

STATEMENT BY THE UK GOVERNMENT ABOUT NANOTECHNOLOGIES

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1. GOVERNMENT'S VISION FOR NANOTECHNOLOGIES

1.1 The vision of the UK Government for nanotechnologies is -

“for the UK to derive maximum economic, environmental and societal benefit from the development and commercialisation of nanotechnologies, and to be in the forefront of international activity to ensure there is appropriate control of potential risks to health, safety and the environment”.

In delivering this vision, the Government will be open about its activities and about uncertainties in the science.

2. WHAT ARE NANOTECHNOLOGIES?

2.1 “Nano” means one thousand millionth of a unit. Thus one nanometre is one thousand millionth of a metre (or one millionth of a millimetre), or 10^{-9} metre. Nanomaterials are usually considered to be those typically in the range of 1 to 100 nanometres¹. At the nanoscale, materials often have very different properties from their everyday equivalent. For example, nanoscale materials may be much stronger or more chemically reactive than their larger forms, or they may have different optical, electrical or magnetic behaviours. Nanotechnologies aim to exploit these different properties to create novel structures, devices and systems. Materials can be produced that are nanoscale in one dimension (such as very thin coatings); two dimensions (such as nanowires and nanotubes) or three dimensions (such as nanoparticles).

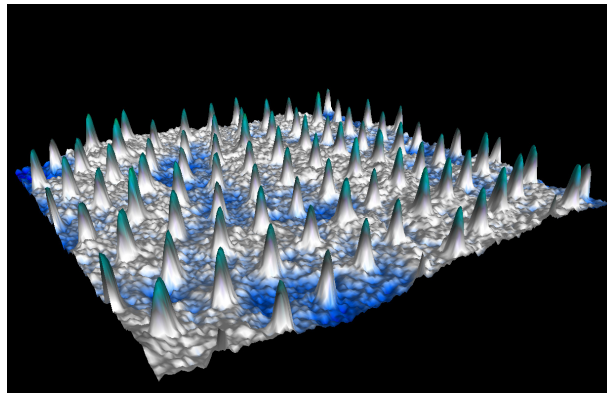


Figure 1. An array of tungsten nanodots grown by electron-beam assisted deposition. The dots are approximately 4nm high. *Image courtesy of the National Physical Laboratory*

2.2 Nanotechnologies cut across traditional scientific disciplines and often involve inter-disciplinary working. Chemists have been creating polymers from nanoscale building blocks for many years, but to create new structures and products at the nanoscale, chemists need to work with people from the biological, physical, engineering and other sciences.

¹ The Royal Society and Royal Academy of Engineering report “Nanoscience and Nanotechnologies: Opportunities and uncertainties”, 2004 considered -

“nanoscience” to be the study of phenomena and manipulation of materials at atomic, molecular and nanomolecular scales, where properties differ significantly from those at a larger scale; and

“nanotechnologies” to be the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale.

2.3 The range of potential applications is very diverse and nanotechnologies will enable the production of a new class of materials and products. Nanoscale materials are already being used in the UK to enhance existing products such as sunscreens and in antimicrobial wound dressings, self-cleaning windows and stain-resistant trousers. For example, pharmaceutical companies have introduced nanotechnologies to hip replacement operations in the National Health Service. Nanotechnology is used in the development of hip prostheses by coating the hip joint with nanoscale silver particles which repel bacteria. This ensures that the artificial hip joint is sterile and does not introduce infection to the patient. Healthcare could be further revolutionised by technologies that will enable illness to be diagnosed even before the onset of clinical symptoms, allowing for treatment to begin earlier and leading to more personalised, targeted treatment. Nanotechnologies may also help us to design systems which localise the delivery and release of drugs, so that they only target the specific areas of the body that need treatment.

2.4 There are promising environmental applications, in particular in reducing greenhouse gas emissions and in improving the efficiency of energy storage, production and conversion systems. A recent report² for Defra highlighted the contributions nanotechnologies can make to the so-called “hydrogen economy” and to photovoltaic device design, fuel efficiency, batteries and insulation. Nanosensors might detect contamination, pathogens and pests in food, water or the wider environment while nanomembranes might be used to clean polluted water or air.

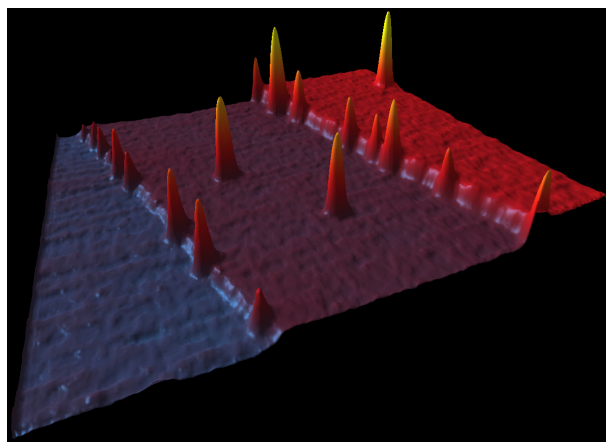


Figure 2. *Clusters of 1.3nm gold nanoparticles on graphite terraces. The lower terrace step is 0.34 nm in height; the upper step is exactly twice this. Image courtesy of the National Physical Laboratory*

2.5 As well as opportunities, there are potential risks associated with nanotechnologies. Concern has been expressed that some may be able to penetrate the skin and trigger the production of reactive molecules that could lead to cell damage. Similarly, it is possible that carbon nanotubes may have properties similar to those of asbestos fibres.

² <http://www.defra.gov.uk/environment/nanotech/policy/pdf/envbeneficial-report.pdf>

2.6 In its 2004 report³ the Royal Society⁴ and Royal Academy of Engineering⁵ identified these risks but advised that many nanotechnologies pose no new risk to health. Almost all of the concerns relate to the potential impacts of deliberately manufactured nanoparticles and nanotubes that are free rather than fixed to or within a material. At present exposure is likely to be limited to those workplaces where nanoscale materials are being manufactured or handled.

2.7 Many nanoscale materials are naturally produced but some manufactured ones have been marketed for several years without evidence of harm to health or the environment. For example, nanoscale particles of zinc oxide have been used in some sunscreen products since 1992.

³ <http://www2.cst.gov.uk/cst/business/files/nano-report-2004-fin.pdf>

⁴ <http://royalsociety.org/>

⁵ <http://www.raeng.org.uk/>

3. HOW THE UK GOVERNMENT IS LOOKING TO PROMOTE THE OPPORTUNITIES OF NANOTECHNOLOGIES

3.1 Nanotechnologies offer potentially huge benefits to the UK economy and to society more generally. Although there are a number of nano-enabled products already on the market, the greater benefits are still some way off, for example through developments to tackle environmental challenges and improve healthcare. The Government is keen that the UK should exploit the global market in nanotechnologies and has taken a number of measures to stimulate the development of nanotechnologies.

3.2 It is not possible to give an estimate of the scale of investment in nanotechnologies by industry over the past decade as originally engineered products were not classified as “nano”. The focus of activity is on engineered nanoscale materials as nanoscale materials occur in nature and are found in many natural products. It has been suggested (the World Nanotechnology Market 2006⁶ that more than \$9.5 billion was spent worldwide on nanotechnology research and development in 2005, of which corporations and Governments contributed nearly \$9 billion. The remainder was from venture capital firms.

3.3 The role of Government is to create the environment within which individuals and organisations can create and market innovative products. It is not to fund that research and development since that is more properly done by business. Developments in this field are heavily dependent on having highly-skilled people, an underpinning base of high quality basic research, knowledge-sharing and transfer, and essential, sometimes costly equipment. Measures to encourage the development of the skills base and the physical and communications infrastructure are therefore the key components of the Government’s strategy to encourage the development of nanotechnologies.

Nanometrology

3.4 The development of nanotechnologies cannot advance without progress in nanometrology. This is the ability to measure and characterise nanoscale materials, objects and devices according to their shape, size, physical, chemical and biological properties and in an accurate, reliable, reproducible and repeatable way. Nanometrology is supported by the development and use of a common terminology, ensuring that all stakeholders use the same term for the same product, properties and features in whichever country they are studied or marketed. It is essential for legislation to be effective and, similarly, industry needs to be able to guarantee and demonstrate (to purchasers and enforcement bodies) that they have reproducible processes for their materials and devices.

⁶ http://www.piribo.com/publications/technology/world_nanotechnology_market_2006.html

3.5 Well characterised and stable reference materials are also needed to enable us to -

- understand if certain types of nanoscale materials behave in similar ways;
- ensure that measurement equipment is working correctly and that test methods provide repeatable and reproducible results no matter where they are applied;
- interpret studies and compare results with research carried out in laboratories across the world;
- determine unambiguously the effects of exposure to a nanoscale material on a cell, tissue, organ or animal.

3.6 The Department for Innovation Universities and Skills (DIUS)⁷ spends about £60 million per annum funding the National Measurement Programmes which support measurement activities in a number of laboratories and across a number of different areas including Chemical and Biological Metrology; Engineering and Flow Metrology; Materials and Thermal Metrology; and Physical Metrology. As part of these programmes the Department is spending £4.8 million per annum on nanometrology work at the National Physical Laboratory.

3.7 The Engineering and Physical Sciences Research Council⁸ with funding from the relevant Funding Councils has supported two centres to grow the research base in nanometrology with a total investment of £6 million under its Science and Innovation Awards Scheme.

