GLIMPSES OF NANOTECHNOLOGY

PART-II

Nanotechnology : Potential Health and Environmental Risk Analysis

DR.S.ANAND GIRI
PROFESSOR
CHEMISTRY DEPARTMENT
DIT, GREATER NOIDA
U.P. INDIA

I. INTRODUCTION

Nanomaterials

What is Nanotechnology?

Nanotechnology is engineering at the atomic or molecular (group of atoms) level. It is a group of enabling technologies that involve the manipulation of matter at the nanoscale (generally accepted as 100 nanometres or less) to create new materials, structures and devices. At this very small scale, the chemical and physical properties of materials can change, such as colour, magnetism and the ability to conduct electricity. Nanotechnology research and its applications have been growing rapidly worldwide for the past decade, with an increasing number of nanotechnology products becoming commercially available. These include nanoscale materials, powders, solutions and suspensions of nanoscale materials as well as composite materials and devices having a nanostructure.

Nanotechnology, its products and applications have the potential to offer significant social and environmental benefits. For example, it is anticipated that nanotechnology will lead to new medical treatments and tools, more efficient energy production, more effective pollution reduction, and stronger, lighter materials. The potential benefits of nanotechnology to industry and the community in general have been highlighted in several reports (see list of information sources). However, there are concerns that some applications and products of nanotechnology may present health, safety and environmental hazards and risks. Nanotechnology can be either a 'top-down' technique, such as etching and milling of larger material, or a 'bottom-up' technique that involves assembling smaller subunits to produce the nanoscale product.

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 0.3nm across. People are interested in the nanoscale (which we define to be from 100nm down to the size of atoms (approximately 0.2nm)) 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 nanometer 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.

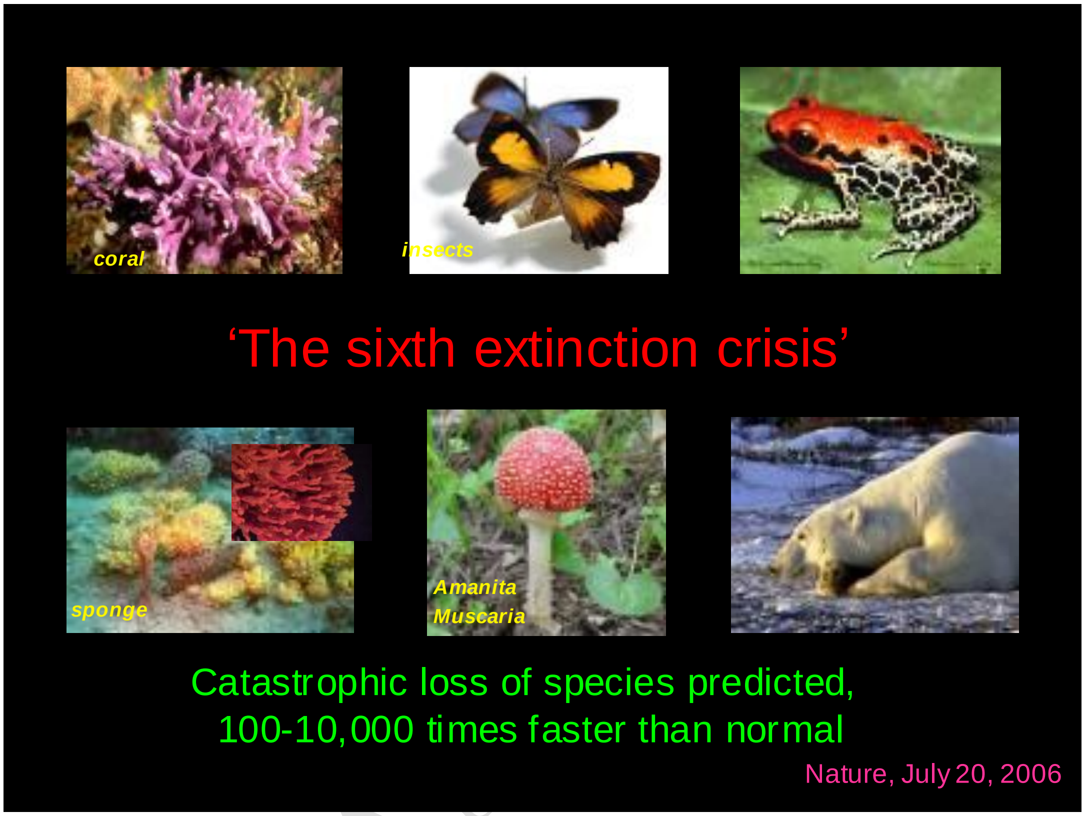


Fig.1 The Sixth extinction Crisis

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. It is therefore found it more appropriate to refer to ‘nanotechnologies’.

Definitions

Nanotechnology and its various derivative terms have in recent times come increasingly into the public domain. In the context of this document, it is important that there is clarity and a common understanding of the nano-terms used in this document. Whilst the science purists may have their own view on certain definitions, the purpose here is to convey the essence of the terminology.

Nanoscience and nanotechnology are new approaches to research and development that aim to control the fundamental structure and behaviour of matter at the level of atoms and molecules. Applications of nanotechnology are emerging and will impact on the life of every citizen.

Nano – The definition of nanotechnology is based on the prefix “nano”, which is from the Greek word meaning “dwarf”. In more technical terms, the word “nano” means 10^{-9}, or one billionth of something. One nanometre (nm) equals one thousandth of a micron (µm) or one millionth of a millimetre (mm). To give an idea of scale, a human hair is on the order of 50 microns in diameter, i.e. 50,000 nanometres!

Nanoscience – Nanoscience is primarily the extension of existing sciences into the realms of the extremely small. Nanoscience is often referred to as "horizontal", "key" or "enabling" since it can pervade virtually all technological sectors. It often brings together different areas of science and benefits from an interdisciplinary or "converging" approach. It has its applications in areas such as nanomaterials, nanochemistry,nanobio, nanophysics, etc..

Nanotechnology -Nanotechnology is the manipulation or self-assembly of individual atoms, molecules, or molecular clusters into structures to create materials and devices with new or vastly different properties. It comprises any technological developments on the nanometre scale, usually 0.1-100nm. This can be achieved by reducing the size ofthe smallest structures to the nanoscale (e.g. photonics applications innanoelectronics and nanoengineering) or by manipulating individual atoms andmolecules into nanostructures, which more closely resembles chemistry or biology.

Nanoengineering – Represents the extension of the engineering fields into the nano- scale realm (nanofabrication, nanodevices, etc.) and concerns itself with the fabrication of objects which are anywhere from hundreds to tens of nanometers in size.

