UK Government Response to The Royal Commission on Environmental Pollution (RCEP) Report "Novel Materials in the Environment: The Case Of Nanotechnology"

Presented to Parliament
by Command of Her Majesty
June 2009

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CHAPTER 1

INTRODUCTION

1. Nanotechnology is the manufacture, manipulation and measurement of materials with one or more dimensions in the range 1 to 100 nanometres.

2. Many reactions naturally occur at the nano-scale and nanomaterials are not new. For instance, they are formed during volcanic eruptions and are part of the bubbles in beer. However, technological advances are now allowing greater manipulation of materials at this scale, leading to an expansion in the use of this novel technology.

3. There are a growing number of potential future applications – in areas as diverse as healthcare, energy and construction – which could help improve our quality of life. Indeed, nanotechnologies have already started to help us respond to the key challenge of climate change by improving the performance of solar panels, batteries and fuel burning processes.

4. Whilst this area of innovation is still at a relatively early phase of development, it is expected to grow and to influence an increasingly diverse array of products and applications.

5. In its Report, the Royal Commission on Environmental Pollution (RCEP) has looked at the properties of nanomaterials and the potential pathways by which these materials could enter and present potential hazards to the environment and people.

6. Whilst the Royal Commission recognised that the Government is doing much to ensure the responsible development of nanotechnologies, we are in agreement that more needs to be done. In particular, the Government shares the Royal Commission's understanding that there is no evidence of actual harm resulting from the use of nanotechnologies, but accepts that this is a possibility and that there is a need to develop our understanding further.

7. To address this, the Government has already established a large programme of work, ranging from the development of the research base through to the provision of guidance for those who work with certain nanomaterials.

8. The Royal Commission's Report has provided a valuable opportunity to review progress and reflect on wider lessons for the way in which the Government deals with novel science and technologies. However, many of the Royal Commission's recommendations require long-term work and discussion with others to identify the right way forward.

9. Therefore, the Government intends to develop a UK Strategy for nanotechnologies. This Strategy will build on previous and existing activities and review the UK's priorities and strategic direction. The Government will launch an evidence gathering exercise with stakeholders in the summer to inform its development.

10. This response addresses each of the Royal Commission's recommendations, grouping these around the following five main themes, which reflect the Government's key strategic priorities:

i) Government co-ordination on nanotechnology
ii) Protecting human health and the environment
iii) Building the evidence base
iv) Delivering more effective regulation
v) Widening public engagement and capturing the benefits

11. This Command Paper forms the Government's response to the Royal Commission's Report, and has been developed in consultation with the Devolved Administrations.

CHAPTER 2

GOVERNMENT CO-ORDINATION ON NANOTECHNOLOGY

1. From development and manufacture, through application and disposal, to potential impacts on human and environmental health – the use of nanotechnologies presents a number of cross-cutting challenges.

2. In order to meet these, the Government has established a twin-track approach to facilitate knowledge sharing and take forward action in this area. Firstly, through structured groups which meet regularly, and secondly, through the use of more dynamic and informal networks.

The Royal Commission recommended that responsible organisations set up structured systems to keep a watching brief on the development of novel materials and to enhance the sharing of information and the opportunities to work together to identify and manage emerging problems.

The Government agrees with this recommendation and recognises that there may be a need to adjust existing systems to create a more integrated approach to nanotechnologies, engaging a wider range of stakeholders to enhance the sharing and understanding of available information. The Government will consider this during the development of the UK Strategy on nanotechnologies.

Summary landscape of UK organisations and networks

3. In order to effectively manage the challenges and maximise the opportunities for the UK presented by nanotechnologies, Government Departments and Agencies work together in partnership with wider stakeholders.