3.8 The Technology Strategy Board, Devolved Administrations and Regional Development Agencies fund 22 Micro and Nanotechnology Centres (see paragraph 3.27 below). Two of these centres offer services on the characterisation of micro and nano-scale materials. They are the Centre for Excellence in Metrology in Micro and Nano Technology⁹ (www.cemmnt.co.uk) and Begbroke¹⁰ (www.begbrokenano.com) located in Loughborough and Oxford respectively. They are funded jointly by the Technology Strategy Board and industry which provide total funding of around £14 million over a period of five years, after which the centres are expected to become self-financing.

Development of skills

⁷ <http://www.dius.gov.uk/>

⁸ <http://www.epsrc.ac.uk/>

⁹ <http://www.cemmnt.co.uk/>

¹⁰ <http://www.begbroke.ox.ac.uk/default.php>

3.9 The development of the skills base starts in schools and there are a number of schemes which encourage scientists, including “nano” scientists, to engage with the public and, in particular with school children. These schemes include the Beacons for Public Engagement¹¹; the Science Technology Engineering and Mathematics Network¹² and the Science and Engineering Ambassadors¹³.

3.10 The MNT Academy at Cardiff University focuses on training for engineers and apprentices¹⁴ and a number of universities are offering nanotechnology components of undergraduate courses such as electronic engineering, chemistry, materials and mechanical engineering. Some also offer Masters¹⁵ level courses in nanotechnologies and research training at PhD level, often with Research Council funding. The Institute of Nanotechnology has recently introduced an accreditation scheme for Masters level courses with support from industry and academic institutions across Europe. Opportunities for post-doctoral research in nanotechnologies are, at present, primarily in universities and other academic institutions but will increasingly be in industry.

Comment - a recommendation from public dialogue was that scientists should improve their communication skills, including going into schools to encourage science as a career path to all children. The place of nanotechnologies in education should be considered. The voices of young people need to be heard in decisions about nanotechnologies and the environment.

Fundamental research

3.11 Fundamental or “blue skies” research seeks to understand the basic science. This research is carried out in universities and other related institutions and generates the underpinning knowledge which is essential for any product or technology development. The Government (through the Department of Innovation, Universities and Skills) provides funding of over £3 billion per annum to the seven Research Councils¹⁶. Across the Research Councils around £50 million goes on nanotechnology research per annum. This funding supports research across the remits of the Research Councils so runs from basic research in the physical and biological sciences through to more applied research aimed at a range of application areas. Much of this applied research is conducted in collaboration with industry.

¹¹ <http://www.rcuk.ac.uk/sis/beacons.htm>

¹² <http://www.stemnet.org.uk/>

¹³ http://www.stemnet.org.uk/ambassadors_seas.cfm

¹⁴ <http://www.mntacademy.org>

¹⁵ <http://www.nano.org.uk/nanomasters/>

¹⁶ <http://www.dius.gov.uk/publications/sciencebudget.html>

3.12 In December 2007, the Research Councils announced a cross-Council programme which will provide an additional £50 million in areas where the UK nanotechnology research base can make a significant impact on issues of societal importance such as healthcare. These societal or economic Grand Challenges will be addressed in a series of calls for large-scale integrated projects. They will be led by the Engineering and Physical Sciences Research Council, in collaboration with stakeholders including other Research Councils, industry, the Technology Strategy Board and the Nanotechnology Research Coordination Group.

3.13 To focus the UK research effort the funders will work through a series of Grand Challenges developed in conjunction with researchers, users and the public in areas of societal importance such as energy, environmental remediation, the digital economy, and healthcare. They will include basic research through to application plus studies on risk governance, economics, and social implications.

3.14 The Engineering and Physical Sciences Research Council has already called for proposals for the first Grand Challenge in the area of exploiting nanotechnology to enable cheap, efficient and scalable ways to harvest solar energy. The focus of the second Grand Challenge call, which will be in the area of nanotechnology for healthcare, is being developed through consultation with the research and user community. In addition, the Engineering and Physical Sciences Research Council in conjunction with the Economic and Social Research Council¹⁷, will seek input from the public on their concerns and aspirations concerning nanotechnology for healthcare.

3.15 Where the community of researchers needs creating or expanding, the Research Councils take active steps to encourage this. For example –

- the Biotechnology and Biological Sciences Research Council has a bionanotechnology research priority to stimulate the submission of proposals and help build the research community¹⁸;
- the Engineering and Physical Sciences Research Council has appointed a Senior Strategic Advisor for Nanotechnology who is raising the profile of nanotechnology and promoting inter-disciplinary research collaborations, including those called for under the Grand Challenges;
- the Medical Research Council¹⁹, following discussion with the Department of Health, issued a nanotoxicology highlight notice in March 2007 encouraging the development of a community of nanotoxicologists to pursue research into the potential health implications of nanotechnologies;

¹⁷ <http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/index.aspx>

¹⁸ <http://www.bbsrc.ac.uk/>

¹⁹ <http://www.mrc.ac.uk/index.htm>

- the Natural Environment Research Council²⁰ has, in collaboration with Defra and the Environment Agency²¹, set up the Environmental Nanoscience Initiative to build research capacity in the areas of ecotoxicology and the environmental fate and behaviour of nanomaterials;
- the Natural Environment Research Council is leading on a joint Environment and Human Health Programme which aims to build research capacity across disciplines in areas where the natural environment and human health interact and has funded research into the potential human health hazards from nanomaterials through environmental exposure; and
- the Research Councils have pooled funding to support inter-disciplinary projects, and have provided £20 million for two Interdisciplinary Research Centres in nanotechnology and bionanotechnology. These centres now have an international reputation.

3.16 In addition, the Research Councils' coordinating body, RCUK, has established a Nanotechnology Group in order to facilitate cross Council working in the area.

3.17 Much of the funding for research and training comes from the Engineering and Physical Sciences Research Council which in recent years has invested up to £40 million per annum in responsive mode research grants in the area of nanotechnology and supports 40 new PhD studentships each year.

3.18 The Biotechnology and Biological Sciences Research Council²² spent £5.3 million in total on grants, studentships and interdisciplinary research collaborations in bio-nanotechnology in 2005/06. The research supported has a focus on healthcare and analytical technologies.

3.19 The Research Councils agree their overall strategic direction with the Department of Innovation, Universities and Skills, but the Government does not seek to influence decisions on individual projects. Researchers submit project proposals to a Research Council for funding. Decisions on whether or not to fund a project are taken on the basis of the quality of the research; if the proposed research is of a sufficiently high quality it will be funded regardless of the subject matter. This is known as "responsive mode" funding, which accounts for a significant proportion of Research Council funding. In other cases Research Councils can work in more directed fashion through managed activities such as those described in 3.15, although research quality remains an important consideration, the extent to which the proposal meets the aims of the initiative is also taken into account.

²⁰ <http://www.nerc.ac.uk/>

²¹ <http://www.environment-agency.gov.uk/>

²² <http://www.bbsrc.ac.uk/>

“Pull-through” of ideas and skills from the research community to industry

3.20 Through the Technology Strategy Board²³, the Government funds a number of activities to translate the knowledge and ideas generated by fundamental research into new products and services in areas where there are market opportunities and where the UK has academic and industrial capability.

3.21 The Technology Strategy Board is a non-departmental public body and has an important leadership role to stimulate innovation in those areas which offer the greatest scope for boosting UK growth and productivity. The Technology Strategy Board operates across all important sectors of the UK economy, in partnership with a large number of others, including Government departments, Research Councils, Regional Development Agencies and Devolved Administrations. Over the next three years the Board will develop and lead a strategic programme worth £1 billion through a number of key UK technology and application areas. Of this, £180 million will be allocated by the Regional Development Agencies and £120 million by the Research Councils. As part of this strategic programme, a Nanotechnology Strategy for the UK will be developed over the coming months in consultation with key stakeholders.

3.22 The Technology Strategy Board, together with its partners -

(a) identifies **emerging technologies** and provides the opportunity for business to take advantage at an early stage of exciting research that is taking place in the science base. The commercialisation of nanomedicine is one area that is currently identified for support;

(b) funds **Knowledge Transfer Partnerships**²⁴ which place high calibre, recently-qualified graduates into businesses and social enterprises to work on innovation projects. These partnerships enable businesses and organisations to improve their competitiveness through the use of the knowledge, technology and skills that reside within academic institutions. They also increase the relevance of the research and teaching within academia. In 2006/07 expenditure was around £32.7 million and there were over 1000 on-going partnerships. However, nanotechnology is still an emerging area and there are currently only two Knowledge Transfer Partnerships in this area. The Technology Strategy Board is looking to increase the number of these partnerships for a range of technologies, including nanotechnologies;

(c) funds business and researchers to work together on **collaborative research and development** which may deliver successful new products, processes and services. Over 600 projects are currently being supported with a combined business and Government investment of over £1 billion (with just over half from business). To date, the Technology Strategy Board has provided funding in collaboration with business of around £40 million for nanotechnology

²³ www.innovateuk.org

²⁴ <http://www.ktponline.org.uk/>

projects. Some of the supported projects have been co-funded with the Research Councils and Government departments such as the Home Office, Ministry of Defence and Department of Health. Some of these projects will be finishing in the next 12 months and the Technology Strategy Board will produce case studies of successful projects that are of societal benefit; and

(d) sponsors **Innovation Platforms** which create the opportunity to bring together key partners (Government and business) to address a major societal challenge. The platforms work with business and research organisations to deliver innovative solutions through demonstration and developmental projects. Current Innovation Platforms are -

- Intelligent Transport Systems and Services;
- Network Security;
- Low Carbon Vehicles; and
- Assisted Living.