"Top-down" Fabrication for Nanoelectronics

Top-down methods start with large area blocks of a material and carve out structures by selectively patterning and processing well-defined areas on the block surface. Continued miniaturisation of transistor devices over the last 40 years has resulted in exponential increases in both processor speed and also the number of transistors per chip (Moore's Law), thus enabling greater functionality. Processor chips for modern PCs are fabricated using short wavelength (193 nm) light sources and optical lithography processes which produce transistors with feature sizes as small as 70 nm across wafer slices of silicon crystals up to 300 mm in diameter. These methods are amenable to mass manufacturing, which has resulted in reduced costs (per transistor) for high-end electronics products. However, exponentially increasing fabrication costs and fundamental physical limitations remain significant challenges for continued top-down miniaturisation over the next decade.

Bottom-Up Nanofabrication

'Bottom-up' processes use chemically- or biologically-inspired routes for synthesis and assembly of nanoscale building blocks into complex nanoarchitectures with novel electronic or optical properties. Self- and directed-assembly mechanisms are often found in nature, from the growth of crystals to the formation of complex functional biotechnological systems – including the cells of the human body. The advantages of bottom-up processes include drastically reduced fabrication costs; however development of controlled assembly strategies for integration of bottom-up nanostructures and nanoarchitectures into electronic devices and circuits remains a significant long-term challenge. In the medium term, development of hybrid top down/ bottom-up fabrication strategies for electronics represents a key opportunity.

What are 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 siliconbased electronics, displays, paints, batteries, micromachined 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 ealized z in diameter and up to a few ealized za 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.

Metrology

Metrology, the science of measurement, underpins all other nanoscience and nanotechnologies because it allows the ealized zation 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 ealized zation to allow calibration of equipment and we recommend that the Department of Trade and Industry ensure that this area is properly funded.

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 90nm, but it is predicted that by 2016 this will be just 22nm. Much of the ealized zation 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.

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 ealized 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.

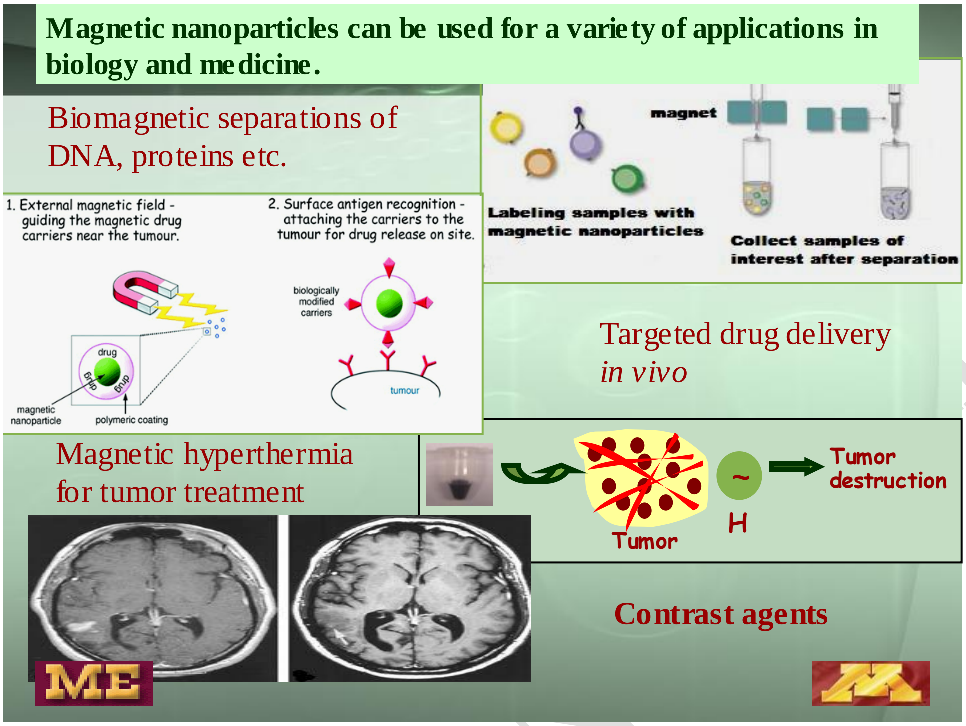


Fig.2 applications of nanoparticles in biology and medicines

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).

This can be concluded that there is no evidence to suggest that mechanical self-replicating nanomachines will be developed in the foreseeable future.

European Union

The European Commission has proposed actions as part of an **integrated approach** to maintain and strengthen European R&D in nanosciences and nanotechnologies. It considers a range of issues important to the creation and exploitation of the knowledge generated via R&D including:

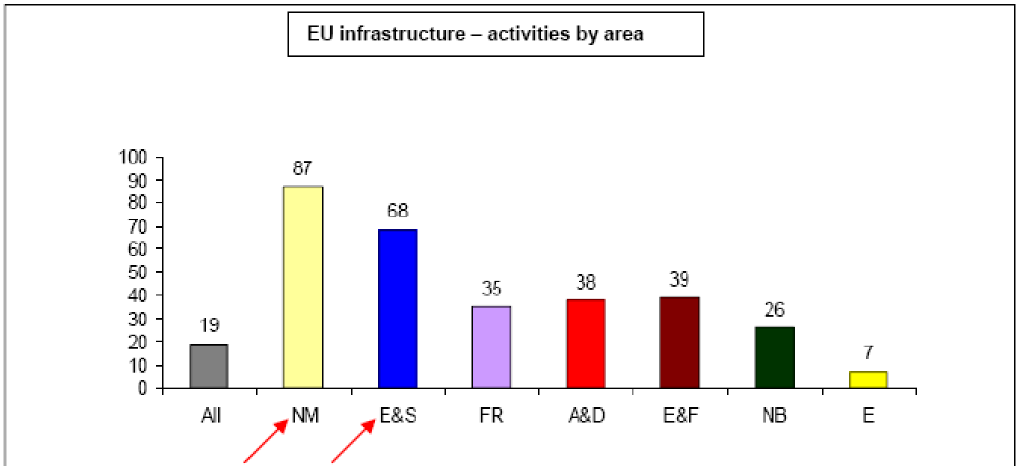
- increase investment and coordination of R&D
- develop world-class competitive R&D infrastructure
- promote the interdisciplinary education and training
- ensure favourable conditions for technology transfer and innovation
- integrate societal considerations into the R&D process at an early stage
- address any potential public health, safety, environmental and consumer risks upfront.

