Nanoscience and nanotechnologies: opportunities and uncertainties[1]

Summary

Overview

Nanoscience and nanotechnologies are widely seen as having huge potential to bring benefits to many areas of research and application, and are attracting rapidly increasing investments from Governments and from businesses in many parts of the world. At the same time, it is recognised that their application may raise new challenges in the safety, regulatory or ethical domains that will require societal debate. In June 2003 the UK Government therefore commissioned the Royal Society and the Royal Academy of Engineering to carry out this independent study into current and future developments in nanoscience and nanotechnologies and their impacts.

The remit of the study was to:

- define what is meant by nanoscience and nanotechnologies;
- summarise the current state of scientific knowledge about nanotechnologies;
- identify the specific applications of the new technologies, in particular where nanotechnologies are already in use;
- carry out a forward look to see how the technologies might be used in future, where possible estimating the likely timescales in which the most far-reaching applications of the technologies might become reality;
- identify what health and safety, environmental, ethical and societal implications or uncertainties may arise from the use of the technologies, both current and future; and
- identify areas where additional regulation needs to be considered.

In order to carry out the study, the two Academies set up a Working Group of experts from the relevant disciplines in science, engineering, social science and ethics and from two major public interest groups.[2] 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. It also reviewed published literature and commissioned new research into public attitudes. Throughout the study, the Working Group has conducted its work as openly as possible and has published the evidence received on a dedicated website as it became available (www.nanotec.org.uk).

This report has been reviewed and endorsed by the Royal Society and the Royal Academy of Engineering.

Significance of the nanoscale

A nanometre (nm) is one thousand millionth of a metre. For comparison, a single human hair is about 80,000 nm wide, a red blood cell is approximately 7,000 nm wide and a water molecule is almost 0.3 nm across. People are interested in the nanoscale (which we define to be from 100 nm down to the size of atoms (approximately 0.2 nm)) because it is at this scale that the properties of materials can be very different from those at a larger scale. We define nanoscience as the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale; and nanotechnologies as the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale. In some senses, nanoscience and nanotechnologies are not new. Chemists have been making polymers, which are large molecules made up of nanoscale subunits, for many decades and nanotechnologies have been used to create the tiny features on computer chips for the past 20 years. However, advances in the tools that now allow atoms and molecules to be examined and probed with great precision have enabled the expansion and development of nanoscience and nanotechnologies.

The properties of materials can be different at the nanoscale for two main reasons. First, nanomaterials have a relatively larger surface area when compared to the same mass of material produced in a larger form. This can make materials more chemically reactive (in some cases materials that are inert in their larger form are reactive when produced in their nanoscale form), and affect their strength or electrical properties. Second, quantum effects can begin to dominate the behaviour of matter at the nanoscale - particularly at the lower end - affecting the optical, electrical and magnetic behaviour of materials. Materials can be produced that are nanoscale in one dimension (for example, very thin surface coatings), in two dimensions (for example, nanowires and nanotubes) or in all three dimensions (for example, nanoparticles).

Our wide-ranging definitions cut across many traditional scientific disciplines. The only feature common to the diverse activities characterised as 'nanotechnology' is the tiny dimensions on which they operate. We have therefore found it more appropriate to refer to 'nanotechnologies'.

[1] The full report of which this is a summary is *Nanoscience and nanotechnologies: opportunities and uncertainties*. London: The Royal Society & The Royal Academy of Engineering, 2004. Available from the Royal Society Publications Sales Department, price £25; also free of charge on the Society's website www.royalsoc.ac.uk/policy and The Royal Academy of Engineering's website www.raeng.org.uk

[2] The membership of the Working Group is given at the end of this document.

Current and potential uses of nanoscience and nanotechnologies

Our aim has been to provide an overview of current and potential future developments in nanoscience and nanotechnologies against which the health, safety, environmental, social and ethical implications can be considered. We did not set out to identify areas of nanoscience and nanotechnologies that should be prioritised for funding.