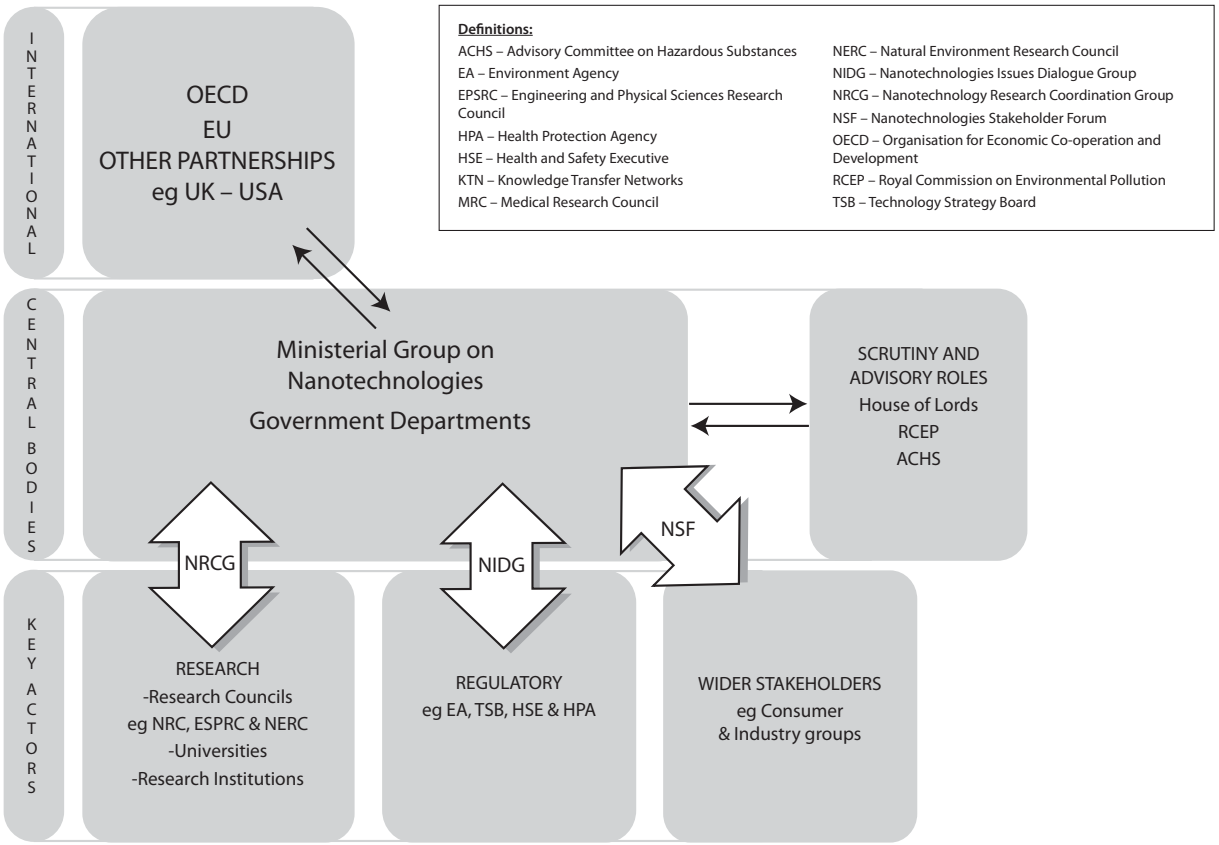
4. This co-ordination is achieved though a number of groups and the diagram at Figure 1 summarises how these interact.

5. The over-arching Government body is the Ministerial Group on Nanotechnologies. It is chaired by Lord Drayson (Minister of State for Science and Innovation) and is the key body through which the Government develops and takes forward UK policy on nanotechnologies.

6. This Group has representatives from the Department for Innovation, Universities and Skills (DIUS); the Department for Business, Enterprise and Regulatory Reform (BERR); the Department for Environment, Food and Rural Affairs (Defra); the Department of Health (DH) and the Department for Work and Pensions (DWP). A list of Ministers is at Annex A.

7. In support of the Ministerial Group is the Nanotechnologies Issues Dialogue Group (NIDG) comprising of officials from Departments the Devolved Administration and Agencies with an interest in the nanotechnologies agenda. The NIDG co-ordinates policy activity to progress the delivery of decisions taken by the Ministerial Group, as well as other aspects of the Government's agenda on nanotechnologies.

Figure 1



8. In wider support, the Government's Nanotechnology Research Co-ordination Group (NRCG) brings together Departments, Agencies, Research Councils and Devolved Administrations to steer the Government's research programme.

9. In order to benefit from further scientific expertise, Departments can consult specialist advisory committees. These include the UK's Advisory Committee on Hazardous Substances (ACHS), which has a broad membership including experts from the fields of medicine, chemistry and ecotoxicology, and the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment.

10. The Research Councils and the Technology Strategy Board also have an invaluable role as funders of research and contributors to capacity building of techniques, scientists and research centres in the UK. Involvement of the Research Councils in the NIDG and NRCG is co-ordinated through the RCUK Nanotechnology Group.

11. The Government has also established the Nanotechnologies Stakeholder Forum (NSF) which provides a valuable means of information exchange on developments in nanotechnologies between the Government and a wide range of stakeholders, such as industry and consumer groups.

12. It is through the ongoing development of this extensive network that Government maintains a pro-active approach to building and sharing evidence, and developing the science and opportunities that underpin nanotechnologies. However, the Government

recognises that there is scope for improvement and will consult on this issue as part of the development of the UK Strategy for nanotechnologies.

Adaptive management

13. The Royal Commission also highlighted the principle of adaptive management. The Government recognises the importance of systems through which information can be channelled, so that there is a timely reaction to new challenges. Clear communication between the Government and its stakeholders is key if the assessment and management of potential risks is to be carried out effectively, and the benefits realised.

14. In order to facilitate this communication a number of networking initiatives have been established, including:

- *The Safenano Initiative:* part of the Micro-Nano Facilities Network funded jointly by the Technology Strategy Board, Devolved Administrations and industry. Safenano is run by the Institute of Occupational Medicine and provides independent, impartial advice concerning the potential risks to human health and the environment from nanomaterials.