The strengthening of the European Commission's strategy for nanotechnology requires that R&D and innovation efforts to be better structured, optimised and integrated into a larger process involving all actors crucial to achieving a successful outcome in a given domain. This is particularly important for the nano-electronics sector which has to face extremely rapid technological development and strong global competition. The sector is of very high strategic importance for the European industry since its products are key enablers for innovation in other sectors.

To that effect, the European nanoelectronics representatives called for the establishment of a **European Nanoelectronics Initiative Advisory Council** (ENIAC). ENIAC has a wide membership of various actors in the sector. Its Steering Group consists of a core group of senior experts from semiconductor manufacturing companies, equipment and materials suppliers, application/system integrators, research organisations, academia, Member States, Regions, Eureka and other public authorities, financial organisations, etc.

ENIAC's main goal is to reflect on and contribute to the realisation of the future research and innovation priorities necessary to support the further development of a truly competitive nanoelectronics industry in Europe. It will do so by establishing and implementing a '**Strategic Research Agenda**' for the next decades for nanoelectronics stakeholders.

Nanoforum has identified a total of 240 nanotechnology and nanoscience (N&N) **centres and networks** in 28 different EU and associated states. 16 centres are classified as major EU research centres and have multi-million (plus) annual budgets. NanoMaterials and Nanoelectronics & NanoSystems represent the most common themes, 87 and 68 centres respectively (Figure 3). *Source: Nanoforum. 2004.* EU infrastructure – activities by area.



N&N infrastructure in the EU and associated states (by area): **NM** nanomaterials, **E&S** electronics and systems, **FR** fundamental research, **A&D** analytical and diagnostics, **E&F** engineering and fabrication, **NB** nanobiotechnology, **E** energy.

Source: Nanoforum. 2004.

Figure 2 - Nanoscience and Nanotechnology infrastructure in the EU and associated states.

Figure 3 -Nanoscience and Nanotechnology infrastructure in the EU and associated states.

There are different strengths between member states; for example, France shows a focus on electronics and nanobiotechnology, while Germany has a broad spectrum of infrastructure covering all areas. Greece supports several different R&D areas and includes some infrastructure for energy. The Netherlands has a number of fabrication facilities and centres for nanoelectronics and nanobiotechnology. Poland has a strong base in NanoMaterials, nanoelectronics, fabrication and analysis. This is also true for the UK, while Switzerland has a number of fabrication and analytical centres, particularly for electronics and systems.

NICNAS and Nanomaterials

NICNAS is the Commonwealth regulatory authority responsible for industrial chemicals. It provides a national notification and assessment scheme for industrial chemicals introduced to Australia, and aims to protect the public and the environment from the harmful effects of these chemicals. Under the *Industrial Chemicals (Notification and Assessment) Act*, 1989 (the Act), a 'chemical' includes chemical elements and compounds or complexes of chemical elements (including those contained in mixtures). An industrial chemical is any 'chemical' that has an industrial use. Therefore, nanomaterials which are considered to be chemicals and are used for industrial purposes will fall within the scope of NICNAS. Chemicals which are used solely as therapeutic agents, agricultural or veterinary chemicals, food or food additives are outside the scope of NICNAS.

NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used or released to the environment. NICNAS also assesses those chemicals that have been in use in Australia, know as existing chemicals, on a priority basis in response to specific concerns about their health and/or environmental effects.

Nanomaterials fall into both categories – new chemicals and existing chemicals. A chemical not listed on the Australian Inventory of Chemical Substances (AICS), which is based on the chemical formula and CAS number of chemicals (with no size definition), is generally regarded as new and must be notified and assessed for human health and environmental risks prior to their introduction and use. Nanoscale forms of chemicals already listed on AICS (ie. have identical chemical formula and CAS number) are currently considered to be existing chemicals. These nanoscale, existing chemicals can be selected for assessment if there is a potential risk of adverse health and/or environment effects. To date, NICNAS has not assessed any nanomaterials with novel properties. NICNAS needs to ensure that the regulatory regime is appropriate for assessing and regulating nanomaterials in order to protect human health and the environment. To do so, it is necessary to understand both the hazards of the nanomaterials and the levels of exposure that are likely to occur.

What industrial Nanomaterials are in use in Australia?

There is very little publicly available information on what nanomaterials are used in Australia for industrial (including domestic and cosmetic) purposes. To date, research, development and commercialisation of nanomaterials has generally been for nanoscale forms of existing chemicals. That is, the nanomaterials have the same chemical formula and CAS number as existing, bulk materials. There are no regulatory requirements for companies to notify the introduction of these types of nanomaterials. Consequently, the extent of use of industrial nanomaterials in Australia is not readily available.

In February 2006, NICNAS issued a voluntary call to Australian industry to provide information on uses and quantities of nanomaterials imported or manufactured for industrial purposes, and use in cosmetics and personal care products. Approximately 20 companies responded, with about one third reporting that the material(s) was only used for research purposes. The largest group of nanomaterials reported was the metal oxides, utilized in surface coatings and toner, adsorbents, catalysts and cosmetics. Other nanomaterials included zeolite and clays for adsorption and structural purposes. This information is valuable as it allow us to understand the extent of use of nanomaterials in Australia and will assist in prioritising regulatory efforts to ensure safe introduction of nanomaterials. Any chemical that is considered to be a new chemical, whether it is in nanoscale or bulk form, must be notified.

Do Nanomaterials pose health and/or environmental risks?

Concerns have been raised about potential health and environmental impacts of nanomaterials. This is principally because of their small size and novel properties and because research in experimental animals and in vitro systems on some nanomaterials has indicated potential environmental and health effects. Almost all concerns have related to free, rather than fixed nanomaterials. There has been little research into the potential hazards (health, safety and environmental effects) of these materials, their exposure, fate or persistence or the risks to people or the environment exposed to them. Due to this lack of information, there are many uncertainties as to whether nanomaterials pose or are likely to pose health and environmental risks. However, the body of data is increasing, as more organisations research the health and environmental aspects of nanomaterials. For example, there is a great deal of ongoing research into nanoscale metal oxides, carbon nanotubes, fullerenes and quantum dots.

Hazards

The same properties that nanomaterials are designed to exhibit are also properties that may cause nanomaterials to present human health and environmental hazards. For example, with decreasing particle size, the surface area to mass ratio becomes greater. This means that there are potentially more atoms on the surface area to react with the environment and other substances. High reactivity is a desired property for many intended applications of nanomaterials, such as catalysts, however, this increased reactivity can lead to greater toxicity for cells and living organisms. The physicochemical properties of nanomaterials are determined by the chemical composition, surface structure (including surface coatings), small size and associated increase in surface to volume ratio, solubility, shape and aggregation. The influences of physicochemical properties on the toxicological and eco-toxicological profile of nanomaterials are not yet fully understood. Changes in physicochemical properties can also increase the potential for some nanomaterials to exhibit fire and/or explosion hazards or catalytic activity.

