RESPONSE TO THE ROYAL SOCIETY AND ROYAL ACADEMY OF ENGINEERING REPORT:

'Nanoscience and nanotechnologies: opportunities and uncertainties'

February 2005

BY HM GOVERNMENT IN CONSULTATION WITH THE DEVOLVED ADMINISTRATIONS

Foreword

In June 2003 I asked the Royal Society and the Royal Academy of Engineering to conduct an independent study identifying the opportunities and uncertainties surrounding nanoscience and nanotechnologies as the basis for a continuing Science and Society dialogue that will seek to ensure that we have a regulatory system which will address public concerns and which allows the development of nanotechnologies in a responsible and innovative way. I also asked them to define what was meant by nanoscience and nanotechnologies and identify areas where nanotechnologies are already in use. Their Report was published in July 2004, after consultation with the public and scientists, and highlighted areas where Government needs to demonstrate that it has a clear agenda to ensure the safety of individuals, animals and the environment and one which can adapt as the technologies develop.

This response to the Report from the Royal Society and the Royal Academy of Engineering sets out the Government's agenda on nanotechnologies; and will be reviewed by an independent body after two and five years. Our commissioning of this Report demonstrates our commitment to the responsible development of new technologies.

These technologies are at an early stage of development. This means that we can concentrate on getting it right – ensuring that developments benefit society and the environment, but do not overburden industry with regulation.

Exciting challenges and opportunities lie ahead in terms of coordinating research, leading the way in developing good practice in public engagement, and in adapting our regulatory frameworks so they are relevant to developments. The Government's agenda sets out our ambition to work actively in partnership with industry, civil society groups, the research community and the public so that we can move forward together, bringing forward our particular perspectives to ensure that we reap the benefits and avoid the pitfalls.

On the international stage, we want to have influence and shape global developments in nanotechnologies. We must maintain our international competitiveness by: participating in international collaboration; projecting the UK as a model of best practice in regulation and public engagement; and having early international engagement to build mutual understanding.

I now look to civil society groups, industry, the research community, and the general public in the United Kingdom to continue to engage with one another and government in a spirit of constructive dialogue.

Lord Sainsbury of Turville
Minister for Science and Innovation

Introduction

1. The Government thanks the Royal Society and Royal Academy of Engineering (RS/RAEng) for its Report, *'Nanoscience and nanotechnologies: opportunities and uncertainties'*,[1] and has reflected on its recommendations carefully.

2. In their Report *'Scientific Research: Innovation with Controls'*,[2] published in January 2003, the Better Regulation Task Force identified nanotechnology as an area of great potential but where concerns are likely to be raised about the risks of the technology. That Report states that Government needs to be ready to deal with these concerns and demonstrate that it has clear policies in place to ensure the safety of individuals, animals and the environment, whilst permitting research to continue.

3. At the request of Lord Sainsbury, the Science Minister, the RS/RAEng were commissioned to conduct an independent joint study. The agreed terms of reference were:

- Define what is meant by nanoscience and nanotechnology.
- Summarise the current state of scientific knowledge about nanotechnology.
- Identify the specific applications of the new technologies, in particular where nanotechnology is already in use.
- Carry out a forward look to see how the technology might be used in future, where possible estimating the likely time scales in which the most far-reaching applications of the technology might become reality.
- Identify what environmental, health and safety, ethical or societal implications or uncertainties may arise from the use of the technology, both current and future.
- Identify areas where regulation needs to be considered.

4. A working group chaired by Ann Dowling, Professor of Mechanical Engineering at the University of Cambridge, oversaw the study. Membership of the working group included experts in science, engineering, social science and ethics and from two major public interest groups. The group consulted widely, through a call for written evidence and a series of oral evidence sessions and workshops with a range of stakeholders from both the UK and overseas. The Report was reviewed and endorsed by the RS/RAEng.

[1] An on-line copy of the report is available at: http://www.nanotec.org.uk/finalReport.htm

[2] An on-line copy of the report is available at: http://www.brtf.gov.uk/reports/scientificresearch.asp

Government's Overall Response

5. The Government wants to make substantial and sustained progress towards building a society that is confident about the governance, regulation and use of science and technology.

6. To do this we have learnt that it is necessary with major technologies to ensure that the debate takes place at an early stage, as new areas emerge in the scientific and technological development process. This involves engaging with the public and understanding their aspirations and concerns around science and new technologies.

7. That is why we commissioned the RS/RAEng Report, to look at the possible ethical, social, health, safety and environmental questions that could be raised by nanotechnologies. Failure to address these issues adequately could delay or foreclose opportunities to realise the potential benefits of these new technologies, or mean that we miss chances to avoid or mitigate potential downsides.

8. The RS/RAEng Report concludes that we are at an early stage of the technologies' development curve. This is important. The Report's recommendations therefore provide the blueprint to help foster the responsible development of this emerging set of technologies. It emphasises that 'nanotechnology' comprises a disparate number of unrelated technologies that cut across many traditional scientific disciplines, whose only common feature is the tiny dimensions at which these activities operate, and that therefore, a more appropriate term is nanotechnologies. This diversity has important implications for how we approach public dialogue, research and regulation.

9. It is also clear that there is an international dimension to the issues raised by developments in nanotechnologies and that we need to introduce mechanisms for broader discussion and collaboration on how to address these issues in an efficient and effective way.

10. People are interested in the nanoscale (which is defined in the Report to be 100nm[3] down to the size of atoms – about 0.2nm) because it is at this scale that the properties of materials can be very different from those at a larger scale. As the Report points out, in some senses, nanosciences and nanotechnologies are not new. Nanoparticles exist in nature and are present in our atmosphere. Chemists have been making polymers which are large molecules made up of nanoscale sub-units for many decades and nanotechnology has been used to create the tiny features on computer chips for the last thirty years. However, 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.

11. The RS/RAEng Report identifies the specific applications of the new technologies, in particular where nanotechnologies are already in use. Much of nanoscience and many nanotechnologies are concerned with producing new and enhanced materials. Current applications of nanoscale materials include very thin coatings used, for example in electronics and active surfaces (for example, self-cleaning windows). In most applications the nanoscale components will be fixed or embedded but in some, such as those used in some cosmetics, free nanoparticles are used. The ability to machine materials to very high precision and accuracy (better than 100nm) is leading to considerable benefits in a wide range of industrial sectors, for example, in the production of components for the information and communication technology (ICT), automotive and aerospace industries. Much of the miniaturisation of computer chips to date has involved nanoscience and nanotechnologies, and this is

[3] One nanometre (nm) is one billionth (10^{-9}) of a metre.

expected to continue in the short and medium term. The Report describes promising applications in bio-nanotechnology and nanomedicine.

12. The RS/RAEng Report highlights that many nanotechnologies pose no new health and safety risks and that almost all concerns relate to the potential impacts of deliberately manufactured nanoparticles and nanotubes that are free rather than fixed in a material.

Co-ordination and review

13. Chaired by the Office of Science and Technology (OST), the Nanotechnology Issues Dialogue Group (NIDG) will co-ordinate activities described in the Government response to the RS/RAEng Report. Its membership comprises representatives from those Government departments and agencies involved with taking forward the actions set out in this response, and this includes the devolved administrations. The NIDG will also provide a platform to monitor progress and delivery. The Government agrees that independent two and five year reviews of our progress, in taking forward the actions that we have set out here and assessing the implications of any new developments, would be valuable. We are pleased that the Council for Science and Technology (CST), the UK Government's top-level advisory body on strategic science and technology policy, has agreed to take on this role. The NIDG will provide evidence to inform CST's two and five year independent reviews of progress (see Recommendation 20).

