THE ROYAL SOCIETY

The Royal Academy of Engineering

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Nanoscience and nanotechnologies: opportunities and uncertainties Two-year review of progress on Government actions: Joint academies' response to the Council for Science and Technology's call for evidence

Summary of key points

- In commissioning our 2004 report on nanotechnologies the UK Government was recognised internationally as having taken the lead in encouraging the responsible development of nanotechnologies. However, its lack of progress on the actions identified in our report – particularly in addressing the uncertainties about the health and environmental impacts of nanomaterials – means that this early advantage has been lost. We urge the Government to dedicate more resources to this area in the next two years and compensate for the slow progress to date.

- We are seriously concerned at the lack of progress made in improving the understanding of the potential health and environmental impacts of free nanoparticles and nanotubes. The UK Government's regulators have themselves concluded that they cannot determine whether current regulations are adequate until the knowledge gaps are addressed. Proportionate regulation to protect the public and the environment is not possible in the absence of evidence of hazard or risk.

- There is a general consensus about the research that is needed to support industry and underpin regulation. The priorities set out in our 2004 report have been endorsed and refined in numerous subsequent national and international workshops and reports, including the Government's first research report. We recognise funding has been allocated for basic measurement and characterisation of nanoparticles, which will underpin research, but an overall lack of targeted funding by the Government means that many of these priorities are not being addressed. Meanwhile, the number of nanotechnologies-based products on the market is increasing.

- Responsive mode funding for research, while important, is not adequate to address interdisciplinary problems in an emerging area. Dedicated funding is required. The academies still believe that an interdisciplinary research centre with a directed research programme would be the best mechanism for addressing the knowledge gaps. A centre, which could be a virtual centre, is required to provide a focus for interdisciplinary and international collaboration and to assist in the international coordination of research. A centre could also stimulate capacity building and enable more effective competition for funding from international sources such as the European Framework Programme. It would be a source of independent expert advice for UK industries and we believe investment in a centre would lead to the UK gaining considerable scientific benefit, and commercial benefit in the longer term.

- The academies are pleased that there has been some progress on the recommendations relating to public dialogue. Outputs could be made more useful by improving the involvement of policy makers in objective setting for dialogue activities and by analysing outputs more rigorously. We hope the Government will build on what has been learnt so far, and develop mechanisms for ensuring the outputs from such activity are taken into account in policy-making.

- We reiterate the need for a coherent research programme into the social and ethical aspects of nanotechnologies. It could provide a basis for developing future public dialogue activities and for involving social scientists in the education and training of postgraduate scientists in the ethical and social implications of advanced technologies. A research programme would also provide a UK focal point for collaboration with the developing international networks on nanotechnologies in society.

- Whilst we welcome the collaboration between Government departments in responding to our report, we strongly recommend that the Government involve independent scientists and social scientists in its activities to a greater degree.

Introduction

In 2004 the Royal Society and Royal Academy of Engineering published the report *Nanosciences and nanotechnologies: opportunities and uncertainties* (RS & RAEng 2004). By commissioning this report, the UK Government was recognised internationally as having taken the lead in establishing the framework necessary to realise the great potential of nanotechnologies in a responsible manner.

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.

The report concluded that nanotechnologies could have a wide range of beneficial applications, and many of these applications pose no new health or safety risks. However, it expressed concerns over the potential health, safety and environmental hazards posed by free, manufactured nanoparticles and nanotubes. Free nanoparticles and nanotubes often have very different physical and chemical properties to the same chemical in larger size and these new properties are being exploited in a range of applications, for example in medicine and cosmetics. These new properties also mean that their toxicology cannot be inferred from that of the same chemical in larger form. The toxicology of nanoparticles is likely to be different because of two size-dependant factors: the larger surface area of small particles compared with larger particles, given equal mass, and the probable ability of nanoparticles to penetrate cells more easily and in a different manner than larger ones. Evidence from studies of exposure to other small particles and fibres, including air pollution, mineral dusts and pharmaceuticals also suggest that some manufactured nanoparticles and nanotubes are likely to be more toxic per unit mass than larger particles of the same chemical.

The report made a number of recommendations addressing the uncertainties around the potential health and environmental impacts of free, engineered nanomaterials and ensuring appropriate regulation. It also discussed the need for interdisciplinary research exploring the social and ethical issues arising from advances in nanotechnologies and to develop a coordinated programme of public and stakeholder engagement. Our response describes our disappointment and concern over the lack of progress that has been made these areas.