Limited data from preliminary studies in experimental animals have shown that some nanomaterials can accumulate in the lungs and translocate to the blood, cross the blood-brain barrier, and produce inflammatory responses and are capable of direct interaction with DNA in vitro. Parallels have also been drawn with the incidentally produced nanoparticles (such as ultrafine particles in diesel exhaust and other combustion products) and their associated adverse health effects. To date, there have been no confirmed reports of adverse effects to humans or the environment as a result of exposure to engineered nanomaterials.

In summary, little is known about the toxicology of nanomaterials, though early indications are that some nanoscale materials have greater reactivity than their bulk counterparts. Based on the limited data that are available, there are concerns that the adverse effects of nanomaterials cannot be reliably predicted or derived from the known toxicity of the bulk material.

Exposure

Factors determining human and environmental exposure include the extent and pattern of use, the exposure pathway and fate and behaviour of the nanomaterial. While reported applications of nanomaterials are diverse, there are very little data on actual uses and applications, thus increasing the difficulty of determining exposure in Australia. Some nanomaterials are designed for use in solution or suspension, others are immobilised in (or on the surface of) other materials, while some applications may require the nanomaterial to be used in an unconstrained form. There is potential for exposure to humans (workers and the public) and the environment during manufacture, use and disposal of nanomaterials, but it is difficult to identify and quantify at present.

Nanomaterials are orders of magnitude smaller than conventional bulk materials, and therefore may result in an increased dose, due to a greater capacity for absorption, and potential for translocation within the body and/or access to cells. Information on routes of exposure, movement or translocation of materials once they enter the body and interaction of materials with the body's biological systems are largely unknown. Due to differences in physical and chemical properties, the fate, persistence and behaviour (such as agglomeration) of nanomaterials may differ from the bulk material and lead to a greater potential for increased exposure and dose.

Priority needs for Nanomaterials

There is insufficient knowledge concerning the characterisation, use and exposure, fate and persistence, toxicology and ecotoxicology of nanomaterials, to allow for adequate assessment of the risks of nanomaterials. The difficulty in collecting this information is compounded by the current lack of uniform internationally accepted nomenclature for nanomaterials, and the absence of standard methods for their characterisation and measurement. Several reviews have identified the following key areas that require further research to enable adequate risk assessment and regulation of nanomaterials.

Definitions, nomenclature and characterisation:

For toxicity testing and exposure measurement of nanomaterials, it is important to adequately characterise the materials. Chemical and physical properties that may be important for characterising nanomaterials include size, size distribution, surface area, shape, chemical composition and agglomeration state, though their importance will vary for different types of nanomaterials. It is probable that new methods will be required to characterise these properties. There is also an overarching need for internationally agreed nomenclature for nanomaterials and nanoparticles, to facilitate harmonised descriptions of the materials and to eliminate ambiguities.

Hazards to human health and the environment:

There is a clear need for more data to understand the hazards that nanomaterials may present to human health and the environment. The existing standard test methods may not be adequate to identify some of the hazards of nanomaterials.

Methodologies for assessing toxicological endpoints may need to be developed or existing toxicity tests adapted. There is also a need to review testing strategies and base datasets for human and environmental hazards and evaluate their adequacy to identify the potential hazards of different types of nanomaterials.

Exposure:

There is a need for data on use and potential sources of exposure to nanomaterials, their fate and behaviour. Methodologies to measure human and environmental exposure may need to be adapted or new ones developed to account for the different characteristics considered to be important for nanomaterials.

What is being done internationally and in Australia?

International activities

Risk assessment of nanomaterials has become the focus of increased international attention. International agencies and individual governments, research teams and industry are actively working to produce, gather and share information to assist in formulating appropriate approaches to the regulatory challenges posed by nanotechnology and nanomaterials. For example, the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology has started work in the area of risk assessment of nanomaterials. The OECD recognises that there should be a coordinated approach towards ensuring the safety of nanomaterials in order to help realise the benefits of nanotechnology. The OECD Chemicals Joint Meeting is considering establishing a Working Group to address issues such as international co-ordination in regulatory approaches; development of assessment methodologies and testing schemes; and information sharing and exchange in risk assessment and management. There is also increasing activity within the international standards community to address standardisation and nomenclature issues arising from the development of nanotechnology. The International Standards Organisation ISO/TC 229, Nanotechnologies, held its inaugural meeting in November 2005.

A number of institutions have published reports discussing the potential environmental, safety and health risks associated with the manufacture, use and distribution of nanomaterials, including the UK Royal Society with the Royal Academy of Engineering, the UK Department for Environment Food and Rural Affairs, the US Environmental Protection Agency, the US National Institute for Occupational Safety and Health, the Woodrow Wilson International Center for Scholars. These reports are varied in approach and scope and are useful sources of information (see attached list). In March 2005, the *Prime Minister's Science, Engineering and Innovation Council* (PMSEIC) Working Group published a report on the opportunities that nanotechnology can provide Australian industry and the impediments to its uptake. Whilst acknowledging the potential benefits of nanotechnology, the report also identified the need to address potential health, safety and environmental implications of nanotechnology and recommended development of a comprehensive impact and risk analysis framework. In response to the PMSEIC report, the National Nanotechnology Strategy Taskforce was established within the Department of Industry, Tourism and Resources to consider options for a coordinated, national approach to nanotechnology across the Federal and State Governments.

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II. *EUROPEAN STRATEGY FOR NANOTECHNOLOGY*

II. European Strategy for Nanotechnology*

Nanotechnology is emerging as one of the key technologies of the 21st Century and is expected to enable developments across a wide range of sectors that can benefit citizens and improve industrial competitiveness. Worldwide public investment in research and development in nanotechnology (R&D) has risen from around €400 million in 1997 to some €3 billion today. However, there are concerns that some aspects of nanotechnology may introduce new health, environmental and societal risks, which need to be addressed.

In May 2004 the European Commission published the Communication "Towards a European Strategy for Nanotechnology" in which an integrated and responsible approach was advocated. This Communication has been discussed at the political level in the European Council under the Irish and Dutch Presidencies. The aim of the survey conducted by Nanoforum was to assess the wider response to the Commission's proposed strategy and provide input to shape future European initiatives. A total of 720 people participated in this survey via an online questionnaire at www.nanoforum.org, and an additional 29 wrote directly to the European Commission, bringing the total response to 749. The majority of the respondents were based in Europe (93%),

*www.nanoforum.org ***December 2004*** **Authors:** Ineke Malsch and Mireille Oud with one third from Germany or the UK. From the respondents who filled in the online questionnaire, most respondents work in research (39%), or in a management role (29%) but a significant number of experts/consultants (13%) and journalists (12%) also participated. SME's and large companies were also well represented (33%).

