9 Conclusions

9.1 Nanoscience and nanotechnologies and their industrial application

1 Nanoscience and nanotechnologies incorporate exciting areas of research and development at the interface between biology, chemistry and physics. They are widely seen as having huge potential, and are attracting substantial and increasing investments from governments and from industrial companies in many parts of the world. We have defined nanoscience as the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties of matter 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 nanometre scale. As the term 'nanotechnology' encompasses such a wide range of tools, techniques and potential applications, we have referred to 'nanotechnologies' in the plural throughout the report.

2 Much of nanoscience is concerned with understanding the properties of materials at the nanoscale and the effects of decreasing the size of materials or the structured components of materials. Nanoscale particles can exhibit, for example, different electrical, optical or magnetic properties from larger particles of the same material. Nanoscience is truly interdisciplinary, with an understanding of the physics and chemistry of matter and processes at the nanoscale being relevant to all scientific disciplines, from chemistry and physics to biology, engineering and medicine. Collaborations between researchers in different areas have enabled the sharing of knowledge, tools and techniques. Some of the benefits of this research are near realisation – for example in improved catalysis – but most are longer-term.

3 Current examples of nanotechnologies are predominately in the areas of characterisation, precision manufacturing, chemicals and materials. At this early stage, these represent predominantly incremental advances, and in some cases, a re-labelling of existing technologies. However, it is clear to us that nanotechnologies have the potential to substantially affect manufacturing processes across a wide range of industries over the medium- to long term. Most products currently enabled by nanotechnologies utilise fixed or embedded nanomaterials, or nanoscale regions of larger objects (for example, electronic components), which form a small percentage of the final product. Other applications use free (but sometimes coated) nanoparticles, which in contrast may have the capability to come into contact with humans and the environment. Of the chemicals produced in the form of nanoparticles, metallic oxides (for example, titanium dioxide, zinc oxide and iron oxide) – whose uses include skincare, electrical storage, and catalysis – dominate. Small quantities of CNTs are being manufactured and used. For example, their electrical conductivity is being exploited in anti-static packaging. Although it is predicted that the demand for nanoparticles and nanotubes will continue to grow, the longer-term focus of industry is expected to be materials with specific properties for applications whose properties will be designed for use in a wide range of electronics, chemicals, communication and consumer products. However, this type of nanomanufacturing has not yet begun in any substantial way and will take decades to mature.

4 Wherever possible we have indicated the time by which we expect certain nanotechnologies to be realised. However it is difficult to give a detailed timescale, because most are at such an early stage of development. Moreover, potential products and applications will not be realised unless there is a market for them. Nor will nanotechnologies be incorporated into products and devices without the development of scalable, cost-effective manufacturing techniques that retain and preserve the properties of the nanoscalar material in the final product. Thus, realising the applications envisaged in this report will require advances in R&D and nanomanufacturing, and the supply of scientists and engineers with the appropriate multidisciplinary skills. Some applications may never be realised, whereas unanticipated scientific breakthroughs may lead rapidly to developments not foreseen at the time of our study.

5 Nanotechnologies have the potential to impact on a wide range of applications in many industries in the medium- and long term. However, some people exaggerate potential benefits whereas others exaggerate the risks. Overstated claims about benefits and risks, neither of them based on sound science, are doing a disservice to these emerging fields. In this report we have tried to separate hype from realistic hopes and concerns. For example, significant benefits to the environment are being claimed from the application of nanotechnologies. We recommend that a life cycle approach be taken to evaluate these claims and to ensure that savings in resource consumption during the use of the product are not offset by increased consumption during other stages.

9.2 Health, safety and environmental risks and hazards

6 Many applications of nanotechnologies pose no new health or safety risks – computer chips exploiting nanoscalar active areas, for example. Currently we see the health, safety and environmental hazards of nanotechnologies as being restricted to discrete manufactured nanoparticles and nanotubes in a free

rather than embedded form. Industry is beginning to exploit these because their physical and chemical properties differ from those of the same chemical at larger size; although it should be stressed that free nanoparticles and tubes represents only a small subset of nanotechnologies and there is currently very little exposure outside the workplace. In assessing and managing any risk it is necessary to understand both the hazard and the exposure pathways.