We are pleased that the Government has appointed CST to review the Government's progress in nanotechnology policy and we welcome the opportunity to respond to the CST's call for evidence (http://www.cst.gov.uk/cst/business/nanoreview.shtml). This document sets out the recommendations of our 2004 report followed by a discussion of the Government's progress. It was prepared in consultation with members of the working group responsible for the academies' 2004 report.

Industrial Applications

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 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.

We were surprised at the Government's response that 'life cycle assessment (LCA) is inherently difficult and methodologies are not fully standardised'. LCA is covered by a set of international standards (ISO 14040 to 14044). It is widely used throughout Europe for policy support, in both the public and private sector, and the EU's Integrated Product Policy (IPP) explicitly relies on LCA. We also note that Defra and the Environment Agency in particular are increasingly using LCA in the UK.

The US Environmental Protection Agency and the European Union (EU) DG Research held a workshop in October 2006 to discuss developing a joint EU/US programme on the application of LCA to nano-engineered products. A member of our nanotechnologies working group who attended the workshop noted that the discussions there supported the recommendations of our report. Current LCA methodology can be applied to nano-engineered products, but studies are needed to investigate where the use of nanotechnologies can lead to improved resource efficiency. Screening LCAs also need to be carried out to identify where in the life cycles of nano-engineered products health and environmental impacts might be anticipated. However, comprehensive LCAs cannot be carried out until there is more known about the health and environmental impacts of nanomaterials.

Possible adverse health and safety impacts

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

We do not believe that the Government's approach to reducing the uncertainties around the health and environmental impacts of nanomaterials, discussed in our report, has been effective. Its reluctance to commit adequate funding or set a time-table for achieving objectives is of serious concern. A substantial amount of research is still required to enable assessment of the risks and to underpin appropriate regulation. Progress has been slow. If the uncertainties are not reduced soon, there could be detrimental societal and economic consequences. Funding the necessary research is an important step in ensuring nanotechnology is a well regulated technology, which will enable investors and the public to have greater confidence in its applications.

We recognise that the UK alone will not be able to fund all of the necessary research. International cooperation and collaboration is required to make best use of resources to tackle this international issue. However, we feel that the UK must dedicate adequate funding to investigating the potential impacts of nanomaterials on the health and environment to provide a platform and the capacity for this coordination and cooperation. We welcome Defra's active involvement with the Organisation for Economic Cooperation and Development (OECD) and hope that the meeting in October 2006 will enable rapid progress to be made. We hope that there will be an opportunity for independent scientists to be involved in OECD's work.

Since the publication of our report there have been a significant number of national and international conferences, workshops and reports on the potential risks associated with nanomaterials. There is a general consensus about the knowledge gaps and the research that is required to support regulators and industry. The Government's own research report *Characterising the potential risks posed by engineered nanoparticles* (HM Government 2005) outlined sound priorities for research but more directed funding is required if the Government is to meet its own objectives. The responsible development of nanotechnologies is dependent on addressing the knowledge gaps, so action is urgently required.

The Government's approach has been to establish the Nanotechnology Research Coordination Group (NRCG) a panel made up of representatives from Government departments and agencies to coordinate the Government's research programme. This programme has principally relied on funding research through Research Councils responsive mode.

We recommended an interdisciplinary research centre, with a programme of funding, be established because we did not believe that the responsive mode research funding would be suitable mechanism for achieving the research objectives identified. There has been a lack of research undertaken in the past two years, which demonstrates to us that responsive mode, whilst important, is not appropriate for addressing interdisciplinary problems in an emerging area.

We remain convinced that a research centre, which could be a virtual centre, would the best mechanism for ensuring that the research vital for underpinning regulation is undertaken. We would envisage the centre:

- Providing a stimulus for interdisciplinary collaboration.
- Building capacity and providing education and training in this emerging area of research.
- Providing a focus for international collaborations and networks. This is crucial as research needs to be coordinated internationally and a dedicated national centre could assist in this coordination.
- Becoming a recognised place for testing of nanomaterials – providing a resource for industries, who in this area are often SMEs, and thereby enabling them to undertake affordable risk assessments.
- Being a resource for Government advisory committees and regulators.
- Providing focus for the UK's expertise and thereby enabling effective competition for funding from international sources, such as the European Commission framework programmes.
- Providing a source of independent advice for all stakeholders.