An Innovation Platform on Low Impact Buildings will be launched shortly.

3.23 The Technology Strategy Board also has responsibility for advising Government about the barriers to exploitation of new technologies and for suggesting ways of removing them.

3.24 The Technology Strategy Board manages and is the main funder of **Knowledge Transfer Networks**²⁵ (KTNs). Access to networks and sources of new knowledge are two of the most important determinants of business innovation performance. These national networks therefore bring together people from businesses, universities, research, finance and technology organisations to stimulate business innovation through knowledge exchange. They operate in specific fields of technology or business application (eg Materials, Chemicals).

3.25 There are 23 Knowledge Transfer Networks²⁶, of which one is the Nanotechnology KTN. As nanotechnology underpins a number of technology areas, the Nanotechnology KTN works with the other KTNs. It has four broad areas of focus:

- promoting and facilitating knowledge exchange;
- supporting the growth of UK capabilities;
- raising industry awareness of nanotechnology;
- providing input into UK policy and strategy.

²⁵ <http://www.businesslink.gov.uk/bdotg/action/detail?type=RESOURCES&itemId=1075067605>

²⁶ <http://www.ktnetworks.co.uk/>

3.26 The Nanotechnology KTN²⁷ works with the UK network of 24 **Micro and Nanotechnology Centres**²⁸. The Technology Strategy Board is providing £54 million to establish and maintain the network for five years after which the centres will be expected to be self-sufficient. The centres have received substantial support from the Regional Development Agencies and Devolved Administrations, who are keen to see the benefits in their regions or administrations, as well as being funded by industry to achieve a total investment of around £170 million.

3.27 The Micro and Nanotechnology Centres have been established to identify spare capacity in business and academia and to drive market development and exploitation of nanotechnology by helping industry access cutting-edge research and resources. The Centres are grouped into four main themes –

- nanometrology;
- nanomaterials (including health and safety – see paragraph 4.11);
- nanomedicine; and
- nanofabrication.

3.28 The Regional Development Agencies and Devolved Administrations operate a Micro and Nanotechnology Centre group that meets regularly. It plays a role in areas such as advising the Technology Strategy Board of strengths within the regions (partly through the Knowledge Transfer Network) and international promotion where the Knowledge Transfer Network has a limited remit.

Comment - public dialogue revealed generally positive attitudes to nanotechnologies and a desire for Government to spend money on nanotechnologies provided that priority is given to funding research and developments that contribute to a wider social good such as new medical innovations and sustainable technologies. The Government should support nanotechnologies that bring jobs to the UK by investment in education, training and research.

Other measures

3.29 Other measures, such as understanding potential risks, engaging stakeholders and addressing public concerns are also important in enabling the development of the industry. These are discussed later in this paper.

²⁷ http://mnt.globalwatchonline.com/epicentric_portal/site/MNT/?mode=0

²⁸ <http://www.nanowerk.com/news/newsid=983.php>

Industry representation

3.30 Until the end of 2008, the Technology Strategy Board is providing support for the Nanotechnologies Industry Association²⁹ (NIA). The Association was created to coordinate the views of the industrial groupings which are actively commercialising nanotechnology. It provides a cross-industry input to policy makers, nationally and internationally, the media and other interested parties, both nationally and internationally.

Outcome of the UK's initiatives

3.31 Some of the measures described above are pump-priming actions designed to enable the nanotechnology industry to develop sufficiently to generate its own income to fund and co-ordinate the activities. They are therefore time-limited. However, many other activities will be on-going because nanotechnologies will enable the development of other products and processes.

3.32 These initiatives have already enabled the UK to become well positioned in a number of key science and technology areas that underpin nanotechnology exploitation. There is a growing number of small companies in the UK, "spun out" from universities and larger companies, which exploit the opportunities offered by nanotechnologies.

3.33 Several are developing products and techniques to improve healthcare. Improved diagnosis is one feature of their work, and includes a hand-held device that can detect a wide range of molecules, proteins and other indicators of ill health, speeding up patient diagnosis and enabling accurate prescription of treatments. It also includes improved medical imaging, by improving the material used to detect X-rays. Better medical strategies for treatment are another feature, with techniques and products to allow the controlled release of drugs to targeted tissues, the more precise location of sites that require surgery (eg in breast cancer) and a framework upon which tissues can be regenerated or bone graft replacements grown.

3.34 Other companies are operating in a range of other sectors. For example, one is developing technologies for the manufacture of Light Emitting Diodes (LEDs) for use in products such as mobile phones. LEDs use less electricity than alternative lighting technologies. Another is developing new tools for use by scientists working with nanoscale materials and has created an atomic force microscope that allows scientists to follow and control chemical or biological processes at the single molecule level. Another company is pursuing the effective delivery of ingredients that are otherwise hard to dissolve, a technique that could have applications in a wide range of products such as agrochemicals, biocides, cosmetics, flavourings and fragrances, and pharmaceuticals.

²⁹ <http://www.nanotechia.co.uk/>

3.35 In the aerospace sector, nanotechnology applications include better devices for engine and flight control and pressure sensors for the cabin and air data measurements. In the automotive industry, nanoscale materials have been incorporated into light weight materials to improve temperature resistance, by raising the melting point. In addition, lightweight materials are being developed which combine recyclability with high impact resistance, and nanoparticle catalysts are being added to fuels to improve fuel efficiency and reduce emissions of pollutants.

3.36 There is now a need for the development of nanotechnologies to move from the “suppliers” alone to those downstream companies that will create and market the products. The Technology Strategy Board is currently considering its strategy for nanotechnologies for the next three years and intends to publish it in the second quarter of 2008. A number of projects on nanotechnologies will finish shortly and the Technology Strategy Board is looking into disseminate the outcomes through the Knowledge Transfer Networks and other communication channels.

4. HOW THE UK GOVERNMENT IS LOOKING TO ENSURE APPROPRIATE CONTROL OF THE POTENTIAL RISKS OF NANOTECHNOLOGIES

Comment – a recommendation from public dialogue was that the Government should continue to identify the potential risks of nanotechnologies and nanomaterials and create new regulation and laws for labelling based on such research.

4.1 Although nanotechnologies offer great potential benefits, there is still much that we do not understand about them and there is concern that some may cause harm, for example if they enter the body or accumulate in the environment. It is important that nanotechnologies are developed responsibly, with potential risks identified and managed before harm is done to health or the environment.

4.2 Although some nanotechnologies may pose a risk, in its 2004 report³⁰ the Royal Society³¹ and Royal Academy of Engineering³² advised that many nanotechnologies pose no new risk to health. Almost all of the concerns relate to the potential impacts of deliberately manufactured nanoparticles and nanotubes that are free rather than fixed to or within a material.

4.3 The Government is committed to understanding the potential risks and to managing them within a proportionate regulatory framework. For example, the UK, in collaboration with others, is undertaking a substantial programme of research and other evidence gathering to inform policy decisions, for example on whether new or amended legislation is needed to cover free engineered nanoscale materials.

4.4 In the meantime, protection is offered by existing legislation. This covers areas as diverse as environmental protection, health and safety, and the safety of food, medicines, medical devices, cosmetics and consumer products and enables prompt action to be taken if products pose a risk to health, safety or the environment.

4.5 Most products are covered by legislation which requires the manufacturer to carry out risk assessments to determine whether new products are safe and can be placed on the market. However, they are not usually required to carry out tests to assess whether the methods for identifying hazards and evaluating risks are adequate to enable reliable risk assessments to be carried out. This is the role of Government. The Government also needs to ensure that the equipment used for detection and measurement equipment is reliable and consistent and we understand the action of nanoscale materials in the body and environment. The research described below is intended to provide the necessary information about nanotechnologies.

³⁰ <http://www2.cst.gov.uk/cst/business/files/nano-report-2004-fin.pdf>

³¹ <http://royalsociety.org/>

³² <http://www.raeng.org.uk/>

4.6 It is worth noting that it is never possible to be completely certain that a product is safe. Risk assessments, even for products which have been on the market for many years, rely on the best available existing knowledge. But there is always the possibility of further information coming to light which challenges the prevailing view. No progress would ever be made were we to avoid using or consuming products until every possible eventuality had been explored. Rather, any risks are managed according to the current state of knowledge, with a precautionary approach taken if there is reason to believe that there might be harm, even if the extent of that harm has not yet been identified.

Regulatory reviews

4.7 To assess whether existing legislation is adequate to deal with potential risks from nanoscale materials, the Government commissioned reviews of the adequacy of existing legislation, and an independent overview to identify any existing or potential gaps, inadequacies or inconsistencies. This work concluded that the existing regulatory framework is broadly adequate, although there is the potential for engineered nanoscale materials to fall outside regulatory control in certain circumstances. For example, there may be a situation where only specified products are covered by the legislation, or where the legislation specifies maximum safe concentrations or marketing thresholds which are appropriate to the macroscale material but may not be appropriate for the nanoscale material. There is also the possibility that products may evade downstream control. Thus if a consumer product assessment indicates that a product is safe to market, the assessment may not also consider how safe it is to dispose of it, for example in a landfill site.

