with its regulatory counterparts.

Nanotechnology is not genetically modified food. Risk management regarding the food supply should be approached from the perspective of balance and proportionality between the costs and benefits of regulation. The regulatory impact of mandatory versus "indirect" approaches versus an absence of regulation should be considered. "Food" is different from "dietary supplements."

See *ScienceDaily* 10 February 2009 "Nanoparticles in Dietary Supplements Cause Health Concerns, Regulatory Challenges;" http://www.sciencedaily.com/releases/2009/02/090909075633.htm. In the United States there is limited regulatory control over the dietary supplements business. They have limited distribution and are perceived to be a niche between the food business and the pharmaceutical business. Most products come with a disclaimer that these products are outside of the review of the Food and Drug Administration. Admittedly this is a regulatory gray area. Further assessment of the use of nanoscale nutrients that are used to boost nutrient adsorption and other alleged health benefits needs further study and assessment.

Answers to Specific Inquiries

(1) The health and safety risks that present the highest risks in food and packaging are leachables from packaging. Testing has not been conducted at the nano scale but may have been tested in some form at the macro scale.

(2) nanoTox assists companies in analyses, stability of the nanoformulation and toxicology testing. Additional research needs to be conducted comprehensively.

(3) We cannot speak for the government. Industry plans to risk assess new food products through CFSAN on a case-by-case basis and nanotechnology will need to be retested. The food industry follows basic toxicology testing guidelines as set forth in the FDA Redbook (guidelines for testing Food Additives . . . Direct and Indirect)

Regulation

We believe that there are six key regulatory governance principles we wish to propose for consideration by all domestic and international nanotechnology regulators without regard to select topics. These are:

(1) The regulatory response should be coordinated; coordination with international entities between states as well as inter-departmental and interagency levels.

(2) Regulatory approaches to nanotech should be adaptive and flexible as we learn more factually about the technology.

(3) Information gathering initiatives, a key first step in an additive regulatory system, should be designed with end points in mind, should offer incentives for participation and should involve industry and academic researchers.

(4) Risk management approaches should strive to be comprehensive, by incorporating a lifecycle approach to govern the potential risks of nanotechnology and should be designed with the importance of scope and timing horizons in mind.

(5) Risk management approaches should strive for balance and proportionality.

(6) An understanding of the profile of the beneficiaries of nanotechnology and the risk bearers in concert with who is accountable ensuring the appropriate deployment of both technology and regulatory oversight. Stakeholders should be engaged appropriately and regulatory systems should be transparent.

The US Government through the Food and Drug Administration believes that it has the necessary expertise and scientific depth to coordinate the involvement of stakeholders in the process for defining nanomaterials and nanotechnologies as they apply to its regulatory area, which includes the topic area. The primary statute applicable to the regulation of nanoproducts falling under the FDA's authority is the Food, Drug and Cosmetic Act (FDCA). For products subject to pre-market approval which includes pharmaceuticals, high risk medical devices, and biological products, existing regulatory requirements are expected to be a sufficiently stringent and flexible to accommodate the regulation of nanotechnology—however, the FDA does recognize that current data requirements, reporting and notification mechanisms do not contain specific information to allow for the assessment of nanomaterial safety.

Some products are subject to post-market surveillance requirements including cosmetics and food. This is perhaps an area that stakeholders may agree that there is a need for increased regulatory scrutiny of products containing nano materials. This is not a trivial matter since many standard scientific tests do not apply to nano and is most cases measurement techniques and instrumentation is not yet developed. This situation is further complicated by the lack of definition with associated materials being tested. For example, "is a flat platelet of nanometer dimensions equivalent to a round particle of the same material?"

A regulatory approach to developing policy options for nanotechnology including food and food packaging should include:

(1) A formal statement of policy or preparation of a jurisdictional strategy.

(2) An attempt to gain more knowledge of nanotechnology's risks especially in the context of its interaction with biological systems.

(3) Commission a regulatory gap analysis.

(4) Make use of existing current regulations to indirectly regulate nanotechnology.

Answers to Specific Inquiries

(1) The US Government today has no single definition of "nanomaterials" and "nanoparticles" but effort is underway by industry, government, academic researchers and consumer stakeholders to define them according to their composition, size, surface area, dimensions, and properties such as their electronic conductivity.

(2) The US Government does not yet have a reporting mechanism for reporting nano-sized materials to the Food and Drug Administration.

(3) The US Government intends through the efforts of the Environmental Protection Agency to monitor and regulate the use of pesticides and fertilizers that contain nanotech materials.

(4) In terms of where nano will be used, CFSAN has no nano notifications as of this time.

(5) The US Government coordinates its work on nanotechnologies through voluntary participation by interested stakeholders. Forums for the purpose have been held at Rice University (Houston, Texas), the Alliance for Nanohealth, Conferences, Workshops, and Conference Calls organized by agencies and Symposia.

Public information and consumer engagement

The American public obviously has a major stake in the acceptance of products that contain nanoparticles and avenues of debate about nanomaterials in food and food packaging must be developed. There are public and private groups that are instrumental in the conduct of this debate. For example, the US Government's Consumer Products Safety Commission has the primary responsibility for organizing stakeholder opinions on product safety. We believe that the Government and its regulating bodies have the following responsibilities when talking about nanotechnology:

(1) The Government should be positive stating its intention to support nanotechnology research and development with the intent to capture future benefits.

(2) Benefits of nanotechnology need to be balanced with statements about potential risks, the extent to which we do not yet fully understand from a scientific perspective.

(3) Jurisdictions need to stress that until such time more information is available, existing regulatory frameworks are sufficient to ensure health and safety of stakeholders including consumers and the environment.

(4) Jurisdictions need to note the current lack of data pertaining to new materials novel properties, the lack of measurement instruments, standards, and methods to deal with hazards, exposure evaluation and overall risk assessment.

(5) Jurisdictions note the need to review the need for nanotechnology specific regulatory frameworks in the future and update existing regulatory frameworks as required.

(6) Jurisdictions should aggressively work with a Company like nanoTox and research universities to speed the process for building and evaluating a fact track model of proposed nanotechnology regulations. It would greatly reduce business uncertainty, foster investment leading to jobs creation needed in the world economy today.

Answers to Specific Inquiries

(1) We cannot ascertain any existing public perception in the United States about food nanotech and therefore we have seen little written or discussed about it in either the scientific or popular media. The United States tends to be much less formal about the regulation of new technology and the strategy is to have the competition in the marketplace define the features and benefits by the producers.

(2) We have yet to see any difference in nano; it is uncertain whether it will have any impact since few products exist. We do not see the need to label something as different if there is no proven difference.

24 June 2009

Memorandum by the Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars

1. There is little doubt that nanotechnologies have an important role to play in the food sector. They have the potential to raise nutritional value, increase shelf life, decrease manufacturing costs, and prevent harm to consumers. These advances will benefit producers and consumers alike. But they do not come without raising the possibility of new potential risks to human health and the environment. As our abilities to construct and manipulate sophisticated materials at ever-smaller scales increase, the challenges of understanding and managing the full implications of these abilities multiply. Without a careful evaluation of emerging risks, and strategies for managing these risks, it is unlikely that the full benefits of nanotechnologies will be realized—whether in the food sector or the many other areas where the technologies are being developed and used. In this context, I am encouraged that the House of Lords Science and Technology Select Committee are investigating the use of nanotechnologies in the food sector, and am pleased to be able to provide evidence from my perspective as an expert in nanotechnology risk research and policy, and as the Chief Science Advisor to the Project on Emerging Nanotechnologies.

2. By way of background, the Project on Emerging Nanotechnologies is an initiative launched by the Washington DC-based Woodrow Wilson International Center for Scholars and The Pew Charitable Trusts in 2005. It is dedicated to helping business, government and the public anticipate and manage the possible health and environmental implications of nanotechnology. As part of the Wilson Center, the Project is a non-partisan, non-advocacy organization that collaborates with researchers, government, industry, non-governmental organizations (NGOs), and others concerned with the safe applications and utilization of nanotechnology. Our goal is to take a long-term look at nanotechnologies; to identify gaps in the nanotechnology information, data, and oversight processes; and to develop practical strategies and approaches for closing those gaps and ensuring that the benefits of nanotechnologies will be realized. We aim to provide independent, objective information and analysis that can help inform critical decisions affecting the development, use and commercialization of responsible nanotechnologies around the globe.

3. My own interest and involvement in nanomaterials stems from research I conducted at the University of Cambridge in the early 1990's, where I explored applying advanced electron microscopy to the characterization of atmospheric nanoparticles. Since then I have worked, published and lectured extensively on the potential benefits and risks of nanotechnologies, as well as broader issues relating to emerging technology and science policy. I was previously co-chair of the US government working group coordinating interagency activities related to nanotechnology risk research and currently serve on a number of nanotechnology-related boards and committees, including the World Economic Forum Global Agenda Council on the Challenges of Nanotechnology and the Executive Committee of the International Council on Nanotechnology.

4. Since its inception in 2005, the Project on Emerging Nanotechnologies (PEN) has undertaken a number of activities relevant to this call for evidence, and I would like to summarize the pertinent points arising from these activities. I will also provide brief answers to some of the specific questions posed by the subcommittee, where they coincide with my particular areas of expertise and knowledge. Where relevant, I have provided links to further resources. However, given the brevity of this submission, I would ask that the subcommittee feel free to contact me directly on any points requiring further clarification. While this submission is written from a US perspective, much of it will hold relevance for the safe use of nanotechnologies in food in the UK.

5. *Regulatory Framework*. In 2006, PEN published a report by Michael R. Taylor—former Deputy Commissioner for Policy at the US Food and Drug Administration (FDA)—on regulating the products of nanotechnology from a FDA perspective.[26] Taylor's top-line recommendation for all FDA-regulated products—including food additives, food ingredients and food packaging—was that criteria need to be established for determining when substances are "new for legal and regulatory purposes," and "new for safety evaluation purposes." He expressed concern that, without such criteria (which still do not exist in the US), FDA and industry lack the means to identify and regulate nanoscale forms of materials that may present new risks due to novel nanostructure-dependent functionality. In particular, he was concerned over the (continuing) lack of clarity concerning how nanoscale versions of substances "Generally Regarded As Safe" should be regulated. The issues surrounding the regulation of nanotechnology-enabled food products by the US FDA have been articulated repeatedly by Taylor.[27,28,29]

6. *Use of nanomaterials in food packaging*. It is currently unclear how the use of engineered nanomaterials in food packaging might impact on consumer safety, either through the release of material for packaging to food, through additional protection afforded by advanced packaging, or through feedback on the safety of food contained within packaging embedded with nanotechnology-enable sensors. In 2008, PEN published the findings of a study focused on assuring the safety of nanomaterials in food packaging—the result of a collaboration between PEN and the Grocery Manufacturers Association (GMA).[30] Using hypothetical scenarios, the study was based on a series of dialogues among experts and stakeholders from the US government, industry and the public interest community exploring the legal and policy issues, as well as scientific and technical issues that might arise in ensuring the safe use of nanomaterials in food packaging. The study concluded that, while current regulatory approaches in the US provide a high level of consumer protection, the current state of scientific knowledge and need for case-by-case evaluation of emerging products requires greater scientific investment and innovation in order to satisfy established regulatory standards.

7. *Tracking consumer products (including food products) allegedly based on nanotechnology.* PEN maintains a publicly available on-line database of over 800 consumer products allegedly using nanotechnology in some form.[31] Entries are based on manufacturer claims, which are not validated independently, and are international in scope. As of 6 March 2009, there were 84 food-related items listed in the database. Nine of these are listed as used in cooking, and range from nanoscale silver particle-infused cutting boards and nanotechnology-enabled non-stick surfaces, to nano-silver sprays for disinfecting surfaces. 20 products are used for food storage—many of them using nanoscale silver particles as an antimicrobial agent. 44 listed products are categorized as dietary supplements, where the use of nanotechnology ranges from silver (and other metal) nanoparticles, to the use of nanoscale ingredients in enhancing uptake and effectiveness, to uses that are somewhat hard to fathom from the manufacturer-supplied information. Only three products listed are entered as "foods," and include oil that contains nanoencapsulated ingredients, a milkshake that uses a nanoscale silica-based compound to enhance the taste, and a tea that claims to use a non-disclosed form of nanotechnology to deliver beneficial components of the drink to consumers.

8. It is currently unknown how many nanotechnology-enabled food products are on the market that are not clearly identified. It is known that the food industry is carrying out research into using nanotechnology to improve manufacturing processes, increase food security and shelf life, and improve nutritional value and consumer satisfaction. And nanoscale materials such as fumed silica have been used in food products for many years. Yet the food industry is reticent to discuss its use of the technology in public, and is currently under no obligation to reveal how nanotechnology is being used in products already on the market.

[26] Taylor, M. (2006). *Regulating the products of nanotechnology*: Does FDA have the tools it needs?, PEN 5 Washington DC, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.
[27] See footnote 26
[28] Public meeting on Nanotechnology Materials in FDA –Regulated Products Available at: http://www.nanotechproject.org/publications/archive/statement_michael_taylor_at_fda/
[29] Taylor, M. R. (2008). Assuring the safety of nanomaterials in food packaging: The regulatory process and key issues. Washington DC, Project on Emerging Nanotechnologies.
[30] see footnote 29
[31] An inventory of nanotechnology-based consumer products currently on the market. http://www.nanotechproject.org/inventories/consumer/

9. *Public perceptions*. Since 2006, PEN has commissioned annual phone surveys of public attitudes towards nanotechnology from Peter D. Hart Research Associates, Inc. The 2007 study, which included 1,014 participants, incorporated questions about attitudes towards the use of nanotechnology in food products.[32] Considering food in general, two thirds of the participants felt the food supply has become less safe in recent years. When asked about the specific use of nanotechnology in food related products and food, a large majority said they needed more information about the health risks and benefits associated with using the technology to enhance these products before they would use them. 13 per cent of respondents said they would not use food storage products enhanced with nanotechnology and 73 per cent said they would need more information before deciding to use them. In regards to food, 29 per cent of adults claimed they would not purchase foods enhanced with nanotechnology, while another 62 per cent said they would need more information before doing so. Adults who initially were more aware of nanotechnology were considerably more likely to report they would use both food storage products and foods enhanced with nanotechnology. Additionally, adults who had heard a significant amount about nanotechnology were nearly three times more likely than adults who had heard nothing to say they would use food storage products enhanced with nanotechnology, and were two and half times more likely to use foods enhanced with nanotechnology.