7 The evidence that we have reviewed suggests that some manufactured nanoparticles and nanotubes are likely to be more toxic per unit mass than particles of the same chemicals at larger size and will therefore present a greater hazard. The fundamental mechanisms of toxicity of nanoparticulates may not be very different: the capacity to induce inflammation by release of free radicals in response to a dose that is adequate to overcome the body's natural defences. However, the difference comes largely from two size-dependent factors: the relatively greater surface area of nanoparticles, given equal mass, and their probable ability to penetrate cells more easily and in a different way. To pose a risk, these nanoparticles must come into contact with humans or the environment in a form and quantity that can cause harm. Currently, the main risk of human exposure to manufactured nanoparticles and nanotubes is in a few workplaces (including academic research laboratories) and through the use of a small number of skin preparations that contain free nanoparticles. However the current lack of available research means that the scale of this risk cannot be fully determined.

8 Humans inhale very many pollutant nanoparticles (millions per breath) produced as the products of combustion. In recent decades it has been suggested, but not proven, that such exposures may be responsible for the observed relationships between air pollution and several diseases, particularly of the heart and the lung. Industrial exposure to fibres such as asbestos is a well-recognised cause of serious illness such as cancer. Nanotubes have physical properties that raise the possibility of similar toxic properties although preliminary studies suggest that they do not readily escape into the air in fibrous form. Sufficient toxicological information has been obtained, on both asbestos and air pollution nanoparticles, to allow reasonable estimates of the likely effects of any new manufactured nanomaterials so long as they are composed of low-toxicity and low-solubility materials. Shape and surface coatings of nanoparticles and nanotubes will also influence toxicity. It is very unlikely that manufactured nanoparticulates of low-toxicity and low-solubility materials (the characteristics of the materials that we have assessed in this report) would be introduced into humans in sufficient doses to cause the effects associated with air pollution or asbestos. Nevertheless (depending on the way in which they are manufactured, stored, transported or incorporated into products), there is the potential for some nanopowders to be inhaled in certain workplaces in significant amounts.

9 Currently, dermal exposure is predominately through the use of cosmetics such as sunscreens that contain nanoparticles of titanium dioxide. Here the issue is whether they can penetrate the protective layers of the skin and then cause damage through the production of free radicals that can damage cells. There is little evidence in the public domain about penetration of the skin by the nanoparticles most commonly used in cosmetics. The toxicological evidence to date indicates that nanoparticles of titanium dioxide do not penetrate through the skin, although there is insufficient evidence available for the relevant scientific advisory committee to provide a judgement about the likelihood of skin penetration by zinc oxide. It is not clear whether skin penetration will be enhanced if these preparations are used on skin that has been damaged by sun (as might be expected in the case of sunscreens) or by common diseases such as eczema. We have recommended further studies of skin penetration by manufactured nanoparticles and that existing information collected by industry is placed in the public domain.

10 There is virtually no evidence available to allow the potential environmental impacts of nanoparticles and nanotubes to be evaluated. With the exception of some experiments on laboratory animals (designed to evaluate human toxicity) and one small study on one species of fish, little information is available about the toxicity of nanoparticulates to non-human species. In addition, the scarcity of published research into how nanoparticulates behave in the air, water, soil and other environmental media makes an assessment of environmental exposure pathways difficult. Nanoparticles and nanotubes that persist in the environment or bioaccumulate will present an increased risk and should be investigated. We have recommended that the release of nanoparticulates to the environment be minimised until these uncertainties are reduced. We have focused on the largest potential sources of manufactured nanoparticles and nanotubes and recommended that until there is evidence to the contrary, factories and research laboratories should treat manufactured nanoparticles and nanotubes as if they were hazardous and seek to reduce them as far as possible from waste streams. In addition, we have recommended that the release of free manufactured nanoparticles into the environment for remediation (which has been piloted in the USA) be prohibited until there is sufficient information to allow the potential risks to be evaluated as well as the benefits.

11 A wide range of uses for nanotubes and nanoparticles is envisaged that will fix them within products. It is impossible to assess whether this will be a significant source of exposure to nanoparticles and nanotubes without information about the rate at which such particles might be released. Because ways of fixing nanoparticles and nanotubes will be proprietary, we believe that the onus should be on industry to assess

such releases throughout a product's lifetime (including at the end-of-life) and to make that information available to the regulator.

12 The explosion of dust clouds of combustible material is a potential hazard in several industries. 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 nanoparticles becoming airborne.