Research into the potential environmental and human health risks of nanotechnologies

14. Deliberately manufactured nanoparticles and nanotubes that are not immobilised in a matrix (i.e. with the ability to move freely) are currently identified in the RS/RAEng Report as a research priority. Nanoparticles and nanotubes can behave differently from larger particles of the same material and this can be exploited in a number of ways. It is important that we determine both the positive and negative effects that they may have on human health and the environment. Manufactured free nanoparticles and nanotubes will encompass a wide range of products. They are not a discrete entity, and their properties will be dependent upon both their size and shape and of the material of which they are made. It is not yet known to what extent the new or enhanced properties of some nanomaterials will be associated with toxicity, but there is some evidence that some materials are more toxic in nanoparticulate form, possibly because of their greater surface area. To pose a risk, these nanomaterials must come into contact with humans or the environment in a form or quantity that can cause harm. Developing a proper understanding of their properties is an essential step to proportionate regulation of any risk from these materials: to people at work; or to members of the public from work activities, other routes of exposure; and to the environment.

15. The Government is 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. The Department of the Environment, Food and Rural Affairs (Defra) will chair a Research Co-ordination Group with representatives from research councils and the relevant Government departments and regulatory agencies including those with responsibility for the relevant health, safety, consumer and environment-related research agendas. This will include the Medical Research Council (MRC), the Biotechnology and Biological Research Council (BBSRC), the Economic and Social Research Council (ESRC), the Engineering and Physical Sciences Research Council (EPSRC), the Natural Environment Research Council (NERC), the National Physical Laboratory (NPL) and representatives from the relevant departments (the Department of Health (DH), the Department of

Trade and Industry (DTI), the Office of Science and Technology (OST), the Food Standards Agency(FSA)), and regulatory agencies (the Health and Safety Executive (HSE), the Medicine and Healthcare products Regulatory Agency (MHRA)). This will have, as part of its remit, a clear role in establishing links internationally to promote dialogue and to draw on and facilitate exchange of relevant information. The Research Co-ordination Group's work will be further enhanced and informed by a process of dialogue between stakeholders, researchers and the public. This will be integrated with our wider plans for stakeholder and public dialogue described in response to recommendations 18 and 19 and follow the guiding principles in Annex B. This dialogue will inform but not determine the decisions of the Research Co-ordination Group. The Research Co-ordination Group will report to the NIDG.

Precaution

16. The RS/RAEng carefully considered the case for a moratorium on the development and release to the environment on manufactured nanoparticles or nanotubes. They concluded that this would be an inappropriate response to the challenge posed by the emergence of new nanotechnologies and their applications. Their rejection of a moratorium is based on the assumption that Government will secure an appropriate and effective regulatory regime as rapidly as possible. Therefore, the Report focuses on precautionary recommendations to ensure that regulations reflect the fact that nanoparticulate material may have greater toxicity than the same material in the larger size range, and that all relevant regulators review regulations to ensure that they keep pace with future developments.

17. As a precautionary measure, in the interim, it recommends that exposure in the workplace and releases to the environment should be minimised until the possible risks posed by nanoparticles and nanotubes are better understood.

18. We are supportive of the precautionary stance taken by the RS/RAEng and agree that sensible and pragmatic steps can be taken now 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.

19. With respect to occupational health and safety, HSE presented technical reports to the Health and Safety Commission (HSC) Advisory Committee on Toxic Substances (ACTS) Working Group on Action to Control Chemicals (WATCH) in January 2005. Dialogue on the further development of the provision of advice for adequate exposure control strategies is now underway and will be communicated widely when finalised.

20. Given the uncertainty associated with risks to the environment from release of novel manufactured nanoparticles and nanotubes, the RS/RAEng Report asks industry to reduce or remove these from waste streams and prohibit their use for environmental remediation, while the uncertainties about the risks they pose are being addressed. We support this recommendation and will work with the Environment Agency and other stakeholders (including Local Authorities), in partnership with industry, to identify and help reduce or remove any waste stream discharges containing manufactured nanoparticles and nanotubes and prevent nanoremediation using these from taking place until we have a fuller understanding of the risks. It is important to recognise that the manufacture and use of nanoparticles and nanotubes is currently on a very small scale in the UK so exposure is likely to be limited, although the present information on use is likely to be incomplete. Government will undertake a detailed and ongoing review of the manufacture and uses of the products of nanotechnologies in order to ensure that there is clear information identifying any inputs

to the environment. We will also assess the regulatory mechanisms available to restrict inputs of nanoparticles and nanotubes into the environment. We will report back on these assessments by the end of 2005. There are significant technological challenges associated with detecting and excluding nanoparticles from waste streams – again this is a topic where we will be supporting further research.

Regulation

21. Because of their novel properties, the Report recommends that manufactured free nanoparticles and nanotubes should be treated as new chemicals under UK and EU legislation, in order to trigger appropriate safety tests and clear labelling. It also recommends that industry should publish details of safety tests showing that the novel properties of nanoparticles have been taken into account.

22. The Government accepts that chemicals in the form of nanoparticles or nanotubes can exhibit different properties to the bulk form of the chemical; sometimes this is beneficial and sometimes it may be potentially hazardous. The Government also accepts that safety testing on the basis of a larger form of a chemical cannot be used to infer the safety of the nanoparticulate form of the same chemical and that therefore individual regulations within the existing framework will need to be reviewed to reflect the possibility that nanoparticulate material may have greater toxicity than material in the larger size range.

23. In addition to assessing the regulatory mechanisms available to regulate inputs of nanoparticles and nanotubes into the environment, the Government will work with the HSE and the MHRA to review the adequacy of the current regulatory frameworks to ensure that safeguards to public health are robust. The HSE has already carried out an initial review of its regulatory coverage and published interim guidance and this was recognised in the RS/RAEng Report. The MHRA will work with its counterparts in EU regulatory authorities to consider the need for specific European guidance on the assessment of risks associated with medicines and medical devices. The MHRA has already raised this topic for discussion for medical devices.

24. The Government agrees that ingredients in the form of manufactured free nanoparticles should undergo a thorough safety assessment by the relevant scientific advisory body before they are used in consumer products. The DTI, and other relevant departments, will discuss with our European partners the most effective mechanisms for referral to the relevant scientific advisory committees and for responding to their advice to ensure the safety of manufactured unbound nanoparticles in cosmetics and other consumer products. We believe that disclosure of testing methodologies used by industry will help set the right climate of co-operation and advancement between industry, regulators, and the science community in developing best practice. Such an open approach will also help build public confidence. We will work with industry and EU partners to explore this further. Government believes in consumers being able to make informed choices. Existing labelling requirements on consumer products would need to be revised to accommodate this. We will work with the public and other interested parties to consider whether unbound manufactured nanoparticles contained in consumer products should be identified as such on lists of ingredients and under what circumstances.