10. *Providing information on the use of engineered nanomaterials in foods*. There has been considerable discussion over the pros and cons of labeling nano-enabled products, although many of the discussions have been somewhat unclear on the purpose behind labeling or the information to be conveyed. Putting the contentious issue of "labeling" aside, information availability and communication is important for effective regulation and informed consumer choice. Regulators need clear information on ingredients and materials that may raise health and environmental concerns if not used appropriately. Manufacturers need clear information on the materials they handle and incorporate into their products, if they are to manage product safety effectively. And consumers need information on biologically relevant ingredients in the food products, if they are to be empowered to make informed choices on what they purchase and eat. The current state of science suggests that there are no underlying mechanisms of action that would justify blanket labeling of food items as containing engineered nanomaterials. Due to the diversity of engineered nanomaterials and their physical, chemical and biological behavior, such labeling would obfuscate evidence-based decision-making. However, current knowledge suggests that some engineered nanomaterials may have an effect on consumers that is associated with physical form as well as chemical make-up, and in these cases it would be helpful to identify the physical, as well as the chemical, form of ingredients. Such identification, whether available on the ingredients list or as supplemental publicly accessible information, would aid regulators and business as well as consumers.

11. *Next generation nanomaterials*. Many engineered nanomaterials currently being used in applications are nanoscale forms of materials that have been in use for some time. For instance, nanosilver consists of nanometer scale particles of metallic silver, and nano-titanium dioxide is a nanometer-scale form of a material used widely as a whitener in foods and other products. However, scientific and technological advances are enabling the formation of nanoscale materials with increasingly sophisticated forms and functions. These more sophisticated materials are often referred to as next generation nanomaterials. While no formal definitions exist for these nanomaterials, they can be typified by materials that are built up of complex arrangements of chemicals at the nanoscale, materials that change their behavior in the presence of different external stimuli (such as heat, light, pH, magnetic fields), materials that are designed to exhibit multiple functions (such as particles that can both deliver a drug to a predetermined site, then release it on demand), and materials that are designed to interact together—essentially to communicate—in complex ways. Such nanomaterials have more in common with complex products than simple chemicals, and raise questions over how their potential health and environmental impact should be evaluated and managed.

12. A number of "next generation" nanomaterials are under investigation for use in food products in the laboratory, although it is unclear whether any have been used in commercial products. Examples include materials designed to self-assemble into ingredient-carrying nanoscale capsules which can disassemble once in the body, and nanoscale sensors which are designed to be placed on or in food, where they can respond to their local environment and signal the presence of contaminants. Although the building blocks of these materials are invisible to the naked eye and may be transitory, they behave very differently from well-defined chemicals upon which many food regulations are based.

[32] Hart, Peter D. (2007) "Awareness of and Attitudes Toward Nanotechnology and Federal Regulatory Agencies" Peter D. Hart Research Associated, Washington DC, conducted on behalf of: Project on Emerging Nanotechnologies and The Woodrow Wilson International Center for Scholars Available at: http://www.nanotechproject.org/process/assets/files/5888/hart_presentation_2007 analysis.pdf

13. *Current state of scientific knowledge*. Although the state of scientific knowledge on engineered nanomaterials in food products is increasing, it is still low. In 2006 I published an assessment of the current state of knowledge, and a plan to fill in the knowledge gaps[33] (this was followed up later that year with a commentary in *Nature* laying out the greatest challenges to ensuring the safe use of nanotechnology across multiple areas of use).[34] At the time, I could not identify any research on the behavior of engineered nanomaterials in the gastrointestinal tract. While there is now a small amount of relevant research being conducted in this area, it remains at a low level. More generally, there are a number of current or recently completed research projects around the world that are concerned with the potential health impacts of engineered nanomaterials in food products. PEN maintains a public database of nanotechnology risk-related research, and searching this using the keyword "food" returns 23 projects.[35]

14. Over the past few years, there have been numerous expert reviews on the state of science regarding potential impacts of engineered nanomaterials.[36] In broad terms, these indicate that many nanomaterials demonstrate functionality that depends on their form as well as their chemical makeup; that different types of nanomaterials behave very differently; that some nanomaterials have the potential to cause harm by getting to normally inaccessible places, and/or demonstrating a biological activity that is associated with their form as well as their chemistry; that conventional toxicology assays may not provide a clear indication of nanomaterial toxicity; and that the potential harmfulness of nanomaterials may change with time and environment. There have been no known cases of health effects directly linked to exposure to engineered nanomaterials. However, there remain many knowledge gaps to understanding how new materials might cause harm, and how to avoid this harm.

15. Regarding food products, questions still requiring answers include: Can engineered nanomaterials in packaging migrate to food products and how can migration, and the resulting consequences, be evaluated? How is the potential toxicity of engineered nanomaterials best tested? How are engineered nanomaterials most appropriately measured and characterized? How do physical form and substance chemistry at the nanoscale influence biologically relevant behavior? How do changes in the physical structure and size of particles affect their absorption, dispersion, metabolism and excretion? Are increased dose rates resulting from decreased particle size and substance encapsulation important? Are people likely to be exposed to substances that can assemble into nanoscale materials in the body, and what might the health consequences be?

16. *Natural versus engineered nanomaterial risks*. Regarding food product safety, the important question is "how might something cause harm, and how can that be avoided", rather than "is this an engineered or a natural material"—the latter question having no direct bearing on safety. Natural nanoscale materials are present in food products, and there are no known cases of these being directly linked to health problems. Indeed, it can be argued that our bodies have evolved to manage and even take advantage of naturally occurring nanoscale substances. It is more relevant therefore to ask whether a new material—whether nanoscale or not—demonstrates properties that could lead to unconventional risks. From the current state of the science, there is a greater likelihood that materials specifically engineered to have nanoscale features will exhibit such novel properties. These include nanometer scale particles that are able to penetrate to regions of the body inaccessible to larger particles, increased dose rates associated with nanoscale materials, and mechanisms of action that are linked to the chemistry and physical form of specific engineered nanomaterials. Not all nanomaterials will be harmful. But there is a chance that some engineered nanomaterials will be more harmful than a conventional understanding indicates.

17. *Research funding*. Unanswered questions over the safe use of nanomaterials in food products currently far outstrip strategic investment in relevant research. In the US, investment in research projects specifically directed to understanding the health and environmental impacts of engineered nanomaterials is on the order of $20 million per year, although significantly more is being spent on research having some relevance to potential impacts. It is difficult to estimate the fraction of this investment dedicated to food-related research, but records in the PEN Nanotechnology Environment, Health and Safety Research Database suggest that it is something less than $1 million per year.[37]

[33] Maynard, A. D. (2006). *Nanotechnology: A research strategy for addressing risk*, PEN 03 Washington DC, Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies.

[34] Maynard, A. D., R. J. Aitken, T. Butz, V. Colvin, K. Donaldson, G. Oberdörster, M. A. Philbert, J. Ryan, A. Seaton, V. Stone, S. S. Tinkle, L. Tran, N. J. Walker and D. B. Warheit (2006). "Safe handling of nanotechnology." *Nature* 444(16): 267–269.

[35] An inventory of current research involving nanotechnology health and environmental implications Available at: http://www.nanotechproject.org/inventories/ehs/

[36] Eg Maynard, A., D. (2007). "Nanotechnology: The next big thing, or much ado about nothing?" *Ann. Occup. Hyg. 51*: 1-12. Oberdörster, G., V. Stone and K. Donaldson (2007). "Toxicology of nanoparticles: A historical perspective." *Nanotoxicology* 1(1): 2–25.

[37] See footnote 35

18. Recently, the US National Academies of Science criticized the US government for not having a robust research strategy in place to address the safe use of nanotechnologies, and recommended the development of a national research strategy.[38] European funding for risk-relevant research appears to be outstripping the US[39], although it is unclear whether current research will lead to answers that will support evidence-based decision-making on the safe use of nanotechnology in food products. My published assessments[40] indicate there remains a significant chasm between the research needed to support the safe use nanotechnologies, and research currently being funded.

10 March 2009

Letter from Dr Anthony Robson, Swansea University

I submit the information below on the recommendation of Professor David Tolfree, Vice President—Africa/Europe of the Micro and Nanotechnology Commercialization Education Foundation (MANCEF) http://www.mancef.org/

My general interest is how better nutrition can help prevent the modern diet induced "diseases of civilization" and includes the potential of nanotechnology food products. I am currently a post-doc researcher at the Institute of Environmental Sustainability, Biological Sciences, Swansea University, UK and likely to move soon to do post-doc research elsewhere.

On behalf of Swansea University, UK, I spoke about preventing diet induced disease on BBC Radio 4 on 29 May 2008. I was paid as a consultant to talk to Kellogg's® (cereal company) nutritionists about preventing diet induced disease in December 2007 (cereals are truly humanity's double-edged sword).

The information I provide is based on my latest (2009) review of peer reviewed scientific research publications, including my own. For example:

Robson A (2006) Shellfish view of omega-3 and sustainable fisheries. Nature 444 (7122), 1002 http://www.nature.com/

Robson A (2008) Preventing Diet Induced Disease. Proceedings from the 13th International Conference of the Commercialization of Micro and Nano Systems, held 27–31 August 2008 in Puerto Vallarta, Mexico http://mancef-coms2008.org/

Robson AA (in review) Preventing Diet Induced Disease. Nutrition Research Reviews http://journals.cambridge.org/action/displayJournal?jid=NRR

Please do not hesitate to contact myself if the committee requires any further information. I would be honoured to give oral evidence at Westminster that has the potential to help prevent the modern diet induced disease epidemic. To help prevent the diet induced diseases of civilization policy makers, nanotechnologists, food producers and consumers need to be made aware of the causal mechanisms of disease by understanding how people die. The fact that modern diet induced inflammatory eicosanoids are major mediators of mortality is not widely known in the public domain, even though the extensively used drug Aspirin is a cox-enzyme blocker that prevents the formation of inflammatory eicosanoids.

State of the Science and its Current Use in the Food Sector

The answer to the question below is referenced using superscript Arabic numerals in parentheses. Please refer to the Appendix on page 12 for further information. Acting on the information in the appendix would be a great service to public health.

What are the main potential applications and benefits of nanotechnologies and nanomaterials in the food sector, either in products or in the food production process?

1. What the World needs is a joined up and sustainable food policy that makes the best, and most appropriate use of the technologies at our disposal. You might be surprised, or not, of how few experts there are in this area—a lot of hype, misinformation and biased views, often based on the distortion of scientific facts and of course deliberate intentions to mislead for political and commercial reasons.

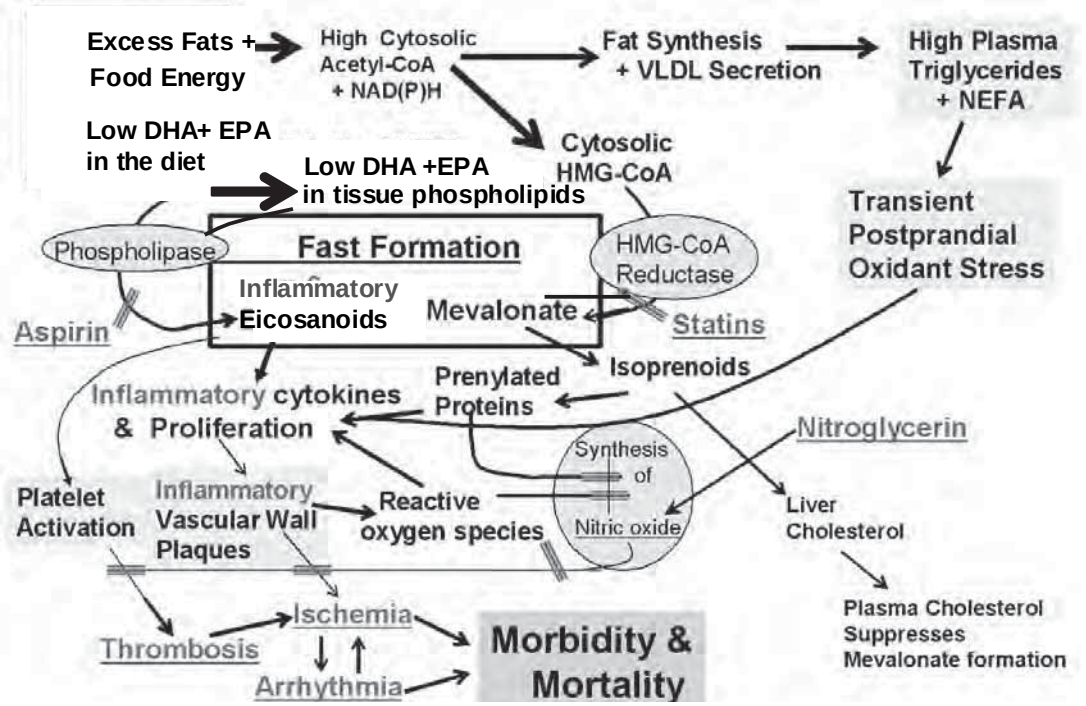
[38] Committee for Review of the Federal Strategy to Address Environmental, Health, and Safety Research Needs for Engineered Nanoscale Materials, Committee on Toxicology, National Research Council. (2008). Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research. The National Academies Press, Washington, D.C.

[39] http://www.nanotechproject.org/news/archive/ehs-update/

[40] Eg Maynard, A. D. (2008). United States House of Representatives Committee on Science & Technology Hearing on: The National Nanotechnology Initiative Amendments Act of 2008. Testimony of: Andrew D. Maynard, Ph.D. Chief Science Advisor, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars, Washington, DC. April 16 2008., Washington DC, Project on Emerging Nanotechnologies.

2. Nanotechnology food products have great potential to help prevent unnecessary human suffering and premature death, especially in future generations. Fundamental changes in the human diet, beginning with the introduction of agriculture and animal husbandry ~10,000 years ago, account for the largest burden of chronic illnesses and health problems Worldwide. In modern societies diet induced diseases typically afflict 50–65 per cent of the adult population. Cardiovascular diseases are the number one cause of death globally (30 per cent of all deaths) and cardiovascular diseases are predicted to continue increasing[1]. In the Europe Union, brain disorders have now overtaken all other burdens of ill health at an estimated cost of €386 billion (€829 a year for each European citizen) in 2004[2] and mental ill health is predicted by the Global Forum of Health (www.globalforumhealth.org) to be in the top three burdens of ill health Worldwide by 2020. Heart disease and mental ill health can start in the foetus in the womb.

3. Primary prevention of cardiovascular disease and mental ill health starts, crucially, with maternal nutrition before the inception of pregnancy and continues throughout life of the new born and includes consuming more DHA, EPA and ALA (alpha-linolenic acid) omega-3 fats and bio-available brain minerals and less LA (linoleic acid) omega-6 fat (eg seed and nut oils) to enhance DHA and EPA synthesis from ALA, so tissues have less intense inflammatory eicosanoid action (eg ~0.35–3.5 g DHA + EPA day^{-1} based on a 2,000-kcal diet dependant on LA intake). The fats and oils from aquatic based-foods contain high contents of these beneficial omega-3 fatty acids but increased consumer demand has also increased strain on the ability of the World's fisheries to meet demand from wild capture. Molecular biology now allows the engineering of oilseeds for the production of DHA + EPA omega-3 HUFAs in a seed oil with an omega-3:6 ratio 1.5:1 (a ratio close to that of many fish oils). Food nanotechnology may also be able engineer currently pro-inflammatory food products to reduce the formation of inflammatory mediators—eicosanoids, cytokines, and reactive oxygen species and increase the formation of anti-inflammatory mediators termed resolvins (Figure 1). Uncontrolled excessive production of inflammatory eicosanoids over prolonged periods of time is associated with heart attacks, thrombotic stroke, arrhythmia, arthritis, asthma, headaches, dysmenorrhea (menstrual cramps), inflammation, cancer (such as colon, breast, kidney and prostate) and osteoporosis[3, 4]. It is important to note that if DHA and EPA oils undergo oxidation it may attenuate their beneficial effects and food nanotechnology may be able to help prevent oxidation. Further, the excessive consumption of anything may cause disease or premature death, even omega-3[eg 5, 6, 7].