13 Our conclusions about health, safety and environmental impacts have by necessity been based on incomplete information about the toxicology and epidemiology of nanoparticulates and their behaviour in air, water and soil, including their explosion hazard. There are uncertainties about the risk of nanoparticulates currently in production that need to be addressed immediately to safeguard workers and consumers and support regulatory decisions. In Chapters 5 and 8 we have identified a series of research objectives aimed at reducing the uncertainties relating to the toxicology and exposure pathways of nanoparticulates, as well as developing methodologies and instrumentation for monitoring them in the built and natural environment. We think that they can best be addressed by the establishment of a dedicated research centre that would probably be based on one or more existing research groups or centres. Our preliminary assessment of the toxicity of nanoparticles is based on those formed from low-toxicity and low-solubility chemicals. In the future, nanoparticles may be manufactured with surface chemistry that renders them more toxic or more able to overcome the body's natural defences. The research centre would ensure that the understanding of the health, safety and environmental risks of nanoparticulates keeps pace with developments in the field and might in time become a self-funded centre for the safety testing of nanomaterials.

9.3 Social and ethical impacts

14 In contrast to the health, safety and environmental concerns that have focused almost solely on a small part of nanotechnology, the social and ethical concerns range across the breadth of nanoscience and nanotechnologies, from concerns about the strategic direction of (and investment in) research into nanotechnologies through to those relating to specific applications. We expect some developments in nanoscience and nanotechnologies to raise significant social and ethical concerns, particularly those envisaged in the medium (5–15 years) and long (more than 20 years) term. Depending on the economic and political impacts of nanotechnologies (as yet unknown), some of these will relate to the governance of nanotechnologies, with concerns about who will decide and control developments and who will benefit from their exploitation. Some facets of nanotechnologies, including their potential to manipulate the fundamental building blocks of materials, have raised concerns similar to those encountered in biotechnology.

15 Given that nanotechnologies are primarily enabling technologies, it is not surprising that, at least in the short- to medium term, the social and ethical concerns that have been expressed about it are similar to those encountered for other technologies as the applications will be similar. Past experience with controversial technologies demonstrates that these issues should be taken seriously even though they are not unique to nanotechnologies. We have therefore recommended that the research councils and the AHRB commission research into the potential social and ethical issues identified in this report. There is also need for researchers working in new technologies to consider the social and ethical implications of their work, and we have recommended that this form part of their training.

16 In the longer term, we expect increased information collection (for example, where sensors incorporate developments in nanotechnologies) to have implications for civil liberties. The expected convergence between IT and nanotechnologies could enable devices that can increase personal security but might also be used in ways that limit privacy. There is speculation that a possible future convergence of nanotechnologies with biotechnology, information and cognitive sciences could be used for radical human enhancement. This currently falls into the category of the far future or science fiction, but should some of the more speculative suggestions ever be realised they would raise fundamental and possibly unique social and ethical issues. We see a need to monitor future developments of nanotechnologies to determine whether they will raise social and ethical impacts that have not been anticipated in this report. Later in this chapter we consider how this might be facilitated, both for nanotechnologies (section 9.6) and for other new and emerging technologies (section 9.7).

9.4 Stakeholder and public dialogue

17 As has been seen with GM crops and food in the UK, public attitudes play a crucial role in the realization of the potential of technological advances. The research into public attitudes that we commissioned indicated that awareness of nanotechnologies among the British population is currently very low, which implies that much will depend on how attitudes to nanotechnologies are shaped over the next few years. Many of the participants in the qualitative workshops were enthusiastic about the possible ways that nanotechnologies might benefit their lives and those of others. However, questions were asked about their health, safety and environmental impact in the long term, and analogies were made with issues such as

nuclear power and genetic modification. Concerns were also raised about the role and behaviour of institutions, specifically about who can be trusted to ultimately control and regulate nanotechnologies.

18 The qualitative workshops reported here represent the first in-depth qualitative research on attitudes to nanotechnologies in the published literature, as far as we are aware. They provide a valuable indication of the wider social and ethical questions that ordinary people might wish to raise about nanotechnologies, but were by necessity limited. We have therefore recommended that the research councils fund a more sustained and extensive programme of research into public attitudes to nanotechnologies that will in turn inform future dialogue.

19 The upstream nature of most nanotechnologies means that there is an opportunity to generate a constructive and proactive debate about the future of the technology now, before deeply entrenched or polarized positions appear. We broadly agree with those who have argued for wider public dialogue and debate about the social and ethical impacts of nanotechnologies, and we have therefore recommended that the Government initiate adequately funded public dialogue around the development of nanotechnologies. Several bodies could be asked to take this forward, including organisations such as the British Association for the Advancement of Science, the national academies, and major charities with experience of public engagement processes. Industry should be encouraged to sponsor public dialogue. Our research into public attitudes highlighted questions around the governance as an appropriate area for early public dialogue, with questions being raised about who can be trusted to ensure that nanotechnologies will develop in a socially beneficial way. Given that the research councils are currently funding research into nanotechnologies, they might be asked to take forward dialogue on this issue.