25. The proposed EC regulation covering Registration, Evaluation and Authorisation of Chemicals (REACH) is currently being negotiated, and is expected to replace existing chemicals legislation within the next two to three years. Central to the new legislation is the requirement that chemicals should only be registered at production or importation levels greater than one tonne per annum and the Government believes that this is an appropriate trigger level for conventional chemicals. For some applications of nanotechnologies it is, however, possible that substances may be produced or

imported in a commercial setting at levels below this threshold. But, to reduce the threshold dramatically to take account of potential issues arising from nanotechnologies would result in a large number of chemicals (in addition to the products of nanotechnologies) that are not being produced on an industrial scale, being subject to regulations designed for industrial products. As a result, and in order to ensure that the products of nanotechnologies are properly regulated, the Government considers it likely that sector specific regulations, in addition to REACH, may be required, and this will be a key question addressed in the regulatory review. In this context, it is important to note that any new regulations could be implemented independently of REACH, and would require agreement at European level. Whilst any new legislation is being developed, at national or EU level, the Government will work with industry to restrict releases of nanoparticles into the environment.

Measurement

26. The UK will continue to contribute to the setting of international norms, including nomenclature, standards, and guidelines. This is fundamental to underpinning regulation, enforcement and quality control. Government will continue to support the National Measurement Scheme working on the development of traceable measurement methods related to dimensional, chemical and functional aspects of nanotechnologies. The UK has been instrumental in establishing a task force in the European Standards Organisation (CEN) to examine future standards requirements in nanotechnologies. NPL is actively involved in this initiative.

Public dialogue

27. The RS/RAEng Report forms part of the basis for further dialogue on the ethical, regulatory, environmental, health and safety issues that are raised. As a society, we need to be aware of the social and economic benefits to be gained from science-derived technologies, but also aware that inevitable scientific uncertainties will mean that new technologies may carry risks. We need to have rational and mature public dialogue informed by good science. This will explore the acceptable uses of new technologies, and processes whereby the outcomes of dialogue help to shape the policies introduced by Government. Annex B sets out the Government's guiding principles for public dialogue on science and technology. These will ensure proper representation of the public and research communities. The Government will facilitate such a dialogue to enable both the science community and the public to explore together both aspirations and concerns around the development of nanotechnologies. The outcomes of such dialogue will inform decision and policy-makers in relation to their role in setting the direction of research and development, and the regulation of nanotechnologies.

Looking ahead

28. The Government recognises the importance of looking forward to identify issues that may arise as a result of new science and its applications. In our ten-year investment framework for science and innovation, published in July 2004[4], we announced the formation of a new centre of excellence in science and technology horizon scanning to be placed in the OST. This work will be overseen by the Government's Chief Scientific Advisor working alongside Research Councils UK (RCUK), the Technology Strategy Board, the Chief Scientific Advisors' Committee (CSAC) and the PM's Council for Science and Technology (CST). It will engage with stakeholders and the public.

29. The Report makes twenty-one recommendations. The remainder of this response considers each of these highlighted recommendations in turn.

[4] Available on-line at: http://www.hm-treasury.gov.uk./spending_review/spend_sr04/associated_documents/spending_sr04_science.cfm

Response to Specific Recommendations

The industrial application of nanotechnologies

R1 We recommend that a series of life cycle assessments be undertaken for the applications and product groups arising from existing and expected developments in nanotechnologies, to ensure that savings in resource consumption during the use of the product are not offset by increased consumption during manufacture and disposal. To have public credibility these studies need to be carried out or reviewed by an independent body. (Section 4.5: paragraph 32)

30. The Report states that overstated claims about benefits and risks, neither based on sound science, are doing a disservice to emerging fields in nanotechnologies, and cite that significant benefits to the environment are being claimed from the applications of nanotechnologies. The Report recommends that life cycle assessments could be taken to evaluate these claims and to ensure that savings in resource consumption during the use of the product are not offset by increased consumption during other stages. Government believes that discussions and debate over the merits or otherwise of emerging technologies should be free and open and that claims about the risks and benefits should be challenged by all, and informed not only by life cycle assessments, but by other important considerations. Life cycle assessments undoubtedly have a role to play in the process and dialogue, but we should not unduly restrict our vision to a simple resource consumption test. For example, batteries consume 100 times more energy to produce than they deliver during their lifetime. Government is committed to developing policies on sustainable consumption and production as part of its wider sustainability agenda and believes that all technologies should move towards developing manufacturing processes that are increasingly sustainable. However, we must be very careful that we do not lose opportunities to exploit these emerging technologies by constraining them at a very early stage and impose harsher expectations that would apply to current technologies. Life cycle assessments is itself inherently difficult and methodologies are not fully standardised. Further work is needed to realise their full potential (see Recommendation 2).

R2 Where there is a requirement for research to establish methodologies for life cycle assessments in this area, we recommend that this should be funded by the Research Councils through the normal responsive mode. (Section 4.5: paragraph 33)

31. Government supports this recommendation, whilst recognising the independent status of Research Councils in determining their research priorities. Research of this type is already in progress in the Research Councils and they welcome high quality interdisciplinary proposals from the research community to develop methodologies and dialogue around life cycle assessments. However, Councils would highlight that responsive mode is not the only route by which such work could be funded. In some cases, it is possible to link such research into existing and ongoing programmes of research. For example, the Report highlights the recent Communication from the European Commission: *'Towards a European strategy for nanotechnology'*[5], which recommends that it would be advantageous to pool systematically knowledge on life cycle assessments at international level. Current nanotechnology projects funded under Framework 6 already include work on risk assessment, which will provide valuable data to develop methodologies for life cycle assessments. Framework 7 will develop this process and our understanding further.

[5] Available at: http://www.cordis.lu/nanotechnology/src/communication.htm

Possible adverse health, safety and environmental impacts

R3 We recommend that Research Councils UK establish an interdisciplinary centre (probably comprising several existing research institutions) to research the toxicity, epidemiology, persistence and bioaccumulation of manufactured nanoparticles and nanotubes as well as their exposure pathways, and to develop methodologies and instrumentation for monitoring them in the built and natural environment. A key role would be to liaise with regulators. We recommend that the research centre maintain a database of its results and that it interact with those collecting similar information in Europe and internationally. Because it will not be possible for the research centre to encompass all aspects of research relevant to nanoparticles and nanotubes, we recommend that a proportion of its funding be allocated to research groups outside the centre to address areas identified by the advisory board as of importance and not covered within the centre. (Section 5.6: paragraphs 55 & 56)

32. Government accepts the need for the better co-ordination of relevant nanotechnology research involving the Research Councils, Government departments and the regulatory agencies.

33. Government recognises the benefits of interdisciplinary research and that there is much baseline fundamental science to be done. Society looks to Government, its agencies and regulators to address the health and environment-related research agenda. 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. They are best placed to develop links with industry to deliver the necessary research on the basis of need in the context of specific products and applications of nanotechnologies. The more fundamental research to underpin regulatory development is better pursued by the Research Councils.

34. There is a need to establish a forum to ensure that a comprehensive research programme is developed that focuses on regulatory needs but draws widely on the established expertise of the science research community. Defra will chair a Research Co-ordination Group with the Research Councils (MRC, BBSRC, ESRC, EPSRC, NERC), NPL and representatives from the relevant departments (DH, DTI, OST, FSA) and regulatory agencies (HSE, the MHRA, and the Environment Agency) which includes those having responsibility for health and safety related research agendas. Departmental funding will be from existing Departmental allocations to ensure that research in this area proceeds rapidly and the Research Co-ordination Group will publish its first report on ongoing and projected research programme, including funding, by the Autumn of 2005. The NIDG (chaired by OST), will ensure that the work of the Research Co-ordination Group is integrated with other parts of the programme of work set out in the Government's response.