- Working with industry, academia and regional development agencies to enhance the UK's competitiveness.

We estimated that £5-6 million per annum for 10 years would be needed to fund such a centre. Once the stimulus of a centre has built capacity, there will be a critical mass of researchers able to take advantage of responsive mode funding, as envisaged by the Government.

The initial investment in the centre would provide considerable scientific benefits and commercial benefits in the longer term. The development of nanotechnologies is likely to continue for decades and many nanotechnology based products are expected to be produced. An interdisciplinary centre could provide a competitive advantage for the UK and research in this new field could generate new opportunities for exploitation.

Since publishing its first research report the NRCG has established five task forces that are responsible for making progress on the research objectives outlined in the report. The majority of the task forces are made up of representatives of Government departments and agencies. We welcome the cross-government collaboration under Defra's leadership and the meetings that Defra continues to organise to gain input from a range of stakeholders. However, we strongly recommend that the Government include more independent scientists and social scientists in its task forces. The task forces will soon be publishing a progress report, but this was not available for consideration when we prepared our response.

Defra has established a Voluntary Reporting Scheme for engineered nanomaterials, following an open consultation. The scheme requests nanomaterial manufacturers, researchers, users and importers to provide information on the properties and characteristics of the nanomaterials they use. The academies' response to the consultation was generally supportive of the scheme, but emphasised that directed research into the uncertainties around nanoparticles and nanotubes is still urgently required (RS/RAEng 2006). The scheme could be a useful supplement to directed research, but is not a replacement. Our response also emphasised that Defra needs to be clear how the data collected will be analysed and how this analysis will be used to inform further development of the scheme, identify research priorities and develop specific regulations. We highlighted the importance of involving independent scientists in the analysis of the data and recommended that if participation in the scheme is poor, Defra should be prepared to act quickly to make the scheme mandatory. If the scheme is not effective, public confidence will be lost and this could hinder the UK's ability to capitalise on developments in nanotechnologies.

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.

The application of nanoparticles to the environment for remediation is likely to be the greatest potential source of concentrated environmental exposure to engineered nanoparticles in the near-term and this remains our principle concern in terms of potential environmental impact. The Government's response to our report supported the precautionary approach to releasing manufactured nanoparticles into the environment

that was advocated in our report. However, the review of gaps in environmental regulations for the products and applications of nanotechnology concluded that nanotechnologies fall outside of the scope of much legislation (Defra 2006) and the release of free nanoparticles cannot be prohibited unless evidence of harm is demonstrated. The Government is relying on industry to refrain from deliberately releasing free manufactured nanoparticles into the environment. It is essential that research on the potential effects of manufactured nanoparticles on the environment is undertaken rapidly to enable the benefit and risks involved in nanoremediation to be assessed and to inform regulation.

The number of nanoparticles released into the environment from diffuse sources is also likely to increase. For example, the anti-microbial properties of silver nanoparticles are being exploited in washing machines and articles of clothing in some countries and are likely to be discharged in waste water.

We welcome the establishment, in 2006, of the Environmental Nanotechnology Initiative (ENI), a programme of research into the environmental risks and benefits of manufactured nanoparticles, co-funded by Defra, the Environment Agency and the Natural Environment Research Council. Whilst we are pleased that some directed funding has been made available, the current level of funding (which will include covering the full economic costs of grants) is not adequate for determining the potential risks or exploiting the potential benefits of environmental nanosciences. The Government stated in its response that it expected to have made substantial progress on this recommendation by the time CST reviewed their actions. We do not believe that significant progress has been made.

The academies are pleased that the Government fulfilled its commitment to facilitating dialogue on nanoremediation. The *NanoDialogues* project, led by Demos, was commissioned through the OSI's Sciencewise programme to undertake four 'experiments' in public engagement related to developments in nanotechnology. The first experiment *Nanoparticles, risk and regulation* was undertaken in partnership with the Environment Agency, and involved a 'peoples' inquiry' on land remediation. The inquiry resulted in 12 recommendations, including that nanoparticles should not be used to clean up the environment until their long-term effects are known. The findings were presented to Defra and the Environment Agency, and we look forward to them publishing a joint response to the project.