(i) Nanomaterials

Much of nanoscience and many nanotechnologies are concerned with producing new or enhanced materials. Nanomaterials can be constructed by 'top down' techniques, producing very small structures from larger pieces of material, for example by etching to create circuits on the surface of a silicon microchip. They may also be constructed by 'bottom up' techniques, atom by atom or molecule by molecule. One way of doing this is self-assembly, in which the atoms or molecules arrange themselves into a structure due to their natural properties. Crystals grown for the semiconductor industry provide an example of self assembly, as does chemical synthesis of large molecules. A second way is to use tools to move each atom or molecule individually. Although this 'positional assembly' offers greater control over construction, it is currently very laborious and not suitable for industrial applications.

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 cosmetics and in some pilot environmental remediation applications, 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.

It is rarely possible to predict accurately the timescale of developments, but we expect that in the next few years nanomaterials will provide ways of improving performance in a range of products including silicon-based electronics, displays, paints, batteries, micro-machined silicon sensors and catalysts. Further into the future we may see composites that exploit the properties of carbon nanotubes – rolls of carbon with one or more walls, measuring a few nanometres in diameter and up to a few centimetres in length – which are extremely strong and flexible and can conduct electricity. At the moment the applications of these tubes are limited by the difficulty of producing them in a uniform manner and separating them into individual nanotubes. We may also see lubricants based on inorganic nanospheres; magnetic materials using nanocrystalline grains; nanoceramics used for more durable and better medical prosthetics; automotive components or high-temperature furnaces; and nano-engineered membranes for more energy-efficient water purification.

(ii) Metrology

Metrology, the science of measurement, underpins all other nanoscience and nanotechnologies because it allows the characterisation of materials in terms of dimensions and also in terms of attributes such as electrical properties and mass. Greater precision in metrology will assist the development of nanoscience and nanotechnologies. However, this will require increased standardisation to allow calibration of equipment and we recommend that the Department of Trade and Industry ensure that this area is properly funded.

(iii) Electronics, optoelectronics and ICT

The role of nanoscience and nanotechnologies in the development of information technology is anticipated in the International Technology Roadmap for Semiconductors, a worldwide consensus document that predicts the main trends in the semiconductor industry up to 2018. This roadmap defines a manufacturing standard for silicon chips in terms of the length of a particular feature in a memory cell. For 2004 the standard is 90 nm, but it is predicted that by 2016 this will be just 22 nm. Much of the miniaturisation of computer chips to date has involved nanoscience and nanotechnologies, and this is expected to continue in the short and medium term. The storage of data, using optical or magnetic properties to create memory, will also depend on advances in nanoscience and nanotechnologies.

Alternatives to silicon-based electronics are already being explored through nanoscience and nanotechnologies, for example plastic electronics for flexible display screens. Other nanoscale electronic devices currently being developed are sensors to detect chemicals in the environment, to check the edibility of foodstuffs, or to monitor the state of mechanical stresses within buildings. Much interest is also focused on quantum dots, semiconductor nanoparticles that can be 'tuned' to emit or absorb particular light colours for use in solar energy cells or fluorescent biological labels.

(iv) Bio-nanotechnology and nanomedicine

Applications of nanotechnologies in medicine are especially promising, and areas such as disease diagnosis, drug delivery targeted at specific sites in the body and molecular imaging are being intensively investigated and some products are undergoing clinical trials. Nanocrystalline silver, which is known to have antimicrobial properties, is being used in wound dressings in the USA. Applications of nanoscience and nanotechnologies are also leading to the production of materials and devices such as scaffolds for cell and tissue engineering, and sensors that can be used for monitoring aspects of human health. Many of the applications may not be realised for ten years or more (owing partly to the rigorous testing and validation regimes that will be required). In the much longer term, the development of nanoelectronic systems that can detect and process information could lead to the development of an artificial retina or cochlea. Progress in the area of bio-nanotechnology will build on our understanding of natural biological structures on the molecular scale, such as proteins.

