COUNCIL FOR SCIENCE AND TECHNOLOGY

Nanosciences and Nanotechnologies:

A Review of Government's Progress on its Policy Commitments

MARCH 2007

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The Nanotechnologies subgroup was chaired by Professor Sir John Beringer and comprised Professor Geoffrey Boulton, Mr. Andrew Gould, Dr. Hermann Hauser and Dr. Sue Ion, as well as three external members co-opted for their expertise: Professor Jacquie Burgess, Professor Ken Donaldson and Professor Mark Welland.

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Front cover picture: Focused Ion Beam Magnetic Force Microscope – viewed through sight glass

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Executive Summary

In July 2004 the Royal Society and Royal Academy of Engineering (RS/RAEng) published the report "Nanoscience and Nanotechnologies: Opportunities and Uncertainties." The report was highly influential internationally and led to the UK being seen as a world leader in its engagement with nanotechnologies. However, the clear message today is that the UK is losing that leading position and falling behind in its engagement with this fast developing field, primarily due to a distinct lack of Government activity or funding in research into toxicology, health and environmental effects of nanomaterials.

The worldwide market for nanotechnologies is predicted to be $1trillion by 2015. Nanotechnologies have applications in medicine, commercial products and industry and involve a disparate range of technologies. The unifying feature is the tiny dimensions at which the materials concerned are being manipulated. Nanoparticles exist naturally in large quantities in the environment and most nanotechnologies pose no new health and safety risks. Engineered nanomaterials are currently produced in very small quantities with low risk of exposure to workers or the public. However, the Government's stated precautionary stance suggests a need to investigate the potential health, safety and environmental effects of nanomaterials.

At Government's request the Council for Science and Technology (CST) agreed to carry out the two year review of the commitments set out by Government in its response to the RS/RAEng report. Since February 2005 there have been no nanotechnologies developments which raise new issues not addressed in the Government's response. The Government's response and the RS/RAEng report thus remain fully valid.

Government has made good progress on many commitments. Internationally it has driven forward the agenda. Support for the development of standards has been high. There have been several valuable public engagement initiatives though future projects must be better connected to policy makers. Dialogue with industry has limited the presence of nanomaterials in waste streams and prevented releases for remediation until the evidence base is improved. The Health and Safety Executive (HSE) and Health and Safety Laboratory (HSL) have committed substantial resources to nanotechnologies work, particularly for workplace exposure. The Defra Voluntary Reporting Scheme is promising but must secure high industry participation to be successful.

In contrast Government has not made sufficient progress on its commitments for research. Government committed to "an immediate programme of research" and said "we would expect substantial progress after two years". Government spent £10m on nanometrology over the last five years which is welcomed. However, in that five years only £3m was spent on toxicology and the health and environmental impacts of nanomaterials. This should be compared with the £40m/annum awarded by the Engineering and Physical Sciences Research Council (EPSRC) to drive forward progress in nanotechnologies and the £90m invested over six years by the Department of Trade and Industry (DTI) to promote their commercialisation. The balance between research that develops new applications of nanotechnologies and that which provides the necessary underpinning for its safe and responsible development must be addressed.

Government has relied too greatly on Research Council responsive mode funding to fill the knowledge gaps. A strategic programme of direct spending by Government departments is necessary to deliver Government's commitments. CST supports the RS/RAEng's recommendation that Government should invest a minimum of £5-6m/year over the next ten years to research the toxicology, health and environmental effects of nanomaterials. Without a substantial home research effort the UK will be unable to effectively take part in future international collaborations. Nanotechnologies' importance to the future UK economy, concern over nanomaterials and industry's inability to carry out all the necessary research justify the case for Government strategic funding.

The original RS/RAEng report was highly influential internationally. At the time of publication it was felt that the UK enjoyed a leading position in its engagement with nanotechnologies. It is now widely believed – by stakeholders from industry, academia, learned societies and non-governmental organisations – that the UK is no longer as highly regarded. CST urges Government to take the swift and determined action necessary to regain its leading position in nanotechnologies.

Summary of CST's Recommendations

Coordination and Review (Paragraphs 34–36)

I There is a need for greater strategic cross-Government action across different departments and agencies, particularly in the area of research. **A Government department, body or agency** should be given the responsibility and power to allocate funds and instigate action to drive forward the actions set out in Government's response.

II Championship of the issues surrounding nanotechnologies within Government, **at Ministerial level**, would both give greater leverage to coordinated action on nanotechnologies and help to bolster industrial, business and public confidence.

Research Funding Methods (Paragraphs 37-46; 63–80)

III If **Government** is to achieve its stated aim of resolving the uncertainties surrounding nanotechnologies it must cease to rely primarily on responsive mode funding to fill the knowledge gaps.

IV **Government** must embark upon an immediate programme of strategic research spending in order to achieve the objectives identified by the Nanotechnology Research Coordination Group (NRCG).

V Future **Government programmes that support the nanotechnology industry** should consider ring-fencing a proportion of the budget – which could still be channelled through industry – to research toxicology and health and environmental impacts of nanomaterials. This would ensure that the nanomaterials being tested were those on or near the market and would aid in building capability within industry.

VI **Government** must continue to engage proactively with the European 7th Framework Programme to ensure that sufficient funding is allocated to the responsible development of nanotechnologies, including metrology, toxicology, health and environmental impacts and life cycle assessments, throughout the programme.

The Nanotechnology Research Coordination Group (Paragraphs 68–71)

VII **Government** should explore the possibility of making the Nanotechnology Research Coordination Group (NRCG) more directly involved in awarding research funding, in order that its valuable work in identifying research priorities will have an immediate impact.

VIII **The NRCG** should adopt a higher profile within the research community in order to increase awareness of its work.

IX **The NRCG** is encouraged to continue its recent efforts to include more social and independent scientists on its taskforces.

Research Priorities (Paragraphs 47–49)

X **Government** must ensure that the following research priorities are achieved:

- An urgent priority is formulating short-term toxicity protocols, focusing on the types of nanomaterials – including metals, metal oxides and carbon nanotubes – currently on the market and being used by industry.
- A longer term need for substantive research into the toxicology, health and environmental impacts and long term environmental fate of nanomaterials.
- Development of methodologies for life cycle assessments involving nanomaterials and the carrying out of life cycle assessments themselves would also be valuable, though is of lower priority than the above.
- Although much work remains to be done in the field of nanometrology, discussions with HSE and with industry indicate that the substantive investment up to this point has succeeded in developing the field to the extent that responsive mode and demand from industry should be sufficient to develop the capabilities to the required standard, with only minimal further directed programmes from Government.

CST stands by the recommendation of the RS/RAEng that **Government** should spend a minimum of £5-6m/year over the next ten years to achieve these aims:

International Engagement (Paragraphs 72–75; 80; 135)

XI **Government** should maintain momentum in its excellent engagement with organisations such as the International Standards Organisation (ISO), the European Union (EU), the Organisation for Economic Cooperation and Development (OECD) and the United Nations Educational, Scientific and Cultural Organisation (UNESCO) in standards and regulation development and in collaborative research.

XII **Government** is encouraged to explore the possibility of greater bilateral collaboration on research with other countries heavily involved in nanotechnologies.

The Interface with Industry (Paragraphs 81–87; 90–93; 144)

XIII **Government** must streamline the interface between it and industry to aid communication between industry and Government – currently different Government departments, the Regional Development Agencies and the EU are all involved. Simplification would allow both parties to work with each other more effectively and smooth access for non-Governmental organisations (NGOs) and the media.

XIV **Government** should explore the possibilities of involving industry in public engagement exercises in order to communicate better the positive potential of nanotechnologies.

XV **Government** and the **Nanotechnology Industries Association (NIA)** are encouraged to work together in carrying out these recommendations.

Regulation (Paragraphs 94–111)

XVI **Government** must move swiftly to address the regulatory gaps identified by the DTI commissioned overview review of regulatory gaps (December 2006) by seeking extensions where necessary to the existing regulatory framework at the appropriate level; domestic, European or international.

XVII **Government**, with its European partners, must carry out the necessary research and produce the required supporting documents – including rules and guidance, hazard and risk assessment procedures or test methods – to allow existing health, safety and environmental regulation to be implemented effectively for nanotechnologies.

The Voluntary Reporting Scheme (VRS) (Paragraphs 90–93)

XVIII **Industry** is strongly encouraged to submit data to the VRS. The NIA should increase its efforts to encourage its members to participate in the scheme.

XIX **Defra**, through dialogue with the NIA, must resolve any remaining concerns that industry may have concerning protection of intellectual property.

XX **Defra**, in its review of the VRS after two years, must be rigorous in assessing whether the scheme has achieved a high take-up by industry. It must also ensure that the data received has not been compromised by evidence showing negative impacts being withheld.

XXI **Defra** must consider alternatives to the VRS should the two-year review show that it has been unsuccessful. The alternatives considered should, if necessary, include a compulsory reporting scheme. It is emphasised that this is an option of last resort: full participation in the voluntary scheme would be greatly preferred.

Public Engagement (Paragraphs 140–147)

XXII **Government** should maintain an ongoing programme of public engagement as nanotechnologies are a fast developing field. Future public engagement initiatives should be carefully formulated so that the information they deliver is in a form that will be useful to policy makers.

XXIV **Government** should conduct deeper and more in depth deliberative dialogue processes than have occurred to date to deliver results of greater value to policy makers. It should consider how best to involve industry and NGOs in the engagement process.

XXV **The Nanotechnologies Issues Dialogue Group (NIDG)** should improve the links between those running public engagement programmes and policy makers in relevant Government departments.

Introduction

1 In July 2004 the Royal Society and Royal Academy of Engineering (RS/RAEng) published the report *"Nanoscience and Nanotechnologies: Opportunities and Uncertainties"*[1]. The report has been greatly influential and is widely recognised internationally as having helped to set the agenda in the responsible development of nanotechnologies.

2 Government published its formal response in February 2005[2]. In the response Government agreed that there should be independent two and five year reviews of its progress in taking forward the actions it set out in the report and assessing the implications of any new developments.

3 The Council for Science and Technology (CST) has, at the request of Government, agreed to carry out the two year review.

4 The Review assesses whether Government has fulfilled the commitments it made in its response to the RS/RAEng report. It evaluates the extent to which Government has taken forward the commitments described in its response and the timeliness and effectiveness of the actions taken by Government.

5 CST emphasises that the Review does not discuss wider arguments on the use of nanotechnologies in society, nor does it discuss whether the commitments made by Government were the correct course of action.

6 One further part of CST's remit was to consider whether there have been significant developments in nanoscience and nanotechnologies since February 2005 which raise new issues Government did not address in its Response. CST has found that there are no such issues, and that the RS/RAEng report and Government's response are as valid today as when they were first published.

Conducting the Review

7 A subgroup chaired by Professor Sir John Beringer, Chair of the Governing Council of the John Innes Centre and former Pro-Vice-Chancellor at the University of Bristol, oversaw the Review. The subgroup's composition included five members of CST – Professor Sir John Beringer, Professor Geoffrey Boulton, Mr. Andrew Gould, Dr. Hermann Hauser and Dr. Sue Ion – and three co-opted members, Professor Jacquie Burgess Professor Ken Donaldson and Professor Mark Welland, co-opted for their expertise in nanotechnologies or in public engagement.

8 The subgroup collected evidence by means of an open Call for Evidence[3] which resulted in much valuable information being received from twelve organisations, including Government, industry, learned societies and NGOs. The group also conducted a series of oral evidence sessions and seminars with a range of stakeholders from both the UK and overseas, and from a wide variety of perspectives[4].