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.

The academies are disappointed that, as far as we are aware, no assessments of the risks of the release of nanoparticles and nanotubes throughout the lifecycle of products have been undertaken.

The Government highlighted that the significance of this recommendation will depend on whether specific types of free nanoparticles or nanotubes are hazardous. However, the Government's failure to provide adequate directed research funding to investigate this means that there remains insufficient evidence. We hope the UK Government will support the approach to life cycle analysis for nano-engineered based products being developed by DG Research and US EPA (see our response under R1&2)

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.

The academies are disappointed that the Government has not been more successful in encouraging industry to disclose safety data and methodologies.

The academies recommended that scientific advisory committees require that safety assessment data, and the methodologies used to obtain them, to be placed in the public domain for two reasons. Firstly it would allow independent scientists to scrutinise the methodologies used. This is important given that existing methodologies (that are used to test larger sized chemicals) are unlikely to be appropriate for nanoparticles (see R12 iv). Secondly, it could enable academics to work with industrial scientists in developing new standard methodologies, building on the methodologies that industry has been using. Scrutiny of safety testing and the development of improved tests would give the public more confidence in products containing free manufactured nanomaterials. We expect it to be possible for this to be done in a way that does not reveal proprietary information about the composition of individual products.

In our submission to the consultation on the Voluntary Reporting Scheme for engineered nanomaterials (mentioned under recommendation 3) we suggested that the scheme request safety testing methodologies in addition to safety testing data. We are pleased that Defra has agreed that these should be requested. It is not yet clear how many companies will submit this information as the scheme is not mandatory. It is also unclear whether the information will be publicly available. The academies urge industry to make the information relating to safety assessments publicly available.

We believe the development of consistent, standardised testing methodologies will be an advantage to UK industry as it will enhance the ability of companies to take new products to market.

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.

We are pleased that the Government has implemented this recommendation and that Defra (Defra 2006), the Health and Safety Executive (HSE 2006) and the Food Standards Agency (FSA 2006) have published regulatory reviews. However, the Government's own reviews have indicated that research to fill knowledge gaps around the health and environmental impacts of nanotechnologies is required to enable a proper assessment of the adequacy of current regulations, and to draft amendments or new regulation if necessary. Once again this highlights the need for the Government to provide the funding required to fill the knowledge gaps that are vital for ensuring appropriate regulation is in place.

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.

The academies welcome the Government's positive response to this recommendation. We are pleased that regulators and their advisory committees recognise that developments in nanotechnologies should be regularly reviewed. We are pleased that HSE have established a horizon scanning mechanism that will keep a number of new and emerging technologies, including nanotechnologies, under review.

We note that the Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC), the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) and Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) issued a joint statement on the nanotechnologies in December 2005. It recognised concerns around the toxicity of nanomaterials (COC, COT and COM 2005) and concluded that research into determining exposure and identifying hazards should be a high priority. Again, we are concerned that the Government is not funding the research that its advisory committees identify as important.

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.

We remain concerned that REACH will not adequately address the regulation of nanoparticles and we hope the UK Government will keep this under consideration when it implements REACH.

The competent authorities for the implementation of the NONS and the Existing Substances Regulation (ESR) (HSE and Defra in the UK) have agreed that substances in nanoform that are not on the European Inventory of Existing Commercial Chemical Substances (EINECS) (eg fullerenes) shall be regarded as new substances. This requires a structured notification procedure under NONS, which includes submission of information on hazard identification, exposure assessment, risk assessment and risk management. However, if the nanomaterial is a smaller form of a substance already registered on the EINECS (eg titanium dioxide nanoparticles) it would not be subject to notification.

The European Council reached a common position on REACH in June 2006, which is expected to be adopted by the end of 2006. The position does not make any special provisions for nanomaterials. As with existing regulations, REACH will require registration of structurally new nanomaterials, but, the nano-form of a chemical will be treated the same as the larger form of that chemical.

The current and future regulations allow results from safety testing of larger sized particles to be submitted for the registration of nanoparticles of the same chemical. This disregards that fact that nanoparticles can have very different physicochemical properties to the larger form of the same chemical. We therefore remain concerned that nanoparticles could be registered without having undergone appropriate safety testing.