- *Nanotechnology Knowledge Transfer Network:* the Technology Strategy Board has established this three-year £2.5m project, to facilitate the transfer of knowledge and experience between researchers and industry. This is vital in bringing together technology providers and end users across a number of important market sectors.

- *AssuredNano Ltd:* provides an independent, EU-wide, human and environmental health accreditation scheme for organisations producing nanomaterials and nano-enabled products, which promotes the application of good practice.

15. These initiatives provide fora within which new information can be disseminated and shared on an ongoing basis but, as the Royal Commission notes, more needs to be done to improve the sharing of information about new developments and potential risks.

16. The Government will consider further how these and other mechanisms might be used to complement the more formal Government-led networks described above.

CHAPTER 3

PROTECTING HUMAN HEALTH AND THE ENVIRONMENT

1. The Government shares the understanding with the Royal Commission that no evidence exists of actual harm caused by nanomaterials, but accepts this is a possibility.

2. The protection of human and environmental health has always been – and remains – a clear priority for Government and much has already been done to progress the understanding and management of potential risks.

The Royal Commission recommended the establishment of clear priorities for testing, beginning with those nanoparticles with functionality which suggests that they might pose the greatest risk of harm to the environment or human health.

The Government recognises the need to prioritise research into nanomaterials which pose a higher potential risk, in particular those which are currently available or close to the market, and has already progressed much work in line with this principle.

The Royal Commission recommended that environmental monitoring to detect manufactured nanoparticles should be the responsibility of the Environment Agency in England and Wales, the Scottish Environment Protection Agency and the Northern Ireland Environment Agency, to ensure that robust processes are used.

The Government agrees that the monitoring of manmade nanomaterials is important and, where a specific risk has been identified, responsibility for the monitoring of manmade nanomaterials in the environment should fall to the relevant agency. However, the specific tools and techniques required are not currently available and the Government has commenced work to develop these.

3. This section contains text boxes summarising steps already taken in relation to the three nanomaterials noted in particular by the Royal Commission: nanosilver, carbon nanotubes and Buckminsterfullerenes.

Protection of human health

4. Exposure to nanomaterials is not new and many natural processes take place at the nanoscale. However, recent advances have resulted in the development of new products containing these manufactured nanomaterials. For example, nanosilver is sometimes used in cleaning products to improve their effectiveness.

Nanosilver

Nanosilver is well known to have antimicrobial properties. The Woodrow Wilson Centre's inventory of nano-products states that there are currently 235 products using nanosilver commercially available throughout the world.

Whilst this includes all types of products, there is currently only limited marketing in the UK. For example, a small number of colloidal silver food supplements and cleaning products.

However given the potential for use of nanosilver in products such as clothing, cosmetics and wound dressings, the Government has asked the UK's Advisory Committee on Hazardous Substances (ACHS) to consider the research undertaken to date and advise on how the use of this material may be best managed.

5. It is important that as the use of these products increases we act to build our understanding and have in place regimes to protect human health and the environment.

6. There is already much legislation in place to deal with potential risks. Whilst the legislation is not 'nano-specific' it places an emphasis on the need for products to be safe. For example:

- The Biocidal Products Directive requires rigorous evaluation of both the active substance(s) and the biocidal products containing them, before they are placed on the market.

- The Cosmetic Products (Safety) Regulations prohibit the supply of a cosmetic product liable to cause damage to human health under normal or reasonably foreseeable conditions of use.

- For human medicines the manufacture, sale, supply and importation of medicinal products into the UK is governed by Directive 2001/83/EC as amended by Directives 2003/63/EC and 2004/27/EC. All medicines on the UK market have been considered to be acceptably efficacious and safe.

- On food products, dating from the 1800s, the UK has only permitted safe food products to be placed onto the market. This is now applied through the EU's General Food Law Regulation. In addition, the EU Novel Foods Regulation requires specific safety testing and authorisation before novel food products, such as those containing new manufactured nanoparticles, can be placed on the market.

- More widely, the Product Safety Directive places a duty on suppliers of consumer goods to supply only products that are safe in normal or reasonable use.

7. The Government recognises the need to further increase the understanding about the potential effects of nanomaterials in order to inform decisions about what, if any, further action is needed.

8. A great deal of this work is ongoing, including:

- The Department of Health is providing £1.25m of research into the issue of nanotoxicology, with four research projects totalling £600k having recently been funded by the Department.

- Since 2007, the Medical Research Council (MRC) has awarded £3m of research grants into nanotoxicology research.

- The Health Protection Agency (HPA) has established the National Nanotoxicology Research Centre (NNRC). Work at the Centre will commence in late 2009, focusing on the biokinetics of nanomaterials – their uptake via inhalation and dermal routes, and their transport and distribution within, and removal from, the body.

Carbon Nanotubes

In 2004 the Royal Society and Royal Academy of Engineering reported that carbon nanotubes (CNTs) warranted particular attention due to their physical characteristics being similar to those of asbestos.

Following this, the Health and Safety Executive (HSE) published guidance in June that year on management issues related to nanomaterials advising that a risk assessment should be the first step in ensuring effective control within the workplace.