35. This Research Co-ordination Group will aim to ensure good research is commissioned to bear on the most relevant and pressing issues with best use of resources. The group will not in itself be a UK centre of advice on the potential health, safety and environmental impact of nanotechnologies. This was a function envisaged in the RS/RAEng Report under its terms of reference for a centre to be established by RCUK. Such advisory functions lie with the specialist and independent advisory bodies that give advice to Government departments and its agencies on health and safety. The Research Co-ordination Group will have, as part of its remit, a clear role in establishing links internationally to promote dialogue and to draw on and facilitate exchange of relevant information. It will operate in an open and transparent way and all research Reports and publications from its research programme will be peer reviewed before publication and placed in the public domain. Once the Research Co-ordination Group is established, it will decide how best to interact with those

collecting similar research data in Europe and internationally, and how best to maintain an effective data base.

36. The Research Co-ordination Group's work will be further enhanced and informed by dialogue between stakeholders, researchers and the public. This will be integrated with our wider plans for stakeholder and public dialogue described in response to recommendations 18 and 19 and follow the guiding principles in Annex B. This dialogue will inform but not determine the decisions of the Research Co-ordination Group.

Research programme

37. Government accepts there is a need for research to better understand the risks posed by nanoparticles and nanotubes. Developing a proper understanding of any hazardous properties is an essential step to regulating in a proportionate way any risk from these materials to: people at work, members of the public from work activities, or other routes of exposure, and the environment.

38. We will carry out work to determine the extent to which nanoparticles and nanotubes are being manufactured in the UK. This will be an ongoing project, aimed at providing regulators with an overview of the potential areas where action may be required.

39. The Government considers that there are two main priority areas for research:

- The development of robust and reliable measurement and detection technologies for nanoparticles and nanotubes. This work is of fundamental importance in determining and monitoring potential exposure routes, both in the workplace and the environment.

- Work to underpin the robust assessment of potential risks associated with nanoparticles and nanotubes. In particular, investigation of their toxicology, both in humans and in the wider environment. An important component of this work will be the development of toxicological methods appropriate for nanoscale materials.

40. In addition, the Government agrees that there is a need for further work on the environmental fate and potential bioaccumulation of nanoparticles and nanotubes, recognising that these will be as varied as the range of products and compounds of which they are made. This work will depend on the development of appropriate measurement technologies. In order to further our knowledge of the environmental fate of nanoparticles and nanotubes and their potential for environmental remediation, some small-scale controlled environmental release may be needed. The Government will review legislation covering environmental release for research purposes within the regulatory review to ensure that any release is undertaken in a safe and controlled manner and does not pose significant risks to the environment and human health. Throughout the research programme, it will be important that the work is co-ordinated, both at a national level and in the context of international research activity, such as that conducted as part of the EU-funded NANOSAFE and NANOSAFE 2 projects. The latter project has just received EU funding and will start shortly. This will ensure that all the required research areas are pursued, while minimising duplication.

R4 Until more is known about environmental impacts of nanoparticles and nanotubes, we recommend that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible. (Section 5.7: paragraph 63)

R5 Specifically, in relation to two main sources of current and potential releases of free nanoparticles and nanotubes to the environment, we recommend:

(i) that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous, and seek to reduce or remove them from waste streams. (Section 5.4: paragraph 41)

(ii) that the use of free (that is, not fixed in a matrix) manufactured nanoparticles in environmental applications such as remediation be prohibited until appropriate research has been undertaken and it can be demonstrated that the potential benefits outweigh the potential risks. (Section 5.4: paragraph 44)

41. The Government supports the precautionary stance taken in Recommendations 4 and 5, which are general and specific aspects of the same issue and are addressed together.

42. The Government is committed to the best possible outcome for the environment from nanotechnologies, considering both the significant benefits that developments may produce and any undesirable effects that might be associated with them. Making this assessment is particularly difficult at an early stage of development of any technology, when there are considerable uncertainties concerning both risks and benefits.

43. We agree with the RS/RAEng view that there are significant gaps in knowledge, particularly concerning the environmental fate of free manufactured nanoparticles and nanotubes and their toxicity. As stated in our response to Recommendation 3, the Government is strongly committed to filling these gaps in knowledge through research. In the case of furthering our knowledge of the environmental fate of nanoparticles and nanotubes, some small-scale deliberate environmental release may well be needed to obtain robust information.

5(i) Waste streams

44. We are supportive of the precautionary stance taken by the RS/RAEng in their report. Given the uncertainty associated with risks to the environment from release of free manufactured nanoparticles and nanotubes, the Report asks industry to reduce or remove these from waste streams. We support this recommendation and will, with other stakeholders (including Local Authorities), work in partnership with industry, to help implement it.

45. It is important to recognise that nanoparticles and nanotubes are currently manufactured and used on a very small scale in the UK, although the present information on use is likely to be incomplete. In addition to supporting industry to undertake this recommendation, Government will undertake a detailed and ongoing review of the manufacture and uses of the products of nanotechnologies in order to ensure that there is clear information identifying any inputs to the environment (as indicated in Recommendation 3). We will also assess the regulatory mechanisms available to restrict harmful inputs of nanoparticles and nanotubes into the environment. We will report back on these assessments by the end of 2005. There are significant technological challenges associated with detecting and excluding manufactured nanoparticles and nanotubes from waste streams – again this is a topic where we will be supporting further research (see Recommendation 3). It will also be necessary to consider the wider implications of any steps to limit the presence of nanoparticles in waste streams. In particular, any changes to work practices should be fully assessed to avoid any inadvertent increase to the risks for workers.

5(ii) Deliberate release for environmental remediation

46. Concerning the deliberate release of free manufactured nanoparticles and nanotubes for environmental remediation to detoxify pollutants in soil and ground water, it is important to emphasise that the development of nanotechnologies in this field is at an early stage, so that there is little, if any, remediation-related deliberate release currently occurring in the UK. In the absence of information on the risks and benefits, Government accepts the recommendation of the of the RS/RAEng that a precautionary approach should be taken, and we will work in partnership with the industry to prevent the deliberate release of manufactured nanoparticles until there is sufficient evidence that the benefits outweigh any adverse effects. It is Government's current view that further information concerning the environmental fate and toxicity of nanoparticles is required before the impact of such releases can be fully assessed. The review of environmental regulations discussed under Recommendation 8 will consider the legislation covering the use of nanotechnologies in environmental remedial applications. The Government will facilitate a dialogue on nanoremediation and the output of the research programme (discussed under Recommendation 3) will contribute to inform the debate. We would expect substantial progress to have been made when the CST reviews progress after two years (see Recommendation 20).

R6 We recommend that, as an integral part of the innovation and design process of products and materials containing nanoparticles or nanotubes, industry should assess the risk of release of these components throughout the lifecycle of the product and make this information available to the relevant regulatory authorities. (Section 5.4: paragraph 42)

47. The Government endorses the findings of the Report in encouraging comprehensive risk assessment at the earliest possible stage in product development. However, the significance of this recommendation will be dependent on whether a particular nanomaterial in its free form is potentially hazardous. Where prior research shows, for example, that a particular nanomaterial is non-toxic in its free form, information about its release is not relevant to the safety assessment. Where research indicates that the material is a potential hazard, the risk assessment should then evaluate risk, taking into account a number of factors including exposure and in such cases the likelihood of release of the free nanomaterials will be a relevant consideration in the assessment. This information should be made available to the regulatory authorities. Methods to manage the risk may then be considered. There is a very 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. Understanding these mechanisms is key to assessing the risk of release of nanoparticulates and NPL and others in the UK science base have been working for many years to develop our understanding of these degradation mechanisms. Whether these degradation models can be extended to form the basis of future models relating to nanomaterials remains to be seen and will require research. This is an area we will seek to address under the research programme (see Recommendation 3).