20 Nanotechnologies are likely to pose a wide range of issues, so it would be inappropriate to identify a single method of public dialogue. Instead, the precise means of dialogue would need to be designed around specific objectives and should be agreed by an independent steering board comprising a range of relevant stakeholders and experts in public engagement. Finally, dialogue must be properly evaluated, so that good practice in public dialogue can be built on.

9.5 Regulation

21 Proportionate and flexible regulation (informed by scientific evidence) benefits and protects consumers, workers, industry and the environment, and also generates public confidence in new technologies. We expect the research, development and industrial application of nanotechnologies to impact on a diverse range of regulations, including those relating to health and safety at work, environmental protection, licensing of medicines and the management of products at the end of their life. We believe that for the foreseeable future, the present regulatory frameworks are sufficiently broad to encompass nanotechnologies, and that a separate regulator or regulatory framework is unnecessary. Although many nanotechnologies are accommodated within existing regulations, it will be necessary to modify some regulations within existing frameworks to reflect the hazard presented by free nanoparticles and nanotubes. Our case studies were selected to illustrate how regulation will need to be adapted to reflect the fact that the safety of substances in the form of nanoparticles cannot be inferred from knowledge of their hazard in larger form. The examples were selected because of concerns raised during the study, and in most cases they relate to situations where there is potential for exposure in the short- or medium term.

22 We believe that chemicals in the form of nanoparticles and nanotubes should be treated separately to those produced in a larger form. Given the evidence that increased surface area can lead to greater toxicity per unit mass, regulation of exposure on a mass basis to nanoparticles and nanotubes may not be appropriate. Currently, the main source of exposure to nanoparticles and nanotubes is inhalation in the workplace. While HSE performs a wider review of the adequacy of current regulation to assess and control workplace exposure to nanoparticles and nanotubes, we have recommended that it consider setting lower occupational exposure levels for chemicals in this form. In addition, there is a need to review procedures relating to accidental exposure.

23 Under current UK chemical regulation (NONS) and its proposed replacement under negotiation at European level (REACH), the production of an existing substance in nanoparticulate form does not trigger additional testing. We have recommended that this regulatory gap be addressed by treating nanoparticulates as new substances, thus requiring additional testing, under both NONS and REACH. As more information about the toxicity of nanoparticles becomes available, a review should be undertaken of whether the toxicological tests required under NONS and REACH, and the production amounts that trigger these tests, are appropriate to nanoparticles and nanotubes.

24 Under EU cosmetics regulations, 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. Given our concerns about the toxicity of nanoparticles if they penetrate the skin, we have recommended that their use in products is dependent on a favourable assessment by the relevant EC scientific safety advisory committee. Thus, nanoparticles of titanium dioxide could be permitted for use (as its safety

has been assessed in the context of their use as a UV filter) but nanoparticles of chemicals such as zinc oxide and iron oxide (should manufacturers wish to use in Europe) would await a safety assessment. In addition to taking into account our concerns about the potential for nanoparticles to penetrate damaged skin, the safety advisory committee should consider whether the tests introduced as alternatives to tests on animals are appropriate for the testing of the safety of nanoparticles. In the light of the regulatory gaps that we identify, we have also recommended that the EC (encouraged and supported by the UK Government and informed by its scientific advisory committees) review the adequacy of the current regulatory regime for the introduction of nanoparticles into all consumer products, not just cosmetics. We have recommended a similar regulatory review be performed about the use of nanoparticles in medicines and medical devices.

25 Although we expect nanoparticles or nanotubes to have a low likelihood of being released from materials in which they have been fixed, we see the risk of exposure being greatest during disposal, destruction or recycling. Under the European Take-back Directives, industry is responsible for recovering used products and recycling materials or re-using components from vehicles and electrical and electronic equipment, two sectors that are expected to use materials containing fixed nanoparticles. We have recommended that these sectors publish procedures outlining how these materials will be managed to minimise human and environmental exposure to free nanoparticles and nanotubes. Avoiding end-of-life release should form an integral part of the innovation and design process of all components using embedded nanoparticles and nanotubes.