Example of Diet Induced Disease

Figure 1. Low DHA and EPA dietary intake and excess food energy link diet to disease and premature death[modified from 8]. Three types of medication, Aspirin, Nitroglycerin, and Statins used widely to diminish the processes set in motion by the two nutritional factors shown in the upper left of Figure 1 are noted, to show the step in the process at which these familiar drugs intervene. It should be noted that the hydrophilic statin Pravastatin may promote the development of cancer (inflammation) by causing an increase in mevalonate synthesis in extrahepatic tissues[9–11].

4. Globally in 2005, at least 20 million children under the age of five years were overweight, approximately 1.6 billion adults (age 15 +) were overweight and at least 400 million adults were obese[12]. The World Health Organization further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese. Within the past 20 years, substantial evidence has accumulated showing that long term consumption of high glycemic load carbohydrates can adversely affect metabolism and health[13–15]. A healthy diet-plus-exercise is most effective for preventing diabetes mellitus[16]. Nanotechnology may be able to engineer the novel Neolithic and Industrial Era foods that dominate the typical modern diet (generally energy dense, nutrient poor, processed foods such as breakfast cereals, bread, cake, cookies, crackers, cheese, fried food, pizza, pasta, kebabs, sandwiches, soft drinks, alcoholic drinks, sweets, chocolate bars, ice cream, condiments and salad dressings) to maintain low glycemic loads (diet low in refined sugars with moderate levels of carbohydrates and not as low in fat and protein as a low fat diets[see 17]) and reduce any insulinotropic properties with potential positive effects on metabolism and health.

5. Protein has more than three times the thermic effect of either fat or carbohydrate[18] and because it has a greater satiety (feeling of fullness) value than fat or carbohydrate[18, 19], increased dietary protein may represent an effective weight-loss strategy for the overweight or obese. Studies have indicated that fish protein may have a greater effect on satiety compared to other protein sources of animal origin[see 20]. Clinical trials have shown that calorie-restricted, high-protein diets are more effective than are calorie-restricted, high-carbohydrate diets in promoting[21–23] and maintaining[24] weight loss in overweight subjects while producing less hunger and more satisfaction[25]. Furthermore, high protein diets have been shown to improve metabolic control in patients with type two diabetes[26–28]. In obese women, hypocaloric, high-protein diets improved insulin sensitivity and prevented muscle loss, whereas hypocaloric, high-carbohydrate diets worsened insulin sensitivity and caused reductions in fat free mass[29]. In numerous population studies, summarized by Obarzanek *et al*[30], higher blood pressure has been associated with lower intakes of protein. An increasing body of evidence indicates that high-protein diets (approximately one third of total food energy intake at the expense of lowered carbohydrate) may improve blood lipid profiles[27, 28, 31–33] and thereby lessen the risk of diet induced disease. Improvements in the nutritional value of crop plants, in particular the protein composition has been a major long-term goal of plant breeding programs. The future of bio-nanotechnology/molecular biology looks promising to increase protein consumption at the expense of carbohydrate in the human diet, with potential health benefits.

6. Endemic clinical and sub-clinical iodine deficiency is present in about 20 per cent of humans Worldwide. Two billion people, over 30 per cent of the World's population are anaemic, many due to lack of iron[34]. Iron and other key minerals needed for brain development and function (zinc, copper, selenium) are more bio-available from shellfish and fish than from plant-based diets where their absorption is impaired by phytates and other anti-nutrients. Plant based diets rich in staples like cassava or soy (the basis of many vegan and vegetarian food products) are not only a very poor source of iodine but they also contain goiterogens which inhibit iodine absorption[35]. Bio-fortification of novel foods through modern methods of nanotechnology and biotechnology has the potential to help offset essential nutrient deficiencies and improve human health through elevated levels of essential nutrients, reduced levels of toxic factors and anti-nutrients that impact bioavailability and utilization of nutrients, and increased levels of factors that enhance bioavailability of nutrients[36, 37].

7. Diets low in dietary fibre may underlie or exacerbate constipation, appendicitis, hemorrhoids, deep vein thrombosis, varicose veins, diverticulitis, hiatal hernia, and gastroesophageal reflux[38]. Fibre type and quantity are undoubtedly under genetic control, although this topic has received little attention. The technology to modify fibre content and type by nano-engineering would be a great benefit in persuading the many individuals who, for taste or other reasons, do not include adequate amounts of fibre in their daily diet. For example, fibre content could be added to more preferred foods (eg milk, cheese, ice cream, refined cereals and white bread—but these are all novel foods that can promote the diet induced diseases of civilization) or the more common sources of dietary fibre could be altered for greater health benefits.

8. In conclusion, to promote health and help prevent disease the future direction of food production should be towards greater production of anti-inflammatory (DHA, EPA, ALA, LA and ARA profile similar to aquatic foods eg mussels *Mytilus spp*), higher protein ($\sim$ one third of total food energy intake at the expense of lowered carbohydrate), low glycemic load, high fibre (25–30 g day^{-1}), bio-available nutrient rich, high

potassium—low sodium, brain foods (foods rich in preformed DHA, EPA, Iodine, Iron, Copper, Zinc and Selenium). Advances in food bio-nanotechnology that focus on these diet issues will in the long-term help prevent unnecessary suffering and premature death.

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What is the current level of public awareness of the issues surrounding the use of nanotechnologies in the food sector?

1. Almost non-existent. When informing the public on any matter, great care must be taken because most of the population is scientifically illiterate. I often read, see and hear the over-simplification and miscommunication of rigorously peer reviewed and well established health science by health agencies and health charities in the press, on the radio and TV (eg the Food Standards Agency advert about eating excess saturated fat is misleading. It is eating too much food energy per meal that is the problem—see Figure 1). It is very easy to make a convincing argument to the majority of consumers by adding two bits of (im)plausible science together and then coming to an implausible conclusion. See **Science communication** on page 346 in the appendix for further information.

2. In my experience, even when aware of the diet induced diseases of civilization, most people still want to have their cake (modern diet) and eat it. We can make the consumer aware of several options:

    1. eat wild ancestral (eg shore-based) foods, which is almost impossible for the vast majority of the population in countries surrounded by novel and domesticated human foods and polluted coastal waters. Further, there are more humans on Earth, than can be sustained by the natural World.
    2. continue eating the modern diet and thus, continue the diet induced disease epidemic (unnecessary suffering and premature death).
    3. modify the novel foods in the modern diet (while still looking and tasting the same as before modification), so they cannot induce the diseases of civilization.

What are the risks posed to consumers by the use of nanotechnologies and nanomaterials in the food sector?

1. The risks of well regulated and rigorously tested food nanotechnology products that help prevent disease are likely to be insignificant when compared with the magnitude of the current problem of the diet induced disease epidemic. Using bio-nanotechnology (or molecular biology) to engineer novel foods so they cannot promote the diet induced diseases of civilization is likely to be of great benefit to mankind. In reality there are already more humans on Earth, than can be sustained by the natural World.

2. The World spent US$4.4 trillion on health in 2005[30]. Chronic illnesses and health problems either wholly or partially attributable to diet account for the largest burden of chronic illnesses and health problems Worldwide. The modern diet (the replacement of ancestral foods (eg aquatic-based foods) by the excessive consumption of refined seed and nut oils, cereals, dairy products, refined sugars, fatty meats, salt, and combinations of these foods) adversely affects the following dietary indicators (1) fatty acid composition, (2) glycemic load, (3) macronutrient composition, (4) micronutrient density, (5) acid-base balance, (6) sodium-potassium ratio and (7) fibre content.[39]

APPENDIX

PREVENTING DIET INDUCED DISEASE BIO-AVAILABLE NUTRIENT RICH, LOW-ENERGY-DENSE DIETS

Anthony A Robson

Key Words: nanotechnology, diet, disease, cardiovascular disease, diabetes, cancer, prevention, DHA, EPA, brain, mental, ill, health, obesity, food, pregnancy, salt, energy, nutrition

Abstract

What the World needs is an integrated and sustainable food policy that makes the best, and most appropriate use of the technologies at our disposal to promote health and help prevent disease. Diet induced diseases account for the largest burden of chronic illnesses and health problems Worldwide. Historically a lack of knowledge about the human nutritional requirements (including for the brain) helped promote diet induced disease. The scientific knowledge exists to help prevent many of the current deficiencies and imbalances in human diet. Primary prevention of cardiovascular disease and mental ill health starts, crucially, with maternal nutrition before the inception of pregnancy and continues throughout life of the new born and includes consuming more DHA, EPA and ALA (alpha-linolenic acid) omega-3 fats (and their co-factors) and bio-available brain minerals and less high-energy-dense foods (eg refined sugars and land-based fats and oils), so tissues synthesize less inflammatory mediators and lower transient short-lived meal-induced oxidative stress, inflammation, proliferation and impaired nitric oxide (eg $\sim$0.35–3.5 g DHA + EPA day^{-1} dependant on energy intake and availability of co-factors). Micro- and nanotechnologies are already engineering foods for human (and livestock) consumption that may eventually (without excessive consumption) prevent the current diet induced disease epidemic, especially in future generations, by preventing the causal mechanisms of disease. Greater knowledge about the causal mechanisms of disease awaits to be discovered, which could further enhance the human desire to increase longevity in optimum health (creating more problems and challenges for society).

Introduction

Diet (oral ingestion) has always been a major mediator of disease and mortality in humans eg malnutrition, typhoid fever and polio. Currently many of the chronic diseases epidemic in human populations are diet induced diseases. This paper attempts to provide an understanding of the magnitude of the problem of diet induced disease. The primary objective is to provide information on how to help prevent diet induced disease, including the use of food nanotechnology. Nanotechnology promises to transform medicine from being therapeutic to being preventative. It is estimated that within the next two decades human life expectancy for healthy people will approach 100 years[1]. This means that many people reading this paper could see the 22nd century. Meeting people's aspirations to increase life expectancy, with all the problems it will bring to society, should be coupled with living as long as possible in good health (disease free). To achieve that future potential, it is necessary to look beyond the *status quo* eg medical efforts focusing more on treatments for older people than on preventing primary causes of diet induced disease before they occur—starting with appropriate maternal nutrition before the inception of pregnancy and continuing throughout the life of future generations. To understand our dietary needs it is necessary to look at human diets in relation to the causal mechanisms of disease. The review begins with the importance of diet as a fuel supply for the brain.

Nutrition for the Brain

The brain evolved containing DHA (omega-3) in the sea 500–600 million years ago[2]. DHA has been used in neural signalling systems over a 500–600 million year stretch of evolution. DHA is involved in neural receptor domains, gene expression with derivatives providing protection from oxidative stress in the brain and resolution of injury[3]. Shellfish, fish and shore-based animals and plants are the richest dietary sources of the key nutrients needed by the brain; the preformed dietary omega-3 fatty acids—DHA, EPA, iodine (I), iron (Fe), copper (Cu), zinc (Zn) and selenium (Se)[4, 5]. The omega-6 fatty acid arachidonic acid (AA) is also

important for brain development and present in shellfish and other aquatic-based foods (Table 1). DHA and AA are transferred across the placenta and accumulated in the brain and other organs during fetal development and maternal diet impacts fetal DHA and AA accretion[6, 7]. Postnatal nutrition is also a priority to ensure good maternal health and nutrition for the mother and her breast milk[8]. Increasing dietary alpha-linolenic acid (ALA) intake has little effect on increasing maternal transfer of DHA to the foetus, or on increasing DHA secretion in breast milk[9, 10]. Similarly, increasing the intake of ALA in infants, as in adults, has little effect on increasing circulating levels of DHA[eg 11, 12].

Historically a lack of knowledge about the human nutritional requirements (including for the brain) helped promote diet induced disease. There is growing awareness that the profound environmental changes (eg in diet and other lifestyle conditions) that began with the introduction of agriculture and animal husbandry ~10,000 years ago occurred too recently on an evolutionary time scale for the human genome to adapt[13–16]. In conjunction with this discordance between our ancient, genetically determined biology and the nutritional, cultural and activity patterns in modern societies, many of the so-called diseases of civilization have emerged[13–23].

Chronic Disease Epidemic

The World spent US$4.4 trillion on health in 2005[24]. Chronic illnesses and health problems either wholly or partially attributable to diet account for the largest burden of chronic illnesses and health problems Worldwide. Cardiovascular diseases are the number one cause of death globally (30 per cent of all deaths) and cardiovascular diseases are predicted to continue increasing[25]. An estimated 17.5 million people died from cardiovascular diseases in 2005[25]. Cancer is a leading cause of death Worldwide and accounted for 7.9 million deaths (around 13 per cent of all deaths) in 2007 and deaths attributable to cancer are projected to continue rising[26]. An estimated one-third of all cancer deaths are due to nutritional and life style factors[27, 28]. Taking into account deaths in which diabetes was a contributory condition (heart disease or kidney failure) approximately 2.9 million deaths in 2005 were attributable to diabetes[29]. Type 2 diabetes is rapidly becoming a disease of children and adolescents. In 2000, it was estimated that 30 per cent of boys and 40 per cent of girls born in the USA are at risk for being diagnosed with type 2 diabetes at some point in their lives[30]. Globally in 2005, at least 20 million children under the age of five years were overweight, approximately 1.6 billion adults (age 15+) were overweight and at least 400 million adults were obese[31]. The World Health Organization further projects that by 2015, approximately 2.3 billion adults will be overweight and more than 700 million will be obese. In the Europe Union, brain disorders have now overtaken all other burdens of ill health at an estimated cost of €386 billion (€829 a year for each European citizen) in 2004[32] and mental ill health is predicted by the Global Forum of Health (www.globalforumhealth.org) to be in the top three burdens of ill health Worldwide by 2020.

Human Diet

There are universal characteristics of pre-agricultural hominin diets that are useful in understanding how the modern diet may predispose humans to chronic disease. Increasingly, clinical trials and interventions that use dietary treatments with nutritional characteristics similar to those found in pre-industrial and pre-agricultural diets have confirmed the beneficial health consequences predicted by the template of evolutionary discordance theory.[15, 16, 33]

Before the development of agriculture and animal husbandry hominin dietary choices would have been necessarily limited to minimally processed, wild foods. Agriculture, introduced novel foods as staples for which the hominin genome had little evolutionary experience. More importantly, food-processing procedures were developed, particularly following the Industrial Revolution, which allowed for quantitative and qualitative food and nutrient combinations that had not previously been encountered over the course of hominin evolution. Although refined seed (vegetable oils) and nut oils, dairy products, cereals, refined sugars, and alcohol make up 72.1 per cent of the total daily energy consumed by all people in the USA, these types of foods would have contributed little or none of the energy in the typical pre-agricultural hominin diet.[34] Additionally, mixtures of these foods make up the ubiquitous, generally energy-dense, nutrient poor, processed foods (eg breakfast cereals, bread, cake, cookies, crackers, cheese, fried food, pizza, pasta, kebabs, sandwiches, soft drinks, alcoholic drinks, sweets, chocolate bars, ice cream, condiments and salad dressings) that dominate the typical modern diet.