(v) Industrial applications

So far, the relatively small number of applications of nanotechnologies that have made it through to industrial application represent evolutionary rather than revolutionary advances. Current applications are mainly in the areas of determining the properties of materials, the production of chemicals, precision manufacturing and computing. In mobile phones for instance, materials involving nanotechnologies are being developed for use in advanced batteries, electronic packaging and in displays. The total weight of these materials will constitute a very small fraction of the whole product but be responsible for most of the functions that the devices offer. In the longer term, many more areas may be influenced by nanotechnologies but there will be significant challenges in scaling up production from the research laboratory to mass manufacturing.

In the longer term it is hoped that nanotechnologies will enable more efficient approaches to manufacturing which will produce a host of multi-functional materials in a cost-effective manner, with reduced resource use and waste. However, it is important that claims of likely environmental benefits are assessed for the entire lifecycle of a material or product, from its manufacture through its use to its eventual disposal. We recommend that lifecycle assessments be undertaken for applications of nanotechnologies.

Hopes have been expressed for the development and use of mechanical nano-machines which would be capable of producing materials (and themselves) atom-by-atom (however this issue was not raised by the industrial representatives to whom we spoke). Alongside such hopes for self-replicating machines, fears have been raised about the potential for these (as yet unrealised) machines to go out of control, produce unlimited copies of themselves, and consume all available material on the planet in the process (the so called 'grey goo' scenario). We have concluded that there is no evidence to suggest that mechanical self-replicating nanomachines will be developed in the foreseeable future.

Health and environmental impacts

Concerns have been expressed that the very properties of nanoscale particles being exploited in certain applications (such as high surface reactivity and the ability to cross cell membranes) might also have negative health and environmental impacts. Many nanotechnologies pose no new risks to health and almost all the concerns relate to the potential impacts of deliberately manufactured nanoparticles and nanotubes that are free rather than fixed to or within a material. Only a few chemicals are being manufactured in nanoparticulate form on an industrial scale and exposure to free manufactured nanoparticles and nanotubes is currently limited to some workplaces (including academic research laboratories) and a small number of cosmetic uses. We expect the likelihood of nanoparticles or nanotubes being released from products in which they have been fixed or embedded (such as composites) to be low but have recommended that manufacturers assess this potential exposure risk for the lifecycle of the product and make their findings available to the relevant regulatory bodies.

Few studies have been published on the effects of inhaling free manufactured nanoparticles and we have had to rely mainly on analogies with results from studies on exposure to other small particles – such as the pollutant nanoparticles known to be present in large numbers in urban air, and the mineral dusts in some workplaces. The evidence suggests that at least some manufactured nanoparticles will be more toxic per unit of mass than larger particles of the same chemical. This toxicity is related to the surface area of nanoparticles (which is greater for a given mass than that of larger particles) and the chemical reactivity of the surface (which could be increased or decreased by the use of surface coatings). It also seems likely that nanoparticles will penetrate cells more readily than larger particles.

It is very unlikely that new manufactured nanoparticles could be introduced into humans in doses sufficient to cause the health effects that have been associated with the nanoparticles in polluted air. However, some may be inhaled in certain workplaces in significant amounts and steps should be taken to minimise exposure. Toxicological studies have investigated nanoparticles of low solubility and low surface activity. Newer nanoparticles with characteristics that differ substantially from these should be treated with particular caution. The physical characteristics of carbon and other nanotubes mean that they may have toxic properties similar to those of asbestos fibres, although preliminary studies suggest that they may not readily escape into the air as individual fibres. Until further toxicological studies have been undertaken, human exposure to airborne nanotubes in laboratories and workplaces should be restricted.

If nanoparticles penetrate the skin they might facilitate the production of reactive molecules that could lead to cell damage. There is some evidence to show that nanoparticles of titanium dioxide (used in some sun protection products) do not penetrate the skin but it is not clear whether the same conclusion holds for individuals whose skin has been damaged by sun or by common diseases such as eczema. There is insufficient information about whether other nanoparticles used in cosmetics (such as zinc oxide) penetrate the skin and there is a need for more research into this. Much of the information relating to the safety of these ingredients has been carried out by industry and is not published in the open scientific literature. We therefore recommend that the terms of reference of safety advisory committees that consider information on the toxicology of ingredients such as nanoparticles include a requirement for relevant data, and the methodologies used to obtain them, to be placed in the public domain.