9 The subgroup presented the final text of the Review to the full Council where it was approved and endorsed.

1 http://www.nanotec.org.uk/finalReport.htm
2 A copy of Government's response may be found at Annex D.
3 A copy of the Call for Evidence may be found at Annex B.
4 A list of those consulted may be found at Annex A, and records of all written and oral evidence received may be found at Annex C.

What are Nanotechnologies?

10 Nanotechnologies comprise a disparate array of unrelated technologies that cut across many traditional scientific disciplines, including chemistry, materials science, engineering, physics, biosciences, medicine and environmental sciences. The only unifying feature is the tiny dimensions at which the material concerned is being manipulated. It is for this reason that we, in common with the RS/RAEng and many other organisations, consider "nanotechnologies" to be a more appropriate term than "nanotechnology".

11 It is important that the breadth and diversity of nanotechnologies be recognised by all parties concerned with the field. It would be a mistake if research, regulation or public dialogue attempted to treat such a broad field as if it were uniform.

12 In addition to the diversity of the field, there is a lack of consensus as to what constitutes nanoscience or nanotechnologies. This consequentially means that there can be disagreement over whether or not something is a nanomaterial.

13 Throughout this Review we use the same definition as used in the RS/RAEng report: that the nanoscale is the regime of 100nm down to about 0.2nm. A nanoparticle is a particle that has all three dimensions in this regime; a nanotube has two dimensions in this regime and nanosurfaces have one dimension in this regime. The definition excludes simple ions and atoms.

14 It is also important to distinguish between free and fixed nanomaterials. In the majority of applications, nanomaterials are fixed or embedded in a matrix but in some, such as cosmetics, free nanomaterials are used. It should be noted that in some cases fixed nanomaterials may be free at some stage in their production, or as they wear and degrade during their lifecycle.

15 Another distinction is between natural and manufactured nanomaterials. Nanoparticles are naturally present in large quantities in our atmosphere. Between 10^4 and 10^9 nanoparticles may typically be found per cubic metre of air. Manufactured nanomaterials include accidentally produced – largely combustion-derived – nanomaterials and bulk manufactured nanomaterials (e.g. titanium dioxide, carbon black and alumina), all of which have been present for decades, as well as the most recent generation of "engineered" nanomaterials that are the focus of more recent concerns. We would like to emphasise the point made in the RS/RAEng report and confirmed during our review that most nanotechnologies pose no new health and safety risks and that almost all concerns relate to the potential impacts of deliberately manufactured nanomaterials that are free rather than fixed in a matrix.

Importance of Definitions

16 The importance of definitions is crucial when discussing such a broad field. Firstly it allows precision in order to consider different nanotechnologies appropriately.

17 Definitions and standards are also crucial when considering research needs or in order for appropriate regulation, if necessary, to be devised. With this in mind we commend the work of the British Standards Institute (BSI)[5] and of the ISO Technical Committee on Nanotechnologies (ISO/TC 229)[6], established and chaired by the UK, whose work we will be discussing in more detail below.

5 http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/BSI-Committee-for-Nanotechnologies/
6 http://www.iso.org/iso/en/stdsdevelopment/tc/tclist/TechnicalCommitteeDetailPage.TechnicalCommitteeDetail?COMMID=5932

18 The lack of standard definitions is also of the highest importance in the field of public engagement and consumer confidence. Currently many commercial products are labelled as "nano" despite them not involving nanotechnologies. The appellation in such cases is a marketing term. Case Study Box One, concerning "nanosilver" and its use in washing machines, provides an illustration of the difficulties that conflicting definitions and terminology can cause.

Case Study Box One

Samsung's Silver Nano washing machine is advertised as using silver nanoparticles as an antibacterial agent. The machine produces silver ions – referred to as nanoparticles – by electrolysis which are released into the washing machine during the wash cycle. As the particles are then released into the water system, concerns have been raised over whether the silver ions could have a detrimental effect on the environment and on waste water treatment. It has been cited to us as an example of how the use of nanotechnologies could be resulting in unknown risks.

However, the Health and Safety Executive (HSE), the Competent Authority for non-agricultural biocides has stated that as the silver is produced and used in ionic form – at the atomic rather than at the nano level – this is not a nanotechnologies issue. The RS/RAEng concurs, stating that "if this is indeed a simple ion (eg as in a solution) then it is strictly a chemical additive not a nanoparticle and should be treated as such".

The view of HSE is that the use of silver ions to kill bacteria in clothes in washing machines and as a biocide in other products, is subject to the Biocidal Products Directive (98/8/EC). This is implemented in Great Britain by the Biocidal Products Regulations 2001. The decision by the USA's Environmental Protection Agency (EPA) to regulate the silver used in Samsung's washing machine is in line with the European stance.

19 While such lack of standard definitions might be viewed as harmless it is, at best, confusing for the public and consumers who are being confronted with a new technology. In addition it can cause complications for regulators and other relevant authorities, particularly if different countries take different stances.

20 Another problem is that should the product malfunction or be unsafe this can result in a lack of trust in Government, in science and, in the worst case, could contribute to the rejection of the new and valuable field of nanotechnologies – despite the fact that the product concerned did not contain any nanomaterials whatsoever.

21 Case Study Box Two describes such a situation involving an aerosol sealant spray, Magic-Nano, in Germany. We are happy to note that, in this case, the incident has had little effect on Germany's high investment, both public and private, into the development of nanotechnologies.

Case Study Box Two

In Germany in March 2006 an incident relating to an aerosol sealant spray known as "Magic-Nano" led to approximately 100 people being hospitalised with severe respiratory conditions. However, a thorough investigation by the German Federal Institute for Risk Management (BfR) found that, despite the product's name, the product did not actually contain nanoparticles, a finding confirmed by chemical analyses performed at two separate specialist chemical laboratories. The BfR found that the health problems were caused by inhalation of the aerosol spray. This finding was supported by the fact that no health problems had been reported when the product was sold in a pump bottle rather than an aerosol spray can.

22 CST is therefore pleased to note that the BSI is currently developing a Publicly Available Specification (PAS) on Good Practice Guide for Labelling of Nanoparticles and Products Containing Nanoparticles. Such guidance will both allow consumers to make informed decisions and help to reduce confusion, such as that which initially surrounded Magic-Nano, over whether or not a product genuinely involves nanotechnologies.

Why are Nanotechnologies Important?

23 Although nanotechnologies are not new – colloid chemistry[7] is a nanotechnology in a liquid medium and has been carried out for decades – they are becoming increasingly important. Advances in the tools that allow atoms and molecules to be examined and manipulated with great precision are enabling the expansion and development of nanoscience and nanotechnologies.

24 Current and future applications are extremely varied including use in electronics and active surfaces (for example, self cleaning windows); use of titanium dioxide nanoparticles in sun cream to protect against ultraviolet light; nanoremediation, the decontamination of ground contaminated by polychlorinated biphenyls (PCBs) through the use of nanoparticles of iron; the use of carbon nanotubes to strengthen tennis rackets; gold, aluminium and palladium nanoparticles as catalysts in fuel cells and in the automotive industry; paramagnetic nanospheres as drug delivery systems and many other uses.

25 The industry is expanding rapidly and is predicted to have a worldwide market of over $1trillion/year by 2015[8]. As of November 2006 the Woodrow Wilson International Centre for Scholars' Nanotechnology Consumer Products Inventory[9] listed 356 products or product lines ranging from the AMD® Athlon™ 64FX Processor to Nanotea, a type of tea enriched with nanoparticles of selenium. In March 2006 the database contained 212 products. This is an increase of almost 70% in only eight months and attests to the rapid growth of the industry.

26 Although the UK has both a strong background and a good academic base in nanotechnologies, other countries are investing heavily. Since 2000 the US Federal Government has spent $1 billion a year on nanotechnologies research, with a similar amount invested by industry and a further $400 million by states. Japanese Government funding in 2004 was 97.1 billion yen (c. £500 million) and German Government funding in the same year was €290 million (c. £200 million). This compares with UK Government funding for 2004 of €133 million (c. £90 million)[10,11].

7 Colloid chemistry involves the study of mixtures in which very small particles of one substance are distributed evenly throughout another substance.
8 Societal Implications of Nanoscience and Nanotechnology (Roco and Bainbridge 2001)
9 http://www.nanotechproject.org/44
10 The money invested by the DTI to support the commercialisation of nanotechnologies is £90m over six years. The fact that the overall Government funding in 2004 – which includes funding by Government departments and by the Research Councils – is also £90m is coincidental.
11 A List of Nanoscience and Technology Funding Requirements (*Martin Wegener, 2006*)

27 To maximise the technological, societal, environmental and wealth-creating opportunities for the UK it is thus crucially important that Government maintains and increases its current focus and support for nanoscience and nanotechnologies.

Are There Concerns?

28 In the nano regime the properties of materials can be very different from those at a larger scale. These new properties are what make nanomaterials potentially so useful in such a wide variety of novel applications. However, it also means that understanding the properties of a material at the bulk scale doesn't necessarily grant an understanding of the nanoscale properties. The example of gold, presented in Case Study Box Three, demonstrates how properties may alter.

Case Study Box Three

In its bulk form gold is inert; it is amongst the least reactive elements in the periodic table. However, when in nanoparticle form it becomes an effective catalyst with potential for use in the chemical and automobile industries.

Reactivity is not the only property of gold that alters as the particle size enters the nano regime. Gold's colour changes from yellow to red to blue as the particle size decreases. Furthermore, although gold remains non-toxic until far below the 100nm upper limit of the nano regime, when the particle size reaches approximately 2nm it potentially becomes harmful as the particles are able to bind to the major groove of DNA.

29 The greater surface-area to mass ratio that results when the particle size is reduced to the nano regime is one of the reasons why properties alter. It can result in the reactivity of a material being greatly enhanced – which may be either desirable or undesirable.

30 Very small alterations in the type of nanomaterial – for example slight changes in the particle size or attaching ligands to the surface – may further alter the properties radically.

31 These changing properties may lead to the toxicological properties changing. The potential toxicological and long-term environmental properties of many nanomaterials are not yet well understood.

32 CST wishes to emphasise that, as it has consistently heard throughout the consultation, many nanomaterials pose no new health and safety risks. However, evidence from research indicates that some nanomaterials may be deleterious to health.[12] Until these were better understood, Government in its response elected to take a precautionary stance, controlling possible risks to environmental and human health from the manufacture of new free nanoparticles without the need to halt development activity. We commend this approach.

12 A Matter of Size: Triennial Review of the National Nanotechnology Initiative (*Committee to Review the National Nanotechnology Initiative, National Research Council, 2006*); Nanomaterials – Potential risks for human health and the environment (*Oberdorster, G. 2006*); Nanoparticles – Known and unknown health risks (*Hoet et al, 2004*)

Overarching Issues

33 In addition to reviewing the commitments made by Government in response to each specific recommendation, we wish to highlight a number of overarching issues that touch on many of Government's commitments.

Coordination

34 The Nanotechnology Issues Dialogue Group (NIDG) has been established and has proved an effective means by which activities across Government are coordinated. It has achieved a wide and representative membership and been invaluable in maintaining contact between a wide variety of Government departments and agencies. The NIDG has also provided a platform from which to monitor progress and delivery, in particular in coordinating Government's submission of evidence to this review.