R7 We recommend that the terms of reference of scientific advisory committees (including the European Commission's Scientific Committee on Cosmetic and Non-food Products or its replacement) that consider the safety of ingredients that exploit new and emerging technologies like nanotechnologies, for which there is incomplete toxicological information in the peer-reviewed literature, should include the requirement for all relevant data related to safety assessments, and the methodologies used to obtain them, to be placed in the public domain. (Section 5.3.2b: paragraph 30)

48. The Government supports this recommendation and believes that disclosure of information related to safety assessment helps set the right climate of co-operation and advancement between industry, regulators, and the science community in facilitating the development of best practice for emerging technologies. Such an open approach is important in building public confidence. The Report recognises a key dilemma: manufacturers need to safeguard their commercial interests in a highly competitive market place. Because the development of these new substances is often the result of a major investment in research, they must keep their formulations confidential. The RS/RAEng Report proposes a solution, the risk assessment data and tests (the methodology) are disclosed and the product identity is kept confidential. We will consult with industry and stakeholders about this issue, and discuss it with the relevant EU bodies.

Regulatory issues

R8 We recommend that all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environment from the hazards outlined in this Report and publish their review and details of how they will address any regulatory gaps. (Section 8.5: paragraph 48)

49. The Government supports this recommendation. While it is likely that the development and deployment of many nanotechnologies will be covered by existing regulatory regimes, it is vital that we assess any regulatory gaps at an early stage, to ensure that human health and the environment are adequately protected. A thorough, independent study will be initiated by Defra into the implications of nanotechnologies on environmental regulations, and the outcome of this study will be published during 2005. A study by HSE has not identified any gaps in health and safety legislation but the position will be reviewed as more is known of the potential risks posed by nanomaterials. We will also work with our partners in Europe to influence the development of EU regulatory frameworks or guidance in relation to medicines, medical devices, cosmetics, other consumer products and environmental protection to address any regulatory gaps.

R9 We recommend that regulatory bodies and their respective advisory committees include future applications of nanotechnologies in their horizon scanning programmes to ensure any regulatory gaps are identified at an appropriate stage. (Section 8.5: paragraph 50)

50. The Government supports this recommendation. Nanotechnologies have already been identified as a key area in a number of contexts. For example, the Defra Science Forward Look[6] identifies the development of nanotechnologies as a key driver in determining the future evidence base that Defra requires to deal with potential risks to the environment. MHRA's internal Nanotechnology Working Group, which has been in existence since June 2003, comprises regulatory, scientific and technical specialists who meet on a regular basis to carry out horizon scanning, share information and raise internal awareness of issues that may arise from nanotechnologies. MHRA's specialists are committed to horizon scanning and to ensuring that their relevant expert advisory committees are informed of relevant developments in nanotechnologies.

51. Government will review the advisory committee structure for the provision of advice on potential risks to human health and the environment associated with nanotechnologies. Advice on safety for various aspects or uses of nanotechnologies will rest with a large number of advisory committees, listed in Annex A. We will ask them to consider issues as they arise and seek to ensure that nanotechnologies will be explicitly mentioned in their terms of reference. There will be co-ordination amongst regulatory bodies and a means of co-opting specialists from a shared pool of expertise.

[6] Defra Science Forward Look 2004-2013, July 2004, http://www.defra.gov.uk/science/ForwardLook/

52. HSE will continue to monitor developments in the nanotechnology sphere to identify possible developments in work activities that may affect the health and/or safety of workers or members of the public who might be affected by work activities. They will work in partnership with agencies such as the Environment Agency, which have also identified, through their horizon scanning processes, nanotechnologies as an issue of which they need to be aware. HSE will ensure that the relevant HSC advisory committees and working groups have the opportunity to consider and advise on such developments in nanotechnologies as part of their horizon scanning activities.

R10 We recommend that chemicals in the form of nanoparticles or nanotubes be treated as new substances under the existing Notification of New Substances (NONS) regulations and in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (which is currently under negotiation at EU level and will eventually supersede NONS). As more information regarding the toxicity of nanoparticles and nanotubes becomes available, we recommend that the relevant regulatory bodies consider whether the annual production thresholds that trigger testing and the testing methodologies relating to substances in these forms should be revised under NONS and REACH. (Section 8.3.2: paragraphs 18 & 19)

53. The Government accepts that a chemical in the form of nanoparticles or nanotubes may exhibit different properties to the bulk form of the chemical; sometimes this is beneficial and sometimes it may be potentially hazardous.

54. The Registration, Evaluation and Authorisation of Chemicals (REACH) proposal is currently being negotiated at European level, and is expected to replace existing chemicals legislation within the next two to three years. Central to the new legislation is the requirement that chemicals should only be registered at production or importation levels greater than one tonne per annum and the Government believes that this is an appropriate trigger level for conventional chemicals. For some applications of nanotechnologies it is, however, possible that substances may be produced or imported in a commercial setting at levels below this current threshold. But, to reduce the threshold dramatically to take account of potential issues arising from nanotechnologies would result in a large number of chemicals (in addition to the products of nanotechnologies) that are not being produced on an industrial scale being subject to regulations designed for industrial products. As a result, and in order to ensure that the products of nanotechnologies are properly regulated in line with this recommendation, the Government considers it likely that sector specific regulations, in addition to REACH, may be required, and this will be a key question addressed in the study initiated in response to Recommendation 8. In this context, it is important to note that any new regulations could be implemented independently of REACH, and would require agreement at European level.

55. In the meantime, chemicals will continue to be regulated under the Notification of New Substances (NONS) and Existing Substances Regulations (ESR). The NONS Regulations do not require re-notification for different physical forms, but the risk assessment submitted in support of a notification would include appropriate exposure routes which would in part depend on the physical form of the substance in question. The Regulations require that any significant new use is made known to the regulatory authorities so that additional information can be provided, if required. It may be that additional tests would be necessary for a chemical in the form of nanoparticles or nanotubes, but this will vary on a case-by-case basis.

56. Under the ESR, producers of chemicals are required to provide certain data to the European Commission, but only for those chemicals whose production levels exceed 10 tonnes per year. As discussed in relation to REACH, it is likely that sector specific regulations will be needed to ensure that products produced as nanoparticles are appropriately regulated. Whilst any new legislation is being developed, at national or EU level, the Government will work with industry to restrict releases of nanoparticles into the environment (see Recommendation 5).

R11 Workplace:

> (i) We recommend that the Health & Safety Executive (HSE) review the adequacy of its regulation of exposure to nanoparticles, and in particular considers the relative advantages of measurement on the basis of mass and number. In the meantime, we recommend that it considers setting lower occupational exposure levels for manufactured nanoparticles. (Section 8.3.1: paragraph 11)

57. HSE has already carried out an initial review of its regulatory coverage and this was acknowledged in the Report. This initial review was quickly followed by the publication of the HSE Horizon Scanning Information Note (HSIN1)[7] on nanotechnology. HSE and Health and Safety Laboratory (HSL) scientists have carried out reviews of the toxicological and occupational hygiene issues raised by nanotechnologies. Technical reports were presented to HSC's relevant advisory committees early in 2005 and further decisions will be taken, following presentation of these reports, on the provision of advice for adequate exposure control strategies. Further research is needed which will be carried out in collaboration with other interested parties through the mechanism outlined in the response to Recommendation 3.