In 2008 the University of Edinburgh published research showing that certain forms of CNTs could produce similar reactions to some types of asbestos fibres when injected into the abdominal cavity of mice. While this research does not prove that CNTs will cause the same effects as asbestos, it does prove that one step in the causal chain for mesothelioma is the same.

Subsequently, Defra sought advice from Cambridge University on the use of CNTs in consumer products. This work suggested that current uses and applications of CNTs were unlikely to present a serious risk to the public, but that further study was needed. As a result a CNT life cycle exposure study has now been commissioned by Defra which is due to report in summer 2009.

In addition, the HSE issued specific guidance in spring 2009 on the safe use and handling of carbon nanotubes, recommending that in the use of CNT's a high level of control should be exercised.

Environmental protection

9. As noted earlier, nanomaterials are not new and many processes within the environment naturally take place at the nanoscale. However, protection of the environment from potential impacts of nanomaterials is a key strand of the Government's approach.

10. Again, legislation is already in place to do this, including:

- The EU REACH Regulation which requires chemicals identified as being of high concern to be authorised for particular uses before they can be marketed. Reviews can also be undertaken if there is new evidence to suggest that they may cause harm to human or environmental health.

- The Plant Protection Products Regulations 2005 provides powers for garden pesticides to be the subject of restriction and prohibition if evidence of harm to human health or the environment emerges.

- The Hazardous Waste Regulations requires waste containing nanomaterials to be disposed of in limited, specified ways should it pose a risk to human or environmental health, with those responsible being required to register with the relevant environmental regulator.

11. However, further understanding of the environmental pathways of nanomaterials and potential areas for accumulation in ecosystems is necessary. In this context, the UK has embarked on a substantial research programme to significantly increase our knowledge base, in particular through the Environmental Nanoscience Initiative (ENI).

12. The ENI was set up by the Natural Environment Research Council (NERC), Defra and the Environment Agency to begin to answer questions about the fate, behaviour, ecotoxicology and ecological effects of engineered nanoparticles.

13. In phase 1, launched in 2006 and ending earlier this year, 17 small-scale research projects were funded covering multiple areas including ecotoxicology in freshwater and marine model systems. These projects highlighted the need for existing test guidelines to be reviewed and this is now being taken forward with the OECD.

14. The UK and USA have now launched Phase 2 of the ENI (ENI-2). This joint programme will build on the achievements of Phase I, and draw on complementary strengths in the UK and USA to produce robust, validated models that predict transport, fate and bioavailability of nanomaterials and their interaction with biological and ecological systems.

15. The purpose of this £6m+ international collaborative research programme is to strengthen the support for research on the potential implications of nanotechnology and engineered nanomaterials on human health and the environment.

16. By maximising complementary and interdisciplinary strengths, the outputs of this collaborative endeavour should not only be a comprehensive understanding of key classes of nanomaterials, but also the development of predictive tools for exposure, bioavailability and effects. This will in turn support more confident statements concerning their effects and appropriate responses to mitigate potential risk.

Buckminsterfullerenes (C_{60})

The use of Buckminsterfullerenes in the UK is very limited. As a result this nanomaterial does not form a primary focus of our work, but does form part of the OECD-level programme on characterisation in which the UK is a full partner.

This provides a good example of how, by working collaboratively, countries can progress research into these materials much more quickly than by individual countries working alone.

We outline the work of the OECD Working Party on Manufactured Nanomaterials in more detail in Chapter 4.

Monitoring

17. Specific to the issues raised by the Royal Commission on monitoring nanomaterials in the environment, the Government is already undertaking an extensive programme of work to enhance our measurement capabilities.

18. A substantial programme of work on nanoparticle measurement and characterisation was established under the DIUS-led National Measurement System (DIUS NMS) shortly after the 2004 publication of the Royal Society and Royal Academy of Engineering report.

19. This work has been designed to address the current and future measurement and characterisation requirements for toxicologists, eco-toxicologists and environmental scientists both in the laboratory and in the field. Around £5m has been committed specifically to addressing fundamental metrology for nanoparticles.

20. A key early success was the establishment at the National Physical Laboratory (NPL) of a facility focused on the detection and measurement of airborne nanoparticles. This has led to the launch of the world's first accredited and traceable calibration service for airborne nanoparticle number concentration. Current research is focused in a number of areas including detection of engineered nanoparticles against ambient background levels and on measurement of key characteristics of airborne nanoparticles such as size and surface area.

21. In addition, work supported by DIUS, Defra, the Technology Strategy Board and the Engineering and Physical Sciences Research Council (EPSRC) is currently developing new technologies to allow the detection of manufactured nanomaterials in the wider environment. As a result of the ENI programme, the NERC has identified this as a key need and has recently established a Facility for Environmental Nanoparticle Analysis and Characterisation.

CHAPTER 4

BUILDING THE EVIDENCE BASE

1. The Government believes that a co-ordinated and targeted research programme is vital if research needs are to be met and the appropriate scientific skills base is to be developed.