The annual production threshold that triggers testing remains at one tonne. Some nanomaterials are being produced in quantities over one tonne per year, but in the short term most nanomaterials are likely to fall outside the scope of REACH on the basis of the low tonnage. In some cases, sub-tonne levels of production could be considered to be industrially significant (ie quantum dots). We still believe that the annual threshold production that triggers testing may need to be revised as it does not recognise the fact that substances in nanoparticles form may have different health and environmental impacts per unit mass.

A recent report from the European Parliament's Committee on Industry, Research and Energy reflects this concern and suggests that nanoparticles be treated as new substances under REACH and threshold levels be considered (European Parliament 2006).

Workplace

R11 (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.

HSE publications (HSE 2004a, HSE 2004b, HSE 2006) have identified key knowledge gaps that prevent HSE from comprehensively determining whether current regulations are adequate. It recommends how these gaps, including the development of appropriate metrics and exposure assessment could be addressed. HSE also agree that the present Workplace Exposure Limits may not be appropriate for nanoparticles, but again state that there is insufficient data to determine whether the limits should be lowered and if so, by what amount.

We are pleased that HSE has undertaken considerable work to review the adequacy of the current relevant regulations. However, it is very disappointing that two years after the HSE first published documents stressing the need to address knowledge gaps, little research has been commissioned towards achieving this.

(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.

The review of environmental regulations published by Defra (Defra 2006a) revealed that the Directive on the Control of Major Accident Hazards Involving Dangerous Substances (COMAH) currently has limited potential to prevent major accidents involving nanomaterials or limit the consequences for humans and the environment of any accidents that do occur. However, the HSE believes that the nanotechnologies industry is not at a stage where the quantities of materials being stored will be relevant to this legislation (HSE 2006).

We are pleased that the Government has acted upon our recommendation and undertaken these reviews. The nanotechnologies industry is likely to expand significantly in the coming decade and it will become more important that these regulations are applicable. We hope regulators will keep this issue under review.

(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.

We are pleased that HSE has reviewed methods relating to exposure and concluded that the necessity of using electron microscopy to determine particle size should be stressed to industry if submitting a nanomaterial under NONS. It has also concluded that specific exposure measurement methods may need to be developed for nanofibres. We hope that HSE will continue to examine the best methods for assessing and controlling exposure.

Consumer Products

R12 (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.

Since our report was launched the Scientific Committee on Consumer Products (SCCP - formerly SCCNFP) has published its second opinion on the safety of microfine zinc oxide (ZnO) used in sunscreens. It stated 'more information is required to enable a proper safety evaluation of microfine zinc oxide for use as a UV filter in cosmetic products. Consequently, an appropriate safety dossier on microfine ZnO itself, including possible pathways of cutaneous penetration and systemic exposure, is required.'

We are concerned that over 3 years after the SCCNFP originally requested industry to submit additional information on microfine ZnO, it appears that this information has not been submitted. The SCCNFP opinion calls to the attention of the Commission and Member States that microfine and ultrafine ZnO is widely used in sunscreen products on the European market and the safety to the consumer of this use remains to be assessed. Given that these sunscreens are available on the UK market, we trust the Government will put pressure on industry to provide the information requested.

(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.

As described under R7, the academies' response to the Voluntary Reporting Scheme (RS & RAEng 2006) consultation recommended that the information package requested from those submitting information to the scheme include the methodologies used for safety assessments. Defra's response to the consultation submissions agreed that methodologies should be requested (Defra 2006c). It is not yet clear how many companies will submit this information since the scheme is not mandatory and it is also unclear whether the information will be publicly available.

The academies are disappointed that the Government has not been more successful in encouraging industry to disclose safety data and methodologies. We urge industry to make this information publicly available.

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

We recognise that the issue of labelling is complex, but we are disappointed that, as far as we are aware, no progress has been made on this recommendation. This is despite the Government's agreement that consumers should be able to make informed choices. We believe it is particularly important that consumers should be able to make informed choices about products whilst there are uncertainties around the health and environmental impacts of nanoparticles and nanotubes. This is especially relevant given the delay in undertaking the necessary research and the fact that industry has not submitted safety data to SCCNFP on ultrafine zinc oxide. Labelling would also help address the confusion that exists over which products contain nanomaterials, and which claim to but do not.