35 Whilst the work of the NIDG has been good, CST is concerned that there remains a need for greater strategic cross-Government action across different departments and agencies. As discussed below, CST has similar concerns about the Nanotechnology Research Coordination Group (NRCG) which, although it prioritises research, has no power to commission funding. If Government is to deliver fully on its commitments it must recognise that a method of delivering strategic action, not simply coordination, is required. If a Government department, body or agency were given the responsibility and power – with strong Ministerial backing – to allocate funds and instigate action across Government, this would greatly help in driving forward the actions set out in Government's response.

36 CST also wishes to highlight a more generic issue concerning the way in which Government identifies, funds and manages obstacles to the exploitation of new technologies. For example, in the case of nanotechnologies Government has allocated a significant sum – £90m over six years – to promote their commercialisation, but placed insufficient emphasis on the need to investigate the health, toxicology and environmental effects of nanomaterials, despite such research being vital if commercialisation is to ultimately succeed. This need to take a strategic, cross-departmental viewpoint reinforces the importance of a Government department, body or agency having the responsibility and power to allocate funds and instigate action across Government.

Research

37 In its response, Government said that it was "strongly committed to filling gaps in knowledge through an immediate programme of research aimed at reducing the uncertainties relating to toxicity and exposure pathways for nanoparticulates, as well as developing instrumentation to monitor these in the workplace and the environment."

38 Whilst there have been some Government initiatives, for example the formation and work of the Nanotechnology Research Coordination Group (NRCG), the evidence we have received is almost unanimous that the amount of activity in many areas of research has been unsatisfactory with little tangible advance in knowledge since February 2005. The potential health and environmental effects of many nanomaterials are still not well understood, nor has instrumentation suitable to routinely monitor workplace exposure to free manufactured nanomaterials been developed. In the area of nanoremediation there is as yet little conclusive data concerning the long-term environmental fate and toxicity of nanomaterials

despite Government's statement that it "would expect substantial progress to have been made when the CST reviews progress after two years."

39 Such lack of progress might be acceptable were Government able to point to a substantial research programme that would shortly be delivering results. However, no such programme exists and the amount of funds committed have been tiny. The Environmental Nanoscience Initiative (ENI) provided £500k in September 2006 for grants exploring the environmental effects of engineered nanoparticles, the Natural Environmental Research Council (NERC) has made awards of £750k into environmental fate, behaviour and ecotoxicology whilst Defra's nanotechnologies budget for 2006/2007 is only £250k.

40 In total, the Department of Trade and Industry estimates that in the last five years approximately £13m has been allocated across Government to address the potential risks posed by engineered nanoscale materials and the social and economic implications of nanotechnologies.[13] Almost £10m of this funding has been for nanometrology – EPSRC has funded grants totalling £9.9m – leaving only approximately £3m for toxicology and health and environmental impacts (full details of current and proposed projects may be found in the NRCG progress report14). This quantity of funding is not sufficient to fill the knowledge gaps and CST urges Government to do more.

41 These levels of spending should be contrasted with the £40m/annum awarded by EPSRC as responsive mode research grants in the area of nanotechnologies, the £19.8m interdisciplinary research collaboration by EPSRC, BBSRC and the MRC and the £90m invested over six years by the Department of Trade and Industry (DTI) on research and infrastructure that promotes the commercialisation of nanotechnologies. The balance between research that develops new applications of nanotechnologies and that which provides the necessary underpinning for its safe and responsible development must be addressed.

42 CST stands by the recommendation of the RS/RAEng report that the UK Government should invest a minimum of £5-6m/year over the next ten years to research the toxicology and health and environmental effects of nanomaterials. When one considers that the total UK Government funding for nanotechnologies in 2004 was approximately £90m[15], this figure could be achieved by a relatively modest rebalancing of the existing spend.

43 CST considers the primary reason for this lack of activity to be due to an over-reliance by Government on responsive mode funding, rather than on directed programmes by Government departments to deliver the necessary research. To quote the Safety of Nanomaterials Interdisciplinary Research Centre (SnIRC)[16], "it is difficult to see how a piece-meal approach such as this can result in the necessary strategic programme of research given that all of these proposals will be assessed individually." With the exception of nanometrology, in which EPSRC has made awards totaling £9.9 million, the amount of activity is disappointing.

44 The past two years have shown that responsive mode will not be sufficient to rectify the gaps in knowledge for, in a wide and developing field such as nanoscience and nanotechnologies, there is no guarantee that the research necessary to public safety and the research that interests the scientific community will be identical[17]. In addition, basic

13 Parliamentary Question 108402: Commons Written Answer to Dr. Ian Gibson MP, 19th December 2006
14 http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf
15 A List of Nanoscience and Technology Funding Requirements (*Martin Wegener, 2006*)
16 *SnIRC evidence, October 2006*
17 As the RS/RAEng state, "Responsive mode funding for research, while important, is not adequate to address interdisciplinary problems in an emerging area. Dedicated funding is required."

toxicology work, although vital, may not be the most innovative or cutting-edge research and thus will rightly not be funded by the Research Councils. To put it bluntly, the safe development of a new technology should not depend on whether an academic wins a highly competitive research grant.

45 Possible methods of carrying out the necessary research include a strategic programme of direct spending by Government departments, granting the NRCG the power to award funding and ring-fencing for toxicology studies a proportion of the money used to support industry.

46 CST thus strongly recommends that Government shifts its reliance on responsive mode funding and embarks upon the comprehensive programme of strategic Government spending necessary to fulfill Government's commitments. Nanotechnologies' importance to the future UK economy, concern over nanomaterials and industry's inability to carry out all the necessary research justify the case for Government strategic funding.

Future Funding

47 CST recognises that the UK cannot be expected to carry out all the necessary research itself and we applaud Government's engagement with international organisations to prevent duplication of research effort (see paragraphs 72-75). However, without a substantial home research effort to allow us to contribute effectively to international fora, our ability to engage in future international dialogue risks being compromised.

48 CST welcomes the fact that more funding will become available shortly, including over €1 billion on nanotechnology for EU members as part of the European 7th Framework Programme (FP7). We urge Government to ensure that UK researchers and research organisations can effectively tap into such sources so that substantial progress can be made as soon as possible. It must also continue to engage proactively with FP7 to ensure that sufficient funding is allocated to the responsible development of nanotechnologies, including metrology, toxicology, health and environmental impacts and life cycle assessments, throughout the programme.

49. After weighing the evidence that we have received, CST sees the future priorities for research as being:

- Urgently formulating short-term toxicity protocols, focusing on the types of nanomaterials – including metals, metal oxides and carbon nanotubes – currently on the market and being used by industry.
- A longer term need for substantive research into the toxicology, health and environmental impacts and long term environmental fate of nanomaterials.
- Development of methodologies for life cycle assessments involving nanomaterials and the carrying out of life cycle assessments themselves would also be valuable, though is of lower priority than the above.
- Although much work remains to be done in the field of nanometrology, discussions with HSE and with industry indicate that the substantive investment up to this point has succeeded in developing the field to the extent that responsive mode and demand from industry should be sufficient to develop the capabilities to the required standard, with only minimal further directed programmes from Government.

Precautionary Issues

50 Government's response was supportive of the precautionary stance recommended by the RS/RAEng. It agreed that sensible and pragmatic steps should be taken to control possible risks to environmental and human health from the manufacture of new free nanoparticles without the need to halt development activity, and that such steps should be taken alongside action to understand their properties. Exposure in the workplace and releases to the environment were to be minimised until the possible risks posed by nanomaterials were better understood. The case for a moratorium was rejected.

51 In response to our Call for Evidence we received differing opinions as to whether Government's actions actually constituted a precautionary response. This lack of consensus was confirmed at the seminar held in September, in which there was significant disagreement both as to what would constitute a precautionary response and whether Government's actions could be so described.

52 Some organisations, including Greenpeace and the Soil Association, suggest that a moratorium is a necessary part of any precautionary approach. Others such as the RS/RAEng, Swiss Re and the Health and Safety Executive (HSE) back Government's position that a precautionary stance did not necessitate a moratorium, but instead a responsible and careful attempt to minimise exposure to workers and the wider public and to prevent or minimise releases of nanomaterials into the environment until their properties are better understood.

53 The following characterisation of the precautionary principle states that it should be invoked when: (i) there is good reason, based on empirical evidence or plausible causal hypothesis, to believe that harmful effects might occur, even if the likelihood of harm is remote; and (ii) a scientific evaluation of the consequences and likelihoods reveals such uncertainty that it is impossible to assess the risk with sufficient confidence to inform decision-making[18]. CST accepts this characterisation.

54 After consideration of the evidence, CST agrees that there is sufficient concern about the potential impacts of nanotechnologies to legitimise the application of the precautionary principle. However, the evidence that we have received does not suggest that there is serious reason to believe that nanotechnologies will cause global or irreversible effects that would justify the case for extreme actions such as a moratorium.

55 CST thus agrees that Government's policy and practices are currently compliant with its stated precautionary stance. CST rejects the case for a moratorium. As we will discuss in more detail below, both industry and the universities are acting responsibly to minimise workplace exposure and prevent release into the environment and Government has successfully worked with industry to prevent environmental releases for nanoremediation until such time as we obtain better knowledge of any potential impacts.

56 However, CST would also join the RS/RAEng and many others in reiterating that such a precautionary approach relies upon the conduction of a substantial research programme in order to resolve the uncertainties surrounding nanotechnologies, particularly with respect to toxicology and environmental impact. Only by such a research effort – which, as discussed in paragraphs 37-46, has yet to occur – can Government's precautionary stance be justified.

57 CST's conclusion is likewise supported by Schmid et al in their book Nanotechnology: Assessment and Perspectives which is described in Case Study Box Four.

18 The Precautionary Principle: Policy and Application (*UK Interdepartmental Liaison Group on Risk Assessment*) http://www.hse.gov.uk/aboutus/meetings/ilgra/pppa.pdf

Case Study Box Four

The question of what is a reasonable application of the precautionary principle in the specific case of nanoscience and nanotechnologies is considered in depth in "Nanotechnology: Assessment and Perspectives" (*Schmid et al, 2006*). The book is the output of an initiative of the Europäische Akademie Bad Neuenahr-Ahrweiler GmbH to evaluate the state of the art in nanoscience and nanotechnologies, conducted by a working group consisting of internationally acknowledged experts from all fields of nanoscience and nanotechnologies.

They conclude that although there is reasonable concern about nanotechnologies which legitimates the application of the precautionary principle, there is no reason for serious concern that these will cause global or irreversible effects. There is thus no justification for the adoption of very strict measures such as a moratorium on nanomaterials.

Instead, an appropriate response is to minimise exposure to nanoparticles with unknown risks, to systematically monitor the development of the knowledge base and to adapt existing regulation schemes should new knowledge show it to be necessary. This is in line with the UK Government's statement of its precautionary stance.

However, this statement should not be misused. There are urgent tasks to be done by Government in order to close the large knowledge gaps and a comprehensive research programme should be embarked upon to, amongst other things, develop a nomenclature for nanomaterials, improve the knowledge base in toxicology and develop and approve tools for screening and testing.

Review of Progress on Responses to Specific Recommendations

Life Cycle Assessments | R1-2

58 Government stated that life cycle assessments (LCAs) "undoubtedly have a role to play" in the dialogue on nanotechnologies. However, to date very few have been carried out, either by industry or by independent bodies. Even for large companies, the resources required to do full LCAs are demanding and for most SMEs, which make up the bulk of the UK's nanotechnologies sector, the capability is simply out of reach.