The novel foods (refined seed and nut oils, cereals, dairy products, refined sugars, fatty meats, salt, and combinations of these foods) introduced as staples during the Neolithic and Industrial Eras fundamentally altered several key nutritional characteristics of ancestral hominin diets and ultimately had far-reaching effects on health and well-being. As these foods gradually displaced the minimally processed wild foods in human diets, they adversely affected the following dietary indicators (1) fatty acid composition, (2) glycemic load, (3)

macronutrient composition, (4) micronutrient density, (5) acid-base balance, (6) sodium-potassium ratio and (7) fibre content[33].

Using cereals (eg wheat, rice and maize) as an example, cereal grain consumption may appear to be historically remote but it is biologically recent; consequently the human immune, digestive and endocrine systems have not yet fully adapted to a food group which provides 56 per cent of humanity's food energy and 50 per cent of its protein[21]. Cereal grains are truly humanity's double-edged sword[21]. For without them, our species would likely have never evolved the complex cultural and technological innovations which allowed our departure from the hunter-gatherer niche. However, because of the dissonance between human evolutionary nutritional requirements and the nutrient content of these domesticated grasses, many of the World's people suffer disease and dysfunction directly attributable to the consumption of cereals.[21]

Dietary Fat, Essential Brain Nutrients and Health

Substantial evidence now indicates that to prevent the risk of chronic disease, the absolute amount of dietary fat is less important than is the type of fat.[35] Fatty acids fall into one of three major categories: (1) saturated fatty acids, (2) mono-unsaturated fatty acids and (3) polyunsaturated fatty acids (PUFAs). Essential PUFAs required by all mammals are not produced within the body, and must come from the diet and occur in two biologically important families, omega-3 and omega-6 (Table 1). The most prominent omega-6 fatty acids in the human diet are the highly unsaturated fatty acid (HUFA) ARA found in aquatic foods and animal meat and the PUFA linoleic acid (LA) found in foods including seeds, nuts and their oils (Table 1) which can be converted into the HUFA ARA by enzymes. Existing USA and UK recommendations to increase the consumption of EPA/DHA to 1 g day^{-1} and 0.5 g day^{-1} for those with and without existing cardiovascular disease respectively[36, 37] include consumption of shore-based foods eg shellfish and not just mainly pelagic oily fish eg mackerel and salmon[38] and high strength DHA + EPA oils. Much of the evidence upon which these guidelines are based, however, comes from supplemented intakes of preformed EPA/DHA at levels in excess of 1 g day^{-1} and $\sim$3.5 g DHA/ EPA day^{-1} has been recommended by some for current USA diets[39]. The high requirement for DHA/EPA can likely be reduced to one-tenth of that amount by consuming less energy per meal and less energy per day (ie low-energy-dense food and drinks—see Table 2) (compare [39] with [40]). Major dietary sources of the omega-3 PUFA ALA include seed oils (Table 1), which can be converted to EPA and then DHA by enzymes. However, the conversion of ALA through to the EPA and DHA is inefficient and may be an evolutionary consequence resulting from the ubiquitous presence of DHA + EPA HUFA containing foods in the food chain of our human ancestors, thus reducing the importance of the *de novo* synthesis pathway[41].

The cardio-protective effects of DHA/EPA have been recognized for over 50 years with the low incidence of mortality rate from CHD (coronary heart disease) in Greenland Eskimos, a population consuming a high fat diet, but rich in DHA/EPA[42]. In Greenland, coronary heart disease is almost undetectable[43, 44], while globally cardiovascular diseases account for 30 per cent of all deaths[25]. The totality of evidence for the positive effects of DHA and EPA from aquatic food and fish oil products on various outcomes of cardiovascular disease is almost incontrovertible, according to the review by Griffin[45]. However, others state that DHA, EPA and ALA do not have a clear effect on total mortality, combined cardiovascular events, or cancer[eg 46]. The section of the Cochrane study[46] regarding cardiovascular disease has been formally rejected by the Society for the Study of Fatty Acids and Lipids[47]. A more recent review highlights the important cardio-protective effect of DHA/EPA in the secondary prevention of sudden cardiac death due to arrhythmias, but suggests caution to recommend dietary supplementation of PUFAs to the general population, without considering, at the individual level, the intake of total energy and fats[40]. The current review suggests that the real value of DHA and EPA in the primary prevention of cardiovascular disease starts, crucially, with adequate maternal consumption of DHA and EPA (dependant on energy intake and availability of co-factors) before the inception of pregnancy and continues with adequate intake of DHA and EPA during pregnancy and lactation and throughout the life of the new born child. The slow progressive injury to human tissues that eventually becomes cardiovascular disease and premature death becomes irreversible overtime[48, 49]. Thus, secondary prevention of cardiovascular disease using DHA/EPA dietary interventions may not repair all the damage already done to human tissues by the lack of DHA and EPA and other factors in the diet earlier in life. It is important to note that if DHA and EPA fish oils undergo oxidation it may attenuate their beneficial effects[50]; bioactive-packaging made from nanomaterials can help to control the oxidation of food stuffs[51]. Further, the excessive consumption of anything may cause disease or premature death, even omega-3[eg 52, 53, 54].

In the United States, during the 90 year period from 1909 to 1999, a striking increase in the use of seed oils occurred. Specifically, per capita consumption of salad and cooking oils increased 130 per cent, shortening consumption increased 136 per cent and margarine consumption increased 410 per cent[55], which directly increased daily energy intake due to their high energy-density (Table 2). These trends occurred elsewhere in

the World and were made possible by the industrialization and mechanization of the oil-seed industry[56]. The trend towards an increase in daily energy intake was exacerbated by the excessive human consumption of energy-dense cereals, seeds and nuts, and as meat from grain fed cattle, poultry and other livestock became the norm in the Western diet over the past 100 years[23, 57].

The top predicted causes of death and disability Worldwide for 2020 (ischemic heart disease and unipolar major depression) and three top causes in developed regions (ischemic heart disease, cerebrovascular disease and unipolar major depression)[58] all seem linked to a lack of preformed DHA and EPA in the diet and excess food energy (imbalance between the expenditure/intake of energy). The close interaction between omega-3 (including DHA/EPA) and omega-6 (including GLA, DGLA and AA) fatty acids on the ability to modify inflammatory markers, production of PGI2, PGE1, PGI3, LXs, resolvins[59], neuroprotectins, NO (nitric oxide), nitrolipids, and the action of statins (HMG-CoA reductase inhibitors) and glitazones (PPARs agonists) on essential fatty acid metabolism and NO explains the relationship between various fatty acids and CHD and stroke[60]. Uncontrolled excessive production of pro-inflammatory mediators over prolonged periods of time is associated with heart attacks, thrombotic stroke, arrhythmia, arthritis, asthma, headaches, dysmenorrhea (menstrual cramps), inflammation, cancer and osteoporosis[61, 62] and the American Heart Association urged putting more omega-3 HUFAs into daily diets[63]. However, most epidemiologic cohort studies found no association between DHA and EPA intake and cancer risk[64–66]. But, inverse associations with breast cancer have been reported in Chinese and Japanese women having omega-3 HUFA intakes up to 40 times greater than Western intakes[67–69]. A large cohort study on breast cancer suggested that women with the lowest DHA and EPA intake but highest omega-6 PUFA intake (highest energy intake/excess food energy?—20–30 per cent of dietary fatty acids undergo betaoxidation to acetyl-CoA to enter the Kreb's cycle generating ATP[40]) could benefit from increasing their omega-3 HUFA intake[70]. Another study[67] found a direct association between omega-6 PUFA intakes (energy intake/excess food energy?) and breast cancer risk confined to women having the lowest intakes of omega-3 HUFAs. Such observations are consistent with the effect of the absolute amount of omega-3 fatty acids on the biosynthesis of anti-inflammatory 3-series eicosanoids[45]; AA derived 2-series tumor promoting eicosanoids and/or decreased synthesis of anti-inflammatory and beneficial eicosanoids most likely being an underlying mechanism for cancers such as colon, breast, kidney and prostate cancer[71–73]. Tumor cells undergo apoptosis on exposure to certain fatty acids (especially in response to DHA, EPA and GLA) due to an increase in intracellular free radical generation and the formation of lipid peroxides[60]. Further studies are required to better explain the Worldwide variations in the incidence of cancer which may be linked to differences in diet and lifestyle.

Additional evidence showed important actions of omega-3 HUFAs in brain function[74]. DHA is an important component of human retinal and brain membranes and has been shown to play a role in the cognitive development of infants[75–77]. Poor maternal health and nutrition before and during pregnancy disadvantages fetal development with permanent mental and cognitive deficits[78] and behavioural dysfunction[79, 80] with a risk of heart disease, diabetes and stroke in later life—prenatal programming[81, 82]. Maternal nutrition before and during pregnancy is an independent risk factor for low birth weight and poor pregnancy outcome[83–87]. A diet high in omega-6 PUFAs is generally thought to be associated with an increased risk of preterm delivery[88]. Increasing evidence suggests that depression, bipolar disorder, behavioral disorders and cognitive impairment in later life (dementia) also relate to a lack of DHA and EPA in the human diet [reviewed by 89]. Supplementation with a combination of both DHA and EPA (or consumption of aquatic-based foods) is likely to be more effective than use of either alone[90]. There is increasing evidence that the reasons for brain disorders are related to the replacement of aquatic-based foods by land-based foods[80, 91, 92]. Thus, it is especially important to eat a diet rich in essential brain nutrients DHA, EPA, I, Fe, Cu, Zn and Se (aquatic foods) before the inception of pregnancy, during pregnancy and breastfeeding and to give it to young infants (eg in baby food) to ensure optimal brain development and help prevent mental ill-health. The regular consumption of essential brain nutrients should continue throughout life because although the brain recycles its constituents rather than relying on imports, the process is not 100 per cent efficient and the continual loss needs to be replaced by some import.

The growing awareness of the importance of DHA and EPA omega-3 fats is evident from the single major personal health change recommended by the health and nutrition division members of the American Oil Chemists' Society: to eat more fish and take an omega-3 supplement[93]. The fats and oils from aquatic based-foods contain high contents of these beneficial omega-3 fatty acids but increased consumer demand has also increased strain on the ability of the World's fisheries to meet demand from wild capture. Many consumers are choosing fish oil supplements or are eating foods that have been complemented with fish oils instead of consuming aquatic foods directly. However, removing undesirable odours, flavours and contaminants is expensive. In contrast, oils derived from land plants such as soybean are inexpensive and contaminant free. Given the potential benefits to the environment with regards to over-fishing and the health prospects of increased consumption of these healthy fatty acids, producing these fatty acids in oilseeds is a desirable and

worthy goal (except for the high-energy density of oils (and fats) which may be reduced using nanotechnology[94]). Molecular biology now allows the engineering of oilseeds for the production of DHA and EPA omega-3 HUFAs in a seed oil with an omega-3:6 ratio 1.5:1 (a ratio close to that of many fish oils)[41]. A bread containing nanocapules of DHA/EPA omega-3 fatty acids is being sold in Australia as Tip-Top Bread[94].

Increasing human consumption of DHA, EPA and ALA omega-3 fats and by humans eating less food energy per meal (eg a 2,000-kcal daily diet consumed in six smaller energy portions—breakfast, brunch, lunch, afternoon tea, dinner and supper, rather than three large portions) to lower transient short-lived meal-induced oxidative stress[95–97], inflammation, proliferation and impaired nitric oxide[98–102], ultimately could have far-reaching effects on health and well-being. However, appreciating the nutrients essential for brain development[4, 5], the addition of I, Fe, Cu, Zn and Se to daily diets including DHA and EPA rich engineered seed oils with reduced levels of toxic factors and anti-nutrients (eg phytic acid) that impact bioavailability and utilization of nutrients and increased levels of factors that enhance bioavailability of essential nutrients[103, 104], would have even greater positive implications for human mental health in addition to helping prevent diet mediated inflammatory diseases. Further, for their physiological/beneficial action(s) PUFAs need many co-factors such as folic acid, vitamin B12, vitamin B6, vitamin C, tetrahydrobiopterin (H4B), zinc, magnesium, calcium, L-arginine, and small amounts of selenium and vitamin E[105]. Hence, it is essential that these co-factors should also be provided in adequate amounts to bring about the beneficial action of omega-3 and omega-6 fatty acids. Although principally a lack of DHA and EPA and excess food energy link diet to cardiovascular disease and premature death, evidence gleaned over the past three decades now indicates that virtually all so-called diseases of civilization arise from a complex interaction of multiple nutritional factors directly linked to the replacement of ancestral foods by the excessive consumption of novel Neolithic and Industrial era foods, along with other environmental agents and genetic susceptibility [c.f. 33].

Energy-density

Refined grain and sugar products nearly always maintain much higher energy densities than unprocessed fruits and vegetables. In the typical USA diet, sugars with a high energy density (HFCS 42, HFCS 55, sucrose, glucose, honey, and syrups) now supply 18.6 per cent of total energy, whereas refined cereal grains with a high energy density supplies 20.4 per cent of energy[33]. Soybean oil 8.8 kcal g^{-1} (data calculated from USDA National Nutrient Database for Standard Reference), appears to deliver 20 per cent of all calories in the median USA diet, with $\sim$9 per cent of all calories from LA alone[55]. Within the past 20 years, substantial evidence has accumulated showing that long term consumption of high-energy-dense (>2 kcal g^{-1}[106]) foods can adversely affect metabolism and health[107–109]. Hence, 39 per cent of the total energy in the typical USA diet is supplied by foods that may promote the causes of insulin resistance[110–115]. In addition to high-energy-dense carbohydrates, other elements of Neolithic and Industrial Era foods may contribute to the insulin resistance underlying metabolic syndrome diseases. Milk, yogurt and ice cream are highly insulinotropic, with insulin indexes comparable with white bread[116]. It is known that omega-3 PUFAs are of benefit in type 2 diabetes by decreasing insulin resistance[117]. Diseases of insulin resistance include obesity, type 2 diabetes and hypertension.