Most respondents are very much involved in nanotechnology either in R&D, the issues, or both. For many of the technical questions, the participants could choose not to reply. In those cases, we have excluded them from the total such that the percentages given in this executive summary reflect only those who expressed an opinion. The results not only represent the personal opinions of individuals, but also the views of 107 organisations.

There is a large consensus that nanotechnology will have a strong impact on European industry (90%), and on European citizens (80%), within ten years. In terms of sectors, respondents expect the greatest impact on chemistry and materials (94%), followed by biotechnology (88%), information and communication technologies, ICT (79%), healthcare (77%) and security/defence (58%). Energy, environment, equipment engineering and consumer products are expected to have a moderate to high impact.

North America is perceived to be the world leader both in nanosciences (76%) and the transfer of nanotechnology to industry (77%), with Europe and Asia falling far behind. Most respondents believe that investment in nanotechnology in Europe R&D is lower (80%) than in the USA and Japan. In terms of R&D areas in nanotechnology, the EU should reinforce support for sensor applications, information and communication technologies, and health, safety, environment and societal issues. Broad support was expressed for a significant increase in funding for nanotechnology Broad support was expressed for a significant increase in funding for nanotechnology in the next EU Framework Programme compared to the current one (79%). Some respondents (25%) wanted to see a doubling of the budget or more, while only 12% wanted the same budget or less. Divided opinions were expressed as to whether the EU Framework programme should be oriented more towards basic or more applied R&D – it depends upon whether the respondent is coming from a university, research organisation or industry.

Europe appears to be lacking a coherent system of infrastructure and the need for a critical mass was identified as the most critical issue (90%). The responses indicate that there is a need to raise awareness and exploitation of existing infrastructure. At the same time, the majority of respondents highlighted the need for new large infrastructure at European (64%) and national/regional level (34%). A number of suggestions were also received stressing the need for cross-disciplinary infrastructure in fields such as nanomedicine, nanomaterials and information technology/nanoelectronics.

Human resources was identified as a priority with almost one-half of participants in the survey indicating that there is likely to be a shortage of skilled personnel for nanotechnology within ten years and another quarter of participants in even five years. There is also an urgent need for development of nanotechnology education and training with 90% of participants indicating that interdisciplinarity is considered to be crucial. The EU policy aims of 'mobility for researchers'; 'further training opportunities' and 'equal opportunities for women' are supported by a majority of respondents.

Consensus emerged that the EU needs an integrated strategy to be competitive in relation to other countries (85%), and that established industries must recognise the potential of nanotechnology early (70%). Almost half of the respondents feel that the EU, or international bodies, should regulate nanotechnology within 5 years (46%) or 10 years (25%). SME's and start-ups are crucial as the main source for new jobs and innovation but face many difficulties including a lack of highly skilled personnel, effective cooperation with universities and research centres, a lack of public or private funding. Many respondents agree that Europe needs to take account of risks and societal impact of nanotechnology from an early stage (75%), which requires communication and dialogue with the public. All parties involved must engage in informing the public including national/regional governments, the media and the European Commission. The importance of establishing a dialogue and the need to take into account the disruptive character of nanotechnology was also highlighted.

With regard to public health, safety, environmental and consumer protection, over 75% of respondents agreed that risk assessment must be integrated as early as possible in the R&D process and that such assessments should be carried out at EU level (61%). The priorities for more R&D to address knowledge gaps include free manufactures nanoparticles. Human exposure to these is deemed most important (72%), followed by environmental release (56%). Many respondents highlighted that nanoparticles are already present in nature through e.g. high-temperature combustion processes.

International cooperation with industrialised countries is important (96%). The majority of respondents are in favour of an international 'code of conduct' for the responsible development of nanotechnology (87%). Over three quarters of respondents are also in favour of collaborations with less developed countries, in particular to help them build research capacity and ensure an equitable transfer of knowledge.

Background

In recent years there have been several activities taking place at European level to develop a coherent strategy for the successful development of nanotechnology in Europe. Aside from maintaining European R&D excellence and industrial competitiveness, the need to address any risks or uncertainties in terms of environmental, health, ethical and social aspects has emerged as a priority. During the EuroNanoForum 2003 that took place in Trieste, Italy with over 1000 participants, the concept of an 'integrated and responsible' approach to nanotechnology was conceived[1]. This was followed by the publication of a Communication "Towards a European Strategy for Nanotechnology"[2] by the European Commission in May 2004, which was discussed on the political level in the Council of the European Union under the Irish and Dutch Presidencies.

On September 23 2004 the Competitiveness Council adopted their conclusions[3] in which the proposed integrated and responsible approach was endorsed together with the publication of an Action Plan for nanotechnology in early 2005 by the Commission following a wide ranging stakeholder debate. The purpose of the open consultation reported here was to gather the views of these stakeholders.

At the same time, with the publication of the Communication "Science and technology, the key to Europe's future - Guidelines for future European Union policy to support research", the debate has started on the Seventh European Framework Programme for Research and Technology Development (2007-2010). Taking into account the above, it is therefore crucial that the views of the nanotechnology community are heard and taken into account.

Attention was paid to ensuring that the open consultation was conducted according to general principles and standards set by the Commission[4]. Two channels were provided: an online survey was established by Nanoforum (www.nanoforum.org) and a dedicated email inbox at the Commission (rtd-nano-strategy@cec.eu.int). The open consultation ran for two and a half months from July 30 to October 15 2004.

To launch the consultation a press release[5] was issued on July 30 2004 and reported by 45 general and specialised publications. Information was also sent to many 'multipliers' including the Nanoforum contact list (around 2000 persons) and the Institute of Nanotechnology (almost 30,000). Many coordinators of EC-funded nanotechnology projects were also invited to participate.

The structure of the on-line questionnaire was based upon the structure of the Commission's Communication as listed above and covering all the elements namely research and development, infrastructure, education/training, innovation, societal issues, public health, safety, environmental and consumer protection, and international cooperation. A total of ten sections comprised all these aspects together with additional questions on the impact of nanotechnologies and perceived position of Europe.

In total, 720 people filled in the online questionnaire at www.nanoforum.org including 92 representatives of organisations and 623 individuals. In addition, 29 contributions were received via email or letter sent directly to the European Commission. With a total of almost 750 respondents, it is one of the largest surveys of its kind conducted in Europe and already indicates the high level of interest in nanotechnology. It should serve as a useful source of information for policy makers and the wider community.