59 Furthermore, a clear conclusion from CST's seminar on 4th September 2006 was that there is not yet sufficient knowledge as to how to carry out LCAs upon products containing nanomaterials. This problem was recognised by the RS/RAEng report and by Government's response; however, there has been little progress to resolving these uncertainties in the two years since.

60 Government's response said that this research should be carried out by the Research Councils through the normal responsive mode. CST believes that this is an inadequate means of conducting this research, for the reasons discussed in paragraphs 43-46. We believe that this is a case where a Government funded initiative to adapt LCA methodologies to products containing nanomaterials would reap great dividends, by better enabling industry or other interested bodies to carry out LCAs for themselves. The ability to carry out rigorous LCAs will allow the environmental benefits of nanotechnologies to be assessed and, if upheld, will assist public acceptance of the technologies. Case Study Box Five demonstrates an example of how nanotechnologies have the potential to greatly benefit the environment.

Case Study Box Five

Oxonica is a small but fast growing nanotechnologies company spun out from Oxford University in 1999. Its turnover in 2005 was £1.2m, up from £0.4m in 2004.

One of its commercial products is Envirox™, a fuel-borne catalyst based on cerium oxide designed to improve fuel economy and reduce emissions from diesel powered applications. Envirox™ is used commercially by Stagecoach in the UK and by a number of petroleum companies in the Philippines. The material is classified as non-hazardous for road transport and requires the same handling precautions as standard diesel fuel.

Independent field trials have shown that Envirox™ reduces fuel consumption in diesel engines by 5-10%, with a corresponding decrease in CO_2 emissions. Envirox™ has also been shown to reduce particulate emissions by up to 15%. Although full life-cycle assessments have not yet been carried out, preliminary studies, including weighing the benefits against the energy used in production and a modelling of how it is deposited in soil, have concluded that using Envirox™ is of net benefit to the environment.

61 CST supports Government's statement that responsive mode is not the only route by which such work is funded and that it would be advantageous for the UK Government research community to engage with FP7 to fund research and to systematically pool knowledge on LCAs at an international level. We would urge Government to ensure that it is fully engaged to support such processes and suggest that an effective vehicle for international cooperation

would be the International Standards Organisation (ISO) committee on nanotechnologies, ISO/TC 229. Any adaptations could thus form an extension to ISO14040-14044, the ISO standards for life cycle assessments.

62 CST also agrees that the discussion and debate over nanotechnologies should be "informed not only by life cycle assessments, but by other important considerations" and is pleased to note that this has been the case. However, this does not alter the fact acknowledged by Government that LCAs "undoubtedly have a role to play" and that so far, not only have very few been done, but that significant research needs to be carried out to adapt LCA methodologies to products containing nanomaterials.

Possible adverse health, safety and environmental impacts | R3

63 Government stated that "The identification of applied research on the more immediate issues of the exposure of people and the environment to these materials is the responsibility of Government departments and the regulatory authorities that have an understanding of the sectors of industry with which they deal."

64 However, CST is disappointed to note that the amount of money committed by Government departments and agencies is insufficient to resolve the current uncertainties in knowledge. One of the larger programmes, the Environmental Nanoscience Initiative (ENI), funded by Defra, NERC and the Environment Agency, provided £500k in September 2006 for grants exploring the environmental effects of engineered nanoparticles. Defra funding is £250k in 2006/2007; the Department of Health (DH) has not funded any research programmes and whilst we welcome the £90m devoted by the Department of Trade and Industry (DTI) over six years to support the commercialisation of nanotechnologies and to set up the Micro and Nano Technology (MNT) Measurement club, focused on metrology related issues, we are disappointed that none of this funding was ring-fenced for health, safety and environmental impacts, despite these matters being crucial to the development of the nascent industry.

65 In total, the DTI estimates that over the last five years Government has funded approximately £3m of research into the toxicology, health and safety and environmental impact of nanotechnologies (full details of current and proposed projects may be found in the NRCG progress report[19]). This level of spending should be contrasted with the £40m/annum awarded by EPSRC as responsive mode research grants in the area of nanotechnologies, the £19.8m interdisciplinary research collaboration by EPSRC, BBSRC and the MRC and the £90m invested over six years by the Department of Trade and Industry (DTI) on research and infrastructure that promotes the commercialisation of nanotechnologies.

66 CST would like to emphasise that the deficiency of funding is not fundamentally the fault of individual departments, but of the means whereby Government has attempted to carry out such research. We would highlight the example of Defra which, despite facing significant budget cuts and a freeze on R&D spending, has nevertheless achieved an exemption for its research on nanotechnologies, spending £250k in 2005/2006, with spending projected to rise to £450k in 2006/2007. Whilst this sum remains inadequate, individual departments facing competing pressures and budget cuts are not the best agencies to rely upon to deliver the necessary research. As discussed in paragraphs 69-71, a central coordinating authority, with the power and funding to commission the necessary research, would be the best means for Government to deliver its research commitments.

19 http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf

67 The balance between research that develops new applications of nanotechnologies and that provides the necessary underpinning for its safe and responsible development must be addressed. Our evidence is almost unanimous in concluding that the current level of spending into the health, safety and environmental impacts of nanotechnologies is far below what is needed. CST notes that the situation is similar in many other countries and suggests that this may thus be an area where the UK could gain a comparative advantage, a further incentive for Government to do more. The innovation opportunities that will arise from research into areas such as toxicology or minimising the presence of nanomaterials in waste streams should not be overlooked.

68 A major commitment in Government's response was the creation of a Nanotechnology Research Coordination Group (NRCG). The NRCG was established in early 2005 to develop and oversee the implementation of a cross-Government research programme into the potential human health and environmental risks posed by free engineered nanoscale materials. The Group is comprised of members of Government Departments, Agencies and the Research Councils with an interest in nanotechnologies and its work has been informed by dialogue with stakeholders, including the public, through the Nanotechnologies Stakeholders' Forum.

69 CST commends the NRCG for its work in identifying 19 research priorities[20] and for its progress report[21], published in October 2006. However, we are concerned that the body has no powers to award research funding and that they rely primarily on responsive mode funding through the Research Councils in order for the work to be carried out. Although the NIDG has successfully ensured that the work of the NRCG is integrated with other parts of Government, the Royal Society of Chemistry (RSC) and Institute of Physics (IOP) have stated that "the scientific research community is largely unaware of the progress that has been made by the NRCG". We would thus urge the body to maintain a higher profile amongst the research community.

70 In addition we would like to point out that the body has been criticised by the Nanotechnology Industries Association (NIA) for making slow progress[22] and by the RS/RAEng for not including enough independent and social scientists[23]. CST understands that the NRCG has recently been engaging with the Royal Society, the NIA and others in order to publicise the fact that the task forces are open to any person with expertise at the chair of the task force's discretion and hopes that this will result in a wider representation on task forces.

71 Connecting the work of NRCG more directly to the awarding of research funding may be one means of ensuring that resources are directed appropriately and would give it the ability to "ensure good research is commissioned to bear on the most relevant and pressing issues with best use of resources", a key aspect of its role identified in Government's response.

International Efforts

72 CST recognises that the UK cannot be expected to carry out all of the necessary research alone and is glad that Government has actively established international links to promote dialogue to facilitate the exchange of relevant information.

20 http://www.defra.gov.uk/environment/nanotech/research/pdf/nanoparticles-riskreport.pdf
21 http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf
22 "Progress by these working groups has been very slow with little input from outside Government on the industrial needs" (*NIA evidence, October 2006*)
23 "We strongly recommend that Government include more independent scientists and social scientists in its task forces" (*RS/RAEng evidence, October 2006*)

73 Internationally the UK has been very proactive and is seen as a leader. It has set up and chairs ISO/TC 229, the ISO standards committee on nanotechnologies; participated in a series of National Science Foundation (NSF) international meetings and has been instrumental in setting up a series of EU member state meetings and in engaging with the Commission on issues concerning nanotechnologies.

74 In the OECD the UK has also been strongly engaged. The first meeting of the OECD working group on the safety of nanomaterials was held in London in October 2006 and a programme of work for 2006-2008 was agreed. The work programme is substantive, consisting of six projects covering topics such as safety testing of nanomaterials, developing test guidelines and cooperation on voluntary schemes and regulatory programmes. The UK is on the steering group for five out of six of these projects and leads on the project for cooperation on risk assessments and exposure measurements. The OECD has stated to us that from the first the UK has been one of the countries most committed to driving forward the agenda and that it is sufficiently engaged that all findings of the OECD should directly feed back into the UK knowledge base.

75 CST strongly commends Government for its significant international engagement. However, we would note that such international projects, particularly those of the OECD, rely upon the contributions and research of member countries in order to make progress. Without a substantial home research effort, the UK's ability to engage in future international dialogue risks being compromised.

Research Programme

76 Government accepted that there was a need for research to better understand the risks proposed by nanomaterials. However, as discussed above, there has been insufficient funding to gain a better understanding of potential risks and there has been little tangible progress since 2005. The over-reliance upon responsive mode to deliver this research is largely responsible for this, as discussed in paragraphs 43-46.

77 Government identified two main priority areas for research: metrology and toxicology. In metrology, we are pleased to note that significant progress has been made due to a substantial commitment of funds, including £9.9 million in grants awarded by EPSRC, a seminar held by the National Physical Laboratory (NPL) in September 2005 and the establishment of the Micro and Nano Technology Network (MNT) Measurement Club which focuses on metrology and related issues such as national and international standards and regulations. Although we are still far from achieving the objective of robust and reliable measurement and detection technologies suitable for monitoring potential exposure routes, CST believes, based on discussions with HSE and with industry, that there should be sufficient industry demand to move forward the development of the technology. Other research areas should thus be considered to now be a greater priority for Government funding, including toxicology and environmental fate and impact of nanomaterials.

78 In the other priority area, toxicology, our understanding is little better than it was two years ago. Although CST wishes to emphasise that, as we have consistently heard throughout the consultation, many nanomaterials pose no new health and safety risks, it is aware of some evidence from research that indicates that some nanomaterials may be deleterious to health[24]. In order to secure public acceptance of nanotechnologies it is essential to obtain a

24 A Matter of Size: Triennial Review of the National Nanotechnology Initiative (*Committee to Review the National Nanotechnology Initiative, National Research Council, 2006*); Nanomaterials – Potential risks for human health and the environment (*Oberdorster, G., 2006*); Nanoparticles – Known and unknown health risks (*Hoet et al, 2004*)

good understanding of the toxicology of any nanomaterials currently or soon to be on the market. We thus strongly recommend that Government make a greater commitment to toxicology research, with a focus upon those nanomaterials being used by industry (including metals, metal oxides and carbon nanotubes) and in areas where toxicology concerns have been raised by researchers or NGOs, for example investigating the postulated link between carbon nanotubes and asbestos. Confirming or refuting a link with asbestos is vital to determine how carbon nanotubes can be safely developed and manufactured.

Case Study Box Six

Nanosafe2 is a major European collaborative research project aiming to develop risk assessment and management for secure industrial production of nanoparticles. It contains four major subprojects: (1) measurement of exposure to and characterisation of airborne nanoparticles; (2) potential health effects; (3) procedures for safe production and handling; and (4) standards, regulations and societal implications.

A complementary project is Nanosh, also a multi-centre European research initiative but focused on occupational exposure to nanoparticles, including in universities, and their health effects.