4.8 In this respect, nanotechnologies are no different from other new products and technologies and it should be recognised that these are potential, not necessarily real, regulatory gaps. To determine whether there is a real regulatory gap, we need a better understanding of the potential risks and thus of the adequacy of the risk assessment models that sit within the existing legislation. Research is being undertaken to acquire this understanding.

4.9 The Government agrees with the Royal Society, Royal Academy of Engineering, Council for Science and Technology³³ and the Economic and Social Research Centre for Business Relationships, Sustainability and Society³⁴ that a moratorium on the marketing of nanotechnologies would not be an appropriate response. However, the legislation will be kept under review as research results and other evidence become available. Government expert advisory committees have played a role in the reviews of existing legislation and their expert advice will continue to be sought as new developments occur and in the light of horizon scanning activities.

³³ <http://www2.cst.gov.uk/>

³⁴ <http://www.brass.cf.ac.uk/>

Non-legislative controls

4.10 Guidance and advice are further tools to respond to any potential risks posed by nanotechnologies. The regulators provide guidance to industry on the methodologies to be used for risk assessments; if research suggests that changes are needed, these will be updated. There are also organisations which provide advice to industry.

4.11 For example, the Technology Strategy Board is funding SAFENANO³⁵, a free information service (<http://www.safenano.org/>) run by the Institute of Occupational Medicine³⁶, with a focus on capturing emerging scientific evidence and translating it in a way that enables industry to develop nanoscale technology safely and responsibly. In addition, the Institute of Occupational Medicine has launched the SAFENANO Scientific Services to provide companies with a multi-disciplinary range of solutions to ensure that they can offer employees a safe and healthy working environment and products that are safe for consumers. This has been funded by the Technology Strategy Board, and Scottish Enterprise (Edinburgh and Lothian)³⁷.

4.12 The Nanotechnologies Industry Association is working with the Royal Society, Insight Investment³⁸ and the Nanotechnology Knowledge Transfer Network to develop a Code of Conduct³⁹ (the Responsible Nano Code) for all those involved in the development and exploitation of nanotechnologies. We welcome this initiative and hope that it forms the basis for international standards in this field. The European Commission is proposing to develop a parallel Code for researchers in academia.

Labelling

4.13 Currently a number of products are being marketed as “nano” products as this is considered to confer a marketing advantage. However, other than in the General Product Safety Directive, there is no legal requirement for products to be so labelled.

4.14 The General Product Safety Directive requires the labelling of goods sold in the European Union if there is the possibility of risk inherent in their use. Such products may only be sold if customers are provided with appropriate information (i.e warnings and instructions) enabling them to assess the risks. The Directive does not require labelling of other products.

³⁵ <http://www.safenano.org/>

³⁶ <http://www.iom-world.org/>

³⁷ <http://www.scottish-enterprise.com/edinburghandlothian/>

³⁸ <http://www.insightinvestment.com/>

³⁹

http://www.insightinvestment.com/Documents/responsibility/Briefings/opportunity_and_uncertainty_nanotechnology.pdf

4.15 The Royal Society and the Royal Academy of Engineering considered that chemicals in the form of nanoparticles should be treated as new chemicals and that labelling would be good for openness and transparency. They proposed that the ingredients list of consumer products should identify the fact that manufactured nanoparticulate material has been added.

4.16 The British Standards Institute recognises that labelling helps consumers to make informed choices and should facilitate traceability and the monitoring of health and environmental impacts. A common approach to labelling could also help to avoid confusing or inappropriate use of the term “nano”.

4.17 The British Standards Institute in consultation with a wide range of stakeholders has therefore produced a good practice guidance document PAS 130:2007 “Guidance on the labelling of manufactured nanoparticles and products containing manufactured nanoparticles”⁴⁰. It provides guidance on labelling for both sellers and users, by:

- promoting a standardised approach to labelling;
- ensuring that users of manufactured nanoparticles and products containing manufactured nanoparticles can correctly identify the manufactured nanoparticles contents for the purposes of making informed decisions throughout the life-cycle of the product in the areas of selection, purchase, distribution, handling, use and disposal;
- informing regulatory authorities and assisting healthcare professionals, technicians, health and safety officers and others so they can make informed decisions in relation to matters of occupational, consumer, public and environmental health and safety;
- standardising the use of the term “nano” in labels; and
- providing guidance on the use of other specific terms in these labels.

Research into health, safety and environmental implications

4.18 The UK research programme is a cross-Government effort. It is described in two research reports^{41 42}, published in 2005 and 2007, which discuss and prioritise the research needs in five inter-related work areas -

⁴⁰ <http://www.bsigroup.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/Nano-Downloads/>

⁴¹ http://www2.cst.gov.uk/cst/business/files/nanotech_final.pdf

⁴² http://www2.cst.gov.uk/cst/business/files/nano_review.pdf

- metrology, characterisation and standardisation;
- exposure, sources, pathways and technologies;
- human health hazard and risk assessment;
- environmental hazard and risk assessment; and
- social and ethical dimensions of nanotechnologies.

4.19 Not everything can be done at once. It takes time to build a consensus about the specific research that is needed and to establish a scientific community, especially one with the strength of inter-disciplinary collaboration that nanoscience requires. Initial work has therefore focused on establishing the scientific community, building capacity and addressing fundamental underpinning issues, in particular the ability to measure, detect and characterise nanoscale materials. Such techniques must be developed before meaningful research in other areas, such as toxicology studies, can proceed. International consensus about the techniques is also important if a common approach to the regulation of nanotechnologies is to emerge, and considerable resource is being invested to achieve such agreement (see section 6).

Capacity building

4.20 A major aim of the Government's first research report was to take a first step towards building a nanoscience research community by raising awareness of the research priorities and funding opportunities here and in Europe. The Research Councils introduced initiatives to raise awareness of research requirements and capacity across disciplines.

4.21 For example, the Natural Environment Research Council is leading a joint Environment and Human Health programme to build relevant research capacity across disciplines (environmental, physical, medical and social science) that can be brought to bear on understanding the environmental and human health hazard from nanomaterials. Defra, the Environment Agency, Ministry of Defence, Medical Research Council, Economic and Social Research Council, the Biotechnology and Biological Sciences Research Council, Wellcome Trust, Engineering and Physical Sciences Research Council and the Health Protection Agency⁴³ have all contributed to the programme. The projects cover a range of research including the hazards of nanoparticles to health and the environment and the impacts of inhaling nanoparticles in the atmosphere.

4.22 As described in paragraph 3.15, the Medical Research Council issued a highlight notice in March 2007 to encourage the development of a community of

⁴³ <http://www.hpa.org.uk/>

nanotoxicologists and the submission of innovative, high quality research applications in nanotoxicology relevant to human health.

Metrology, characterisation and standardisation

4.23 The work being done on measurement and characterisation of nanoscale materials is described in paragraphs 3.4 - 3.8. A substantial number of recent independent reports, road maps and market surveys indicate the increasing demand for nanometrology to meet the innovation requirements of nano-related industries and to underpin toxicology and safety assessment. Government has a role in supporting the development of nanometrology and funding further work to enable the detection of nanoscale materials for hazard, exposure and risk assessment purposes, and for toxicology dose characterisation. In these areas the Government hopes to coordinate actions with the industry to avoid duplication and ensure that the work is complementary and will be accepted internationally.

Exposure, sources, pathways and technologies

4.24 The ways in which exposure to nanotechnologies occurs are key to understanding human and environmental effects. At present, exposure to engineered free nanoscale materials is most likely to occur in industrial and university laboratories where research on new materials and applications is being undertaken. A priority for research has therefore been to assess exposure through such routes, and considerable work is being undertaken in this area. The results will enable the Health and Safety Executive⁴⁴ to work with the British Standards Institute and others to refine the recently published good practice guidance⁴⁵ on the safe handling and disposal of manufactured nanomaterials.

4.25 The Health and Safety Executive is also investigating the fire and explosion risks of nanoparticles, developing new test methods as necessary, with a view to providing advice and guidance to those working with nanoparticles.

4.26 A Defra study on the environmental exposure of currently used nanomaterials⁴⁶ was published in 2007.

4.27 For life cycle modelling (ie what happens to a product from manufacture through to disposal) the key issue is the detection and measurement of engineered nanoscale materials, particularly nanotubes⁴⁷, released into the external environment

⁴⁴ <http://www.hse.gov.uk/>

⁴⁵ <http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/>

⁴⁶

http://www2.defra.gov.uk/research/project_data/More.asp?I=CB01070&M=KWS&V=cb01070&SUBMIT_1=Search&SCOPE=0

⁴⁷ Nanotubes are extremely small tubes made from pure carbon

during the product life cycle. The environment is full of carbon-containing nanomaterials derived from natural causes such as fires or volcanoes or from combustion of diesel fuel and there are very few methods that can distinguish engineered nanomaterials from this naturally occurring nanomaterial. The ability to distinguish between engineered and naturally occurring nanoparticles is one of the priority subjects being considered in the metrology programme.

Human health hazard and risk assessment

4.28 The Health and Safety Laboratory funded a review of *in vitro* methods for assessing the toxicology of nanoscale materials. The results were published in modified form in 2006 as part of the Government's research progress report. They provide a guide for regulators, applicants for funding and assessors of funding bodies and have informed the Government's research reports.