2. It is widely recognised that materials on the nanoscale frequently exhibit different properties and functionalities from their bulk forms. These differences form much of the focus for research in this area, but it is also necessary to understand their behaviour in the wider environment so consideration can be given to which organisms, if any, are at risk of exposure.

The Royal Commission strongly recommended a more directed, more co-ordinated and larger response led by the Research Councils to address the critical research needs raised by their report, with emphasis on regulatory and policy programmes.

The Government believes that the Nanotechnology Research Co-ordination Group – in which the Research Councils play a key and active role – is best placed to achieve this. However, the NRCG is currently undertaking a review of its research priorities and we will consider the options for a centrally managed approach as part of this.

The Royal Commission recommended that urgent attention is given to undergraduate and postgraduate training in toxicology across all of its domains and that DIUS, the university sector and the professional societies that represent medical toxicologists and ecotoxicologists establish new initiatives to build multidisciplinary capacity in this field.

The Government recognises this needs to be addressed and has commissioned a study to determine the scale of the issue and identify how it might be tackled. Once that study reports, DIUS, DH, BERR, Defra and the MRC will lead the necessary actions to implement the recommendations.

3. In order to gain a better understanding of nanomaterials a multi-million pound multi-disciplinary research programme has been established, spanning domestic, European and wider international partners.

At the UK level

4. In their 2004 report “Nanoscience and Nanotechnologies: Opportunities and Uncertainties”, the Royal Society and the Royal Academy of Engineering recommended that immediate research be commissioned to address uncertainties about the nature, behaviour and health and environmental effects of nanomaterials.

5. The Government responded by establishing the Nanotechnology Research Co-ordination Group (NRCG) in 2005 whose role is to co-ordinate research in the UK into nanotechnologies. The group adopted 19 Research Objectives (listed at Annex B) which have been taken forward by five Task Forces:

TF1 – Metrology, characterisation and standardisation

TF2 – Exposure sources, pathways and technologies

TF3 – Human health hazard and risk assessment

TF4 – Environmental hazard and risk assessment

TF5 – Social and economic dimensions

6. More recently, in recognition of the potential need to prioritise specific areas the NRCG commissioned the 'EMERGNANO'[1] project, which reviewed 650 research projects undertaken since 2004 both in the UK and overseas.

7. One of the aims of that project was to identify specific areas where research may need to be focused in order to more fully develop understanding of manufactured nanomaterials.

8. The NRCG is now considering the results of this report in the context of the wider review of its research objectives, which it expects to conclude later this year.

At the European level

9. The European Commission is a significant funder of nanotechnologies research. Since 2004 nano research has been taken forward through the Sixth and Seventh Framework Programmes (FP6 and FP7). The total value of FP7 (which will run from 2007 to 2013) is 53.2 billion Euros, of which the UK expects to receive approximately 100m Euros for nanotechnologies-related research.

10. By their nature, Framework Programmes are multidisciplinary and co-operative and so it is difficult to identify exact total expenditure on nanotechnologies. However, this multi-million pound initiative provides a valuable stimulus for such research. For example, FP7 funds UK Nanoretox which is a two year project worth around £4.4m to examine the reactivity and toxicity of nanoparticles and the risk they pose to human health.

11. The UK is in a strong position to influence work within the EU as it has developed leading roles in a number of projects, as well as strong industrial, academic and governmental links to European nanotechnology policy makers.

[1] http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=16006

At the international level

12. The challenges posed by nanotechnologies mean that far more can be achieved through collaboration at the international level. For this reason, the UK Government has been among the leaders in the international effort to promote dialogue and facilitate the exchange of information.

13. The Organisation for Economic Co-operation and Development (OECD) provides an overarching structure for sharing information on nanotechnologies through two groups, the Working Party on Manufactured Nanomaterials (WPMN) and the Working Party on Nanotechnology (WPN)[2].

14. The Working Party on Manufactured Nanomaterials (WPMN), established in London in June 2006, aims to promote international co-operation in human health and environmental safety related aspects of manufactured nanomaterials. The UK has a key role in this group as a member of the steering Bureau.

15. The work of the WPMN includes a £30-40m research programme to develop understanding of the functionalities of fourteen of the most widely used nanomaterials (listed at Annex C), as well as developing nano-specific testing methods.

16. The UK is the lead sponsor of two of these fourteen nanomaterials (cerium oxide and zinc oxide), taken forward through the £3.7m PROSPEcT project which brings together the Engineering and Physical Sciences Research Council (EPSRC), Defra, the Technology Strategy Board and UK industry as joint sponsors. The project aims to build understanding of the characteristics of these nanomaterials and their likely ecological impact.

17. These international links allow the research effort to be shared between countries, enabling co-ordinated progress to be made, whilst making the best use of resources and avoiding unnecessary duplication. Through such an approach the Government seeks to optimise the use of available expertise and evidence to respond to critical research needs and inform policy makers.

Developing the skills base

18. The Royal Commission also made specific note of the need to build capacity in nanotechnology research. Progress has been made towards promoting training in this field, but the Government recognises that more needs to be done.