HSE/HSL have contributed £573k to Nanosh (total budget £27m) and £70k to Nanosafe2 (total budget £8.3m). All participating countries share in the findings; therefore, by spending £643k the UK has obtained £35.3m worth of research.

79 On Government's secondary priorities, the environmental fate and potential bioaccumulation of nanomaterials, there has also been less work than would be desired. The Defra-commissioned regulatory review published March 2006[25] concluded that "Land where nanomaterials are released is likely to fall outside the Part IIA [of the Environmental Protection Act 1990] regime, pending future developments in scientific knowledge." As discussed in paragraphs 85-87, we urge Government to ensure that these developments in scientific knowledge occur.

80 UK participation in international cooperation and coordination is good, as discussed in paragraphs 72-75. The UK is participating in a number of international research efforts including Nanosafe2, Nanosh and a project of the Nanoparticle Occupational Safety and Health (NOSH) Consortium. CST commends this activity: Case Study Box Six shows how effective this can be in making the most efficient use of limited funds. However, there is still opportunity for further cooperation, in particular bilateral communication or research projects with other leading nanotechnologies nations.

Release of nanomaterials | R4-R5

81 Government committed itself to a precautionary stance and, as discussed in paragraphs 50-57, its actions and policies have been in accordance with that stance. However, as previously mentioned, it has not taken sufficient action to fill the gaps in the knowledge base that would resolve the uncertainties surrounding nanotechnologies.

25 A scoping study to identify gaps in environmental regulation for the products and applications of nanotechnologies (*Chaudry et al, 2006*)

Waste streams | R5(i)

82 Government has pursued a thorough and effective dialogue with industry to encourage industry to reduce or remove nanomaterials from waste streams. The Nanotechnology Industries Association (NIA), the trade body for companies involved in the development, production or exploitation of nanomaterials, supports Government's position and has assisted in this dialogue.

83 Industry itself appears to be acting responsibly to take steps to minimise waste streams (see Case Study Box Seven) and has had good dialogue with the Health and Safety Executive (HSE) and the Environment Agency. Although, due to the lack of ability to monitor nanomaterials to the degree desired, it can be difficult to know for certain whether or not nanomaterials are being released, overall, HSE believes that at the current low levels of production industry is dealing with nanotechnologies in a responsible way[26].

84 Government completed a detailed review of the manufacture and uses of the products of nanotechnologies in September 2005[27] and a review of the regulatory mechanisms available to restrict harmful inputs of nanomaterials into the environment in March 2006[28]. The end of 2005 was the deadline committed to in Government's response. CST believes that both pieces of work are valuable and would urge Government to act swiftly on the findings.

Case Study Box Seven

Thomas Swan is a leading chemicals manufacturer based in County Durham. Since 2004 they have been producing high-purity single and multi-wall carbon nanotubes under the *Elicarb™* label. The nanotubes can be produced in commercial (kilograms/year) quantities and are used by other companies in a range of applications including fuel cells, energy storage, advanced electronics and advanced composites. The production process was developed in collaboration with the University of Cambridge.

As there is currently some uncertainty as to the toxicological properties of carbon nanotubes, Thomas Swan is acting in a responsible and precautionary manner concerning its nanomaterial waste. Instead of disposing of it, they keep the small quantities of waste that they produce in secure storage until the uncertainties are resolved and they receive clear guidelines from Government as to how best to dispose of it.

Remediation | R5(ii)

85 Government has successfully worked with industry to cause it to refrain from any release for remediation until there is sufficient evidence that the benefits outweigh any adverse effects. The Environment Agency is not aware of any remediation-related releases of nanomaterials in the UK.

86 Government has not, however, devoted sufficient resources to resolving the uncertainties of such risks and benefits, in particular research concerning the environmental fate and toxicity of nanomaterials, despite its statement that it "would expect substantial progress to have been made when the CST reviews progress after two years."

26 "Both university and industry are acting in a precautionary manner due to the unknown risk... the risk of exposure to researchers or workers is thought to be extremely low." (*HSE Oral Evidence, November 2006*)
27 http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01070&M=KWS&V=cb01070&SUBMIT1=Search&SCOPE=0
28 http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0

87 CST is concerned that this lack of research may prevent uses of nanoremediation – such as the use of nanoscale zero valent iron to remove PCBs in contaminated land – that have the potential to be extremely beneficial to the environment. We would urge Government to commission the necessary research to ensure that the UK does not miss out on such a potentially valuable use of nanotechnologies (see Case Study Box Eight). Exploring the possibility of collaboration with other nations, in particular the United States, may be helpful in gaining more information on this potential use of nanotechnologies.

Case Study Box Eight

Nanoremediation is a young technology which has the potential to greatly benefit the environment. It uses materials such as nanoscale zero-valent iron to remediate soil contaminated by toxic pollutant chemicals such as PCBs or PBDEs. Performance trials in the US and Europe have indicated that the technique is extremely effective at removing the pollutants whilst avoiding the build up of hazardous by-products such as vinyl chloride.

Although the potential benefits to the environment are significant, the evidence base regarding the potential risks to the environment of nanomaterials used in remediation is quite poor, although it is not expected that iron, being a non-toxic substance, will have negative impacts. In addition, some field trials suggest mobility in groundwater is low. While pilot studies have been done elsewhere in the world, to date the Environment Agency is not aware of any remediation-related releases of nanomaterials in the UK, although a number of contractors have expressed an interest in doing so.

CST is concerned that unless Government commissions the necessary research to better understand nanoremediation, the UK may miss out on the benefits of this highly promising application of nanotechnologies.

Information on risk of release | R6

88 Government's response stated that whether the risk of release of a nanomaterial should be considered as part of the safety assessment would depend on whether the nanomaterial concerned is hazardous in its free form. CST would concur, but would wish to add that for many nanomaterials, it is uncertain as to whether or not they are hazardous, a circumstance that has not substantially changed since the time of Government's response.

89 Furthermore, Government acknowledged that there is a wide range of wear and degradation mechanisms at play during the lifecycle of any product which will give rise to the release of materials of construction and that research would be required to assess whether the current degradation models can be extended to form the basis of future models relating to nanomaterials. The commitment that "This is an area we will seek to address under the research programme" has not been satisfactorily addressed and is subject to similar criticisms as the rest of the research programme, in particular an over reliance on responsive mode.

Safety assessment data | R7

90 Government has decided that the best way of achieving disclosure of information related to safety assessment data was by voluntary methods rather than by regulation. The Defra Voluntary Reporting Scheme (VRS) was launched in September 2006 after wide public consultation to provide a framework whereby data may be passed to Government.

91 The VRS has strong support from industry[29] and the NIA is working closely with Defra to assuage industry's concerns that confidential information may be released under the Freedom of Information Act[30]. The dialogue is progressing well and a solution whereby the data is submitted via trade associations in order to anonymise it appears to be a satisfactory solution for both industry and Defra. Government must recognise that concerns over the protection of intellectual property are of vital importance to companies, particularly to small or medium sized enterprises for whom it may be their only major asset.

92 Defra is releasing quarterly reports to update the community on the information it has obtained from the VRS. CST is concerned, particularly given the strong support for the scheme expressed to us by industry, that the first quarterly report records that only three organisations have submitted data. Industry must actively participate in this scheme if it is to be a success and if the need for a compulsory scheme is to be avoided. CST recognises the concerns over protection of intellectual property and trusts that the ongoing dialogue between Defra and the NIA will resolve any remaining concerns as quickly as possible. It strongly urges industry to follow through on their expressions of support and to submit data to the scheme as soon as possible.

93 CST believes that Government has successfully carried out its commitments under R7 in balancing the need for openness on safety data without compromising commercial confidentiality. We support the decision that a voluntary rather than a regulatory approach is wise in the current circumstances. When the VRS is reviewed after two years, however, it will be necessary to assess whether the scheme has failed to achieve a high take-up by industry and that the data received has not been compromised by evidence showing negative impacts being withheld. If the review show that either of these has occurred it will be necessary to reconsider the policy.

Regulatory Issues | R8

94 A number of regulatory reviews have been commissioned by Government departments and agencies including by HSE (February 2006)[31], Defra (March 2006)[32], the Food Standards Agency (FSA) (March 2006)[33] and the Medicines and Healthcare Products Regulatory Agency (MHRA) (September 2006)[34]. Each review focused upon its relevant department or agency's area of responsibility. The reviews commissioned by HSE and MHRA both concluded that existing regulation was currently satisfactory, but that if future research showed that nanomaterials possessed radically novel properties then the regulatory position would need to be reassessed.

95 The review commissioned by the FSA similarly concluded that there were no major gaps in regulation, but that there was some uncertainty in some areas as to whether applications of nanotechnologies would be picked up consistently. The Defra commissioned review, on the other hand, identified a number of regulatory gaps, particularly in areas relating to thresholds and exemptions under existing legislation; current scientific knowledge and understanding of risks; lack of information or uncertainties over clear definitions; and reliable and validated methods for monitoring exposure and potential impacts on human and

29 The Defra Voluntary Reporting Scheme (VRS) is supported by industry as an aid to such communication. (*NIA oral evidence, December 2006*)
30 "Industry has reservations about this scheme that have been communicated to DEFRA, particularly in regard to the confidentiality and subsequent use of the information provided by industry, but progress on this recommendation has been made." (*NIA written evidence, October 2006*)
31 http://www.hse.gov.uk/horizons/nanotech/regulatoryreview.pdf
32 http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01075&M=KWS&V=Nanotech&SUBMIT1=Search&SCOPE=0
33 http://www.foodstandards.gov.uk/multimedia/pdfs/nanotech.pdf
34 http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=996

environmental health. CST finds it disappointing that in the nine months between March and December 2006 Government did not appear to take any significant action based on these findings, instead waiting to give a formal response or policy statement until the overview review was completed.

96 The overview review of regulatory gaps (December 2006)[35], commissioned by the DTI and carried out by the ESRC Centre for Business Relationships Accountability Sustainability and Society (BRASS), has been carried out. The BRASS report is an analysis of the potential gaps in the regulation of the development, manufacture, supply, use and end of life of free engineered nanoparticles across all current and future foreseeable applications of nanomaterials.

97 The report identifies a large number of potential regulatory gaps, though emphasises that these arise largely as a result of incomplete information about the implications of human and environmental exposure to nanoparticles, rather than any major regulatory oversight. In particular, there are potential for gaps where thresholds are set to govern whether materials of products fall within regulation or where the regulation of substances coming to market depends upon their equivalence to substances already well regulated and understood. Other potential gaps include areas where regulation is too narrow, where it is not yet possible to monitor the escape or emission of nanomaterials and where regulation classifying a product as hazardous takes no account of its size.

98 The European Commission is also carrying out a regulatory review as part of its Nanosciences and Nanotechnologies Action Plan. Although the report is currently being finalised, the Commission notes that nanomaterials fall under the scope of existing health, safety and environmental regulation, even if they are not mentioned explicitly. However, implementation in many areas can be difficult, as current methodologies for identifying hazards and evaluating risks of substances may not necessarily allow fully specific properties of substances in the nano-scale to be taken into account.

99 There is currently a lack of "supporting documents" – for example binding rules and guidance, standards, hazard and risk assessment procedures or test methods – detailing how existing regulations are to be applied to nanotechnologies. In the absence of such guidance, it can be difficult for the relevant authorities to assess when it is necessary to intervene for health, safety or environmental reasons.

100 Most EU action in relation to nano technologies and materials is thus likely to occur at the implementation rather than the regulatory level – generating the required supporting documents. CST emphasises that there is a clear difference between a statement that more regulation is needed and a statement that uncertainties in knowledge mean it may be difficult to implement existing regulation. CST considers the latter to be closer to the truth.