4.29 Although limited work on toxicology has been funded to date, the Department of Health will contribute £1.25m over the next five years to support health-related research needs. The Department has recently issued a call for research proposals⁴⁸ in relation to –

- the characteristics of nanomaterials that may confer toxicity;
- inhalation; and
- the transfer of nanomaterials across skin.

The Department has also issued a call for research on air pollution, which could include proposals on nanoparticles. The results of such studies will be used for hazard identification and risk assessment.

4.30 The Health Protection Agency is refurbishing a facility for studying the effects of exposure by inhalation, to establish a National Nanotoxicology Inhalation Research Centre. Work will be undertaken in conjunction with five leading academic centres in the UK and with the Toxicology Unit of the Medical Research Council. Work undertaken by the centre will provide fundamental information on the handling of nanomaterials by the body and their effects on organ systems. This will enable improved hazard identification and risk assessment. In addition, the Institute of Occupational Medicine is providing an independent and impartial information service for UK Industry (SAFENANO).

4.31 The Food Standards Agency⁴⁹ is funding two projects to assess the safety implications of the use of nanoscale materials in food packaging, and as food additives or ingredients.

⁴⁸ <http://www.nihr-ccf.org.uk/site/callsproposals/prp/default.cfm>

⁴⁹ <http://www.food.gov.uk/>

Environmental hazard and risk assessment

4.32 The Natural Environment Research Council is supporting fundamental research in this area through studentships and responsive mode grants, and the Environmental Nanoscience Initiative was established as a joint venture between the Natural Environment Research Council, Defra and the Environment Agency to develop a community of researchers in the fields of ecotoxicology⁵⁰ and the environmental fate and behaviour of nanotechnologies. This Initiative is funding 17 projects.

4.33 Defra has funded work to identify the appropriateness of current ecotoxicology regulatory tests for nanomaterials and identified where additional tests might need to be developed or existing methods modified. An EU working group under the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has looked at test methods in respect of the impact of nanomaterials on the environment and human health.

Social and ethical dimensions of nanotechnologies.

4.34 The Economic and Social Research Council has carried out the world's most authoritative review of the social, ethical and economic aspects of development of nanosciences and nanotechnologies. The reports, published in 2003 and a follow-up in 2007, explain the existing and potential consequences of nanotechnologies, and identify important issues for research and society. To follow up this work, the Economic and Social Research Council will ensure the Research Councils' 'Grand Challenges' in specific areas of nanotechnology address the following questions –

- what are the key drivers of public and scientists' perceptions of risks and opportunities of nanotechnologies in this application?
- what is the likely impact on industry and economies, including from the convergence of nano with other technologies?
- how will the global development of science and innovation and their multi-level regulation affect these technologies?
- how, when and why will public engagement and social influences affect development of these technologies?

⁵⁰ [The study of the harmful effects of chemical compounds on species, population and the natural environment.](#)

4.35 The Economic and Social Research Council is also exploring opportunities to work with the independent International Risk Governance Council⁵¹ on 'Appropriate risk governance strategies for nanotechnology applications in food and cosmetics'⁵².

4.36 The Government has identified as one of its key research priorities the need to understand the social and ethical implications of nanotechnologies, through a programme of public dialogue and social research. There is a diversity of ethical issues surrounding the development of nanotechnologies and the Government has encouraged and funded upstream engagement to identify these concerns. This has enabled prioritisation of an extensive programme of social and ethical research, which includes -

- an exploration of the social impacts of the geographical clustering of the economic clustering of the UK's nanotechnologies innovation communities;
- nanotechnologies in medical research and related ethical issues;
- the life cycle effects of the products of nanotechnologies; and
- an exploration of whether lessons can be applied to nanotechnologies from the experiences of technologies and products such as genetically modified crops and asbestos.

Defra will be issuing a call for proposals shortly, to address the first part of the programme, and is working with potential funding partners to scope the remainder.

Public engagement

4.37 The Department of Innovation, Universities and Skills funded two public engagement activities, Nanodialogues and the Nanotechnology Engagement Group. Their final reports^{53 54} were launched in June 2007. As well as helping us learn about public attitudes to nanotechnologies, they also provided much useful information about how to operate upstream public engagement and dialogue.

4.38 Nanodialogues was developed to find out what people think about this complex science and its possible applications in order to inform policy decisions. The project also aimed to explore how far "upstream" (i.e. ahead of policy decisions being made) such engagement should take place and how extensive the engagement should be.

⁵¹ <http://www.irgc.org/>

⁵² <http://www.irgc.org/Appropriate-risk-governance.html>

⁵³ http://www.bbsrc.ac.uk/society/dialogue/activities/nanodialogues_report.pdf

⁵⁴ <http://www.involve.org.uk/negreport>

The project was run by Demos⁵⁵ and delivered four different experiments in public engagement around nanotechnology. Each had a different partner -

- Experiment 1: Environment Agency
- Experiment 2: Practical Action⁵⁶
- Experiment 3: The Biotechnology and Biological Sciences Research Council and the Engineering and Physical Sciences Research Council; and
- Experiment 4: Unilever⁵⁷

4.39 All of the experiments were “deliberative” in that they involved people coming together to discuss the issues with experts, going away to reflect then coming back together to discuss further. The experiments did not look at any particular application over another but allowed free range in the discussions. Each dialogue process was tailored to the needs of the partner, who used the results to help develop their own policies on nanotechnology and consider how they would engage with the public and other stakeholders in the future.

4.40 The Nanotechnology Engagement Group was set up to capture the learning from Nanodialogues and a range of other public engagement on nanotechnologies. The aim was to find out what worked and to evaluate the use of the outcomes by policy creators.

4.41 In this statement, we are seeking to address issues such as the need for information on the roles and responsibilities of the organisations that fund nanotechnologies. We have also indicated in the text where public dialogue revealed particular aspirations and concerns. In addition, there was a public desire for the provision of information, forums, debates and literature. We are considering how to take this forward.

4.42 Further dialogue is being undertaken by the Research Councils but at present there are no further plans for Government-funded public dialogue on nanotechnologies although they are likely to feature in work to follow up the results from the Wider Implications of Science and Technology, described in paragraph 4.44 below. Nevertheless, we hope that industry will reflect on the messages that emerged about the need for them to understand that consumers are not only concerned about the safety of products. Rather they are worried that new products are of no real value to society.

⁵⁵ <http://www.demos.co.uk/>

⁵⁶ <http://www.practicalaction.org/>

⁵⁷ <http://www.unilever.co.uk/>

4.43 The Technology Strategy Board has a role in contributing to building public confidence in, and understanding of, research into, and the development and exploitation of, science, technology and new ideas. The Technology Strategy Board will encourage greater public engagement in areas where it invests and will work with the Department of Innovation, Universities and Skills on the wider public engagement agenda.

Wider implications

4.44 The Horizon Scanning Centre⁵⁸ in the Government Office for Science has been running a Wider Implications of Science and Technology⁵⁹ (WIST) programme of stakeholder engagement to identify the safety, health, environmental, ethical, regulatory and social implications of new and emerging areas of science and technology. This has been closely integrated with a Department of Innovation, Universities and Skills funded Sciencewise⁶⁰ programme (sciencehorizons⁶¹) of public engagement on emerging technologies. Both the stakeholder and public engagement programmes covered all areas of emerging science and technology, with nanotechnologies emerging as a key issue.

4.45 The findings showed that there was plenty of interest, even excitement, about the potential benefits offered by nanomaterials and "nanofoods" (foods engineered at the nanoscale), but that enthusiasm should be tempered with caution about their potential health, safety and environmental consequences. Two issues stood out. First, there was concern that the science of nanometrology is undeveloped in comparison with the rate of advance of the technologies themselves. Secondly, "nanofoods", although presenting abundant opportunities for business and to improve human health, could generate a backlash from the public unless the public can see a clear benefit: public engagement might direct their response onto a more acceptable course.

⁵⁸ http://www.foresight.gov.uk/HORIZON_SCANNING_CENTRE/index.html

⁵⁹ http://www.foresight.gov.uk/HORIZON_SCANNING_CENTRE/WIST/Index.html

⁶⁰ <http://www.sciencewise.org.uk/>

⁶¹ http://www.sciencewise.org.uk/html/projects.php?source=projectdetail&project_ID=9

Government funding

4.46 Government Departments and Agencies fund research to answer specific policy questions. Defra, the Health and Safety Executive and the Environment Agency have all committed funds for nanotechnology research over the past few years and this has been reported in the two Government reports referred to in paragraph 4.18. More recently, the Department of Health has also committed funding for research into the implications for human health.

4.47 Government Departments funded around £10 million of nanotechnology-related health, safety and environmental research between 2005 and 2008. This sits alongside the Research Council funded nanotechnologies research under their responsive mode programmes outlined in paragraph 3.19. Departments, agencies and Research Councils have also pooled resources to create collaborative projects, such as the Environmental Nanoscience Initiative, to develop the community of researchers. The substantial investment by the Research Councils provides a valuable underpinning base for those conducting further research into the health, safety and environmental implications of nanotechnologies. This base covers a wide range of activities, not only those on the health, safety and environmental implications, and we recognise that more needs to be done to improve understanding, particularly on characterisation of nanoparticles and human health impacts.