> (ii) We recommend that the HSE, Department for Environment Food and Rural Affairs and the Environment Agency review their current procedures relating to the management of accidental releases both within and outside the workplace. (Section 8.3.1: paragraph 12)

58. HSE will review its current procedures to identify and address any gaps in the knowledge base. In the light of more robust information about the risks of some nanomaterials HSE will take the necessary action to provide advice for employers, workers and members of the public affected by work activities on the management of accidental releases.

59. The Environment Agency has procedures in place for dealing with incidents involving unknown toxins/materials and this recommendation does not have significant implications for the Agency's incident management policy or process framework. The Environment Agency will work with the DH and the Health Protection Agency to ensure that advice is readily obtainable if required, accepting the fact that little is known about environmental impacts of engineered nanoparticles and nanotubes.

> (iii) We recommend that the HSE consider whether current methods are adequate to assess and control the exposures of individuals in laboratories and workplaces where nanotubes and other nanofibres may become airborne and whether regulation based on electron microscopy rather than phase-contrast optical microscopy is necessary. (Section 8.3.1: paragraph 13)

60. HSE recognised that there could be potential weaknesses in existing arrangements and because of this produced prompt advice through the information note mentioned under Recommendation 11(i) to ensure that a precautionary approach is adopted in controlling exposure.

[7] http://www.hse.gov.uk/horizons/nanotech/index.htm

61. HSE, in collaboration with others, is undertaking a review to assess whether current methods are adequate and, dependent on the results of the review, will help develop and implement a programme of research to address any gaps. The first stage of this review involved an International Nanomaterials Symposium that was held in October 2004, the report of which will be available in early 2005.

R12 Consumer products:

(i) We recommend that ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in products. Specifically: we recommend that industry submit the additional information on microfine zinc oxide that is required by the SCCNFP as soon as reasonably practicable so that it can deliver an opinion on its safety. (Section 8.3.3: paragraph 24 & 23)

62. The Government agrees 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. We will discuss with our European partners the most effective mechanisms for referral to the relevant scientific advisory committees and for responding to their advice to ensure the safety of manufactured free nanoparticles in cosmetics and other consumer products. On the specific issue of microfine zinc oxide, the European Cosmetic Toiletry and Perfumery Association is currently compiling the additional dossier, as requested. They say that the additional dossier will be submitted to the relevant EC Scientific Committee shortly. We expect that the Committee will give an updated Opinion, based on that dossier, in the first half of this year. We will then decide, with EU partners, what action to take.

(ii) We recommend that manufacturers publish details of the methodologies they have used in assessing the safety of their products containing nanoparticles that demonstrate how they have taken account that properties of nanoparticles may be different from larger forms. (Section 8.3.3: paragraph 25)

63. We believe that disclosure of methodologies will help set the right climate of co-operation and advancement between industry, regulators, the science community in developing best practice. Such an open approach would also help build public confidence. We will work with industry and EU partners to explore this further.

(iii) We recommend that the ingredients lists of consumer products should identify the fact that manufactured nanoparticulate material has been added. (Section 8.3.3: paragraph 26)

64. The current use of free nanoparticles in consumer products is limited to a few cosmetic products. It is probable that in future they will be used in consumer areas such as food and pharmaceuticals. Government believes in consumers being able to make informed choices. Existing labelling requirements on cosmetic products would need to be revised to accommodate this. The feasibility of labelling needs to be fully investigated and we will work with the public and other interested parties to consider whether manufactured free nanoparticles contained in consumer products should be identified as such on lists of ingredients and under what circumstances.

(iv) We recommend that the EC's new Scientific Committee on Emerging and Newly Identified Health risks gives a high priority to the consideration of the safety of nanoparticles in consumer products. (Section 8.3.3: paragraph 27)

65. Government agrees that the new Scientific Committee on Emerging and Newly Identified Health Risks gives a high priority to the consideration of the safety of manufactured free nanoparticles in consumer products. We will communicate our views to the Committee. DG Sanco has now mandated the Scientific Committee on emerging and Newly Identified Health Risks to consider the use of nanotechnology.

> (v) In the light of the regulatory gaps that we identify we recommend that the EC (supported by the UK) review the adequacy of the current regulatory regime with respect to the introduction of nanoparticles into consumer products. In undertaking this review they should be informed by the relevant scientific safety advisory committees. (Section 8.3.3: paragraph 28)

66. It is essential that regulatory regimes keep abreast of technological developments and take account of the best science and commission relevant research as necessary. We have forwarded the Report to the European Commission, who in turn have informed members of the Standing Committee on Cosmetic Products, including DG Enterprise, DG Sanco, representatives from other Member States' governments, representatives from European industry and consumer associations. The Standing Committee has discussed the use of nanoparticulate substances in cosmetics before and we will continue to use the Report's recommendations as a tool for further discussions regarding the regulatory regime on the introduction of nanoparticles into consumer products. DG Enterprise is mandating the Scientific Committee on Consumer Products to seek a recommendation on the extension of testing methodology to take account of new technology, including nanotechnology. The Government strongly endorses this approach.

R13 We recommend that the Department of Health review its regulations for new medical devices and medicines to ensure that particle size and chemistry are taken into account in investigating possible adverse side effects of medicines. (Section 8.3.4: paragraph 29)

67. The Government support this recommendation whist recognising that UK regulations on medicines and medical devices are based on European legislation. These are designed to ensure that the quality, safety and performance of a very wide range of products and technologies are appropriately assessed and assured. The Regulations require manufacturers to carry out an analysis of the risks associated with a medicine or medical device, eliminate or reduce them and assess the balance of risks and benefits. For medicines, the legislation requires that the MHRA reviews this analysis. For both medicines and medical devices, particular attention must be paid to the chemical, physical and biological properties of the materials used with regard to their toxicity and their compatibility with tissues, cells and body fluids. Once authorised, products are monitored through market surveillance and the balance of risks and benefits reviewed.

68. MHRA is asking its counterpart regulatory authorities within the EU, via European Commission working groups, to consider the need for specific European guidance on the assessment of risks associated with medicines and medical devices that incorporate nanotechnologies. MHRA contributes, via the British and European Pharmacopoeia, to the development of European standards and specifications for materials used within medicines. 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. The Agency will ensure that standards currently being developed on chemical, physico-chemical, morphological and topographical characterisation of medical device materials are relevant to the safety assessment

of new products that incorporate nanotechnologies. MHRA is also participating in the development of international standards on nanotechnologies in general, to ensure that issues specific to therapeutic products are taken into account.

R14 We recommend that manufacturers of products that incorporate nanoparticles and nanotubes and which fall under extended producer responsibility regimes such as end-of-life regulations be required to publish procedures outlining how these materials will be managed to minimise human and environmental exposure. (Section 8.3.5: paragraph 32)

69. The existing EU Directives covering extended producer responsibilities, such as the End of Life Vehicles Directive 2000/53/EC, already deal with the treatment of all materials including those presenting special hazards. There are two aspects to this:

- new materials to be added to component and material coding standards; and
- a new requirement to publish procedures would need to be established.

70. Both of these measures will require extensive consultation to agree which materials to include and the format for published procedures. The European Commission has a duty to keep the materials listed in material coding standards under review in the light of new knowledge on an international scale and is likely to be receptive to well thought out proposals to improve the operation of these directives. As information on the safety of nanoparticles and nanotubes develops, the Government will draw this to the attention of the European Commission as necessary. It is vital that regulation is proportionate, targeted and results in the desired outcomes.