101 Swiss Re, a company that has been proactive in investigating the potential risks associated with nanotechnology[36], has recommended that whilst "it does not consider that new laws are necessary at the moment given that general liability laws apply, regulation could be best added on a secondary level; i.e. enabling chemicals or product approval bodies to set their own criteria, strictly based on nano-specific hazards, potentially on a case by case basis." CST considers this suggestion to be a sensible method of proceeding and would urge Government to consider it.

35 http://www.dti.gov.uk/science/science-in-govt/st_policy_issues/nanotechnology/page20218.html)
36 http://www.swissre.com/internet/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/ulur-5yaffs?OpenDocument

102 The BRASS report is a comprehensive and thorough piece of work and we commend Government for having commissioned it. We trust that they will move swiftly to address the regulatory gaps identified by seeking extensions where necessary to the existing regulatory framework at the appropriate level; domestic, European or international. CST would hope that significant progress will have been made by the time it conducts its five-yearly review in 2010.

Regulatory Bodies and Advisory Committees | R9

103 In September 2005 the chair of NIDG wrote to the nine advisory committees listed in Annex A of the Government's response. The matter was discussed thoroughly in an NIDG meeting in January 2006. The committees were asked whether their terms of reference were broad enough to adequately consider nanotechnologies, the details of their horizon scanning mechanisms and whether these were sufficient to consider nanotechnologies and how committees ensured that they had sufficient expertise to assess issues concerning nanotechnologies. All nine of the advisory committees responded to the enquiry.

104 With the exception of the Advisory Committee on Hazardous Substances (ACHS), the advisory committees' terms of reference do not explicitly mention nanotechnologies. However, CST concurs with the committees that their terms of reference are broad enough to fully cover nanotechnologies. It would be unnecessary and inappropriate to specifically mention nanotechnologies whilst not referring to other scientific and technological fields of equal significance.

105 All nine committees have well established channels of co-opting experts and routinely do so. Horizon scanning mechanisms are also in place in a regular, formal and satisfactory manner and, as of March 2006, the majority of the advisory committees had either already considered the issue of nanotechnologies or had scheduled time to do so. We are, however, slightly disappointed to note that none of the advisory committees had approached the Horizon Scanning Centre within the Office of Science and Innovation which has spent a significant amount of time considering the future impact of nanotechnologies (see paragraphs 150-154). We suggest that in the future closer collaboration between horizon scanning bodies would be of benefit to all parties to assist them to share knowledge and expertise across Government.

106 As discussed in paragraphs 112-117, HSE has been conscientious in monitoring developments in nanotechnologies that may impact upon health and safety issues and in working with the relevant bodies to address issues that arise.

Chemicals Regulation | R10

107 Chemicals will shortly be regulated under the European Registration, Evaluation and Authorisation of Chemicals (REACH) Regulation37 which was adopted on 18 December 2006 by the Council of Environment Ministers and will enter into force on 1 June 2007. REACH will supersede the existing Notification of New Substances (NONS) Regulation and Existing Substances Regulations (ESR).

108 The European Commission has considered the issue of nanomaterials and how best they should be included within REACH. With the exception of certain specific types of nanomaterials such as fullerenes which are addressed specifically under REACH and considered novel, for most materials, the size of the particle does not affect how it is

classified, meaning most nanomaterials will be classified and treated as if they were bulk scale materials.

109 Furthermore, central to the REACH regulation is the requirement that chemicals should only be registered at production or importation levels greater than one tonne per annum. Government recognised in its response that although this is an appropriate trigger level for conventional chemicals, it may not always be appropriate for nanomaterials. As such, it said in its responses that "Government considers it likely that sector specific regulations, in addition to REACH, may be required" and that "it is important to note that any new regulations could be implemented independently of REACH, and would require agreement at a European level." Such areas, where regulation relies on certain thresholds, were also identified as a potential regulatory gap by the recent BRASS report (see paragraphs 96-97).

110 CST hopes that, following the recent adoption of REACH and the publication of the BRASS report, the UK Government will continue to actively engage at a European level to ensure that any necessary sector specific regulation is negotiated swiftly and appropriately.

111 As discussed in paragraphs 82-84, Government has successfully worked with industry to minimise releases of nanomaterials into the environment.

Workplace | R11

112 The Health and Safety Executive (HSE) and Health and Safety Laboratory (HSL) have been active and thorough in carrying out their responsibilities under Recommendation 11. They have carried out a sizeable body of research including a study of the health effects of nanomaterials[38], a literature review into the fire and explosion risks association with nanopowders[39], a study on the assessment of different metrics of the concentration of nano (ultrafine) particles in existing and new industries[40] and a literature-based review of *in vitro* methods for assessing the toxicity of nanomaterials, drawing together much previous research[41]. CST welcomes this research, though would suggest that in future it may be advisable to consider whether some work might not be better commissioned from one of the existing centres of excellence in the UK, rather than carried out internally.

113 Current activities include a three-year £0.9m investment project in improving capabilities at HSL to provide services to industry to control health and safety risks from production and use of nanomaterials and a £573k project by HSE to investigate current exposure levels and control measures in university laboratories, currently in its early stages. This is being carried out as part of Nanosh, a European multi-centre research effort focused on occupation exposure to nanoparticles and their health effects (total budget of £27m).

114 HSE and HSL are also actively participating in two other international research projects. They have committed £35k to the Nanoparticle Occupational Safety and Health (NOSH) Consortium's project to measure and investigate the behaviour of aerosol nanoparticles (total budget of $680k); and £70k to Nanosafe2, another European research project with foci including measurement, health effects, procedures for safe handling and societal issues (total budget of £8.3m). As all data from such international efforts are shared amongst all participants, such activity is an excellent way of leveraging large amounts of information from relatively modest expenditure of funds.

37 http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm
38 http://www.hse.gov.uk/horizons/nanotech/healtheffects.pdf
39 http://www.hse.gov.uk/research/hsl_pdf/2004/hsl04-12.pdf
40 http://www.hseresearchprojects.com/ProjectSearch.aspx?id=1442
41 http://www.defra.gov.uk/environment/nanotech/research/reports/progress-report061019.pdf Annex 4

115 HSE states that both industry and the universities have been acting responsibly to minimise workplace exposure, taking a precautionary approach until any potential risks of nanomaterials are better known. At the current levels of production, HSE considers the risk of exposure to researchers or workers to be extremely low.

116 The Environment Agency and the Health Protection Agency have procedures in place for dealing with incidents involving unknown toxins/materials, including nanomaterials, and have a joint working group on incident management. HSE has produced an information sheet (HSIN1)[42] on nanotechnologies, recommending that a precautionary approach is adopted in controlling exposure. This is welcomed although industry would welcome more concrete support for the development of best practice guidelines for the handling of nanomaterials.

117 Overall, CST finds that HSE and HSL have been thorough and conscientious authorities in the work that they have done to promote the safe development and handling of nanomaterials. Much remains to be done as the field develops, and the issues will become increasingly significant as the scale of production of nanomaterials increases, so we would urge Government and HSE to ensure that adequate funding for issues concerning nanotechnologies continues to be present in the future.

Consumer Products | R12

118 The Government's response stated that "ingredients in the form of manufactured free nanoparticles should undergo a full safety assessment by the relevant scientific advisory body before they are used in consumer products." However, under existing regulation, including REACH, if a nanomaterial is considered to be non-toxic and non-harmful in its bulk form it may not be required to undergo a sufficiently rigorous safety assessment before being included in a consumer product. This potential regulatory gap was highlighted in the BRASS report (see paragraphs 96-97) and we would encourage Government, in cooperation with its European partners, to ensure that it is addressed.

119 On the specific issue of microfine zinc oxide, CST is pleased to note that the relevant dossier has been submitted to the Scientific Committee on Cosmetic and Non-Food Products (SCCNFP)[43]. CST is pleased that the document was finally submitted, but is concerned that it took so long for it to occur – the SCCNFP drew the attention of the Commission and Member States to this fact in a statement in September 2005[44]. CST does not consider this to be primarily the responsibility of the UK Government, but suggest that it works hard, in conjunction with its European partners, to ensure that such delays do not occur in future.

120 As discussed in paragraphs 90-93, Defra's VRS is Government's primary chosen means of facilitating the disclosure of safety methodologies to ensure the right climate of co-operation between industry, regulators and the science community. CST believes that the VRS currently appears to be an effective initiative though stresses the need for high participation by industry.

121 Government must, however, continue to be vigilant to ensure that companies are not acting irresponsibly. Such companies may not be part of the NIA and thus may be less interested in maintaining a dialogue with Government. A similar caution must be maintained over consumer products from abroad, particularly any that are manufactured in countries with weaker consumer protection regulations than the UK.

42 http://www.hse.gov.uk/pubns/hsin1.pdf
43 "Thank you very much for your interest in the SCCP work. For your information we have received the submission from industry on zinc oxide and the Committee is working on it." (*letter from SCCNFP, 26th February 2007*)
44 http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_00m.pdf

122 The British Standards Institution (BSI) is currently developing a Publicly Available Specification (PAS) on Good Practice Guide for Labelling of Nanoparticles and Products Containing Nanoparticles, to provide information to allow consumers to make choice whilst reducing the need for regulation. The NIA is participating in this process and the BSI intends to publish the PAS before the end of 2007. CST commends this work and recommends that Government works with industry to encourage its adoption.

123 The EC's Scientific Committee on Emerging and Newly Identified Health Risks SCENIHR was mandated to consider nanotechnologies. It produced a report on "The Appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies" in September 2005 and updated it in March 2006 after public consultation[45].

124 Currently, SCENIHR is evaluating the Technical Guidance Document for risk assessment in order to determine its fitness for purpose in evaluating nanoparticles. CST is encouraged by the work of SCENIHR and is pleased to see that Government is supportive of its work.

125 Overall, CST considers Government to be fulfilling its commitments on product labelling, SCENIHR and disclosure of methodologies but would urge it to press forward, in cooperation with its European partners, in ensuring that the potential regulatory gaps highlighted by the BRASS report are closed.

Nanomedicine | R13

126 The Medicines and Healthcare products Regulatory Agency (MHRA) conducted a regulatory review, reporting in September 2006, assessing whether existing regulation was sufficient to cover the use of nanotechnologies in medicines and medical devices. The review concluded that the existing regulatory framework was satisfactory until such time as future research should identify toxicological risks unique to nanomaterials[46].

127 Existing preclinical trials for medicines and medical devises are very extensive, requiring manufacturers of medical devices to carry out extensive risk analysis. MHRA has concluded that the existing trials procedures are sufficiently rigorous to safely include medicines and medical devices that incorporate nanotechnologies. CST would thus agree that no additional legislation for nanomedicines or new medical devices is required at the current time.

128 CST is, however, deeply concerned by MHRA's withdrawal of support for standardisation, in particular through ending its participation in the BSI NTI/1 Nanotechnologies Standardisation Committee. This is in contradiction to Government's otherwise excellent support for standards and is also in direct contradiction to Government's response which stated that "MHRA also contributes, via the British Standards Institute, to the development of international and European standards that can be used to demonstrate conformity with particular aspects of the European Medical Device Directives." BSI has described the situation to us as "deeply worrying" and CST believes that MHRA should lose no time in reengaging with the development of standards for nanotechnologies.