19. Defra has already commissioned an evaluation of the current toxicology and ecotoxicology skills base in the UK and this study, which is due to report in the summer of 2009, will provide an estimate of the requirement for toxicologists and ecotoxicologists.

20. The report will also recommend measures to address issues affecting retention and recruitment in this area. It will provide the evidence base to allow DIUS, DH, BERR and Defra to engage in a productive dialogue with, and provide a policy steer to, the Sector

[2] www.oecd.org/sti/nano

Skills Councils and National Skills Academies, and also enable the Research Councils to identify where further action may be needed.

21. The Research Councils have a crucial role in developing the skills base. For example, in 2007 the Medical Research Council (MRC) posted a policy highlight notice for nanotoxicology to encourage innovative, high quality research applications. This has already drawn considerable interest and resulted in funding commitments of approximately £3m.

22. Training awards in nanotoxicology are further supported through the Integrative Toxicology Training Partnership (ITTP), which is managed by the MRC Toxicology Unit in Leicester. This aims to produce a further 20 toxicologists.

23. More broadly, to enable the UK to make an international impact, a new mission programme of the Research Councils UK (RCUK) was formed in 2006 called 'Nanoscience through Engineering to Application'. This programme will develop a series of interdisciplinary Grand Challenges in areas that are important to society and where UK nanotechnology research can make a significant contribution – for instance healthcare, energy and the environment.

24. This approach is led by the EPSRC and has already resulted in a commitment of research funding for 2008/09 of £19m, with a further £30m planned for future support of the Grand Challenges. In addition, the programme has also established a network of existing nanotechnology and nanofabrication facilities that can be shared by researchers and funds 40 research students per year through a number of doctoral training centres.

25. The Government will continue to press forward with progress in this area to ensure that the UK skills base is developed. The NRCG has been asked to consider its role in promoting this as part of their review of priorities.

CHAPTER 5

DELIVERING MORE EFFECTIVE REGULATION

1. Legislation plays an important role in managing the risks of any new area of technology. The Royal Commission made a number of recommendations in the area of regulation and in this section we address each in turn.

Revisions to existing legislation

The Royal Commission recommended that:

- *in any revisions to existing regulations, the relevant authorities should focus specifically on the properties and functionalities of nanomaterials, rather than size;*
- *as REACH is adapted to meet the challenges presented by nanomaterials, particular attention should be given to the issue of weight thresholds. In view of the persistent uncertainties involved, a precautionary approach should be adopted when determining new, lower thresholds for nanomaterials.*
- *the UK Government should press the European Commission to proceed with urgency, in consultation with Member States, the European Chemicals Agency and SCENIHR[3], to review REACH and product or sector specific regulations. The object of the review should be to amend the regulations to facilitate their effective application to nanomaterials and the provision of adequate testing arrangements.*

2. The Government agrees with the Royal Commission that the REACH Regulation provides the most sensible legislative framework for the regulation of nanomaterials, in tandem with more specific legislation where this exists (for example on biocidal products). Likewise, the Government recognises that functionality, rather than size, should be the focus of any revisions to REACH, and that weight thresholds must be given particular attention.

3. REACH is based on the principle that manufacturers, importers and downstream users have to ensure that their substances may be safely handled and used, thus improving protection of human health and the environment. Currently, nanomaterials produced or imported in amounts greater than one tonne per year will be covered by REACH, as will any nanomaterials which are produced or imported alongside bulk forms of the substance so that together they meet the registration threshold.

4. In addition, should a nanomaterial be of concern, the European regulatory authorities can undertake work to identify whether use of that material may need specific

[3] Scientific Committee on Emerging and Newly Identified Health Risks

authorisation. Equally, restrictions can be placed on the use of nanomaterials if they are shown to be hazardous.

5. The Government agrees that some changes may be necessary to the current framework to more effectively manage the use of nanomaterials. In particular, the Government recognises the limitations of the annual one tonne threshold for registration and that the test guidelines may need to be extended to cover risks specific to nanoparticles.

6. In order to address this, the UK is engaged at the European level in a Nanomaterials and REACH Sub-Group. This brings together Member State representatives with knowledge of both REACH and nanomaterials issues to consider thresholds as well as other issues relating to their definition and evaluation.

7. This Sub-Group is due to conclude its work in 2012 and, in light of its advice, the European Commission is expected to propose suitable changes to REACH. The Government shares the Royal Commission's opinion that this review, along with the review of other sector-specific regulations, needs to be rapidly progressed. Defra's Secretary of State has already written to the European Commission urging an ambitious timetable for completion of this work.

8. The UK also keeps sectoral legislation under review and, where necessary, seeks to revise this on a case by case basis at the EU level. For example, an EU Cosmetics Regulation, directly applicable in Member States, has recently been drafted to take into account nanomaterials. A revision of the EU Novel Foods Regulation has also begun.