4.48 Progress has been made in joint and collaborative working, upon which we will build, to increase research opportunities and capacity. This will include both directed and responsive mode funding in the UK and via the EU Framework Programme. In addition, the Technology Strategy Board has responsibility for supporting research right across the economy through a number of mechanisms directed at meeting business needs, and can provide a framework and opportunity for Government departments and agencies and the Research Councils to work in partnership with the Technology Strategy Board and the industry.

Stakeholder engagement

4.49 Defra has established and currently chairs the Nanotechnologies Stakeholder Forum. It has proved valuable as a way of informing industry, civil society groups, academics and others of developments, particularly in the field of environmental, health and safety implications of nanotechnologies. The Forum recognises that nanotechnologies can offer significant societal benefits and in the future will take an interest in the development and exploitation of nanotechnologies as well.

Voluntary Reporting Scheme

4.50 It is the responsibility of commercial companies to fund the research necessary to identify potential hazards of specific products that they intend to market. To access that information, Defra has established a voluntary reporting scheme so that industry

and research organisations can provide Government with relevant information on the potential risks posed by new nanoscale materials. The intention was that this information would enable the Nanotechnology Research Coordination Group to prioritise the toxicology and other research requirements for those substances that are most likely to be produced in substantial quantities. However, there has been a disappointing level of submissions so far. We welcome the willingness of the Nanotechnology Industries Association to collaborate to resolve remaining concerns about intellectual property and increase the number of submissions but, ultimately, it may be necessary to make the scheme compulsory, perhaps at EU level. We are also liaising with the European Commission over the possibility of a similar EU scheme which might replace the Defra-led Voluntary Reporting Scheme.

Comment - public dialogue revealed support for the open reporting of tests, good or bad, and a view that companies should be required to do long term research on the effect of nanotechnologies in the environment.

Animal testing

4.51 In its progress report on research requirements in 2006, the Government recognised that there were a range of *in vitro* approaches by which preliminary toxicity data on nanomaterials could be obtained. However, *in vitro* methods alone will not be sufficient for risk assessment purposes and *in vivo* testing (using animals) will be needed in certain circumstances. It is Government policy to minimise the use of animals in regulatory testing of chemicals and it, along with a range of other stakeholders, supports the independent National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs⁶²). The Centre provides a UK focus for the promotion, development and implementation of the 3Rs in animal research and testing. It brings together stakeholders in academia, industry, Government and animal welfare organisations to facilitate the exchange of information and ideas, and the translation of research findings into practice that will benefit both animals and science. The NC3Rs has a programme of work looking into alternative methods for regulatory testing of chemicals.

4.52 The new EU Chemicals Regulation (REACH) also promotes alternative methods for the assessment of hazards of substances and this approach will be carried through into any testing of nanomaterials. REACH requires the sharing of data and avoidance of duplication of testing and, where available, the use of alternative methods to using animals. In support of this policy the Organisation for Economic Co-operation and Development has set up a project to look at how alternative approaches to using animals can be used for hazard identification of manufactured nanomaterials.

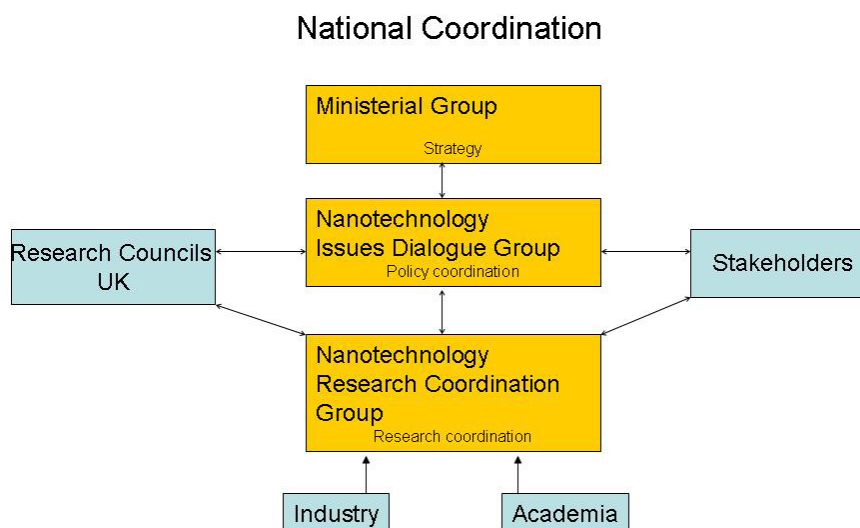
⁶² <http://www.nc3rs.org.uk/>

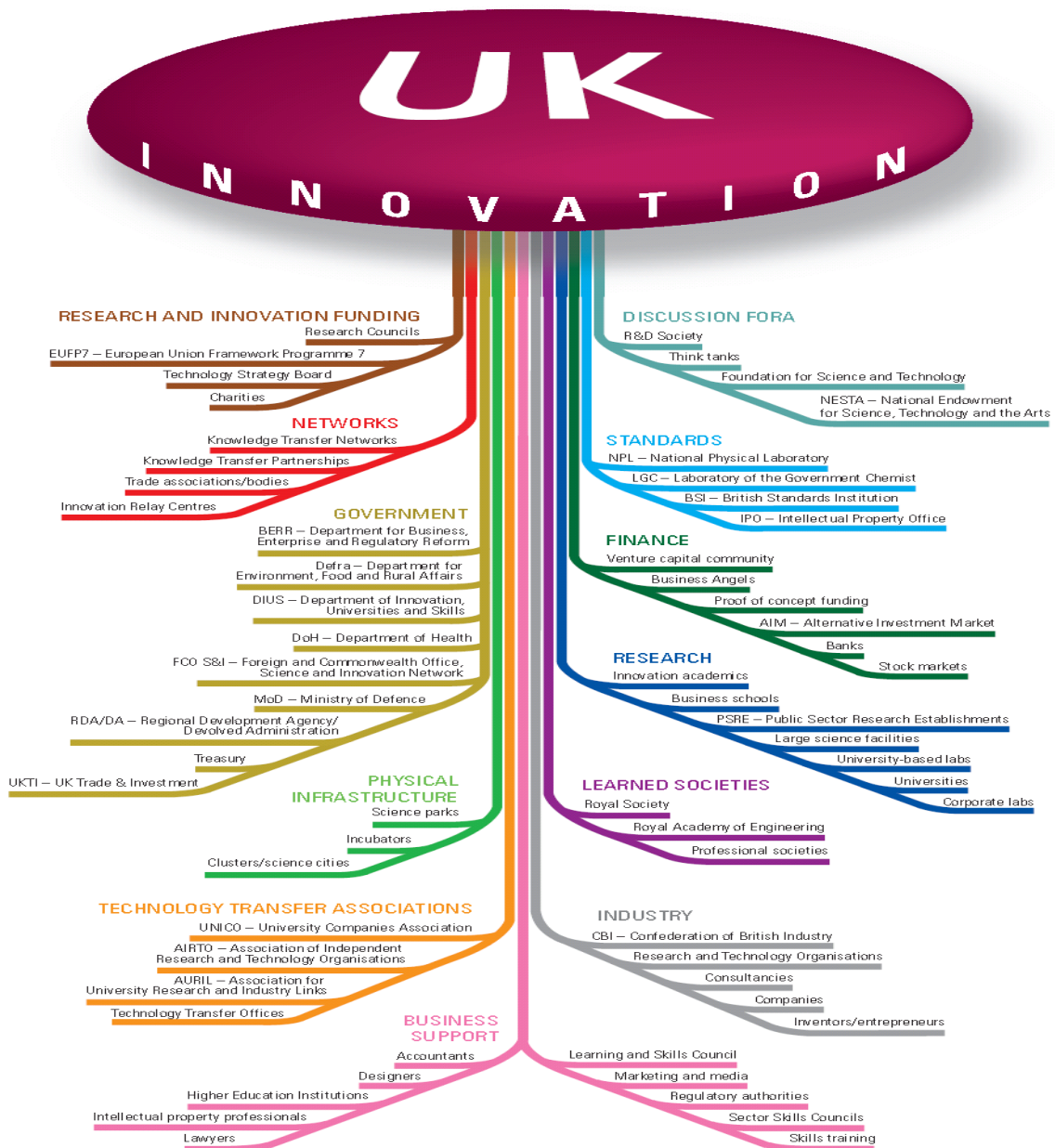
5. NATIONAL COORDINATION

5.1 Because nanoscience crosses scientific disciplines and there are so many potential uses of nanotechnologies and nano-enabled products, their development and regulation crosses traditional departmental responsibilities. Several Research Councils and a large number of Government departments and agencies have an interest in their development, both to ensure that we maximise the opportunities for the UK to benefit and to address potential risks.

5.2 As well as collaborating on a bilateral and multilateral basis with other countries, the UK has put in place structures to bring together the relevant players across Government departments and agencies, the Research Councils, industry, academia and other stakeholders. These coordinating groups are described below. They focus primarily on understanding and managing potential risks and ensuring the responsible development of nanotechnologies, with limited interaction with the Government's agenda for innovation and development, which is coordinated separately. A diagram showing the organisations involved in the latter agenda is attached; a more comprehensive version can be found at www.ukinvest.gov.uk/UKTI-publications/4018023/en-GB.html.

5.3 The creation of a Ministerial group has enabled more effective interaction between both strands of activity, with the policy group being better informed about innovation and the stakeholder coordination group considering both innovation and responsible development. The Technology Strategy Board, the Department for Business, Enterprise and Regulatory Reform, and the Department for Innovation, Universities and Skills now attend the coordination groups as well as those Research Councils, departments and agencies responsible for basic research as well as those who regulate health, safety, food, medicines, the environment and consumer products. The full list of members is available on the relevant website.