26 In many cases, decisions about how regulations should be modified to address particular risks of nanoparticles and nanotubes will require more information than is currently available about hazard to humans and the environment, and a better understanding of exposure pathways. The enforcement of regulations will require appropriate measurement techniques to monitor exposure. The research centre on toxicology and epidemiology of nanoparticles and nanotubes that we recommended will address these knowledge gaps, and one of its functions will be to advise regulators who will also have an opportunity to influence its research programme. We have also identified the need for adequate funding of a programme to develop agreed standards of measurement at the nanometre scale that can be used to calibrate equipment, which is a requirement for regulators and for quality assurance by industry.

27 Transparency of safety assessments is important in areas of new and emerging risks to human heath and the environment. Because the responsibility for assessing the safety of a consumer product often rests with the manufacturer, some information may not be in the public domain. We have therefore recommended that the terms of reference of scientific advisory committees considering the safety of ingredients should make provision for them to place all relevant data related to safety assessments in the public domain. In the meantime we have recommended that manufacturers that are including nanoparticles in their cosmetic products publish information about how they are taking account of the new properties of ingredients in nanoparticulate form in the methodologies used in their safety assessments. Because we believe that nanoparticles should be treated as new chemicals we have recommended that where ingredients are in the form of nanoparticles, they should be identified on the lists of ingredients in consumer products and preparations. There is an additional case for labelling based on transparency.

28 During this study we examined the appropriateness of some of the regulations in several key areas. Consequently, we have recommended that all relevant regulatory bodies review the implications of developments in nanotechnologies for the existing regulations within their remit and make the results of this review publicly available. Our consideration of regulation has focused primarily on current or near-term applications of nanotechnologies, and particularly on nanoparticles and nanotubes. Future applications of nanotechnologies may impact on other areas of regulation. For example, advanced sensors enabled by nanotechnologies may present challenges to regulation relating to privacy. We have also recommended that regulators and their respective advisory committees should include future applications of nanotechnologies into their horizon-scanning programmes. We are pleased to learn that one of the new EC scientific safety advisory committees for consumer products will examine the risks from new technologies, including nanotechnologies.

29 We have considered the calls for a moratorium on the development and release of new nanomaterials. We do not think that there is either the body of scientific evidence to warrant this intervention or a consensus that this is necessary on a precautionary basis. We have recommended measures that will minimise exposure while the uncertainties about the hazards posed by nanoparticles and nanotubes are being addressed, without the need for such a moratorium.

9.6 Responsible development of nanotechnologies

30 Nanoscience and nanotechnologies have huge potential. It is recognised that nanotechnologies and the uses to which they might be put may raise new challenges in the safety, regulatory or ethical domains, which will require societal debate if they are to fulfil this potential. The implementation of our recommendations

will address many of the potential ethical, social, health, environmental, safety and regulatory impacts, and help to ensure that nanotechnologies develop in a safe and socially desirable way. As part of the Government's commitment to the responsible development of nanotechnologies, **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. The academies will also monitor the implementation of these recommendations and would of course be willing to participate in this review.

31 The Working Group gave consideration to the creation of a Nanotechnologies Commission, analogous to UK's Agriculture and Environment Biotechnology Commission, which would continuously monitor emerging nanotechnologies and advise on their implications. However, most of the Working Group believed that, on balance, a commission would not be appropriate at this time. We believe that our recommendations, if implemented, will deal adequately with short- and medium-term developments. It is not clear when, if ever, some of the longer-term possibilities discussed in this report will be feasible. In addition, nanotechnologies cover such a diverse range of techniques and applications with little commonality that it is not clear that a single body would be appropriate to oversee them all. The 2- and 5-year reviews recommended above should reconsider whether there is a need for a nanotechnologies commission.

9.7 A mechanism for addressing future issues

32 Our study has identified important issues that need to be addressed with some urgency. Given the potential impacts that other new and emerging technologies (including nanotechnologies) may have on society, we see it as essential that the Government establishes a systematic approach to identifying health, safety, environmental, social, ethical and regulatory issues of new technologies at the earliest possible stage. Therefore, **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**. As a minimum, we would envisage such a group meeting bi-annually. We appreciate that there are several bodies across Government with horizon-scanning roles; we do not see this group as duplicating their work but drawing on them to fulfil the following remit:

- Undertaking horizon scanning for new and emerging technologies and considering their potential health, safety, environmental, social and ethical implications.
- Commissioning wide-ranging evaluations of issues as they think appropriate to identify areas where there is lack of knowledge about impacts.
- Providing an early warning of areas where regulation may be inadequate for specific applications of these technologies.

33 The work of this group should be made public so that all stakeholders can be encouraged to engage with the emerging issues. This group would be separate to, but may contribute to, the periodic reviews of nanoscience and nanotechnologies that we outline in section 9.6.