Additional legislation

The Royal Commission recommended that the Government impose an additional legal duty on companies to report at the earliest opportunity to the competent authorities any reasonable suspicion that a material presents a risk to people or the environment. Compliance with this requirement should offer duty holders a degree of immunity from criminal liability, should problems associated with the nanomaterials arise in future.

9. The Government agrees with the Royal Commission that it would be very useful to have early access to information that researchers and companies obtain about the possible implications of new materials and products. However, having carefully considered this recommendation, the Government does not consider that a new legislative requirement is an appropriate way forward.

10. Instead, Government will explore alternative ways of obtaining early information about new materials and products through existing structures and stakeholder networks, and will keep this 'horizon scanning' function in mind during the forthcoming development of the UK's Strategy for nanotechnologies.

11. On the issue of immunity for duty holders, the Government has outlined above that specific legislation exists requiring companies to act in a way that protects human and environmental health. Complying with these statutory obligations does not confer any immunity on an operator who reports a potential risk, although it may offer a potential defence. For example, the UK's implementation of food law includes the principle of 'due diligence' as a possible defence when a food operator is being prosecuted, but not *de facto* immunity from prosecution.

12. Ultimately, the decision whether to prosecute would be for the relevant enforcement authorities, taking account *(inter alia)* the scale of the offence, the circumstances in which it occurred and the likelihood of gaining a conviction. If taken forward, it is then a matter for the judiciary to consider the arguments of the defence and prosecution in reaching a decision.

Information exchange with industry

The Royal Commission recommended that:

- *the idea of a simple checklist, as part of an early warning system be developed and defined further by the Government to investigate the potential for development amongst the wider materials community.*
- *Defra should make nanomaterials reporting mandatory.*

13. In 2006 Defra launched a Voluntary Reporting Scheme for manufactured nanomaterials. This had the twin aims of increasing our understanding of nanomaterial use in the UK and developing our knowledge of the properties and characteristics of engineered nanoscale materials by requesting scientific data. 13 responses were submitted.

14. However, given the increasing interest in this area the Government agrees that additional work to boost our understanding is required.

15. The Government believes that a revised version of the earlier reporting scheme will address the 'simple checklist' approach suggested by the Royal Commission, and assist greater partnership working to develop our understanding of the science. This could include details of manufacturers and importers, information on quantities produced and how they are used in wider industry.

16. In doing this, it will also be important to keep in view the requirements of the REACH Regulation. Our initiative should ideally assist the nanomaterials industries in 'building a bridge' to a future REACH nanomaterials regime (which may well include a reporting requirement), rather than creating additional burdens.

17. The Government has not yet reached a final view on the scheme's design and work is currently ongoing to define in more detail how this could effectively be introduced. However, if a revised voluntary scheme is initially preferred and industry does not respond, the Government would re-assess its consideration of a mandatory scheme.

18. The Government will also review its 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.

CHAPTER 6

WIDENING PUBLIC ENGAGEMENT AND CAPTURING THE BENEFITS

1. It is clear that nanotechnologies offer potentially significant benefits, not only to the economy but also to human and environmental health. It will be important to maximise these opportunities.

2. Whilst the Government has a role in effectively managing and increasing our understanding of nanomaterials, there is also a need to promote UK industry's safe development of this technology and engage in a two-way debate with the wider public which responds to their concerns and aspirations.

The Royal Commission recommended it is desirable to move beyond one-off public engagement 'projects' to recognise the importance of continual 'social intelligence' gathering and the provision of ongoing opportunities for public and expert reflection and debate.

The Government agrees that public engagement activities should move towards a more continual dialogue and is taking steps to ensure this.

Engaging the public

3. During 2008, DIUS undertook a UK-wide consultation on Science and Society. Public engagement emerged as a key theme and five Expert Groups are now being established to develop an action plan to help address barriers to effective engagement.

4. The Government has also established the Sciencewise Expert Resource Centre for Public Dialogue on Science and Innovation as a principal mechanism to encourage and support public involvement in policy-making. The Centre is now exploring how a more continuous method of social intelligence gathering could be most effectively implemented.

5. Complementing this work at the international level, the UK led a project within the OECD's Working Party on Nanotechnology. This project undertook a review of member countries' activities in public engagement in nanotechnology and developed a set of guidelines. These are being trialled by member countries during 2009, including the UK, prior to their publication.

6. In addition, the Government has now commissioned a pilot initiative, to provide public access to a balanced source of information on nanotechnologies, including research, products and regulation.

7. This pilot will test the type and level of information that should be provided and trial a method, based around an interactive website, of both providing information and enabling public interaction and debate around nanotechnologies as they develop.

Engaging industry

8. The Government believes that it is important for industry to capture the economic potential of emerging technologies, and is supporting this through a number of initiatives designed to promote the responsible development of nanotechnology.

9. Through the Technology Strategy Board, the Government funds activities to translate knowledge and ideas generated by research into new products and services to capture market opportunities where UK academic and industrial capability exists.