Hit the world running ^{UK}

5.4 The coordination groups are –

(a) the **Ministerial group on Nanotechnologies**, which gives strategic direction to the Government's activities on nanotechnologies. It is chaired by the Minister for Science and Innovation and comprises the Ministers for the Environment, Public Health, Competitiveness, and Health and Safety. It meets every six months;

(b) the **Nanotechnology Issues Dialogue Group**⁶³ (NIDG) which enables the responsible development of nanotechnologies and coordinates the delivery of the Government's commitments on nanotechnologies. It is currently chaired by the Government Office for Science and comprises officials from Government departments and agencies, the Technology Strategy Board and the Research Councils. It meets every four months and reports to the Ministerial group on Nanotechnologies;

(c) the **Nanotechnology Research Coordination Group**⁶⁴ (NRCG) which coordinates publicly funded research into the potential health, safety, environmental, social and environmental implications by the products and applications of nanotechnologies. It is chaired by Defra and meets every three months. It is attended by officials from Government departments, agencies, the Technology Strategy Board and the Research Councils. Academia and the industry are also engaged in discussions about future research needs. The Group reports to the Nanotechnology Issues Dialogue Group;

(d) the **Nanotechnologies Stakeholder Forum**⁶⁵. This brings together key stakeholders from industry, civil society groups (such as the Soil Association and Which?) and academia to inform all policy activities. It meets every four months and is chaired by Defra. It is open to the public. The Ministerial group is kept informed of its views;

(e) the **Nanotechnologies Engagement Group**⁶⁶. The work of this group has now been completed, but it brought together people with expertise in public dialogue and those with experience of running projects in public engagement on nanotechnologies; and

(f) **Research Councils UK** (RCUK), which coordinates the activities of the Research Councils. RCUK has established a Nanotechnology Group in order to facilitate cross-Council working in the area. Representatives from each Research Council, plus a member of the Technology Strategy Board, attend meetings which are held on a quarterly basis.

⁶³ http://www.dti.gov.uk/dius/science/science-in-govt/st_policy_issues/nanotechnology/nano_issues/page20563.html

⁶⁴ <http://www.defra.gov.uk/environment/nanotech/research/index.htm>

⁶⁵ <http://www.defra.gov.uk/environment/nanotech/research/meetings/index.htm#stakemeetings>

⁶⁶ <http://www.involve.org.uk/neg>

6. UK PARTICIPATION IN INTERNATIONAL FORA

6.1 The development of nanoscience and nanotechnologies is still at an early stage but many countries are investing significant sums to encourage research and exploit the resulting opportunities. The UK, like other nations, recognises that the key to success is likely to lie in the successful translation of high quality science and technology into new products, processes and services. The UK Government also recognises that it is important to address the associated ethical, social, health, safety and environmental issues.

6.2 The UK Government wishes to ensure that UK companies are able to compete on a level playing field with their international competitors. Nationally we have taken steps to encourage the development of the infrastructure needed for UK companies to compete internationally. But other measures need to be taken through international organisations to –

- (a) achieve international agreement on the definition of nanoscale materials and how such materials should be measured and characterised; and
- (b) develop, where necessary, an evidence-based, proportionate regulatory framework that addresses the potential ethical, social, health, safety and environmental implications.

6.3 It is beyond the resources of any one Government to provide all the scientific and manufacturing skills and generate all the information needed to advance the development and exploitation of nanotechnologies and inform policy decisions on the regulatory framework. Collaboration with other countries is essential. For several years, the UK Government has been playing a leading role in international fora such as the International Organisation for Standardization (ISO)⁶⁷, the Organisation for Economic Cooperation and Development (OECD)⁶⁸ and the European Union. It remains committed to playing a full role in international discussions to -

- (a) establish common standards for nanotechnologies, including those for terminology and nomenclature, measurement and characterisation of nanoscale materials and devices, and health and environmental safety;
- (b) share information among member countries about research requirements and the results of research, particularly into the environment, health and safety aspects;
- (c) ensure that regulation is evidence-based and proportionate; and

⁶⁷ <http://www.iso.org/iso/home.htm>

⁶⁸ http://www.oecd.org/home/0,3305,en_2649_201185_1_1_1_1_1,00.html

- (d) share information among member countries about public engagement and its outcomes.

6.4 This section describes the international fora which deal with nanotechnologies and in which the UK participates.

Standards setting

International Organisation for Standardization (ISO) and European Committee for Standardization (CEN)

6.5 In a global market, it is important that there is a common understanding of what is meant by nanotechnologies and associated terms, and agreement on how nanoscale materials should be measured, described and evaluated for their health and safety impacts. The International Organisation for Standardization (ISO) is therefore leading this work. It has a number of working groups which are addressing different aspects of terminology and definitions, measurement and characterisation, and the health and environmental safety impacts of nanomaterials.

6.6 At the European level, ISO's sister organisation, the European Committee for Standardization (CEN) prepares standards for aspects of nanotechnologies on which there is unlikely to be international agreement or for which there is a European as opposed to an international necessity. European standards help to support the European single market and can take the place of regulation in certain circumstances.

6.7 The UK's National Physical Laboratory⁶⁹ and the British Standards Institution⁷⁰ have much expertise in this area and are making a substantial contribution to the work of International Organisation for Standardization and the European Committee for Standardization. For example, the UK proposed the establishment of, and chairs, both Technical Committee 229 of the International Organisation for Standardization and Technical Committee 352 of the European Committee for Standardization. Both of these committees have nanotechnology as their primary focus.

6.8 Recently the British Standards Institution has published a number of UK standards that will help to frame the development of international and European standards, including -

- Guide to Safe Handling and Disposal of Manufactured Nanomaterials (PD 6699-2)⁷¹;
- Guidance on the labelling of manufactured nanoparticles and products containing nanomaterials;

⁶⁹ <http://www.npl.co.uk/>

⁷⁰ <http://www.bsi-global.com/>

⁷¹ <http://www.bsi-global.com/en/Standards-and-Publications/Industry-Sectors/Nanotechnologies/PD-6699-2/Download-PD6699-2-2007/>

- Guide to specifying nanomaterials; and
- Six sector specific terminologies.

6.9 These documents, which are unique in the international standards arena, will be used to support proposals for new international and/or European standards.

Information sharing

The Organisation for Economic Cooperation and Development (OECD)

6.10 The Organisation for Economic Cooperation and Development has 30 member countries and shares expertise and exchanges views with more than 100 other countries and economies. One of its roles is to enable countries to compare policy experiences, seek answers to common problems, identify good practice and coordinate domestic and international policies. It operates through Committees which bring together representatives of member countries and invited non-member countries to consider specific issues.

6.11 Although the Organisation for Economic Cooperation and Development does not itself fund research or introduce legislation, it provides a valuable opportunity for member States to share information about nanotechnologies and agree priorities on -

- what research is needed to address the knowledge gaps, what research is already being undertaken and the results of that research;
- how to carry out public dialogue and the outcomes;
- the need for regulation; and
- the opportunities that nanotechnologies might provide and the state of the market.

6.12 Two Organisation for Economic Cooperation and Development Committees have each established a working party on nanotechnologies -

- the Working Party on Nanotechnology⁷² was established by the Committee on Scientific and Technical Policy in March 2007. It will focus on the global environment and the broad policy framework within which nanotechnologies are being developed and marketed; and
- the Working Party on Manufactured Nanomaterials⁷³ was established by the Chemicals Committee in June 2006. It focuses on the research and other

⁷² http://www.oecd.org/document/36/0,3343,en_2649_34269_38829732_1_1_1_1,00.html

⁷³ http://www.oecd.org/department/0,3355,en_2649_37015404_1_1_1_1_1,00.html

work needed to understand and manage the potential risks to health, safety and the environment.

6.13 The Working Party on Nanotechnology will advise on emerging policy-relevant issues in the science, technology and innovation aspects of nanotechnologies. The work programme will cover six policy challenges, mostly by collating information –

- what the global nanotechnology industry looks like. It will collate national information including patent details, research reports, human resources, and economic data and produce a document known as 'Nanotechnology at a Glance';
- business impacts and development;
- international collaboration on the available infrastructure in support of nanotechnology research and development;
- outreach and public engagement;
- information on Science and Technology policies; and
- how nanotechnology may address global issues such as the provision of clean water.

6.14 The Working Party on Manufactured Nanomaterials (WPMN) promotes international co-operation over the health, safety and environmental implications of manufactured nanomaterials. It aims to deliver a high quality, science-based and internationally harmonised approach to hazard, exposure and risk assessment. The work programme, coordinated through eight Steering Groups, covers -

- establishing an international database to help ensure the identification of, and exchange of information on, research relating to the health, safety and environmental implications of manufactured nanomaterials. This will help to identify future research needs, while avoiding duplication;
- co-ordinating and implementing an international strategy to address future research needs;
- identifying and testing a set of the most commonly used manufactured nanomaterials to develop a foundation data set of their physical and chemical properties, fate, health, safety and environmental effects;
- recommending guidelines for the health, safety and environmental testing of nanomaterials;
- sharing information on voluntary and regulatory activities;

- sharing information on the risk assessment approaches for manufactured nanomaterials and making recommendations on how to fill any gaps in current approaches;
- examining the role of alternative methods to animals in studies on nano (eco)toxicology; and
- collecting information on exposure measurement and exposure mitigation to examine where there may be gaps to be addressed.