R15 Measurement:

(i) We recommend that researchers and regulators looking to develop methods to measure and monitor airborne manufactured nanoparticulates liaise with those who are working on the measurement of pollutant nanoparticles from sources such as vehicle emissions. (Section 8.4.2: paragraph 40)

71. The Government accepts this recommendation. Facilitating this interaction will be an important role of the cross-Government Research Co-ordination Group that we will establish in response to Recommendation 3.

(ii) We recommend that the Department of Trade and Industry supports the standardisation of measurement at the nanometre scale required by regulators and for quality control in industry through the adequate funding of initiatives under its National Measurement System Programme and that it ensures that the UK is in the forefront of any international initiatives for the standardisation of measurement. (Section 3.3.5: paragraph 60)

72. The National Measurement System (NMS) is already supporting work on the development of traceable measurement methods related to dimensional, chemical and functional aspects of nanotechnologies. Particular attention is paid to measurements that will underpin regulation and quality control. Currently, such work is being supported in a number of NMS programmes. Furthermore, new projects on characterisation of nanoparticles and powders are being developed in consultation with industry and will be given high priority in the forthcoming Metrology for Emerging Technologies and Materials Programmes.

73. The UK has been instrumental in establishing a task force in the European Standards Organisation (CEN) to examine future standards requirements in nanotechnologies. NPL is actively involved in this initiative and aims to ensure that appropriate measurement standardisation work forms a key element of the standardisation initiative.

Social and ethical issues

R16 We recommend that the research councils and the Arts and Humanities Research Board (AHRB) fund an interdisciplinary research programme to investigate the social and ethical issues expected to arise from the development of some nanotechnologies. (Section 6.8: paragraph 31)

74. The Government is committed to delivering the science and society agenda. This will require close cooperation between the OST and the Research Councils/AHRB. We would stress the importance of involving natural scientists, as well as those from the social sciences and humanities, in any such research programme. We would wish to see the research being geared to the provision of practical guidance and advice on how these issues might be dealt with in policy making, regulation and other decision-making. It will be essential for this programme of research to inform the work of the horizon scanning group where the issues are not unique to nanotechnologies (Recommendation 21).

R17 We recommend that the consideration of ethical and social implications of advanced technologies (such as nanotechnologies) should form part of the formal training of all research students and staff working in these areas and, specifically, that this type of formal training should be listed in the Joint Statement of the Research Councils'/AHRB's Skills Training Requirements for Research Students. (Section 6.8: paragraph 33)

75. The Joint Research Councils/AHRB skills training requirements[8] is a statement of what young researchers 'would be expected to develop during their research training.' Note that each Research Council and the AHRB will have additional specific requirements. Skills may be extant in new students/staff, may be explicitly taught or may be developed. Many of the skills already specified would be suitable for ensuring that research students develop the skills and knowledge necessary to understand and respond to the ethical and social implications raised by new science and technology.

76. There is of course a wide range of mechanisms to support the development of such skills. These include self-direction, supervisor support/mentoring, departmental support, workshops, conferences, elective training courses, formally assessed courses, and informal opportunities.

77. In addition, the Government sees merit in promoting learning by doing: with students and staff participating in public debates and dialogue around nanotechnologies and other topics. This will provide opportunities for learning, personal and professional development, and will build wider capacity among the research community to engage in constructive dialogue with the public to promote mutual understanding. In this way, researchers and staff will act as a source of substantive knowledge and information that will inform the dialogue process itself. At the same time, they will learn more about the issues of interest to the public, and be better able to reflect these in their own work.

78. Against this backdrop, the Government expects the research community to provide access to training, support and practical experience for research students and staff related to the ethical and social issues around the development of new areas of science and technology.

[8] Appendix 3 to the Quality Assurance Agency for Higher Education's Code of Practice for the Assurance of Academic Quality and Standards in Higher Education.

Stakeholder and public dialogue

R18 We recommend that the research councils build on the research into public attitudes undertaken as part of our study by funding a more sustained and extensive programme of research into public attitudes to nanotechnologies. This should involve more comprehensive qualitative work involving members of the general public as well as members of interested sections of society, such as the disabled, and might repeat the awareness survey to track any changes as public knowledge about nanotechnologies develops. (Section 7.2.3: paragraph 19)

79. The Government believes that it is important to have a good understanding of public attitudes to nanotechnologies and is working through the Sciencewise programme (see Box 1) and the Research Councils to achieve it.

R19 We recommend that the Government initiates adequately funded public dialogue around the development of nanotechnologies. We recognise that a number of bodies could be appropriate in taking this dialogue forward. (Section 7.6: paragraph 49)

80. The Government agrees with this recommendation and is committed to promoting constructive dialogue on nanotechnologies. The Government agrees that properly targeted and sufficiently resourced public dialogue will be crucial in securing a future for nanotechnologies. The Government's aim for public dialogue around nanotechnologies is to elicit and understand people's aspirations and concerns around the development of these technologies. Through the dialogue process, scientists and the public can jointly explore existing and potential opportunities, and policy-makers will want to hear about, and then respond to, public concerns related to ethical, social, health, safety and environmental issues.

81. To help meet this aim, the Government is already supporting a number of activities, such as *Sciencewise*.

Box 1. Examples of Government support for public engagement on nanotechnologies

Sciencewise – the Government's new public engagement grants scheme announced in the ten-year investment framework for science and innovation. Nanotechnologies have been identified as a priority area within the current round of *Sciencewise*. Successful projects for the first round will be announced early in 2005.

Nanotechnology, Risk and Sustainability – an ESRC-funded project to encourage early public engagement with nanotechnologies to address (among other things) how dialogue between scientists and the public can be improved so that public responses are integrated into both the innovation process and the development of regulatory frameworks around nanotechnologies.

Small Talk – a public engagement project funded under *Copus* (the Government's previous public engagement grants scheme which has now been superseded by *Sciencewise*). *Small Talk* aims to build a comprehensive understanding of public views on nanotechnologies, feed this intelligence to policy and decision-makers on nanotechnologies, and to further good practice in public engagement.

82. The programme will follow the Government's general approach to public dialogue on science and technology issues (Annex B) and provide sufficient resources in relation to timing, skills and capacity and funding. An outline programme will be provided in spring 2005, followed by a comprehensive programme in autumn 2005.

Ensuring the responsible development of nanotechnologies

R20 We recommend that the OST commission an independent group in two and five years' time to review what action has been taken on our recommendations, and to assess how science and engineering has developed in the interim and what ethical, social, health, environmental, safety and regulatory implications these developments may have. This group should comprise representatives of, and consult with, the relevant stakeholder groups. Its Reports should be publicly available. (Section 9.6: paragraph 30)

83. The Government agrees that independent two and five year reviews of our progress in taking forward the actions that we have set out here and assessing the implications of any new developments, would be valuable. We are pleased that the CST, the UK Government's top-level advisory body on strategic science and technology policies, has agreed to take on this role. CST will work with relevant experts and stakeholders, as is their normal practice, and their reports will be published on their website[9].

R21 We recommend that the Chief Scientific Advisor should establish a group that brings together representatives of a wide range of stakeholders to look at new and emerging technologies and identify at the earliest possible stage areas where potential health, safety, environmental, social, ethical and regulatory issues may arise and advise on how these might be addressed. (Section 9.7: paragraph 32)

84. The Government recognises the importance of looking forward to identify issues that may arise as a result of new science and its applications. In the ten-year investment framework for science and innovation we announced the formation of a new centre of excellence in science and technology horizon scanning. This will be based in OST and build on the work of the existing Foresight programme.