10. The Technology Strategy Board operates across all important sectors of the UK economy, in partnership with many others, including Government Departments, Research Councils, Regional Development Agencies and the Devolved Administrations. The Technology Strategy Board has led on key initiatives, including:

- The Nanotechnology Knowledge Transfer Network (KTN)[4] - a three year, £2.5m project to promote responsible development and offering companies access to information on new processes, patents and funding, as well as keeping them up-to-date with industry regulation.

- Management of the Small Business Research Initiative (SBRI)[5] - a procurement programme whereby Government Departments buy research and development services, helping to bring new technologies to market and leading to the possibility that Government can act as a 'lead market' for new and innovative technologies.

- Collaborative R&D - in Autumn 2007 the Technology Strategy Board launched 'Materials for Energy'. The focus of this competition was on materials for energy generation, transmission, distribution, storage and conversion. Of the resulting 16 projects that were funded, 12 of these incorporated some level of nanomaterials activity.

11. However, the Government also sees industry as having a key role to play in the responsible development of nanotechnologies. For example, the Technology Strategy Board's policy on nanotechnology requires that project proposals involving manufactured nanomaterials are required to consider any potential risk to people and the environment.

12. In addition, to scope current industry efforts the NRCG is taking forward research to examine the nature and extent of Corporate Social Responsibility initiatives practised by the UK nanotechnologies industries. This work is due to complete in summer 2009 and, depending on the findings of this research, the Government will examine whether more needs to be done by industry and ways in which this can be achieved.

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4 www.ktnetworks.co.uk/

5 http://www.innovateuk.org/deliveringinnovation/smallbusinessresearchinitiative/whatissbri.ashx

CHAPTER 7

CONCLUSIONS

1. The Government's over-arching aim for nanotechnologies is to realise the potentially significant benefits to human and environmental health as well as the wider economy, but in a way that appropriately controls potential risks.

2. The Government will **develop an approach that has the protection of human and environmental health at the heart of its agenda** through implementing sound management practices based on evidence to allow us to act effectively, both specifically e.g. workplace guidance, and more widely e.g. at the legislative level. Contributing to this will be the need to realise the potential human and environmental health benefits offered by nanotechnologies.

3. The Government will continue to **ensure an integrated and co-ordinated approach to nanotechnology** through bringing together a wide range of stakeholders, with a focus on understanding and managing potential risks and ensuring the responsible development of nanotechnologies.

4. The Ministerial Group on Nanotechnologies will **continue to provide the strategic lead in this area, with input from relevant groups** including the Nanotechnology Research Co-ordination Group and the Nanotechnologies Stakeholder Forum.

5. **The continued development of the evidence base** is important so that our understanding of the risks and benefits is increased, and decisions can be made on the basis of sound evidence.

6. The Government will continue to **support the research programme at both the domestic and international level**, and looks forward to the completion of the Nanotechnology Research Co-ordination Group's review of its priorities.

7. And where this will prove effective, the Government will continue to **work collaboratively with international partners to deliver more effective management** by assessing the effectiveness of regulatory regimes such as REACH, and considering how best to adapt these to nanotechnology.

8. Importantly, the Government intends to **widen public engagement** to ensure that both the case for nanotechnology and the potential risks and uncertainties are discussed, as well as helping industry to **capture the benefits** in order that the UK realises the human health, environmental and economic gains that nanotechnology can potentially offer.

9. In order to realise these commitments, the Government intends to launch an evidence gathering exercise with stakeholders in the summer to inform the development of a UK Strategy for nanotechnologies

ANNEX A

UK MINISTERIAL GROUP ON NANOTECHNOLOGIES

Lord Drayson
Minister of State for Science and Innovation and Chair of Ministerial Group
Department for Innovation, Universities and Skills

Huw Irranca Davies MP
Minister for the Environment
Department for Environment, Food and Rural Affairs

Dawn Primarolo MP
Minister of State for Public Health
Department of Health

Lord McKenzie
Minister with responsibility for Health and Safety
Department for Work and Pensions

Ian Pearson MP
Parliamentary Under-Secretary of State for Business and Competitiveness
Department for Business, Enterprise and Regulatory Reform

ANNEX B

NRCG RESEARCH OBJECTIVES

RO1 To understand the social and ethical implications of nanotechnologies through a programme of public dialogue and social research

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 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 9 Optimisation, development and application of technologies that enable the measurement of exposure to nanoparticles in soil and water.

RO 10 Research to understand the environmental fate, behaviour and interaction of nanoparticles in soils and water.

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 (i.e. toxicokinetics), identifying potential target organs/tissues for toxicity assessment.

RO 12 Research to establish a clear understanding of inter and intracellular 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.

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 (e.g. 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 (PBT) are when considering nanoparticles. This should lead to the defining of a suite of standard PBT protocols for use in environmental hazard assessment.

ANNEX C

OECD SPONSORSHIP PROGRAMME – LIST OF THE 14 PRIORITY NANOMATERIALS

Sponsorship material	Lead sponsor	Co-sponsor	Contributors
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
Single walled carbon nanotubes (SWCNTs)	Japan, USA		Canada, France, Germany, EC, China, BIAC
Multi-walled carbon nanotubes (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

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