The global epidemic of obesity-associated diabetes is a symptom of the modern diet and lifestyle, in which food is plentiful and exercise is optional. Type 2 diabetes accounts for 90 per cent of all diabetes cases around the World[29]. Obesity and sedentary lifestyles closely linked with this type of diabetes[29] are both modifiable and even preventable risk factors. A healthy diet-plus-exercise is most effective for preventing diabetes mellitus[118]. Unfortunately, in modern societies, it is often easier to persuade people to take a pill, than to persuade them to change their diet and lifestyle for the long-term. Diet induced metabolic syndrome may extend to other chronic illnesses and conditions that are widely prevalent in Westernized societies, including: myopia[119], acne[120], gout[121], polycystic ovary syndrome, epithelial cell cancers (breast, colon, and prostate), male vertex balding, skin tags and acanthosis nigricans[109]. Although sugars and grains with a high-energy-density now represent a dominant element of the modern urban diet, these foods were rarely or never consumed by average citizens as recently as two hundred years ago[33]. Diseases of insulin resistance are rare or absent in hunter-gatherer and other less westernized societies living and eating in their traditional manner[14, 122, 123].

The finding that persons with a low-energy-dense (<1.6 kcal g^{-1}) diet had the lowest total intakes of energy, even though they consumed the greatest amount of food has important implications for promoting compliance with prescribed dietary regimens[106]. A reduction in liquid calorie intake has been found to have a stronger effect than has a reduction in solid calorie intake on weight loss[124]. Of the individual beverages, only intake of sugar-sweetened beverages (SSBs) was significantly associated with weight change[124]. A diet plan that severely restricts the amount of food a patient consumes will likely lead to feelings of hunger and have unfavourable influences on the patient's satisfaction with the diet and long-term compliance. Overweight

and obese patients may develop paradoxical nutritional deficiency from eating high-energy foods with a poor nutrient content. The impact of sedentary lifestyles and availability of energy-dense food in modern societies is undeniable, but substantial individual differences in body weight persist, suggesting that individuals respond differently to the "obesogenic" environment[125]. Psychometric measures of child appetite and child weight suggest that appetitive trait profiles may not only promote obesity but also protect against it and will include both genetic and environmental influences[125] which require further investigation.

High energy density (c.f. Table 2) and low nutrient density (Table 3) which characterise diet in developed countries are major targets that must be overcome. 2,000 kcal day^{-1} = 334g of chocolate (70–85 per cent cocoa), 353g peanuts, 496g cheddar cheese, 554g Kellogg's® Corn Flakes, 1,681g chocolate milkshake, 2,325g mussels, 2,439g cod, 4,444g fresh orange juice or 8,695g spinach (data calculated from USDA National Nutrient Database for Standard Reference). Nanotechnology or molecular biology may be able to engineer high-energy-dense foods abundant in the modern diet to maintain lower energy densities (< 1.6 kcal g^{-1}) while looking and tasting the same as before modification to aid public acceptance and reduce any insulinotropic properties with potential positive effects on metabolism and health.

Macronutrient Composition

In the present USA diet, the percentage of total food energy derived from the three major macronutrients is as follows: carbohydrate (51.8 per cent), fat (32.8 per cent), and protein (15.4 per cent)[33]. Advice for reducing the risk of cardiovascular disease and other chronic diseases has been to limit fat intake to 30 per cent of total energy, to maintain protein at 15 per cent of total energy and to increase complex carbohydrates to 55–60 per cent of total energy [eg 126]. Both the current USA macronutrient intakes and suggested healthful levels differ considerably from average levels obtained from ethnographic[34] and quantitative[127] studies of hunter gatherers in which dietary protein is characteristically elevated (19–35 per cent of energy) at the expense of carbohydrate (22–40 per cent of energy)[34, 127]. Because protein has > three times the thermic effect of either fat or carbohydrate[128] and because it has a greater satiety value than do fat or carbohydrate[128, 129], increased dietary protein may represent an effective weight-loss strategy for the overweight or obese. Studies have indicated that fish protein may have a greater effect on satiety compared to other protein sources of animal origin [see 130]. Clinical trials have shown that calorie-restricted, high-protein diets are more effective than are calorie-restricted, high-carbohydrate diets in promoting[131–133] and maintaining[134] weight loss in overweight subjects while producing less hunger and more satisfaction[135]. Furthermore, high protein diets have been shown to improve metabolic control in patients with type 2 diabetes[136–138]. In obese women, hypocaloric, high-protein diets improved insulin sensitivity and prevented muscle loss, whereas hypocaloric, high-carbohydrate diets worsened insulin sensitivity and caused reductions in fat free mass[139]. In numerous population studies, summarized by Obarzanek *et al*[140], higher blood pressure has been associated with lower intakes of protein. An increasing body of evidence indicates that high-protein diets may improve blood lipid profiles[137, 138, 141–143] and thereby lessen the risk of diet induced disease.

Improvements in the nutritional value of crop plants, in particular the protein composition has been a major long-term goal of plant breeding programs. Molecular biology has produced transgenic potatoes with about 33 per cent more protein and substantial amounts of essential amino acids including lysine[144], which is deficient in many developing countries where diets are heavily based on cereals[21, 103]. Strains of protein-enriched maize have also been created[145]. Some protein based nanotubes are considered food-grade materials[146], which should make their introduction into the human food chain relatively easy and might further facilitate increases in protein composition of currently high carbohydrate foods. The future looks promising to increase protein consumption at the expense of carbohydrate in the human diet, with numerous potential health benefits.

Micornutrient Density

Refined sugars are essentially devoid of any vitamin or mineral (Table 2). Accordingly, the consumption of refined sugar or foods containing refined sugar reduces the total vitamin and mineral (micronutrient) density of the diet by displacing more nutrient dense foods (Table 2). A similar situation exists for refined seed and nut oils (Table 2), except that they contain two fat-soluble vitamins (vitamin E and vitamin K)[147]. Because seed and nut oils and refined sugars contribute $\geq$36.2% of the energy in a typical USA diet, the widespread consumption of these substances, or foods made with them, has considerable potential to influence the risk of vitamin and mineral deficiencies[33]. At least half the USA population fails to meet the recommended dietary allowance (RDA) for vitamin B-6, vitamin A, magnesium, calcium, and zinc, and 33% of the population does not meet the RDA for folate[33]. Wild foods known to be consumed by hunter-gatherers generally maintain higher micronutrient concentrations than do their domesticated counterparts[13, 148], as does the muscle meat of wild animals[147].

Endemic clinical and sub-clinical iodine deficiency is present in about 20 per cent of humans Worldwide. The global problem of iodine deficiency primarily affects people not regularly consuming shellfish, fish or iodized table salt, without which clinical hypothyroidism, subnormal cognitive development and cretinism would still be the public health dilemma they were prior to iodization of table salt[149]. The scale and impact of endemic iodine deficiency is rivalled only by iron deficiency. Two billion people, over 30 per cent of the World's population are anaemic, many due to lack of iron[150]. Unlike iodine, iron is not yet legislated into the food supply but great efforts are being made to find a simple, cheap, reliable way to provide iron supplements where they are needed. Iron and other key minerals needed for brain development and function (zinc, copper, selenium) are more bio-available from shellfish and fish than from plant-based diets where their absorption is impaired by phytates and other anti-nutrients. Plant based diets rich in staples like cassava or soy (the basis of many vegan and vegetarian food products) are not only a very poor source of iodine but they also contain goiterogens which inhibit iodine absorption[149].

The displacement of more nutrient-dense foods (eg aquatic-based foods) by less nutrient-dense novel foods (refined sugars, cereals, seed and nut oils and dairy products) and the subsequent decline in dietary vitamin and mineral density has far reaching health implications, consequences that not only promote the development of vitamin-deficiency diseases but also numerous infectious and chronic diseases[21].

Bio-fortification of novel foods through modern methods of biotechnology/nanotechnology has the potential to help offset essential nutrient deficiencies and improve human health through elevated levels of essential nutrients (including their co-factors[105]), reduced levels of toxic factors and anti-nutrients that impact bioavailability and utilization of nutrients, and increased levels of factors that enhance bioavailability of nutrients[103, 104]. A number of crops, developed with a focus on improving nutritional quality are advancing through regulatory processes towards commercialization[103]. Some examples of nutritionally enhanced crops include cyanogen-free cassava[151]; nutritionally enhanced rice with an elevated level of beta-carotene[152], increased levels of iron and zinc[153], an elevated level of cysteine residues to enhance iron bioavailability and a decreased level of phytates to improve iron and zinc bioavailability[154]; and tomatoes and soybeans with increased antioxidant contents[155]. Food and nutrition products that contain nanoscale additives are already being sold, such as iron in nutritional drink mixes, micelles that carry vitamins, minerals and phytochemicals in oil and zinc oxide in breakfast cereals[51]. Other food nanotechnology products are cooking oils that contain nutraceuticals within nanocapsules and nanoparticles that have the ability to selectively bind and remove chemicals from food ("Nanotechnology in agriculture and food", available at http://www.nanoforum.org). Delivery of fragile micronutrients including their co-factors can be improved through nanoencapsulation[156]. By reducing particle size, nanotechnology can contribute to improve the properties of bioactive compounds (eg DHA and EPA), such as delivery properties, solubility, prolonged residence time in the gastrointestinal tract and efficient absorption through cells[157]. Bioactive compounds that are encapsulated into the packaging itself are a promising approach because this would allow the release of the active compounds in a controllable manner[51].

Acid-base Balance

After digestion, absorption, and metabolism, nearly all foods release either acid or bicarbonate (base) into the systemic circulation[158, 159]. Virtually all pre-agricultural diets were net base yielding because of the absence of cereals and energy-dense, nutrient poor foods, foods that were introduced during the Neolithic and Industrial Eras and that displaced base-yielding fruit and vegetables[159]. Consequently, a net base-producing diet was probably the norm throughout most of hominin evolution[159]. The known health benefits of a net base-yielding diet include preventing and treating osteoporosis[160, 161], age-related muscle wasting[162], calcium kidney stones[163, 164], hypertension[165, 166], and exercise-induced asthma[167] and slow the progression of age and disease-related chronic renal insufficiency[168]. Research is required to determine if micro- and nanotechnologies can modify novel net acid producing cereals to become net base yielding foods.

Salt

The average sodium content (3,436 mg day^{-1}) of the typical USA diet is substantially higher than its potassium content (2,617 mg day^{-1})[169]. The addition of manufactured salt to the food supply and the displacement of traditional potassium-rich foods by foods introduced during the Neolithic and Industrial periods (Tables 3 and 4) caused a 400 per cent decline in the potassium intake while simultaneously initiating a 400 per cent increase in sodium ingestion[13, 22, 170]. The potassium concentrations in vegetables are four and 12 times those in milk and whole grains, respectively, whereas in fruit the potassium concentration is two and five times that in milk and whole grains[147]. The inversion of potassium and sodium concentrations in hominin diets had no evolutionary precedent and now plays an integral role in eliciting and contributing to numerous diseases of civilization[33]. Diets low in potassium and high in sodium may partially or directly underlie or exacerbate a

variety of maladies and chronic illnesses, including hypertension, stroke, kidney stones, osteoporosis, gastrointestinal tract cancers, asthma, exercise-induced asthma, insomnia, air sickness, high-altitude sickness and Meniere's Syndrome (ear ringing)[171–181]. The removal of sodium salt from processed foods and bio-fortification of cereals and dairy products with potassium may help alleviate the current sodium-potassium imbalance in the human diet.

Fibre Content

The fibre content (15.1 g day^{-1})[169] of the typical USA diet is considerably lower than some recommended values (25–30 g)[126]. Refined sugars, seed and nut oils, dairy products, and alcohol are devoid of fibre and constitute an average of 48.2 per cent of the energy in the typical USA diet[33]. Furthermore, fibre-depleted, refined grains represent 85 per cent of the grains consumed in the USA and because refined grains contain 400 per cent less fibre than do whole grains (by energy), they further dilute the total dietary fibre intake[33]. Fresh fruit typically contains twice the amount of fibre in whole grains, and non starchy vegetables contain almost eight times the amount of fibre in whole grains on an energy basis[147]. Fruit and vegetables known to be consumed by hunter-gatherers also maintain considerably more fibre than do their domestic counterparts[148]. Diets low in dietary fibre may underlie or exacerbate constipation, appendicitis, hemorrhoids, deep vein thrombosis, varicose veins, diverticulitis, hiatal hernia, and gastroesophageal reflux[182].

Fibre type and quantity are undoubtedly under genetic control, although this topic has received little attention. The technology to modify fibre content and type by micro- and nano-engineering would be a great benefit in persuading the many individuals who, for taste or other reasons, do not include adequate amounts of fibre in their daily diet. For example, fibre content could be added to more preferred foods (eg milk, cheese, ice cream, refined cereals and white bread—but these are all novel foods that can currently (without modification) promote the diet induced diseases of civilization) or the more common sources of dietary fibre could be altered for greater health benefits.

Science Communication to the Public

The risks of well regulated and rigorously tested food micro- and nanotechnology products that help prevent disease are likely to be insignificant when compared with the magnitude of the current problem of the diet induced disease epidemic. Using bio-nanotechnology (or molecular biology) to engineer foods so they cannot (without excessive consumption) promote diet induced diseases is likely to be of great benefit to mankind. In reality there are already more humans on Earth, than can be sustained by the natural World. However, the consumption of (wild) aquatic-based foods in a sustainable manner should not be discouraged and nanotechnology will probably enhance the production, utilization and food safety of this nutritious resource. Bio-nanotechnology will change society beyond anything that has gone before. This should, but not with any certainty, eventually slow down the spiraling diet induced healthcare costs. Further, today's controversial areas such as nanotechnologies in foods, stem cell research, cloning, gene therapy, human enhancement and biochip implants will become acceptable practice before 2050.[1]

Conclusion

Chronic illnesses and health problems either wholly or partially attributable to diet account for the largest burden of chronic illnesses and health problems Worldwide. These diseases (eg cardiovascular disease) are epidemic in modern societies and typically afflict 50–65 per cent of the adult population, yet they are rare or non-existent in hunter-gatherers and other less Westernized people. What the World needs is an integrated and sustainable food policy that makes the best, and most appropriate use of the technologies at our disposal. To promote health and help prevent disease the future direction of food production should be towards greater production of anti-inflammatory (DHA, EPA, ALA, LA and AA profile similar to aquatic foods eg mussels *Mytilus spp*), higher protein ($\sim$ one third of total food energy intake at the expense of lowered carbohydrate), low-energy-dense, high fibre (25–30g day^{-1}), bio-available nutrient rich (including co-factors), high potassium—low sodium, brain foods (foods rich in preformed DHA, EPA, I, Fe, Cu, Zn and Se—aquatic foods). Micro- and nanotechnologies are already engineering foods for human (and livestock) consumption that may eventually (without excessive consumption) prevent the current diet induced disease epidemic, especially in future generations, by preventing the causal mechanisms of disease. Nanoscience and nanotechnology are new frontiers and their potential cannot be underestimated. There is still an ocean of knowledge about the causal mechanisms of disease that awaits to be discovered, which could further enhance the human desire to increase longevity in optimum health (creating more problems and challenges for society).