85. This horizon scanning function will provide the strategic context to horizon scanning activity in government departments and elsewhere. It will also inform the Government's strategy for public engagement with science to identify at the earliest possible stage areas where potential health, safety, environmental, social, ethical and regulatory issues may arise, and advise on how these might be addressed.

86. As part of the OST, the horizon scanning centre will be overseen by the Government's Chief Scientific Advisor. The Government believes that the centre will be most effective if it works with and alongside existing key bodies such as RCUK, the Technology Strategy Board, CSAC and the CST. In doing this it will also be resourced to engage with the wider range of stakeholders.

87. Work on establishing the centre has begun, and the Government expects progress to be subject to review as part of the wider two and five year programme (Recommendation 20) and as part of the implementation of the ten-year investment framework for science and innovation.

[9] Found at http://www.cst.gov.uk/

Annex A

Relevant Advisory Committees in the UK

Advisory Committee on Animal Feedingstuffs (ACAF)

Advisory Committee on Hazardous Substances (ACHS)

Advisory Committee on Novel Foods and Processes (ACNFP)

Advisory Committee on Toxic Substances (ACTS)

Air Quality Expert Group

Committee on Carcinogenity of Chemicals in Food, Consumer Products and the Environment (COC)

Committee on Medical Effects of Air Pollutants (COMEAP)

Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).

Annex B

Principles for Public Dialogue on Science and Technology

Based on theoretical understandings and practical experience, the essential elements of public dialogue on science and technology are set out below. The Government intends to adopt the approach set out in this document, but recognises that this guidance will continue to be refined as experience grows.

The key principles for public dialogue seek to ensure that:

- the conditions leading to the dialogue process are conducive to the best outcomes (**Context**[10]);
- the range of issues covered in the dialogue are relevant to participants' interests (**Scope**);
- the dialogue process itself represent best practice in design and execution (**Delivery**);
- the outputs of dialogue can deliver the desired outcomes (**Impact**); and
- the process is shown to be robust and contributes to learning (**Evaluation**).

In fulfilling these principles, it is recognised that the specific context of each issue will determine the relative importance of each of the following principles. However as far as practicable, public dialogue on science and technology aims to:

Context[11]

a) Be clear in its purposes and objectives from the outset.

b) Be well-timed in relation to public and political concerns. It will commence as early as possible in the policy/decision process.

c) Feed into public policy – with commitment and buy-in from policy actors.

d) Take place within a culture of openness, transparency and participation.

e) Have sufficient resources in terms of time, skills and funding.

f) Be governed in a way appropriate to the context and objectives.

[10] The means by which dialogue can impact upon policy and decision-making will be specific to each organisation involved in the dialogue process and each issue under consideration. It is important, therefore, that organisations involved in dialogue address their own institutional arrangements and working practices to ensure effective application of dialogue processes.

[11] It may not be advisable to embark upon a dialogue process, where these requirements cannot be met.

Scope

a) Cover both the aspirations and concerns held by the public, scientists in the public and private sector, and policy-makers.

b) Be focussed on specific issues, with clarity about its the scope of the dialogue. Where appropriate we will work with participants to agree framings that focus on broad questions to encourage more in-depth discussion. For example we might start by asking, "How do we provide for our energy needs in the future?" rather than starting by asking "should we build new nuclear power stations?"

c) Be clear about the extent to which participants will be able to influence outcomes. Dialogue will be focussed on informing, rather than determining policy and decisions.

Delivery

a) Ensure that policy-makers and experts promoting and/or participating in the dialogue process are competent in their own areas of specialisation and in the techniques and requirements of dialogue. Measures may need to be put in place to build the capacity of the public, experts and policy makers to enable effective participation.

b) Employ techniques and processes appropriate to the objectives. Multiple techniques and methods may be used within a dialogue process, where the objectives require it.

c) Be organised and delivered by competent bodies.

d) Include specific aims and objectives for each element of the process.

e) Take place between the general public and scientists (including publicly and privately funded experts) and other specialists as necessary. Policy-makers will also be involved where necessary.

f) Be accessible to all who wish to take part – with special measures to access hard to reach groups. Where the objectives require it, media partners may be needed to ensure that the process reaches the wider population.

g) Be conducted fairly – with no in-built bias; non-confrontational, with no faction allowed to dominate; all participants treated respectfully; and all participants enabled to understand and question experts claims and knowledge.

h) Be informed – This will include providing participants with information and views from a range of perspectives, and access information from other sources. The basis on which knowledge claims are made will be open, transparent and subject to challenge (following the scientific principles of peer review).

i) Be deliberative – allowing time for participants to become informed in the area; be able to reflect on their own and others' views; and explore issues in depth with other participants. The context and objectives for the process will determine whether it is desirable to seek consensus, or to map out the range of views.

j) Be 'representative' – the range of participants will reflect the range of relevant interests, and pertinent socio-demographic characteristics (including geographical coverage) of the general public. At times, there may be a need to enable participants to be self-selecting. In these circumstances, there will be measures in place to take account of potential any bias this may cause.

Impact

a) Ensure that participants, the scientific community and policy-makers and the wider public can easily understand the outputs across the full range of issues considered.

b) Ensure that participants' views are taken into account, with clear and transparent mechanisms to show how these views have been taken into account in policy and decision-making.

c) Influence the knowledge and attitudes of the public, policy-makers and the scientific community towards the issue at hand.

d) Influence the knowledge and attitudes of the public, policy-makers and the scientific community towards the use of public dialogue in informing policy and decision-making.

e) Encourage collaboration, networking, broader participation and co-operation in relation to public engagement in science and technology.

f) Be directed towards those best placed to act upon its outputs.

Evaluation

a) Be evaluated in terms of process and outcome, so that experience and learning gained can contribute to good practice.

b) Ensure that evaluation commences as early as possible, and continues throughout the process.

c) Ensure that evaluation addresses the objectives and expectations of all participants in the process.

d) Be evaluated by independent parties (where appropriate).

Annex C

Acronyms

ACTS	Advisory Committee on Toxic Substances
AHRB	Arts and Humanities Research Board
BBSRC	Biotechnology and Biological Research Council
CEN	European Committee for Standardisation
CSAC	Chief Scientific Advisors' Committee
CST	Council for Science and Technology
Defra	Department for the Environment, Food and Rural Affairs
DH	Department of Health
DTI	Department of Trade and Industry
EPSRC	Engineering and Physical Sciences Research Council
ESR	Existing Substances Regulations
ESRC	Economic and Social Research Council
HSC	Health and Safety Commission
HSE	Health and Safety Executive
HSL	Health and Safety Laboratory
ICT	Information and Communication Technology
MHRA	Medicine and Healthcare products Regulatory Agency
MRC	Medical Research Council
NERC	Natural Environment Research Council
NIDG	Nanotechnology Issues Dialogue Group
NGO	Non-Governmental Organisation
NMS	National Measurement System
NONS	Notification of New Substances
NPL	National Physical Laboratory
OST	Office of Science and Technology
RAEng	Royal Academy of Engineering
RCUK	Research Councils UK
REACH	Registration, Evaluation and Authorisation of Chemicals
RS	Royal Society
SCCNFP	Scientific Committee on Cosmetic and Non-Food Products
WATCH	Working Group on Action to Control Chemicals

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