6.15 The UK is well represented on both Working Parties and leads the projects on outreach and public engagement, risk assessment and non-animal testing. Representatives from the relevant Government departments, Research Councils, the Technology Strategy Board⁷⁴ and industry participate.

6.16 The work of the Working Parties of the Organisation for Economic Cooperation and Development will lead towards internationally agreed standards for testing nanomaterials and methods for addressing risk assessment. It will also ensure that countries are pulling together to find answers rather than duplicating effort. Results will take some time but nevertheless it will be more efficient than working alone.

6.17 Because the European Commission participates, along with individual member States, the findings of the Organisation for Economic Cooperation and Development Working Parties inform the development of policy at the European level.

Regulation

European Union

6.18 Most new national legislation nowadays derives from European legislation and, if legislation needs to be introduced or amended to cover nanotechnologies, this will be initiated at EU level. The European Commission has recently carried out a review of all the legislation relating to nanotechnologies and will report early in 2008. The EU review took account of similar reviews already carried out by individual member States including the UK.

6.19 EU legislation already applies to different types of products, such as cosmetics, medicines, chemicals, food and will cover nanomaterials used in those products. It is possible that some changes may be needed to make them more relevant to the specific characteristics of nanotechnologies.

6.20 The European Commission takes advice from its advisory committees such as the Scientific Committee on Emerging and Newly Identified Risks⁷⁵ and the Scientific Committee on Consumer Products⁷⁶.

⁷⁴ <http://www.innovateuk.org/>

⁷⁵ http://ec.europa.eu/health/ph_risk/committees/04_scenihr/04_scenihr_en.htm

Research funding

European Union

6.21 The European Union funds research through the EU Framework Programme 7⁷⁷. This provides significant funding for research into the opportunities and uncertainties associated with nanotechnologies. The programme *Nanosciences, nanotechnologies, materials and new production technologies*⁷⁸ has a budget of about €3,500 million for the period 2007-2013, of which about one third is expected to fund work on nanosciences and nanotechnologies. The remainder will fund other materials and new production technologies.

6.22 The predecessor programme EU Framework Programme 6⁷⁹ has also funded research into nanotechnologies. For example, three on-going projects on nanotoxicology received EU Framework Programme 6 funding of over €8 million. The Framework Programmes also provide mechanisms for the co-ordination of research into nanotechnologies within Europe.

6.23 These opportunities are in line with the UK's objectives and we hope that UK researchers and businesses will take full advantage of them. The Government, through the Technology Strategy Board, supports a National Contact Point⁸⁰ to provide help and advice for UK industry and academia seeking funding for R&D. The Nanotechnology and the Materials Knowledge Transfer Networks support this work and encourages participation, and the Research Councils have an office in Brussels to provide support for academic participation. Assistance to potential proposers is also supplied by the Regional Development Agencies, trade associations and Knowledge Transfer Networks⁸¹ with whom the National Contact Point works closely.

6.24 The UK was actively involved in the development of the EU's "Nanosciences and Nanotechnologies: An action plan for Europe 2005-9"⁸², which addresses aspects of the risk-assessment and control of nanotechnologies. The EU Framework Programme 7 programme is expected to deliver many of the actions proposed in this plan and the UK Government closely

⁷⁶ http://ec.europa.eu/health/ph_risk/committees/04_sccp/04_sccp_en.htm

⁷⁷ http://cordis.europa.eu/fp7/home_en.html

⁷⁸ http://cordis.europa.eu/fp7/wp_en.html#capacities (leads to .pdf document)

⁷⁹ <http://cordis.europa.eu/fp6/dc/index.cfm?fuseaction=UserSite.FP6HomePage>

⁸⁰ <http://www.berr.gov.uk/files/file10209.pdf>

⁸¹ <http://www.ktponline.org.uk/>

⁸² ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nano_action_plan2005_en.pdf

monitors progress to inform its own research programme and inform policy decisions.

European Technology Platform

6.25 Several European Technology Platforms are dedicated to nanotechnology applications such as NanoElectronics, Nanomedicine and Sustainable Chemistry. The Platforms produce vision papers and strategic research agendas which are being reflected in calls for proposals under the Framework Programme 7. Joint Technology Initiatives, introduced as part of the Framework Programme 7, are large public-private partnerships that bring together industry and EU funding and, in some cases, national funding as well. The Joint Technology Initiative for NanoElectronics (ENIAC) will channel nearly €2,000 million towards projects tackling the challenge of scaling, systems integration, materials and equipment, and design tools. The first call for proposals will open later in 2008.

Collaboration

European Union - ERAnet

6.26 The ERAnet⁸³ scheme aims to step up the cooperation and coordination of research activities carried out at national or regional level by EU member States and Associated States so that tasks can be delivered collectively that could not have been dealt with by a single member State. The scheme covers a range of different themes, including nanotechnologies. The Engineering and Physical Sciences Research Council has joined the Nanoscience ERAnet to take advantage of the opportunities it provides for networking and the ERAnet has established a number of collaborative research projects. The level of UK involvement varies but projects include nanomedicine; future manufacturing technologies; nanoelectronics; photonics and sustainable chemistry.

Council of Europe

6.27 The Council of Europe coordinates a pan-European initiative, Eureka⁸⁴, for promoting collaborative business-led R&D in fields of advanced technology, in a network encompassing 36 countries. Individual member States provide funding for their own participants. In the UK this funding comes from the Technology Strategy Board. The benefits for UK companies collaborating in Eureka include access to new technologies, the sharing of costs and risks, reduced timescales and access to new overseas markets.

Bilateral collaboration

⁸³ http://ec.europa.eu/research/fp6/index_en.cfm?p=9_eranet

⁸⁴ <http://www.eureka.be/home.do>

6.28 Bilateral collaboration with other countries is also important. It provides access to overseas skills and facilities to the benefit of British science and attracts inward investment into the UK research base. The UK Government promotes UK nanotechnology and identifies opportunities for research and development collaboration through the UK Trade and Investment (funded by the Department for Business Enterprise and Regulatory Reform⁸⁵ and the Foreign and Commonwealth Office⁸⁶ (FCO)), the FCO's Science and Innovation Network⁸⁷, the Technology Strategy Board's National Contact Point Service and the Government Office for Science. For instance -

- bionanotechnology has been a very successful area for partnership with Japan for four years, bringing together Japan's information and communication technology strengths with the UK's life science expertise. This has led to collaborative research into the behaviour of proteins, several business deals for spin-out companies, and researcher exchanges in both directions;
- a two-year programme to promote and develop UK-German nanotechnology contacts is in place, with an emphasis on energy and environment applications (e.g. fuel cells, advanced photovoltaics, catalysts for emissions reduction);
- UK-US expert exchanges and workshops are intended to promote compatible approaches in regulatory policy as well as research partnerships with leading US institutions. Northern Ireland also participates with the Republic of Ireland in a US-Ireland research partnership;
- A joint UK-India Nanotechnology Working Group was launched in January 2007 to promote collaboration between the two countries. Two exchanges have already taken place and more are planned. Other potential opportunities for collaboration are also being explored;
- in Korea a series of bilateral Nano Forums over the past year have led to new collaborations starting and bids from a number of academic groups for joint funding. Representatives from major Korean companies have also participated in a number of initiatives;
- networking grants have funded UK-Italy and UK-Germany events; and
- Research Councils fund UK participation in international bilateral projects on a "best with best" basis.

International promotion

⁸⁵ <http://www.berr.gov.uk/>

⁸⁶ <http://www.fco.gov.uk>

⁸⁷

<http://www.fco.gov.uk/servlet/Front?pagename=OpenMarket/Xcelerate/ShowPage&c=Page&cid=1020435944848>

6.29 UK Trade and Investment has a role of driving wealth creation and leads the promotion of UK excellence in nanosciences and nanotechnology at an international level. One aim is to generate foreign direct investment, including venture funding, into UK nanotechnology research and development in universities, science parks, innovation centres and all levels of industry. Another aim is to create trade opportunities for UK industries in overseas markets.

6.30 UK Trade and Investment coordinates the promotional activities and resources through a Nanotechnology Promotion Stakeholders Group. Participants in the Group include the Nanotechnology Knowledge Transfer Network, the Technology Strategy Board, the Nanotechnology Industries Association, the FCO Science & Innovation Network and the Regional Development Agencies. As part of a move to commercialise nanotechnologies, the Group directs two key annual events:

- the UK NanoForum in London, supported by both the Science and Innovation Minister and the Business and Competitiveness Minister; and
- the UK presence at the Tokyo nanotechnologies conference.

To date, these events have been funded wholly from the public sector, as pump-priming activities. However, by 2009 the responsibility for funding them will pass to private enterprise and relevant trade associations.

6.31 The Group also identifies markets in which there are trade opportunities for UK companies offering services and products. These markets are the focus of promotional activities. As a result of these promotional activities and the bilateral collaborations, the UK nanotechnology community is recognised as world class⁸⁸ and UK can confidently seek strategically focussed partnerships and collaborations at an international level.

⁸⁸ Lux Research places UK as number four in nanotechnology world rankings in 2007, behind the USA, Japan and Germany