The impact of nanotechnology

On Nanoforum 720 individuals responded to the survey, from 40 specified countries. 7 respondents came from an unspecified other country. 29 people responded directly to the European Commission, which brings the total number of respondents to 749. Among the 749 respondents, 689 were Europeans, including 639 out of the 25 EU Member States and there were also 60 respondents from outside Europe. About one-third of the total of responses came from Germany and Great Britain. www.landenweb.com)

Europe (93%)

Country	*Nr. of resp.*	*Per million inhab.*	*Country*	*Nr. of resp.*	*Per million inhab.*
Austria	18	2/M	Latvia	4	2/M
Belgium	20	2/M	Lithuania	0	0/M
Bulgaria	2	0.3/M	Luxembourg	1	2/M
Cyprus	0	0/M	Malta	1	2/M
Czech Rep.	8	1/M	Netherlands	41	3/M
Denmark	6	1/M	Norway	8	2/M
Estonia	2	2/M	Poland	9	0.2/M

Finland	22	4/M	Portugal	4	0.4/M
France	55	1/M	Romania	8	0.4/M
Germany	154	2/M	Slovakia	5	1/M
Greece	10	1/M	Slovenia	3	2/M
Hungary	6	1/M	Spain	51	1/M
Iceland	2	7/M	Sweden	14	2/M
Ireland	24	6/M	Switzerland	18	3/M
Israel	5	1/M	Turkey	14	0.2/M
Italy	40	1/M	United Kingdom	135	2/M

Rest of the world (7%)

Country	*Nr. of Resp.*	*Per million inhab.*	*Country*	*Nr. of Resp.*	*Per million inhab.*
Canada	1	0.03/M	Taiwan	3	0.1/M
India	1	0.001/M	Ukraine	7	0.04/M
Japan	1	0.01/M	USA		0.1/M
Russia	7	0.04/M	Yugoslavia		0.3/M
Singapore	2	1/M	Other		
South Korea	18	0.02/M			

function	*number of respondents*	*area*	*number of respondents*
Senior management	102	International	376
Management	91	European	95
Researcher	260	National	121
Strategy/policy functions	34	Regional	25
Specialist/expert	48	Local	16
Consultant	43	No response	40
Journalist	87		
Other (please specify below)	154		

The lowest number of responses came from non-EU countries and recently acceded members of the European Union. In the following analysis we will only include statistical information on the respondents which filled in the online questionnaire at Nanoforum. We do include analysis of the comments sent directly to the European Commission. Of all respondents, 107 expressed opinions on behalf of their organisation; the others expressed their own opinion . If we divide the number of respondents per country by the million inhabitants in that country, relatively most respondents came from Iceland and Ireland, followed by Finland.

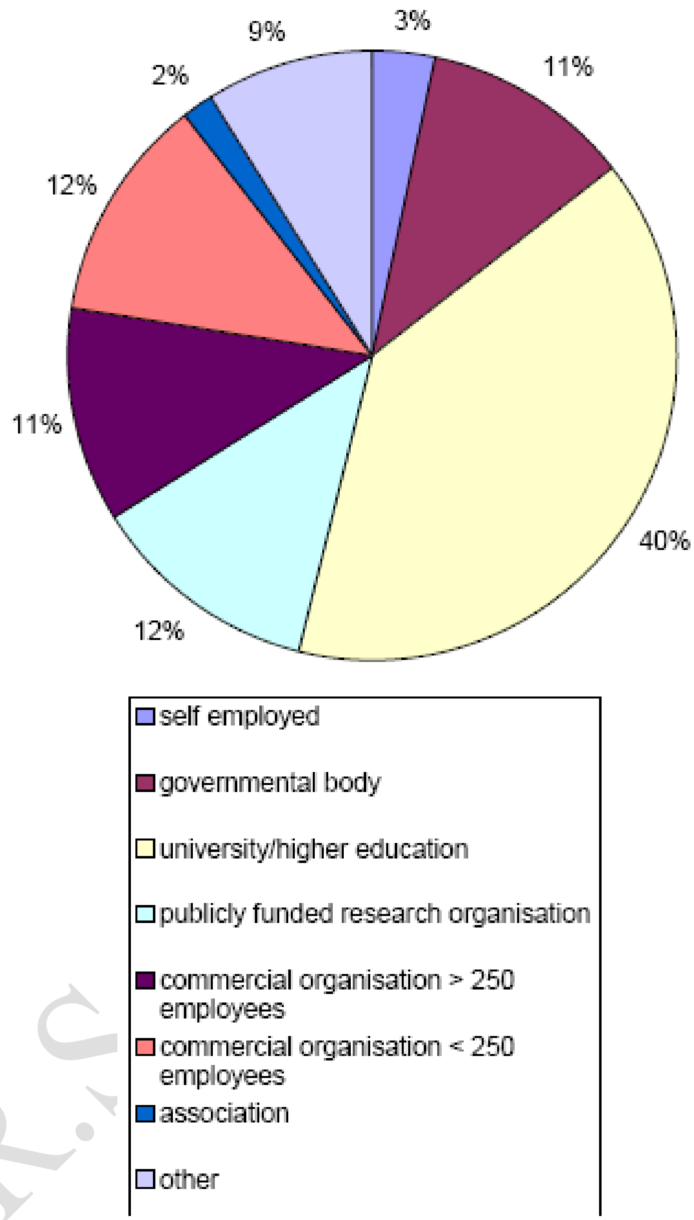

Figure 4: Respondents professional environment in %.