Extended Producer Responsibilities | R14

129 As stated in Government's response, existing EU Directives cover extended producer responsibilities and any new regulations would need to be negotiated at a European level.

45 http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_003b.pdf
46 http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=996

CST is confident that Government is actively engaged with the European Commission on such issues and is committed to pushing forward the agenda. We urge Government and the Commission to continue their efforts to ensure that all regulation in timely, proportionate, targeted and results in the desired outcomes.

Measurement and Standards | R15

Measurement

130 CST is very pleased to observe Government's substantial progress on this commitment. The Department of Trade and Industry (DTI) has established the Micro and Nano Technology (MNT) network, with funding of over £50m to establish and maintain for five years a network of 23 facilities developing nanometrology, nanomaterials, nanomedicine and nanodevices. Significant portions of this funding has been used to advance knowledge in nanometrology.

131 Furthermore, the National Physical Laboratory (NPL) held a seminar in September 2005 to stimulate nanometrology research, Defra issued a call for proposals to prioritise the development of reference materials and EPSRC has issued grants of £9.9m in nanometrology. The UK is also participating in the NOSH Consortium's project and in Nanosafe2, as discussed in paragraph 80.

132 Metrology is crucial as the ability to detect, measure and categorise nanomaterials underpins the ability to monitor matters such as workplace exposure, and to create standards for use in regulation or toxicology. Although there is still a considerable amount to do before we have achieved the capabilities desired to routinely measure, monitor and identify airborne nanomaterials, progress is steadily being made.

133 Dialogue with HSE and industry suggests that the substantial pump-priming has achieved its purpose and that there is now sufficient demand from industry to improve our capabilities in nanometrology with only minimal future Government funding (aside from responsive mode grants and collaboration in international programmes, such as the NOSH consortium's and Nanosafe2). The past spending was necessary, highly effective and welcomed; now, as discussed elsewhere, CST would recommend that future Government programmes give priority to toxicology, health and environmental impacts rather than metrology.

Standards

134 Government support for standards has also been extremely strong. The British Standards Institute (BSI) has established NTI/1, a technical committee on nanotechnologies which has been extremely active. Over twenty interested bodies from academia, industry, professional organisations and Government are represented on the body and its work has included the production and distribution of the freely available PAS7147 – "A Vocabulary for Nanoparticles" and the development of nine new work items including developing terminologies for medical and consumer applications of nanotechnologies, a guide to safe handling and disposal of free engineered nanoparticles and a guide to specifying nanomaterials.

135 Government has also provided strong support for UK engagement in international standards work. The UK holds the chair and secretariat of the European Committee for Standardisation (CEN) committee CEN/TC 352 "Nanotechnologies" and set up and holds the chair and

47 http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/Nanotech-products/PAS-71/

secretariat for ISO/TC 229 "Nanotechnologies". The latter is a particularly effective vehicle for developing standards, containing as it does all major countries involved in nanotechnologies. It has met three times, consists of three working groups – Terminology and Nomenclature, Measurement and Characterisation and Health, Safety and Environment – and liaises closely with national standardisation organisations and CEN/TC 352.

Social and Ethical Issues | R16-17

136 Many social and ethical issues surrounding nanotechnologies are not peculiar to them but have parallels in other developing scientific fields. A £5.2m ESRC research programme[48] has funded research in this area, aiming to facilitate research into the rapidly changing relations between science, including engineering and technology, and wider society.

137 As part of this programme some projects specific to nanotechnologies have been funded, including a project on "The Social and Economic Challenges of Nanotechnology" at the University of Sheffield[49] and a project on "Nanotechnology Risk and Sustainability: Moving Engagement Upstream" at the University of Lancaster[50].

138 More recently the ESRC has started to take forward a programme of research (with matched funding from others) on the adequacy of current risk governance frameworks for nanotechnologies. Furthermore, in the latter part of 2006 it funded a scenarios workshop, which addressed the future social and economic drivers and implications of convergence between nanotechnologies and other technologies. Defra is also funding two projects on the social and economic dimensions of nanotechnologies.

139 Paragraphs 75-78 of Government's response do not commit Government, as distinct from the Research Councils, to any actions, although CST is largely supportive of the sentiments which they express. CST notes that the Research Councils' Skills Training Requirements broadly covers the spirit of the matters discussed here.

Stakeholder and Public Dialogue | R18-19

140 Government has funded a number of public dialogue initiatives including Nanodialogues (as part of the Sciencewise programme), supported by an £120k grant from the DTI with matched funding from other sources, to look at a variety of applications of nanotechnology; Small Talk, a £50k project involving discussing nanotechnologies with the public and scientists and Sciencehorizons, a £330k programme which forms the public engagement section of the Wider Impacts of Science and Technology (WIST) programme (see paragraph 140) that will consider nanotechnologies as one of eight key emerging science and technology clusters. Although not Government funded, Nanojury UK, which brought together fifteen randomly selected people to discuss issues related to nanotechnologies, is also an initiative that can be learned from.

141 The Nanotechnology Engagement Group (NEG) has also been funded by the Sciencewise programme with a grant of approximately £90k. The NEG is made up of people with expertise and projects in this area and is charged with mapping out and analysing the current practices of public engagement on nanotechnologies. It has published a number of reports considering various methods of public engagement on nanotechnologies and held a workshop with interested parties.

48 http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/research/research_programmes/science_in_society.aspx?ComponentId=9122&SourcePageId=9102
49 http://www.shef.ac.uk/physics/people/rjones/PDFs/SECNanotechnology.pdf
50 http://www.sustainabletechnologies.ac.uk/Projects/nanotechnology.htm

142 Although CST is pleased to see these initiatives, we have concerns that in many cases, the public engagement that has occurred has been criticised for not having a major impact on policy[51]. CST's examination of the outputs produced shows that they have contained important messages for policy makers (see Case Study Box Nine)[52]; in particular, that the public's attitudes to nanotechnologies are generally positive but that they believe and expect Government to be funding research into potential risks – something that, as this Review makes clear, is not occurring to a sufficient level.

Case Study Box Nine

Small Talk was a three year public engagement project which aimed to explore the benefits to the scientific communication community in working together on public engagement. Its aim was not only to build an understanding of the public's views on nanotechnologies, but to further good practice in public engagement.

Its core findings on public attitudes to nanotechnologies, as expressed in the executive summary of its final report, are:

- People's attitudes to nanotechnology are not significantly different from their attitudes to any new technology, and are generally positive.
- People are not concerned about specific risks arising from the technologies themselves but, rather, about the structure of regulation that they will have to rely on to deal with any risks.
- The public considers issues of safety of nanotechnologies in absolute rather than relative terms and so 'safe' is assumed to mean that all risks have been identified and eliminated.
- There is a significant gap between the public's perceptions of the role and boundaries of government and the reality, which could be a potential source of tension and distrust in government and governance of science if left unresolved.

143 Policy makers and those involved in public engagement do not appear to have been as well connected as might have been hoped. CST recommends that the NIDG devotes additional resources to establishing direct links between current and future public engagement projects and policy makers in relevant Government departments with the aim of facilitating greater two-way communication. Public engagement programmes should also aim to ensure that such links are built in from the outset.

144 CST also believes that there is the potential for industry to be significantly more involved in the public engagement process, in particular in helping to enthuse the public about the positive potential of nanotechnologies. We recognise the challenges to public confidence that such industry involvement would create – experimentation with new mechanisms for engagement through partnerships with industry may be needed. We recommend that future public engagement processes seek to include industry, where appropriate and with careful thought as to how this might be best undertaken.

51 The NEG has stated that "The recommendations produced by public engagement on nanotechnologies thus far have been criticised for being too generic or unrepresentative to be useful for decision-makers. Policy makers need to ensure that they are clear about what they want from public engagement, that they think through how they will make use of the findings, and that this is communicated clearly to the organisers of public engagement." The RS/RAEng has also stated that "Further involvement and a clear idea of what policy makers need from these activities could result in outputs that are more useful to policy makers."

52 http://www.smalltalk.org.uk/page41g.html

145 Finally, CST does have concerns that a number of the programmes mentioned above are drawing to an end and that it is not clear what will replace them. As the field of nanotechnologies is a rapidly developing one, it will be necessary for Government to continue to engage on the subject, as public attitudes may change. Future public engagement programmes should be careful to consider before-hand what form of outputs would be most useful to policy makers at that time and ensure that the shape of the engagement is designed with this in mind.

146 After such consideration, there will be a need for full, deliberative dialogue involving Government, stakeholders and the public in order to deliver these outputs, a process which would be deeper and more involved than the public engagement initiatives that have occurred to date. As discussed in CST's report, "Policy Through Dialogue"[53], there is a need for Government to engage on a deeper level with the public. Dialogue processes, by creating a space for discussion, enable a constructive exploration of ideas and assumptions, and identify where progress can be made and can thus inform, but not determine, policy. Although such processes are expensive in terms of resources, there is a growing belief and evidence in the UK and beyond that, if done well, the quality of outcomes can justify the input[54]. A further advantage to such dialogue is that it helps to build a cadre of people from academia, Government and stakeholders who are experienced in engaging with the public and will be able to do so more effectively in the future.

147 Finally, the proper evaluation of current activities will be critical to ensuring the next stage of public engagement is fit for purpose.

Independent Review | R20

148 CST would like to commend Government for committing to such an independent review, as well as for its foresight in initially commissioning the RS/RAEng report. We are very glad that Government selected CST to conduct this review and reaffirm our desire to carry out the five year review. We wish to emphasise the need for consistency between Government's initial response, the two year review and the five year review.

149 We urge Government to carefully consider and act upon the findings of our review. In 2004 Government was widely commended for its foresight in commissioning the landmark RS/RAEng report and at that time it was felt that the UK enjoyed a leading position in its engagement with nanotechnologies. It is now widely believed – by stakeholders from industry, academia, learned societies and NGOs – that the UK has lost that leading position, though it has not slipped so far that swift and determined action could not regain it.

Horizon Scanning | R21

150 CST would like to make clear that the following paragraphs should not be taken as a full review of the Horizon Scanning Centre (HSC), nor do we believe that this report, with its primary focus on nanotechnologies, is the appropriate vehicle for carrying out such a review.

151 In March 2005 Government established the HSC within the Foresight Directorate, located in the Office of Science and Innovation (OSI) within the DTI. Its remit is to support strategy, policy formulation, and prioritisation activities across Government by undertaking a systematic examination of potential future threats, opportunities, and developments that may impact from now to 50 years out. The HSC is accountable to the Chief Scientific

53 http://www.cst.gov.uk/cst/reports/files/policy-through-dialogue/report.pdf
54 Participatory Assessment (*Burgess and Chilvers, 2006*)

Adviser (CSA) and others responsible for overseeing the Ten Year Science and Innovation Investment Framework, and is overseen by a cross-departmental sub-group of the Chief Scientific Advisers' Committee (CSAC).

152 The HSC provides a higher-level strategic context to horizon scanning work being carried out in other Government departments. It also carries out a number of initiatives to promote horizon scanning across Government, including a coaching programme for staff and the "FAN Club", a Future Analysts Network launched by the CSA in June 2005. Current work includes a portfolio of cross-Governmental projects. In December 2006 contractors commissioned by the HSC published two scans, the Sigma and Delta scans, containing issues and trends with relevance to the public policy agenda and to future science and technology developments.