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Table 2

AMOUNT (G) OF A SELECTION OF FOODS EQUIVALENT TO THE 119 KCAL OF ENERGY IN ONE TABLESPOON (13.5 G) OF OLIVE OIL (04053)

Food	*g*
Chocolate bar, 70–85% cocoa (19904)	20
Peanuts (16087)	21
Chocolate cookies (18159)	25
Masterfoods®, Snickers Bar (19155)	25
Muffin, blueberry (18274)	30
Cheese, cheddar (01009)	30
Oats (20038)	30
Sugars, granulated (19335)	31
Kellogg's®, Corn Flakes (08020)	33
Distilled alcoholic drink, 50% abv (14533)	41
Beef, brisket (13803)	47
Bread, whole-wheat (18075)	48
Chicken, with skin (05006)	55
Ice cream, vanilla (19095)	58
Pork, loin (10020)	60
Salmon, Atlantic (15076)	84
Anchovy, European (15001)	91
Chocolate milkshake (01110)	100
Shrimp, mixed species (15149)	112
Bananas (09040)	134
Crab, Dungeness (15143)	138

Food	*g*
Mussel, blue (15164)	138
Red wine (14096)	140
Cod, Atlantic (15015)	145
Oyster, Pacific (15171)	147
Clam, mixed species (15157)	161
Potatoes (11354)	172
Apples (09003)	229
Seaweed, wakame (11669)	264
Orange juice, freshly squeezed (09206)	264
Carrots (11124)	290
Budweiser®, beer (14004)	290
Cola, soft drink (14148)	290
Spinach (11457)	517
Tomatoes, red (11529)	661
Lettuce (11251)	700
Drinking water, tap (14411)	N/A

[1] Entries retrieved from the US Department of Agriculture, Agricultural Research Service, 2007, USDA National Nutrient Database for Standard Reference, Release 21, http://www.ars.usda.gov/ba/bhnrc/ndl are followed by a 5-digit nutrient database number in parentheses. Data were not adjusted for country and seasonal specific differences in nutrient compositions of foods.

Table 1

ESTIMATED FATTY ACID COMPOSITION OF A RANGE OF AQUATIC AND LAND BASED FOODS

Food	*Omeag-3 Fatty acids*				*Omega-6 Fatty acids*	
	ALA (18:3w−3)	*EPA (20:5w−3)*	*DPA[2] (22:5w−3)*	*DHA (22:6w−3)*	*LA (18:2w−6)*	*AA (20:4w-6)*
Aquatic		g/100g			g/100g	
Mussel, blue (15164)[1]	0.020	0.188	0.022	0.253	0.018	0.070
Oyster, Pacific (15171)	0.032	0.438	0.020	0.250	0.032	0.038
Shrimp, mixed species (15149)	0.014	0.258	0.046	0.222	0.028	0.087
Crab, blue (15139)	0.000	0.170	0.000	0.150	0.012	0.055
Salmon, Atlantic (15076)	0.295	0.321	0.287	1.115	0.172	0.267
Mackerel, Atlantic (15046)	0.159	0.898	0.212	1.401	0.219	0.183
Catfish, channel (15010)	0.071	0.130	0.100	0.234	0.101	0.149
Seaweed, wakame (11669)	0.002	0.186	0.000	0.000	0.010	0.021
Salmon oil (04593)	1.061	13.023	2.991	13.232	1.543	0.675
Land						
Spinach (11457)	0.138	0.000	0.000	0.000	0.026	0.000
Kale (11233)	0.180	0.000	0.000	0.000	0.138	0.002
Carrots (11124)	0.002	0.000	0.000	0.000	0.115	0.000
Potatoes, white (11354)	0.010	0.000	0.000	0.000	0.032	0.000
Chickpeas, cooked (16057)	0.043	0.000	0.000	0.000	1.113	0.000
Mung beans, cooked (16081)	0.009	0.000	0.000	0.000	0.119	0.000
Milk, 3.7% fat (01078)	0.053	0.000	0.000	0.000	0.083	0.000
Cheese, cheddar (01009)	0.365	0.000	0.000	0.000	0.577	0.000
Butter, unsalted (01145)	0.315	0.000	0.000	0.000	2.728	0.000
Egg, whole (01123)	0.033	0.004	0.000	0.037	1.148	0.142
Chicken, with skin (05006)	0.140	0.010	0.010	0.030	2.880	0.080
Chicken, no skin (05011)	0.020	0.010	0.020	0.030	0.550	0.080
Pork, shoulder (10070)	0.130	0.000	0.000	0.000	1.600	0.100
Beef, sirloin (13954)	0.052	0.000	0.000	0.000	0.303	0.039
Lamb, domestic (17011)	0.320	0.000	0.000	0.000	1.090	0.070
Wheat flour, whole grain (20080)	0.038	0.000	0.000	0.000	0.783	0.002
Cornmeal, whole grain (20320)	0.049	0.000	0.000	0.000	1.589	0.000
Rice flour, brown (20090)	0.042	0.000	0.000	0.000	0.954	0.000
Oats (20038)	0.111	0.000	0.000	0.000	2.424	0.000

Food	*Omeag-3 Fatty acids*				*Omega-6 Fatty acids*	
	ALA (18:3w − 3)	*EPA (20:5w − 3)*	*DPA*[2] *(22:5w − 3)*	*DHA (22:6w − 3)*	*LA (18:2w − 6)*	*AA (20:4w-6)*
Kellogg's,® All-Bran (08001)	0.150	0.000	0.000	0.000	1.960	0.000
Kellogg's,® Corn Flakes (08020)	0.020	0.000	0.000	0.000	0.300	0.000
Kellogg's,® Special K (08067)	0.096	0.000	0.000	0.000	0.705	0.000
Masterfoods,® Snickers Bar (19155)	0.048	0.000	0.000	0.000	2.966	0.000
Muffins, blueberry (18274)	1.234	0.000	0.000	0.000	8.469	0.000
Bread, whole wheat (18075)	0.025	0.000	0.000	0.000	0.574	0.001
Tortillas, corn (18363)	0.034	0.000	0.000	0.000	1.385	0.000
Walnuts, english (12155)	9.080	0.000	0.000	0.000	38.093	0.000
Peanuts (16087)	0.003	0.000	0.000	0.000	15.555	0.000
Pecan nuts (12142)	0.986	0.000	0.000	0.000	20.628	0.000
Brazilnuts (12078)	0.035	0.000	0.000	0.000	20.543	0.000
Almonds (12061)	0.006	0.000	0.000	0.000	12.061	0.000
Sunflower seeds (12036)	0.060	0.014	0.000	0.000	23.050	0.000
Sesame seeds (12024)	0.363	0.000	0.000	0.000	20.654	0.000
Flaxseed (12220)	22.813	0.000	0.000	0.000	5.903	0.000
Apples, with skin (09003)	0.009	0.000	0.000	0.000	0.043	0.000
Bananas (09040)	0.027	0.000	0.000	0.000	0.046	0.000
Oranges, Florida (09203)	0.011	0.000	0.000	0.000	0.031	0.000
Olive oil (04053)	0.761	0.000	0.000	0.000	9.762	0.000
Cottonseed oil (04502)	0.200	0.000	0.000	0.000	51.500	0.100
Groundnut oil (04042)	0.000	0.000	0.000	0.000	32.000	0.000
Corn oil (04518)	1.161	0.000	0.000	0.000	53.515	0.000
Soybean oil (04044)	6.789	0.000	0.000	0.000	50.952	0.000
Sesame oil (04058)	0.300	0.000	0.000	0.000	41.300	0.000
Sunflower vegetable oil (04060)	0.200	0.000	0.000	0.000	39.800	0.000
Palm oil (04055)	0.200	0.000	0.000	0.000	9.100	0.000
Flaxseed oil (42231)	53.300	0.000	0.000	0.000	12.700	0.000
Margarine, 80% fat (04628)	2.040	0.000	0.006	0.000	22.252	0.000
Benecol® , light spread (04687)	2.187	0.000	0.000	0.000	9.724	0.000
Peanut butter (16097)	0.083	0.000	0.000	0.000	14.715	0.000

[1] Entries retrieved from the US Department of Agriculture, Agricultural Research Service, 2007, USDA National Nutrient Database for Standard Reference, Release 20, http://www.ars.usda.gov/ba/bhnrc/ndl are followed by a 5-digit nutrient database number in parentheses. Data were not adjusted for country and seasonal specific differences in nutrient compositions of foods. [2] DPA (docosapentaenoic acid $w-3$) is an intermediary between EPA and DHA.

Table 3

EXAMPLES OF THE ESTIMATED VITAMIN AND MINERAL CONTENT OF REFINED AND UNREFINED SUGAR, A SEED OIL, SHELLFISH, LAND-BASED MEAT, A VEGETABLE AND A FRUIT

	Units /100g	*Food*							
		Sucrose[1, 2] (19335)	*Molasses*[3] *(19304)*	*Sunflower oil (04060)*	*Mussel, blue (15164)*	*Oyster, Pacific (15171)*	*Beef, grass fed (13047)*	*Broccoli (11090)*	*Apples, with skin (09003)*
Vitamin C	mg	0	0	0	8.0	8.0	0	89.2	4.6
Vitamin B-12	µg	0	0	0	12.00	16.00	1.97	0	0
Niacin	mg	0	0.930	0	1.6	2.010	4.818	0.639	0.091
Riboflavin	mg	0.019	0.002	0	0.210	0.233	0.154	0.117	0.026
Thiamine	mg	0	0.041	0	0.160	0.067	0.049	0.071	0.017
Folate	µg	0	0	0	42	10	6	63	3
Vitamin B-6	mg	0	0.670	0	0.050	0.050	0.355	0.175	0.041
Vitamin A	µg[4]	0	0	0	48	81	0	31	3
Calcium	mg	1	205	0	26	8	12	47	6
Iron	mg	0.01	4.72	0.03	3.95	5.11	1.99	0.73	0.12
Magnesium	mg	0	242	0	34	22	19	21	5
Phosphorous	mg	0	31	0	197	162	175	66	11
Potassium	mg	2	1464	0	320	168	289	316	107
Sodium	mg	0	37	0	286	106	68	33	1
Zinc	mg	0	0.29	0	1.60	16.62	4.55	0.41	0.04
Copper	mg	0	0.487	NA	0.094	1.576	0.063	0.049	0.027
Manganese	mg	0	1.530	NA	3.400	0.634	0.010	0.210	0.035
Selenium	µg	0.6	17.8	NA	44.8	77.0	14.2	2.5	0.0

[1] Entries retrieved from the US Department of Agriculture, Agricultural Research Service, 2007, USDA National Nutrient Database for Standard Reference, Release 20, http://www.ars.usda.gov/ba/bhnrc/ndl are followed by a 5-digit nutrient database number in parentheses. Data were not adjusted for country and seasonal specific differences in nutrient compositions of foods. [2] Sucrose is a refined sugar. [3] Molasses is unrefined sugar. [4] Vitamin A units in retinol activity equivalents (RAE).

Table 4

ESTIMATED SODIUM AND POTASSIUM COMPOSITION OF A RANGE OF FOODS AVAILABLE IN MOST DEVELOPED COUNTRIES

Food	*Sodium mg/100g*	*Potassium mg/100g*
Salt, table (02047)[1]	38,758	8
Shrimp, mixed species (15149)	148	185
Salmon, chinook (15078)	47	394
Salmon, chinook smoked (15179)⋆	2,000	175
Spinach (11457)	79	558
Bananas (09040)	1	358
Wheat flour, whole-grain (20080)	5	405
Bread, whole-wheat (18075)⋆	472	248
Milk, 3.7% fat (01078)	49	151
Cheese, cheddar (01009)⋆	621	98
Butter, unsalted (01145)	11	24
Butter, salted (01001)⋆	576	24
Pork, shoulder (10070)	65	302
Pork, salami (07071)⋆	2,260	378
Kellogg's® , Corn Flakes (08020)*	723	79
Kellogg's® , Special K (08067)*	721	196
Masterfoods® , Milky Way Bar (19135)*	167	124
Margarine, 80% Fat (04628)*	654	18
Benecol® , light spread (04687)*	670	4
Soy sauce (16123)*	5,637	217
Peanuts, dry roasted (16390)	6	658
Peanuts, dry roasted (16090)*	813	658

[1] Entries retrieved from the US Department of Agriculture, Agricultural Research Service, 2007, USDA National Nutrient Database for Standard Reference, Release 20, http://www.ars.usda.gov/ba/bhnrc/ndl are followed by a 5-digit nutrient database number in parentheses. Data were not adjusted for country and seasonal specific differences in nutrient compositions of foods. * indicates the addition of sodium salt to the food.

3 March 2009

Memorandum by the Royal Academy of Engineering

Introduction

The Royal Academy of Engineering is pleased to submit evidence to the House of Lords Science and Technology Committee call for evidence on "Nanotechnologies and Food".

In 2004, the Royal Academy of Engineering and Royal Society were commissioned by Government jointly to produce a study on "Nanoscience and nanotechnologies: opportunities and uncertainties"[41]. The study did not focus particularly on the food industry; however most of the recommendations are relevant.

This response is based on contributions from Fellows of the Academy. The Academy is content for its input into this call for evidence to be made public and would be pleased to provide supplementary evidence if required. We have chosen to respond to the broad subject areas outlined in the call for evidence rather than the specific questions.

[41] www.raeng.org.uk/policy/reports/nanoscience.htm

1. *State of the science and its current use in the food sector*

1.1 Nanoparticles occur naturally and have always been created as the products of combustion and food cooking. Naturally occurring nanotechnology is present in many foods. For example, milk contains casein micelles which consist of nanostructures and deliver calcium phosphate to the body.

1.2 New nanotechnologies for food tend to be based on existing systems rather than being completely novel. Producing processing food can involve the creation of micro or nano structures, and understanding how those created structures can be broken down in the digestive system. For example, understanding of how butter emulsions are structured and broken down can be used to build new structures, producing butter with lower fat content yet similar taste and "mouth-feel".

1.3 Nutrition and pharmaceuticals

1.4 Nanoemulsions and particles in food can be used to deliver flavours and nutrients. Examples include bio-nanomaterials that allow metabolic inclusion and controlled release systems that help regulate diet and nutrition. Coupled with a stronger understanding of how foods and nutrients are digested, these applications could result in strong health benefits. It is likely that bio-nanomaterials will increasingly be used for food therapeutics (nutriceuticals).

1.5 Pharmaceutical drug products could also be delivered to the body using similar methods. "Smarter" bio-molecules can be synthesised with tailored release and absorbency characteristics. Nanotechnology will contribute to the low cost manufacture of these bio molecules.

1.6 Some nutritional and pharmaceutical applications (including those mentioned above) could be made commercially available fairly easily, but the food industry tend to be more risk averse than most. The risks of consumer rejection and reputation damage may outweigh any potential benefits of a new food technology.

1.7 Food packaging

1.8 In developed countries, nanotechnology tends to be used to create sophisticated food products and packaging to attract consumers. There is significant research effort in areas such as antimicrobial surfaces and in reactive packaging (eg indicators that change colour when food is unsafe to eat). These packaging technologies have obvious crossover with medicinal applications such as "smart" bandages and anti-microbial hospital surfaces.