Important information about the fate and behaviour of nanoparticles that penetrate the body's defences can be gained from researchers developing nanoparticles for targeted drug delivery. We recommend collaboration between these researchers and those investigating the toxicity of other nanoparticles and nanotubes. In addition, the safety testing of these novel drug delivery methods must consider the toxic properties specific to such particles, including their ability to affect cells and organs distant from the intended target of the drug.

There is virtually no information available about the effect of nanoparticles on species other than humans or about how they behave in the air, water or soil, or about their ability to accumulate in food chains. Until more is known about their environmental impact we are keen that the release of nanoparticles and nanotubes to the environment is avoided as far as possible. Specifically, we recommend as a precautionary measure that factories and research laboratories treat manufactured nanoparticles and nanotubes as if they were hazardous and reduce them from waste streams and that the use of free nanoparticles in environmental applications such as remediation of groundwater be prohibited.

There is some evidence to suggest that combustible nanoparticles might cause an increased risk of explosion because of their increased surface area and potential for enhanced reaction. Until this hazard has been properly evaluated this risk should be managed by taking steps to avoid large quantities of these nanoparticles becoming airborne.

Research into the hazards and exposure pathways of nanoparticles and nanotubes is required to reduce the many uncertainties related to their potential impacts on health, safety and the environment. This research must keep pace with the future development of nanomaterials. We recommend that the UK Research Councils assemble an interdisciplinary centre (perhaps from existing research institutions) to undertake research into the toxicity, epidemiology, persistence and bioaccumulation of manufactured nanoparticles and nanotubes, to work on exposure pathways and to develop measurement methods. The centre should liaise closely with regulators and with other researchers in the UK, Europe and internationally. We estimate that funding of £5-6M pa for 10 years will be required. Core funding should come from the Government but the centre would also take part in European and internationally funded projects.

Social and ethical impacts

If it is difficult to predict the future direction of nanoscience and nanotechnologies and the timescale over which particular developments will occur, it is even harder to predict what will trigger social and ethical concerns. In the short to medium term concerns are expected to focus on two basic questions: 'Who controls uses of nanotechnologies?' and 'Who benefits from uses of nanotechnologies?' These questions are not unique to nanotechnologies but past experience with other technologies demonstrates that they will need to be addressed.

The perceived opportunities and threats of nanotechnologies often stem from the same characteristics. For example, the convergence of nanotechnologies with information technology, linking complex networks of remote sensing devices with significant computational power, could be used to achieve greater personal safety, security and individualised healthcare and to allow businesses to track and monitor their products. It could equally be used for covert surveillance, or for the collection and distribution of information without adequate consent. As new forms of surveillance and sensing are developed, further research and expert legal analysis might be necessary to establish whether current regulatory frameworks and institutions provide appropriate safeguards to individuals and groups in society. In the military context, too, nanotechnologies hold potential for both defence and offence and will therefore raise a number of social and ethical issues.

There is speculation that a possible future convergence of nanotechnologies with biotechnology, information and cognitive sciences could be used for radical human enhancement. If these possibilities were ever realised they would raise profound ethical questions.

A number of the social and ethical issues that might be generated by developments in nanoscience and nanotechnologies should be investigated further and we recommend that the research councils and the Arts and Humanities Research Board fund a multidisciplinary research programme to do this. We also recommend that the ethical and social implications of advanced technologies form part of the formal training of all research students and staff working in these areas.

Stakeholder and public dialogue

Public attitudes can play a crucial role in realising the potential of technological advances. Public awareness of nanotechnologies is low in Great Britain. In the survey of public opinion that we commissioned, only 29% said they had heard of 'nanotechnology' and only 19% could offer any form of definition. Of those who could offer a definition, 68% felt that it would improve life in the future, compared to only 4% who thought it would make life worse.