153 Nanotechnologies have been identified as one of eight key science and technology clusters that have the potential to affect wealth creation, change society or transform public services in the decade to 2017. These eight clusters, including nanotechnologies, underpin the Wider Implications of Science and Technology (WIST) programme. WIST has a number of strands which are co-ordinated by the HSC. HSC's own activities will involve extensive consultation with over seventy stakeholders from Government, industry, academia and NGOs. OSI's Sciencehorizons project (see paragraph 140), also part of WIST, will involve extensive public dialogue and deliberation, and the eight clusters are also informing related work in other Government Departments and agencies such as HSE. Together, these activities will consider the safety, health, environmental, ethical, regulatory and social impacts of emerging technologies. The WIST programme will have a direct line of communication to Government by way of the Science and Innovation Cabinet Committee. CST commends this programme and trusts that Government will continue such activities in the future.

154 CST believes Government has fulfilled the commitments it made on horizon scanning in its response to R21 and, furthermore, would like to note that the House of Commons Science and Technology Committee conducted a more thorough review of the HSC as part of its report on Scientific Advice, Risk and Evidence Based Policy Making (October 2006). This stated "We commend Government CSA and the Office of Science and Innovation on their work aimed at strengthening horizon scanning in relation to science and technology across Government."

Conclusions

155 Overall, CST believes that Government has made good progress on many of its commitments. The NIDG has proved to be an effective means of coordinating and monitoring activity in the UK and, internationally, Government's engagement has been proactive and committed. In the EU, the OECD and the ISO it is widely recognised as having helped to drive forward the agenda.

156 Closer to home, support for the development of standards has been consistently strong and the work of the BSI and the UK's actions in setting up and chairing ISO/TC 229 "Nanotechnologies" is strongly commended. CST finds that HSE and HSL have been thorough and conscientious authorities, committing substantial resources to nanotechnologies work. In particular, they have worked hard to ensure that nanomaterials are treated in a precautionary manner in industry and in the universities so that workplace exposure is minimised. Much remains to be done as the field develops so we would urge Government and HSE to ensure that adequate funding for issues concerning nanotechnologies continues to be present in the future.

157 Government should also be commended for its dealings with industry. It provided support for the establishment of the NIA, thus giving the nascent industry a voice, and has since conducted substantial dialogue that has successfully limited the release of nanoparticles in waste streams and has convinced industry to refrain from any release for remediation until there is sufficient evidence that the benefits outweigh any adverse effects. Though strictly outside the remit of our report, we would note that overall support for industry has been strong, with £90m committed over the six years from 2003-2009.

158 The Defra Voluntary Reporting Scheme, a scheme largely supported by industry and learned societies whereby industry provides Government with information relevant to understanding the potential risks posed by free engineered nanomaterials, is an excellent example of how Government has brought about a climate of cooperation without recourse to regulation. However, we are concerned that the first quarterly report records that only three organisations have submitted data, particularly given the strong support for the scheme expressed to us by industry. CST recognises industry's concerns over protection of intellectual property and trusts that the ongoing dialogue between Defra and the NIA will resolve any remaining concerns as quickly as possible. Industry must actively participate in this scheme if it is to be a success and if the need for a compulsory scheme is to be avoided.

159 Notwithstanding the above successes, there are some areas in which CST is extremely disappointed by Government's progress. The foremost of these is research, in which despite Government's commitment to "an immediate programme of research aimed at reducing the uncertainties relating to toxicity and exposure pathways for nanoparticulates", and its expectation that "substantial progress to have been made when the CST reviews progress after two years", there has been a distinct lack of directed Government funding.

160 In the last five years there has been approximately £13m of Government funding for research into nanometrology, toxicology and health and environmental impacts of nanomaterials. Almost £10m of this funding has been for nanometrology – EPSRC has funded grants totalling £9.9m – leaving only approximately £3m for toxicology and health and environmental impacts. Whilst CST strongly welcomes the support for nanometrology, the level of support for toxicology and health and environmental impacts is insufficient.

161 We consider the primary reason for this lack of research to be due to an over-reliance by Government on responsive mode funding to deliver the necessary research. Basic toxicology work, although vital, may not be the most innovative or cutting-edge research and thus will rightly not be funded by the Research Councils. To put it bluntly, the safe development of a new technology should not depend on whether an academic wins a highly competitive research grant. The past two years have shown that responsive mode will not be sufficient to rectify the gaps in knowledge and that a comprehensive programme of strategic Government spending is necessary to fulfill Government's commitments.

162 Although CST commends the work of the NRCG in identifying nineteen research priorities, its slow progress and its lack of ability to award research funding means that its impact has been less than would have been hoped. We are particularly concerned at a statement by the RSC/IOP that the research community is largely unaware of its work, especially as Government has been primarily relying on responsive mode to carry out the research needs the NRCG identifies.

163 In some areas, although Government has made reasonable progress, CST considers it important that momentum be maintained for much more remains to be done. The issue of regulatory reviews is one such area. We are pleased that departments and agencies have carried out regulatory reviews and consider the recent BRASS report an excellent overview of potential regulatory gaps. However, Government must not rest on its laurels. It must ensure that, where necessary, it addresses potential regulatory gaps by amendment of existing regulation and that, once new information resolves the current uncertainties surrounding many areas of nanotechnologies, the regulatory reviews will need to be updated.

164 The public engagement effort is another area about which CST has mixed feelings. Although a number of good programmes – including Nanodialogues and Smalltalk – have been carried out, it is not clear to what extent their findings have informed policy. CST considers this to be primarily due to insufficient communication between policy makers and those involved in public engagement. Deeper and more in depth deliberative dialogue processes than the public engagement initiatives that have occurred to date might also aid in delivering results more valuable to policy makers. As the current programmes, including Sciencehorizons, come to an end, it is important that Government continues to engage in such a fast developing field.

165 To conclude, although there has been good progress on many commitments the lack of research and the uncertainties that still surround many issues to do with nanotechnologies – particularly long-term environmental fate, health and environmental impacts and metrology, standards and detection – threatens to undermine the UK's good work in other areas. In 2004 Government was widely commended for its foresight in commissioning the landmark RS/RAEng report and at that time it was felt that the UK enjoyed a leading position in its engagement with nanotechnologies. It is now widely believed – by stakeholders from industry, academia, learned societies and NGOs – that the UK has lost that leading position, though it has not slipped so far that swift and determined action could not regain it.

ANNEX A: List of Contributing Organisations and Individuals

The following organisations and individuals contributed to the CST's Review by submitting written evidence, by attendance at seminars or by meeting members of CST.

- BASF
- The Biotechnology and Biological Sciences Research Council
- The British Standards Institute's Nanotechnologies Standardisation Committee
- Cenamps
- Demos
- The Department for Environment, Food and Rural Affairs
- The Department of Health
- The Department of Trade and Industry
- Department of Trade and Industry Embassy Attachés – China, Germany, Japan, USA.
- The Engineering and Physical Sciences Research Council
- The European Commission Inter-Service Group on Nanosciences and Nanotechnologies
- The European Nanotechnology Trade Alliance
- The German Federal Environment Agency
- The German Federal Environment Ministry
- The German Federal Institute for Risk Management
- Greenpeace
- The Health and Safety Executive
- The Health Protection Agency
- The Institute of Food Research
- Her Majesty's Government
- The Institute of Physics
- Johnson Matthey
- Karlsruhe Research Centre
- The London Centre for Nanotechnology
- The Nanotechnology Engagement Group
- The Nanotechnology Industries Association
- The OECD
- Oxonica

- QinetiQ Nanomaterials
- The Royal Academy of Engineering
- The Royal Commission on Environmental Pollution
- The Royal Society
- The Royal Society of Chemistry
- The Safety of Nanomaterials Interdisciplinary Research Centre
- The Soil Association
- Swiss Re
- Thomas Swan
- University of Birmingham
- The Woodrow Wilson Center for International Scholars
- Rob Aitken (Institute of Occupational Medicine)
- Juergen Altmann (University of Dortmund)
- Roland Clift (Centre for Environmental Strategy, University of Surrey; member of the RS/RAEng working group)
- Ann Dowling (University of Cambridge; chair of the RS/RAEng working group)
- Rodger Duffin (The Edinburgh Lung and the Environment Group Initiative)
- Ruth Duncan (Cardiff University)
- Richard Jones (University of Sheffield)
- Anthony Seaton (Department of Environmental and Occupational Medicine, University of Aberdeen; member of the RS/RAEng working group)
- Saul Tendler (University of Nottingham; member of the RS/RAEng working group)

ANNEX B: Call for Evidence

'Nanoscience and nanotechnologies: opportunities and uncertainties' Two-year review of progress on Government actions

Call for Evidence

In July 2004 the Royal Society and Royal Academy of Engineering jointly published a Report 'Nanoscience and nanotechnologies: opportunities and uncertainties'[55], to which the Government responded in February 2005[56].

The Council for Science and Technology will be reviewing the Government's progress after two years in taking forward the actions it set out in the Response, and assessing the implications of any new developments.

As part of the Review, the Council is asking for written submissions on the following issues:

- The extent to which the Government has taken forward the commitments described in its Response.
- The timeliness and effectiveness of the actions taken by Government.
- Whether there have been significant developments in nanoscience/nanotechnology since February 2005 which raise new issues the Government did not address in its Response, and should now.

It is emphasised that the Council will not be discussing wider arguments on the use of nanotechnology in society, nor looking at whether the commitments made by Government were the correct course of action, unless new evidence suggests compelling reasons for doing so.

Submissions should be sent to **nanoreview@cst.gov.uk by Monday 2 October, 2006**.

For enquiries, please contact Jonathan Radcliffe, Deputy Secretary to the Council for Science and Technology, email jonathan.radcliffe@dti.gsi.gov.uk, telephone 020 7215 6579.

Please feel free to draw the Call for Evidence to the attention of others you think may wish to submit evidence to the Review.

Guidance for those submitting written evidence

The deadline for submitting written evidence is Monday 2 October 2006. The Council aims to publish its report in spring 2007.

Submissions should be sent as an email attachment to nanoreview@cst.gov.uk, and include a brief statement of the key points. Evidence will be published on the Council's website.

Please ensure that you include relevant contact details. Evidence should be attributed and dated, with a note of your name and position, and should state whether it is submitted on an individual or corporate basis.

55 Available online at http://www.nanotec.org.uk/finalReport.htm.
56 Available online at http://www.dti.gov.uk/science/science-in-govt/st_policy_issues/nanotechnology/page20218.html.

Information provided in response to this Call for Evidence, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want some information that you provide to be treated as confidential, please inform us but be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

Your personal data will be processed in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. Personal contact details will be retained by the Council's Secretariat and used for specific purposes relating to the Council's work, for instance to seek additional information or to send copies of the Council's Report.

The Council for Science and Technology

The Council for Science and Technology (CST) is the UK government's top-level advisory body on science and technology policy issues.

CST's remit is to advise the Prime Minister and the First Ministers of Scotland and Wales on strategic issues that cut across the responsibilities of individual government departments. CST organises its work around five broad themes (research, science and society, education, science and government, and technology innovation) and takes a medium to longer term approach. Further information can be found on the Council's website: www.cst.gov.uk.

To carry out this Review, a sub-group of CST has been established, chaired by Professor Sir John Beringer, with Professor Geoffrey Boulton, Mr Andrew Gould, Dr Hermann Hauser, and Dr Sue Ion. The Royal Society and Royal Academy of Engineering have nominated two further members to provide expert advice to the sub-group, they are Professor Ken Donaldson, and Professor Mark Welland. Social scientist Professor Jacquie Burgess has also been co-opted on to the subgroup.