1.9 Improving manufacturing

1.10 The food industry is keen to increase manufacturing efficiency and reduce waste. Nonstick surfaces that enable a production plant to be cleaned and re-used more rapidly would reduce water usage and therefore cost. It currently requires several litres of water to produce one litre of mineral water, because of cleaning requirements. A range of products is now being tested in the market, using either nano patterning or structuring methods. However, they are currently too expensive to be widely used, or need further development.

2. *Public engagement and consumer information*

2.1 One of the most important issues to address is the requirement for continued dialogue with the public on nanotechnology. Good public engagement is a two-way process that increases understanding of public attitudes and why barriers in consumer acceptance of new technologies may exist.

2.2 In the US the widespread cultivation of genetically modified (GM) corn is generally accepted, whereas in the UK there has been a backlash against all use of GM materials, including food. UK public attitudes to GM and the reasons for the initial backlash are multi-faceted. The GM example illustrates the need for genuine public dialogue around emerging technologies at an early enough stage to understand people's expectations and concerns, and the reasons underlying these. This indicates the need for public engagement to include those who are not involved in the commercial aspects of the food supply chain.

3. *Health and safety and regulations*

3.1 Regulatory frameworks are currently adequate although there remains uncertainty over the relative toxicity and therapeutic/nutritional benefits of many nanomaterials. Research is occurring that will produce data on the benefits and risks; this should help inform regulation.

3.2 There are no specific provisions for nanomaterials within the Registration, Evaluation and Authorisation of Chemicals (REACH) regulations.

4. *Other comments*

4.1 Food production is a complex system involving many inputs such as water and energy. It is worth noting that nanotechnologies can make an indirect contribution to improving food production by helping produce clean water and energy more efficiently.

March 2009

Memorandum by the Royal Society

1. The Royal Society welcomes this opportunity to respond to the Select Committee's call for evidence on nanotechnologies and food. This submission has been prepared from previous policy work, and takes account of recent developments in nanotechnologies and food. Our submission focuses on aspects of the call under "health and safety", "regulatory frameworks" and "public engagement and consumer information".

Introduction

2. The Society agrees with the Select Committee that the use of nanotechnologies and nanomaterials in the food sector requires investigation. We first reported on the opportunities and uncertainties of nanoscience and nanotechnologies in 2004 (Royal Society and Royal Academy of Engineering 2004). At that time, we noted that nanoparticles and nanomaterials would find future applications in the food sector; we recognise that applications are now with us including food ingredients, food additives and food contact materials (eg Chaudry et al 2008).

3. Nanoscience is likely to bring benefit to manufacturers and consumers of foodstuffs and related products. We note however that technical, social and ethical uncertainties, that we documented in 2004 and which have not been wholly addressed, relate to nanotechnologies and food just as they do for other uses of nanoscience. Yet use in food brings new concerns in the areas of health and safety, regulation, public and stakeholder engagement, and consumer information.

4. There is need for openness and clarity in this area. There is a paucity of information on the current state of commercial development of nanotechnologies applied to food, not helped by industry reticence and by a general difficulty of determining genuine uses of nanoscience and nanomaterials in the commercial field. We would welcome a survey from the Select Committee of the extent of research, development and use of nanoparticles related to foodstuffs, to add to other organisation's inventories (see for example www.nanotechproject.org/inventories/). It would seem reasonable to say that commercial activity is in its early stages (Chaudry et al 2008). Therefore there remains a window of opportunity to address uncertainties, but it will close fast.

Health and Safety

5. When we published our major report on the risks and opportunities associated with nanotechnologies in 2004, we concluded that most nanotechnologies posed no new risks. However, we highlighted at that time, and have done repeatedly since, that there is a lack of evidence about the risks posed by manufactured nanoparticles, particularly those that are free rather than fixed. Our concern has been updated and reinforced by the Royal Commission on Environmental Pollution (RCEP) report *Novel materials in the environment* which concluded that we remain ignorant about many aspects of the toxicology of nanomaterials (RCEP 2008:30).

6. The Food Standards Agency (FSA) has undertaken a review of current procedures for identifying, assessing and controlling any potential risks arising from the use of nanotechnologies or the presence of manufactured nanomaterials in food (FSA 2008). We note that the FSA concluded that whilst current approaches to risk assessment would be appropriate for nanomaterials, there are limited toxicological data on nanomaterials available at present (p15). The European Food Safety Authority (EFSA) came to a similar conclusion but went further, stating that the adequacy of current toxicological tests for nanomaterials has yet to be established (EFSA 2009). We have to improve our fundamental understanding of these substances and high priority must be given to ensuring that the underpinning research is undertaken to allow the assessment of risks associated with manufactured nanoparticles. The balance must be found between the amounts of funding allocated to the development of new applications compared with that being spent on the research needed to underpin the responsible development of these technologies.

7. In March 2007, the Council for Science and Technology said that Government had not made sufficient progress on its commitments to research, pointing in particular to research on toxicology and health and environmental impacts (CST 2007). We acknowledge that Government has directed or contributed to a range of research projects on risk and other aspects of nanotechnologies (eg DIUS 2008, Defra 2007). Previously we

have argued for an alternative approach, suggesting that an interdisciplinary research centre with a directed research programme would be the best mechanism for addressing knowledge gaps (RS/RAEng 2004, 2006a, 2007). The House of Lords might consider if a fragmented approach can grow capability in the UK and lead to outcomes comparable with that which might be expected from a interdisciplinary research centre (physical or virtual).

8. The import of nanomaterials into the food chain through unintended or accidental means must not be overlooked. Previously we noted that organisms such as bacteria and protozoa may take in nanoparticles through their cell membranes, allowing the particles to enter a biological food chain and introducing a possible exposure route (RS/RAEng 2004:36). We note that the RCEP similarly considers incidental mechanisms by which nanomaterials may enter the food chain, and highlight that the issue of bioaccumulation and entry of nanoparticles and tubes into the food web has yet to be seriously addressed (RCEP 2008:38)

Regulatory Framework

9. Mechanisms must be explored that support the commercial development of nanotechnologies and which take into account business interests whilst at the same time addressing uncertainties over the potential environmental, health and safety risks of some nanomaterials. The Society has had success in raising and discussing areas of uncertainty with business and industry, and we acknowledge that it does not only fall to Government to fund research into the potential implications of products. With Insight Investment and Nanotechnology Industries Association, the Royal Society held a workshop in November 2006 to explore strategic responses to technical, social and commercial uncertainties of nanotechnology. The workshop brought together 17 European companies with commercial interests in nanotechnologies from food and chemicals manufacturers to retailers of healthcare and fashion (Royal Society/Insight Investment/ Nanotechnology Industries Association 2007).

10. Participants felt that business should be fully involved in the processes of agreeing common definitions, standards and regulatory approaches so that their needs could be taken into account. One of the main outcomes of the workshop was unanimous agreement on the requirements for a voluntary Code of Conduct for businesses engaged in nanotechnology. To date *Seven principles of the code* and a series of *Examples of good practice* have been published (www.responsiblenanocode.org/). Some organisations represented on the Code Working Group have interests in the food sector. These representatives could be used to develop links with business and industry to explore the specific area of nanotechnologies and food.

11. The early initiation of discussions with businesses in the food sector may avert difficulties that have come to light in the cosmetics sector where environmental, health and safety research has lagged behind commercial exploitation. Lessons need to be learnt from the cosmetics experience. A particular concern concerns methods of risk assessment. The European Commission's Scientific Committee on Consumer Products (SCCP) has indicated that we cannot ensure the adequacy of risk assessment methods for cosmetic products containing nanomaterials, including products already on the market (SCCP 2007). We understand that attempts to assess methods have been hampered by industry reluctance to provide SCCP with information on the use of nanoparticles and methods employed for their risk assessment. We recognise that proprietary and other issues may limit the free and open exchange of information. Yet early discussion with representatives in the food industry may begin to address barriers to business and industry working cooperatively with Government and regulators.

12. Reluctance to participate is a pattern repeated in the Defra Voluntary Reporting Scheme for engineered nanoscale materials (VRS). We have previously said that if participation in the VRS was poor, then Defra should be prepared to take steps to make the scheme mandatory (RS/RAEng 2006b). With eleven submissions in the two years that the voluntary scheme was operational, take-up was not encouraging. We have no reason to change our opinion and recommend Defra look to put in place a mandatory reporting scheme. We note that the RCEP (2008) also recommended mandatory reporting of nanomaterials, and that the Canadian Government recently moved to introduce the world's first mandatory scheme (Sanderson 2009), although we understand that this will be a one-off request for information on material used in 2008 (see eg www.nanotechproject.org/news/archive/7061/).

13. We acknowledge that progress is being made towards understanding the fate and toxicity of particular nanomaterials (eg the work of the OECD, to which the UK Government is contributing; DIUS 2008; Defra 2007). The programme of work however must continually evolve, not only to address sector developments (such as the emergence of nanotechnologies applied to food) but also to assess, and if necessary control, coming generations of nanotechnologies and nanomaterials.

Public Engagement and Consumer Information

14. Public perception is broadly well disposed towards nanotechnologies and public thinking on nanotechnology has previously been explored through engagement projects initiated by Government and others. This should not be considered a finished project. First, public perception is dynamic and may change due to myriad factors. Second, public dialogue on nanotechnologies needs to be more closely linked with policy making processes than has been the case so far. Third, public dialogue needs to be a long term commitment that follows and intersects with the evolution of the field, and considers significant developments as they arise. We suggest that nanotechnologies and food is an area that now needs focused public dialogue work and opportunities should be sought for the findings to feed into policy and innovation processes. A leading example from which lessons can be drawn is the recently completed public engagement work by the Engineering and Physical Sciences Research Council (EPSRC) on potential applications of nanotechnology to healthcare. Public thinking was integrated into EPSRC's subsequent prioritisation process.

15. In 2004 we anticipated the use of free nanoparticles in consumer products including food, yet have been surprised at the speed with which products have reached the market. If food products containing nanoparticles reach the market whilst there are uncertainties over their possible health effects &/or methodologies used in their risk assessment (as has happened in the case of cosmetics), then those products should identify the fact that manufactured nanoparticulate material has been added (cf. RS/RAEng 2006a). But we stress that labelling is no substitute for prioritising research that reduces those uncertainties.

16. The issue of food labelling may be a good candidate for focused public and stakeholder engagement. Nanotechnologies have the potential to bring benefit to manufacturers and consumers, and open dialogue between the science, policy, commercial and public communities will be an important part of realising this.

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March 2009

Memorandum by Hilary Sutcliffe, Responsible Nano Forum

This is the response of Hilary Sutcliffe, Director of the Responsible Nano Forum, to the House of Lords Science and Technology Select Committee Call for Evidence on Nanotechnologies and Food.

Personal Perspective Only

It is a personal perspective only and does not represent the views of the Steering Group or Trustees of the Responsible Nano Forum who have not been consulted and have not contributed to the crafting of this submission.

View informed by . . .

These views are formed in part from my recent involvement in the area of nanotechnology and governance through the development of the Responsible Nano Code for which I ran the secretariat and also through the work of the Responsible Nano Forum, a multi-stakeholder, not-for-profit organisation which was set up in August 2008. It's purpose is: to serve the public good, we aim to inspire and motivate all stakeholders—business, government, scientists, ngos, the public, the media and others—to play their part responsibly in realising the benefits of nanotechnology, minimising risks and involving the public in deliberation about the social, ethical, health and environmental issues it raises. (*See* Appendix 1 for further information).

The research for and attendance at a recent Nano & Food meeting held by the Responsible Nano Forum. This brought together key stakeholders across business, government, ngos, research and academia to discuss the issues which arise in this area. This is part of the RNF remit to provide a "Forum for Reflection" for different stakeholders in the area of nanotechnology and also fulfills its commitment to helping all stakeholders play their part in the responsible development of the nanotechnologies.

State of the Science and its Current use in the Food Sector

Response—the urgent need for a shared understanding of the spectrum of nanotechnologies in all food related applications (and in other products)

It is unlikely that anyone can adequately answer most of these questions posed and the lack of transparency and understanding in this area may be a significant barrier to the effective current or future use of nanotechnologies in food. One of the most important issues getting in the way of a comprehensive response is the lack of a shared understanding of what actually constitutes nanotechnology and where areas of concern really lie.

The lack of a publicly available, agreed, clear description of the different ways in which the various nanotechnologies can be used in food (and many other applications)—from naturally occurring particles in, say, milk, to novel and new materials or processes. This has led to confusion among different stakeholders and perceptions of companies "keeping quiet" about their use of the technology and ngos "inflaming the debate" unnecessarily.

This debate has often got stuck on the discussion about the size of the particles which constitute nanotechnology in many fora, (eg under 100nm, up to 300nm etc), which has not been helpful as the question is richer than simply a size issue. The discussion about safety and usage of nanotechnologies needs to be broader than just a size issue.

In addition to the "what is nano" issue some information is required on where there are potentially real areas of concern and where the technology is an extension of existing processes and the risks are minimal.

Some work is being done on that at OECD, EU and UK government level, but the communication is often so heavily caveated that it is difficult to see, not where the risks lie, but actually where the lack of risk lies.

Informal dialogues with experts in the area indicates that this is certainly possible, but concerns about, among other things, legal and perception issues prevent it from happening.

This will allow for the focus of the discussion to be around these areas of uncertainty and potential concern rather than a general catch all discussion about nano in general.

It will give all stakeholders the ability to focus their attention, whether it be testing, legal issues, campaigning positions etc where it is most needed.

The Responsible Nano Forum, as an independent, multi-stakeholder body would be pleased to assist in the facilitation of this description and the multi-stakeholder dialogue which must support it.

Health and Safety

No response

Regulatory Framework

Response—The effectiveness of voluntary self-regulation

Whilst I am fundamentally opposed to voluntary codes of conduct which are designed to subvert or delay the development of effective legislation, and some are transparently designed for this purpose, I believe that there may be a useful role for the right scheme in the area of nanotechnologies in which food and packaging companies can usefully participate.

Current voluntary schemes

The UK Voluntary Reporting Scheme has been considered ineffective in that it had poor uptake among those groups to whom it was targeted. However this does not mean that a refined version may not achieve its aims, whether a voluntary scheme in this area is appropriate is not certain.

Again the lack of clarity about the spectrum of nanotechnologies is not helpful in assessing which materials and processes are appropriate for such a scheme and which are not and whether a voluntary approach is in itself appropriate. It may be that a more targeted mandatory approach may be more effective where there is agreed concern about risks-as occurs with carbon nanotubes, or a precautionary approach appropriate where expert advice concurs—but not in other areas.

The European Commission's recommendation for a Code of Conduct for Responsible Research exists, but drafting issues and lack of clarity about its monitoring and policing framework adds to the confusion about its role and effectiveness.

In addition the food industry (through the CIAA Code of Conduct) and the chemical industry (through Responsible Care) are looking to demonstrate responsible behaviour through these initiatives. It is not clear how the all important monitoring and evaluation process will work for these, detailed guidance is lacking and industry support unclear.

For these reasons they cannot be considered "effective" in that the behaviours required, the companies involved and the monitoring process has not been fully developed to my current knowledge and so the success of their stated aims is not known. Certainly they have not resulted in increased transparency about safety and testing which is paramount, and therefore have probably not been successful so far.