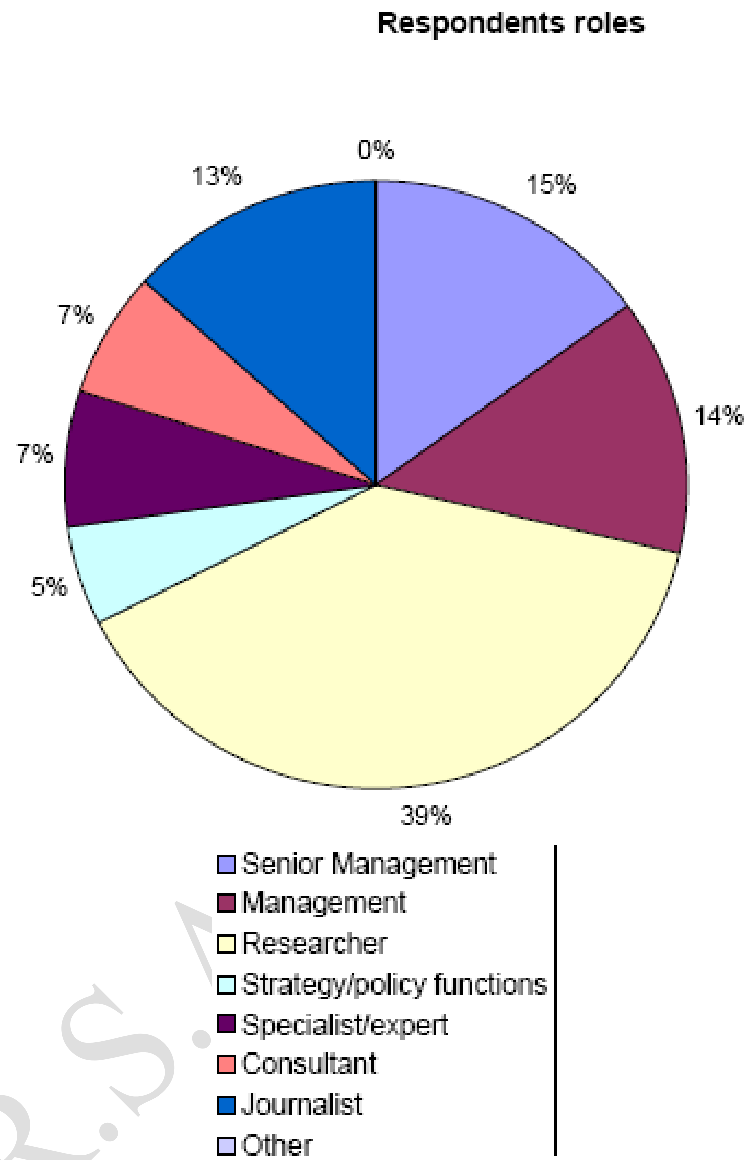

Figure5: Respondents roles in %.

The majority of respondents indicated that they were involved in nanotechnology to a large extent. 40% is very much involved in nanotechnology R&D as well as issues. Overall, the involvement in general nanotechnology issues is almost equal to the interest for specific topics of research and development. 64% of respondents are very much or quite involved in R&D, against 70% in nanotechnology issues. Given the large percentage of research organisations among the respondents

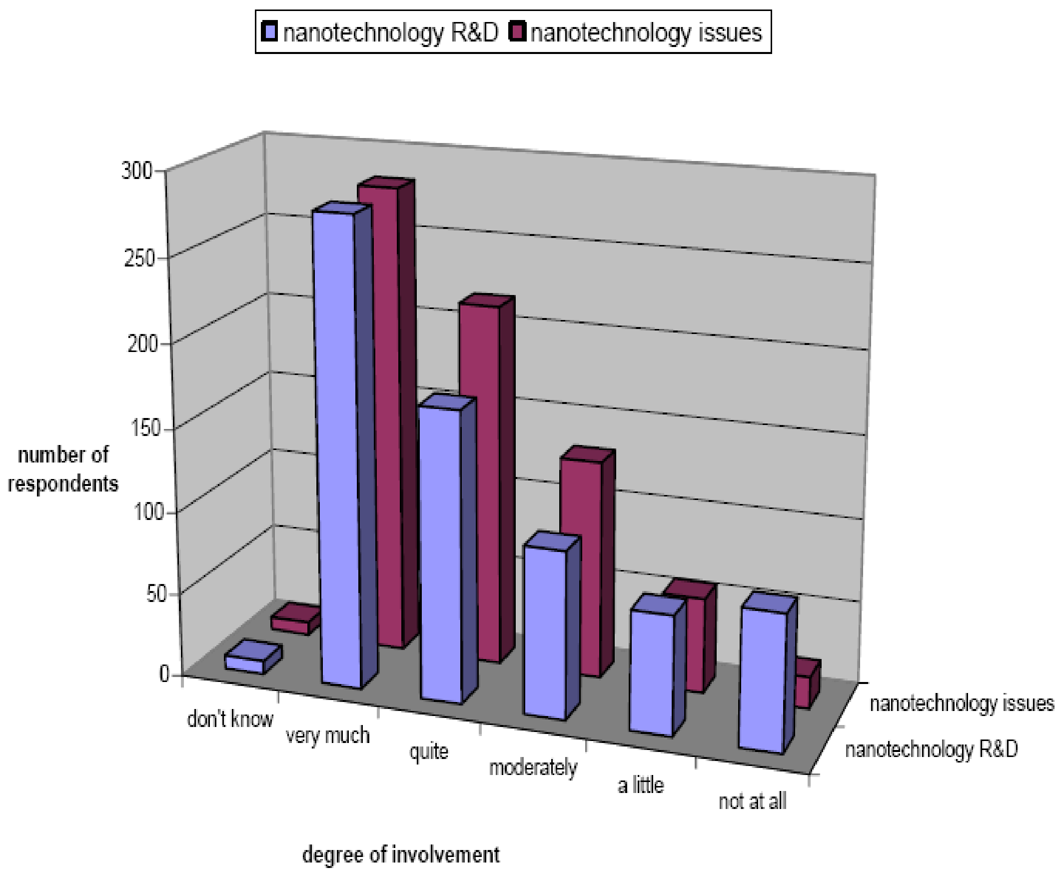

Figure 6 Respondents' involvements in nanotechnology issues in general and in nanotechnology research and development.

(52%), this latter outcome is understandable A relatively large segment of the respondents, about one-third, has moderate to no involvement in nanotechnology. These are likely to be the non-technical professionals such as journalists and consultants, who have a broad field of activities of which nanotechnology is one. It is encouraging that so many people who are less involved have nevertheless taken time to fill out the survey, indicating that nanotechnology issues are important to the wider community.

The impact of nanotechnology

The vast majority of the respondents think that nanotechnology is no longer science fiction: they expect nanotechnology to have an impact on European industry and its competitiveness within ten years from now (92%). The impact on the life of the average European citizen is expected to occur within a similar time-frame (79% in less than 10 years). Of these, 52% believes the impact on industry will occur in less than 5 years, and 45% expects the impact on the EU citizen to occur in 5 years. Only one respondent thought that nanotechnology would never have an impact. 2% of respondents were unsure of the forecast.

In addition to estimating the time span in which nanotechnology will have an impact, the respondents were asked to specify the amount of influence on each of eleven different sectors of industry. The areas that form the foundation of nanotechnology, namely chemistry and materials, are expected by virtually all of the respondents to be impacted (93%, purple and yellow bands in Figure 8).