In two in-depth workshops involving small groups of the general public, participants identified both positive and negative potentials in nanotechnologies. Positive views were expressed about new advances in an exciting field; potential applications particularly in medicine; the creation of new materials; a sense that the developments were part of natural progress and the hope that they would improve the quality of life. Concerns were about financial implications; impacts on society; the reliability of new applications; long-term side-effects and whether the technologies could be controlled. The issue of the governance of nanotechnologies was also raised. Which institutions could be trusted to ensure that the trajectories of development of nanotechnologies are socially beneficial? Comparisons were made with genetically modified organisms and nuclear power.

We recommend that the research councils build upon our preliminary research into public attitudes by funding a more sustained and extensive programme involving members of the general public and members of interested sections of society.

We believe that a constructive and proactive debate about the future of nanotechnologies should be undertaken now – at a stage when it can inform key decisions about their development and before deeply entrenched or polarised positions appear. We recommend that the Government initiate adequately funded public dialogue around the development of nanotechnologies. The precise method of dialogue and choice of sponsors should be designed around the agreed objectives of the dialogue. Our public attitudes work suggests that governance would be an appropriate subject for initial dialogue and given that the Research Councils are currently funding research into nanotechnologies they should consider taking this forward.

Regulation

A key issue arising from our discussions with the various stakeholders was how society can control the development and deployment of nanotechnologies to maximise desirable outcomes and keep undesirable outcomes to an acceptable minimum – in other words, how nanotechnologies should be regulated. The evidence suggests that at present regulatory frameworks at EU and UK level are sufficiently broad and flexible to handle nanotechnologies at their current stage of development. However some regulations will need to be modified on a precautionary basis to reflect the fact that the toxicity of chemicals in the form of free nanoparticles and nanotubes cannot be predicted from their toxicity in a larger form and that in some cases they will be more toxic than the same mass of the same chemical in larger form. We looked at a small number of areas of regulation that cover situations where exposure to nanoparticles or nanotubes is likely currently or in the near future.

Currently the main source of inhalation exposure to manufactured nanoparticles and nanotubes is in laboratories and a few other workplaces. We recommend that the Health and Safety Executive carry out a review of the adequacy of existing regulation to assess and control workplace exposure to nanoparticles and nanotubes including those relating to accidental release. In the meantime they should consider setting lower occupational exposure levels for chemicals when produced in this size range.

Under current UK chemical regulation (Notification of New Substances) and its proposed replacement being negotiated at European level (Registration, Evaluation and Authorisation of Chemicals) the production of an existing substance in nanoparticulate form does not trigger additional testing. We recommend that chemicals produced in the form of nanoparticles and nanotubes be treated as new chemicals under these regulatory frameworks. The annual production thresholds that trigger testing and the testing methodologies relating to substances in these sizes, should be reviewed as more toxicological evidence becomes available.

Under cosmetics regulations in the European Union, ingredients (including those in the form of nanoparticles) can be used for most purposes without prior approval, provided they are not on the list of banned or restricted use chemicals and that manufacturers declare the final product to be safe. Given our concerns about the toxicity of any nanoparticles penetrating the skin we recommend that their use in products be dependent on a favourable opinion by the relevant European Commission scientific safety advisory committee. A favourable opinion has been given for the nanoparticulate form of titanium dioxide (because chemicals used as UV filters must undergo an assessment by the advisory committee before they can be used) but insufficient information has been provided to allow an assessment of zinc oxide. In the meantime 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 into account that properties of nanoparticles may be different from larger forms. We do not expect this to apply to many manufacturers since our understanding is that nanoparticles of zinc oxide are not used extensively in cosmetics in Europe. Based on our recommendation that chemicals produced in the form of nanoparticles should be treated as new chemicals, we believe that the ingredients lists for consumer products should identify the fact that manufactured nanoparticles have been added. Nanoparticles may be included in more consumer products in the future, and we recommend that the European Commission, with the support of the UK, review the adequacy of the current regulatory regime with respect to the introduction of nanoparticles into any consumer products.