As far as we are aware there have not been any public engagement activities specifically on the issue of labelling nanoparticulate ingredients of consumer products. The issue did arise in Nanojury and the participants recommended that free manufactured nanoparticles in consumer products should be labelled. As mentioned under R19, public dialogue activities should take into account the information needs of policy makers when setting objectives, and there should be some mechanism for enabling the output of the activities to be taken into account during the policy making process. The issue of labelling is an example of

where focussed public dialogue is required. Manufacturers, retailers and consumer associations should be consulted in planning these dialogue events and consider their outcome.

(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.

The academies are pleased that the EC's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have studied the appropriateness of existing methodologies to assess the potential risks associated with engineered products of nanotechnologies. We recognise that Defra contributed evidence to their public consultation.

The opinion reached by SCENIHR (SCENIHR, 2005) was that current risk assessment procedures require modification for nanoparticles and the committee identified knowledge gaps relevant to the requirements for new or modified methodologies. We are pleased that the European Commission has requested a scientific opinion from the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials. It is expected to make suggestions for improvement of the methodology by December 2006.

The academies hope that rapid progress will be made on the development of appropriate, standardised international testing protocols for nanomaterials. We expect the EU and the OECD to be instrumental in funding and coordinating progress and we hope the UK Government will strongly encourage this.

(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.

As the regulatory reviews undertaken by the UK Government departments and regulators (discussed above) indicate, many UK regulations are determined at an EU level. The academies hope that the EC will review and, if necessary, amend the relevant regulations relating to consumer products once more evidence on the health and environmental impacts is available. The number of consumer products containing nanomaterials is growing; the Woodrow Wilson Centre estimates that there are over 300 nanotechnologies based products on sale across the world (Woodrow Wilson Centre, 2006). We urge the EC to fund the necessary research to underpin appropriate regulation.

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.

The Medicines and Healthcare products Regulatory Agency (MHRA) believes that the existing regulations for medical devices and medicines are sufficiently broad in scope to cover risks associated with nanotechnology (MHRA website, 2006). In our report we recognised that a stringent regulatory regime governs all new inventions in medicine, however we did note that particular properties of nanoparticles suggest the possibility of unforeseen toxicity on distant organs if introduced into the body in large numbers.

We urge scientists working on nanomedicine to establish a closer dialogue with those researching potential health risks from engineered nanoparticles and nanotubes. The uncertainties around the potential negative

impacts of nanomaterials on health could be reduced by sharing knowledge on the biodistribution and toxicology of nanomedicines exploited for health benefits.

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.

The Defra report on regulatory gaps highlights the difficulty in assessing the applicability of most end-of-life regulations because of the lack of knowledge about the impacts of nanomaterials on health and the environment. It is important that this research is undertaken immediately given that the number of nanotechnology based products is increasing. If these knowledge gaps are not addressed soon, the Government may have to consider treating nanomaterials as hazardous waste.

We hope the Government considers end of life regulations wider than just the End of Life Vehicles Directive 1005/53/EC mentioned in its response.

Measurement

R15 (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.

We are pleased that Defra has acknowledged that its research on pollutants will be applicable to engineered nanoparticles. It appears that the relevant research groups are working together.

(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 (MNS) Programme and that it ensures that the UK is in the forefront of any international initiatives for the standardisation of measurement.

We welcome the fact that Government has pledged £4 million of funding for identifying the most suitable metrics and associated methods for the measurement and characterisation of nanoparticles. We trust that this represents additional funding and that it has not been withdrawn from existing important research. The academies hope that this research will allow the successful exploitation of nanotechnologies for beneficial purposes and the assessment of the potential negative impacts of nanomaterials on health and the environment. An interdisciplinary approach is required and we hope collaboration between NPL, academia and industry will be encouraged.

We are also very pleased that the Government is ensuring that the UK is in the forefront of international initiatives on standardisation of measurements by chairing the ISO committee ISO/TC 229 on nanotechnologies. Rapid progress in agreeing measurement standards is needed because it underpins research in other areas.

Social and Ethical

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.

The Research Councils have not funded a dedicated programme of research on the social and ethical aspects of nanotechnologies. A small number of ad hoc, individual projects have been funded including *Nanotechnology, Risk and Sustainability: Moving public Engagement Upstream* (Dr Phil Macnaghten, University of Lancaster) as part of the Sustainable Technologies programme. The ESRC also commissioned an update of *The Economic and Social Challenges of Nanotechnology*, by Stephen Wood, Alison Geldart and Richard Jones. We are disappointed that no research on public attitudes has been funded (as recommended under R18).