Other commercial certification schemes exist such as AssuredNano in the UK, forumnano in Germany and CENARIOS in Europe. The level of support for these is unclear, though such schemes can make a useful contribution to raising standards.

The Responsible Nano Code

Another scheme for the monitoring and assessment of companies involved in nanotechnologies is the Responsible Nano Code (developed by a multi-stakeholder working group and sponsored by the Royal Society, Insight Investment and the Nano KTN) has the potential to be effective in its stated aims through a process of benchmarking and comply or explain adoption, with transparent governance and reporting schemes. Though it is a principles-based code and necessarily "high level" the Responsible Nano Code could be effective in:

(a) Promoting the issues of responsible nanotechnology to the range of organisations in all parts of the supply chain from materials manufacturers to retailers and those involved in disposal and recycling.

(b) Allowing companies to demonstrate compliance with good practice in a transparent and easily understood way for the consumer. Some aspects of the good practice outlined in the code are enshrined in law, others are not. A voluntary initiative like this allows that information to be made clear in a way that simple adherence to regulation does not.

(c) Some feel that regulation in this area is not clear and fit for purpose, if this is the case a voluntary initiative such as this may help bridge that gap and provide information in the public domain to allay concerns.

There are a number of such principles-based codes in operation in a number of fields, some more effective than others. However where they are not monitored effectively, Codes of Conduct like this can provide a sort of "fig leaf" which is counter productive to the responsible development of the sector and the perception of responsibility with critical stakeholders. This aspect must be effective in order for a voluntary initiative like this to make a useful contribution.

The Responsible Nano Code is designed for use by companies across the world and has support and champions in the US, Asia and Europe. The Responsible Nano Code working group has partnered with Cranfield University for the delivery of the benchmark and adoption process. However its usefulness is dependent on significant funding to enable the secretariat at Cranfield to finalise the appropriate benchmarking and compliance mechanisms to make the code effective.

It is not appropriate that this comes from business alone and the government should consider how the Responsible Nano Code can assist with the responsible development of nanotechnologies and how the UK can take a lead through the support of such an initiative whilst also assisting in the development of a "level playing field" for UK companies operating across the globe.

Public Engagement and Consumer Information

Response—ongoing engagement required—not forgetting social and ethical issues

We believe that it is important that consumer are given information on nanotechnologies because it likely to have a huge impact on all our lives. Not just because of the new and sometimes life changing products it may help create or even the potential risks which may arise from the use of some nano materials or applications, but the ways it, in combination with other technologies, may alter our societies, our attitudes and our approach to our world.

This is central to the core purpose of the Responsible Nano Forum.

Information about the use of the various nanotechnologies in food should be part of that communication and engagement programme. The description of the spectrum of the technology will be helpful in assessing when and what is appropriate. For example labelling may be important in some areas where there is a hazard or an uncertainty, but not in others where this is not the case.

Where there is uncertainty about the uncertainty it may also be appropriate to make this known in some way! (*See* Nano&me below).

Clarity about the benefits will also assist in building confidence in the technology. At the moment it appears, according to a submission to our Nano&Food meeting "there is no 'killer app' in the food area which makes it worth the potential downside". Also companies are too nervous to put their head above the parapet in this area to promote a benefit in case it gets shot off, and the reputational hit affects their other products.

Previous initiatives—basically effective in their context

There isn't any particular reason why the public should currently know much about nanotechnologies, so naturally the awareness is low. Neither is there any stakeholder to whom it is particularly important that they know—ditto.

That being said, the UK is considered to be a leader in the area of public engagement with nanotechnologies—there have been a number of engagement initiatives sponsored by the government, the Research Councils, the consumer group Which?, various social science departments of universities, Phd students and even the East Midlands Development Agency. This is more than most/any other country has done and should be applauded.

The general attitude of the public may be summarised as—supportive, as long as the technology provides real benefits and is made safe for people to use and not destructive of the environment. Not an unreasonable approach to a new technology!

These initiatives were considered effective in achieving their goals in the context in which they took place. However we now believe, as did the recent Royal Commission on Environmental Pollution, that it is now appropriate to develop a more sustained approach to public communication and engagement on nanotechnologies. This is central to the work of the Responsible Nano Forum.

Nano&me—permanent, ongoing information for the public

The Responsible Nano Forum has developed the concept of a website, called nanoandme.org through which we hope to contribute to this sustained approach. (*See attached* www.responsiblenanoforum.org for brief outline of the site's aims and style and "stills" of its proposed style—the pilot site will differ, but not in overall design "feel".)

It aims to provide balanced information to the public and engage them in the debate about the issues—in particular the potential social and ethical issues which may arise from the development of the technology.

We have had significant co-operation from all stakeholders in the development of the content of this site, including a government group convened to help communicate about regulation, ngo involvement in content development and review, and business support and assistance in the development of product sectors and overall review. This is hugely encouraging and will help achieve our aim of providing balanced information, developed through an inclusive mechanism, in an easy to understand format.

DIUS have agreed to fund a pilot of this site for consultation with the participants of the previous public engagement initiatives and opinion formers. The outcome of this consultation and the appetite and scope of a final site should be available in August 2009.

The site will incorporate a "Nano Debate" section which will not only feature the Forum's own direct and on-line engagement initiatives, but will also act as a showcase for others programmes.

For example sponsored initiatives by government or research councils on specific applications, online versions of the relevant DEMOCS engagement projects, "Nano Cafe's" (done successfully in the US), Meet the Scientist events or business engagement projects.

We believe that this is an important contribution to the ongoing dialogue and involvement with the public. It will require significant ongoing funding, which we hope to achieve though multi-stakeholder funding streams from government, business and charitable foundations.

Benefits of nanotechnologies

Our research has indicated that the focus of public debate was very much on the risks of nanotechnologies and that the benefits of the technology and linkages to some of societies pressing problems has not been adequately explored, particularly in relation to the important challenges facing the UK—eg obesity, poverty, energy, ageing etc.

We are aware of ad hoc initiatives looking at the benefits of the technology in specific areas (eg environment, nanomedicine) but that a cohesive strategy had not been developed which makes these connections and links nano development with the UK research strategy, the commercialisation incentives for the technology and the UK development strategy. This maybe particularly interesting in relation to nano in food and the obesity debate.

We believe that the government's ministerial committee has indicated that a public and stakeholder debate about the UK's nanotechnology strategy may be appropriate, but that this is not currently envisaged as linked to some of the UK's challenges. We support that move, but think that it is essential to join up the discussion about nano and other technologies with the pressing issues we face as a society.

The potential for a permanent "Nano Commission" style organisation?

Would it be useful to have a permanent, independent organisation with the authority to engage stakeholders and advise government on these issues—in the style of Human Genetics Commission or the Sustainable Development Commission—with multi-stakeholder governance and an independent remit?

The stakeholder engagement we undertook as part of the development process for the Responsible Nano Forum and our subsequent work has led us to consider that this maybe a useful step in promoting the responsible development of the technology in a way which maximises its potential for the UK and engages the public appropriately in the process of its development. This is as necessary in the area of nano and food as it is in any other.

The Responsible Nano Forum as it is currently configured is funded a charitable foundation (the Esme Fairbairn Foundation) and by money raised for projects. We are more of an "ngo" or "think tank" than a formally constitute organisation. No detailed planning has been undertaken to assess the usefulness of such an organisation, its governance or its remit and if or how the Responsible Nano Forum could contribute to or evolve into such an organisation, neither has our our Steering Group had chance to discuss this thinking.

But we raise it here to contribute to take further the question raised in the original Royal Society report of 2004 and mentioned by the Royal Commission for Environmental Pollution of what institutions may be most appropriate to help ensure the responsible development of the technology, in food and any other area sector.

APPENDIX 1

THE RESPONSIBLE NANO FORUM

Our Purpose

To serve the public good, we aim to inspire and motivate all stakeholders—business, government, scientists, ngos, the public, the media and others—to play their part responsibly in realising the benefits of nanotechnology, minimising risks and involving the public in deliberation about the social, ethical, health and environmental issues it raises.

Why this is Important

Nanotechnology is likely to have a huge impact on all our lives. Not just because of the new and sometimes life changing products it may help create or even the potential risks which may arise from the use of some nano materials or applications, but the ways it, in combination with other technologies, may alter our societies, our attitudes and our approach to our world.

Because of this, we believe it is essential that everyone, particularly the general public, is aware of the nanotechnology, has access to information about its uses and has the opportunity to help shape the way the technology develops. We believe there is a need for an impartial voice in the debates around nano and we will strive to avoid creating concern or confidence where it is not appropriate.

Our Strategy is:

- To ensure easy access to clear and balanced information on nanotechnologies and the products it enables.
- To act as a catalyst for the involvement of the general public in shaping and contributing to the debate about nanotechnologies and the direction of current and future research.
- To stimulate others to play their part in the responsible development of nanotechnologies and nano-enabled applications.
- To be a trusted forum for reflection about some of the social, ethical, health and environmental issues, in which all stakeholders can and do participate.
- To stimulate and promote the development of "socially beneficial" applications of nanotechnology.

Our Plan of Action

Our plan of action will evolve as we continue our process of research, engagement and involvement with opinion formers and the general public. However, an opinion former consultation sponsored by the UK government (DIUS) inspired our plan for a number of important areas of work with which to begin:

- www.nanoandme.org—a website for consumers.
  - The hub of public engagement and communication for the general public.
  - Comprising easy to understand, impartial information on nano, including the range of stakeholder perspectives and current and future social, ethical health and environmental aspects.
  - Highlighting ways people can get involved and contribute to the debate and shape its development.
  - Including database of current UK consumer products using nano, the classification and definitions used in the different sectors and the benefits and any potential risks.
- Public engagement programmes
  - The UK is considered a world leader in public engagement with nanotechnologies.
  - We would like to take this engagement to its next stage as the facilitator and catalyst for deeper and more specific engagement, in particular around the social, ethical and environmental aspects of current and future applications and the direction of research.

- We would work with opinion formers and the public to prioritise the key issues and design a dynamic engagement programme. This may include direct groups such as citizen's juries, or through media partners, You Tube debates, polling and website interaction through Nanoandme.org. We would also hope to work with existing initiatives (eg East Midlands NanoWhat project), to include social and ethical issues in their programmes and where appropriate publicise these initiatives.
- We would articulate the "business case" for public engagement to help businesses and universities understand why public engagement is important and how to do it.

— A trusted forum for reflection—Debates and events on social and ethical issues
- We would undertake deliberative research with opinion formers to prioritise the areas for debate around the wider social and ethical impacts of nanotechnologies and help shape the information available on the consumer website.
- We propose holding a series of debates, both "live" and internet run which explore these issues with opinion formers and the general public.
- We may also facilitate dialogues for others—eg nano labelling—where our independence adds value.

— Stimulate others to play their part in the responsible development of the technology
- Our approach to this area is still under discussion. However we see some valuable contributions through:
- Ongoing involvement with the Responsible Nano Code through Steering Group members participation in oversight group and support of its aims.
- Through the Responsible Nano Forum website providing information and interaction with opinion formers on "what is responsible nanotechnology" and what organisations can do to discharge their responsibilities.
- Initiatives to effectively promote and support responsible nano—eg The Responsible Nano Awards, to highlight responsible behaviours, initiatives and partnerships.

— Stimulate and promote the development of "socially beneficial" applications using nano.
- Our most appropriate contribution to this area is also still under discussion. However we feel that not enough is done to stimulate the socially beneficial aspects and are seeking ways to do that. Eg
- Research to articulate UK priorities for beneficial applications (eg like the Foresight Challenges), including opinion former and public engagement.
- Engage with business leaders, government and scientists to promote these priorities (eg CEO dinners with the Centre for Tomorrow's Company, initiatives with KTN's etc).
- Partnership broking—with ngos, business and government to support highly practical ventures to support the priorities. (Eg arsenic measurement tech in Nepal with Practical Action ngo)

The Way we Work—We are:

Inclusive—this is demonstrated by the multi-stakeholder governance of the organisation, our commitment to balanced debate and bringing stakeholders together to develop solutions.

Trustworthy—this is demonstrated by the importance we give to the integrity of our information and communication; our commitment to transparency and disclosure and the direct and clear style of our communication.

We are mindful of the responsibility which comes with a focus on the public good—ensuring scientific integrity, avoiding bias or sensation, avoiding creating either concern or confidence where it is not appropriate and avoiding "favour" in terms of stakeholders or points of view.

Challenging—these other values do not prevent us from also being challenging without favour or bias. A multi-stakeholder approach can result in watered-down perspectives, stagnancy and bureaucracy. We aim to create an organisation that can retain its dynamism and energy despite these potential constraints, which is actually more enlivened because of our structure and the way we work.

Enthusiastic—we love what we do and we think it is important. This enthusiasm for our work shows—you will find it in our humour, our honesty, a "can do" attitude and a dedication to solving problems, clearing blockages and smoothing feathers to get the best outcomes we can.

1. *Who is Involved?*

The Director of the Forum, Hilary Sutcliffe, has significant expertise running small and "virtual" companies over a 12-year period, both as an executive director of *Addition, Shared View and Responsible Futures* and as a non-executive director of the *Ethical Investment Research Service.* She also has experience in working in communication, public engagement and in corporate responsibility over a period of 27 years, in the UK and USA, working in the field of nanotechnologies since 2006. She previously ran the secretariat for the Responsible Nano Code and is author of the paper *"An uncertain business: the technical, social and commercial challenges presented by nanotechnology"*, sponsored by the Royal Society, Insight Investment and the NIA.

The Managing Director of the Forum—Graham Broadbelt has extensive experience in management and operations for organisations similar in many ways to the Forum, being previously managing director of the think tank Demos and the community involvement charity Common Purpose.

Trustees and The Steering Group

The direction of work for the Responsible Nano Forum is set by a multi-stakeholder Steering Group and delivered by a small executive group and strategic partnerships, while the formal Board of Trustees of the charity will oversee its governance and organisational competence. The Board of Trustees is currently being appointed, but it will be multi-stakeholder in its make up. The Steering Group is comprised as follows: (shown here in alphabetical order):

Mr Frank Barry, *Unite Union*

Mr David Baxter, Lead Researcher, Emerging Risks, *Lloyds (Insurance)*

Mr Stuart Challenor, Trading Law & Technical Manager—*Tesco*

Ms Rachel Crossley, Director, Investor Responsibility, *Insight Investment*

Dr Robert Doubleday, Dept Geography, *University of Cambridge*

Ms Karen Folkes, Head of Public Engagement with Science and Technology, *DIUS*

Professor Richard Jones, FRS, EPSRC Senior Strategic Advisor for Nanotechnology, Professor of Physics, *University of Sheffield*

Dr David Grimshaw, Head of Prog: New Technologies, *Practical Action*

Arved Luth, *forumnano* (A group of German SMEs seeking to build their reputation for responsible nanotechnologies

Gene Matthews, *Leigh Day Solicitors*

Dr David Santillo, Senior Scientist, *Greenpeace International*

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