Although we think it unlikely that nanoparticles or nanotubes will be released from most materials in which they have been fixed, we see any risk of such release being greatest during disposal, destruction or recycling. We therefore recommend that manufacturers of products that fall under extended producer responsibility regimes such as end-of-life regulations publish procedures outlining how these materials will be managed to minimise possible human and environmental exposure.

Our review of regulation has not been exhaustive and we recommend that all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environment from the hazards we have identified, publish their reviews and explain how they will address any regulatory gaps. Future applications of nanotechnologies may have an impact on other areas of regulation as, for example, developments in sensor technology may have implications for legislation relating to privacy. It is therefore important that regulatory bodies include future applications of nanotechnologies in their horizon-scanning programmes to ensure that any regulatory gaps are identified at an appropriate stage.

Overall, given appropriate regulation and research along the lines just indicated, we see no case for the moratorium which some have advocated on the laboratory or commercial production of manufactured nanomaterials.

Ensuring the responsible development of new and emerging technologies

Nanoscience and nanotechnologies are evolving rapidly, and the pressures of international competition will ensure that this will continue. The UK Government's Chief Scientific Adviser should therefore commission an independent group in two years time, and again in five years time, to review what action has been taken as a result of our recommendations, to assess how nanoscience and nanotechnologies have developed in the interim, and to consider the ethical, social, health, environmental, safety and regulatory implications of these developments. This group should include representatives of, and consult with, the relevant stakeholder groups.

More generally, this study has highlighted again the value of identifying as early as possible new areas of science and technology that have the potential to impact strongly on society. The Chief Scientific Adviser should therefore establish a group that brings together representatives of a wide range of stakeholders to meet bi-annually to review new and emerging technologies, to identify at the earliest possible stage areas where issues needing Government attention may arise, and to advise on how these might be addressed. The work of this group should be made public and all stakeholders should be encouraged to engage with the emerging issues. We expect this group to draw upon the work of the other bodies across Government with horizon-scanning roles rather than to duplicate their work.

We look forward to the response to this report from the UK Government and from the other parties at whom the recommendations are targeted. This study has generated a great deal of interest among a wide range of stakeholders, both within the UK and internationally. As far as we are aware it is the first study of its kind, and we expect its findings to contribute to the responsible development of nanoscience and nanotechnology globally.

Recommendations

The industrial application of nanotechnologies

R1 We recommend that a series of lifecycle assessments be undertaken for the applications and product groups arising from existing and expected developments in nanotechnologies, to ensure that 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.

R2 Where there is a requirement for research to establish methodologies for lifecycle assessments in this area, we recommend that this should be funded by the research councils through the normal responsive mode.

Possible adverse health, safety and environmental impacts

The lack of evidence about the risk posed by manufactured nanoparticles and nanotubes is resulting in considerable uncertainty.

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

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.

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;

(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.

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.

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.

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.

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.

Recommendations R10 to R14 are based on applying our conclusions - that some chemicals are more toxic when in the form of nanoparticles or nanotubes and that safety assessments based on the testing of a larger form of a chemical cannot be used to infer the safety of chemicals in the form of nanoparticles - to a series of regulatory case studies:

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.

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.

(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.

(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.

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.

(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.

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

(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.

(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.

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.

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.

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.

(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.

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.

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.

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.

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.

Ensuring the responsible development of nanotechnologies

R20 We recommend that the Office of Science and Technology 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.

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.

Working Group, Review Group and Secretariat members

Working Group

The two Academies are extremely grateful to the Working Group for their hard work.

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Review Group

The two academies gratefully acknowledge the contribution of the reviewers. With the exception of Sir John Enderby and Mr Philip Ruffles, they were not asked to endorse the conclusions or recommendations, nor did they see the final draft of the report before its release.

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The core secretariat was: Sara Al-Bader, Dr Jofey Craig (June 2003 - September 2003), Dr Andrew Dunn (October 2003 – August 2004) and Dr Rachel Quinn at the Royal Society and Richard Ploszek at the Royal Academy of Engineering. Valuable administrative and web support was provided by Karen Scott-Jupp (Royal Society). The secretariat is grateful to the many other staff at the two Academies who contributed to the successful completion of this study.