There is a growing body of research and commentary beyond the UK, particularly reports by OECD, Swiss Re, the Nanoforum, Lux Research and the International Risk Governance Council, that are increasingly influential in this debate. The UK has failed to take a leading international role and this is in part because an interdisciplinary programme has not been established. We reiterate the need for a coherent research programme. It could also provide a basis, and capacity building, for developing future public dialogue activities and for involving social scientists in the education and training of postgraduate scientists on the ethical and social implications of advanced technologies (see R17). A programme would also provide a UK focal point for collaboration with the developing international networks on nanotechnologies in society.

The academies emphasise the need to include independent experts on Government taskforce 5 which is addressing the social and ethical dimensions of nanotechnologies and is responsible for taking forward the Government's actions in this area. The additional members should also be a benefit given there are currently only four members of this taskforce. We recognise that Defra consults academics through its stakeholder workshops, but our experience of producing our 2004 report has demonstrated the benefit of having stakeholders represented on the working group, as well as consulting widely.

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.

The Joint Statement of the Research Councils' Skills Training Requirements broadly meets the spirit of this recommendation. However, there is currently uneven provision of effective training courses by Research Council's in this area as most focus on traditional communication skills training or general research ethics. There are some examples of courses on the ethical and social implications of advanced technologies, but these are specific to particular undergraduate or post graduate courses.

The academies made this recommendation because nanotechnologies raise a number of complex social and ethical issues, some of which are not fully understood or recognised as yet. In particular, as nanotechnologies converge with other technologies over time (eg with biotechnology and the cognitive/information sciences) some of the emergent social and ethical issues are likely to raise matters of significant and profound public interest. We therefore urge the Research Councils to consider how they could enable postgraduate scientists to reflect on the social and ethical issues around advanced technologies. The current arrangements are too narrow and ad hoc.

This recommendation was considered an important outcome by those interviewed for a study which evaluated the joint academies' project (Rogers-Hayden & Pidgeon, forthcoming). The academies believe that as scientific research raises more complex social and ethical issues, scientists should receive formal training to enable them to consider these issues. This is a crucial part of the development of new and emerging technologies.

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.

Comments as under R16 (above).

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.

The Government has funded or supported a variety of public engagement initiatives surrounding nanotechnology and the academies welcome the Government's commitment to public engagement in this area.

The academies recognise that incorporating the results of public engagement activities into policy is not straight-forward, but we hope the Government will build on what has been learnt so far, and develop mechanisms for ensuring the outputs from such activity is taken into account in policy-making. Although policy makers have been involved in setting the objectives for a limited number public engagement activities, further involvement and a clear idea of what policy-makers need from these activities could result in outputs that are more useful to policy makers. More effective and rigorous analysis of the outputs from these projects and better dissemination is also needed.

The academies feel that there is also a strong need for the business community to be involved in public dialogue about nanotechnologies to a greater degree and we encourage them to do so.

Ensuring responsible development of nanotechnologies

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

The academies are very pleased that the Government has commissioned the Council for Science and Technology (CST) to review the Government's actions. We welcome the open and transparent approach that CST has adopted, including the open call for evidence and publication of the minutes of its meetings on its website. We recognise that CST is evaluating the Government's actions measured against the Government's response to our report; however, we hope that CST will also take into account our original recommendations and the context in which they were made.

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.

The Horizon Scanning Centre (HSC), based in the Foresight Directorate of the Office of Science and Innovation, was established in November 2004.

Outputs from the Centre will inform the Government's public engagement strategy, as it pledged, through a project launched in September 2006 called Sciencehorizons. The project has developed public engagement activities on the thematic priorities emerging from the HSC. Although this is an interesting project, the academies have concerns over whether the methodology developed for the engagement is sufficiently rigorous to enable meaningful conclusions to be drawn from the project, and subsequently fed into policy making.

The academies were concerned that the HSC has not been engaging with stakeholder groups, however we recognise that the HSC is working on this. It is important that the results of the strategic horizon scans are discussed with a wide range of stakeholder groups to consider what emerging and potential health, safety, environmental, social, ethical and regulatory issues may arise and how these might be addressed. Stakeholder groups are likely to identify issues which Government departments may not consider.

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