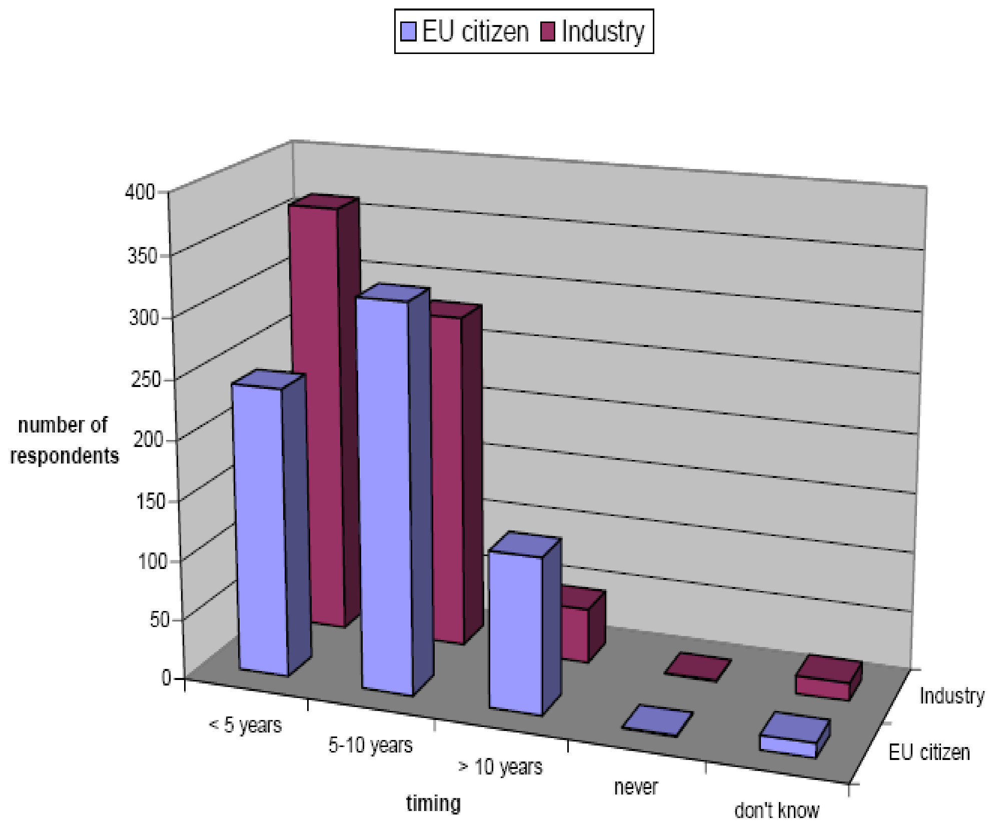

Figure 7 Expected time span in which nanotechnology will affect society and industry. The questionnaire asked: "Will nanotechnology have an impact on the life of the average European citizen?" and "Will nanotechnology have an impact on European industry and competitiveness?"

This was closely followed by the other two enabling technologies, biotechnology and ICT, which were expected to be influenced significantly by nanotechnology by more than 80% of the respondents who expressed an opinion. The important area of health attracted an almost equal ranking to biotechnology and ICT.

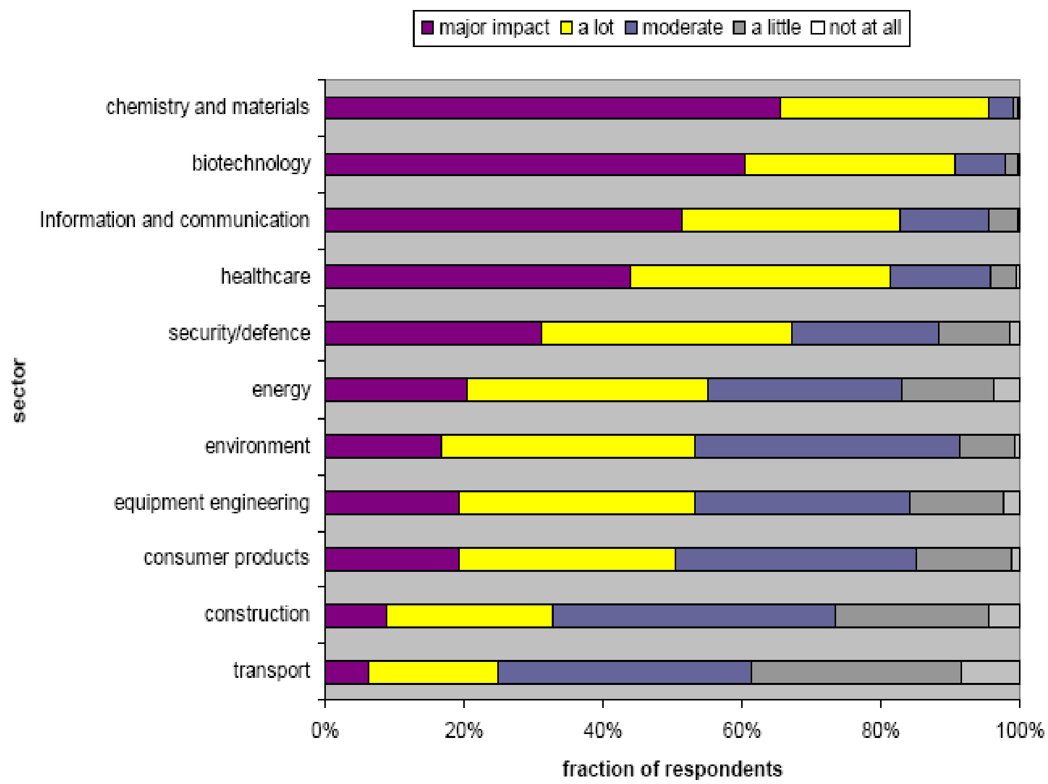

Figure 8 Respondents views on the question "Will nanotechnology have an impact on the following sectors?" Excluded are the respondents who did not express a forecast.

About 65% of the respondents thought that security and defence issues are likely to be affected by nanotechnology. Lesser effects were expected on sectors in social infrastructure (energy, transport, and environment) and in supporting industry (construction, equipment) and in the broad area of consumer products.

Apart from the eleven sectors that were specified in the questionnaire, respondents cited several other sectors which nanotechnology was expected to play an important role. Space science was frequently mentioned, and so were food related issues (production, safety, packaging, agriculture). Furthermore a number of non-industrial sectors and issues were mentioned: education, entertainment, social interactions, political and administrative issues, and financial services. When considering the above analysis, it is worth bearing in mind that the responses cannot be related to the sector in which they are active. Interestingly, only one respondent made reference to “advanced nanotechnology”, which has been the subject of much debate, in particular in North America 0%.

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III. *RESEARCH AND DEVELOPMENT*

III. Research and Development

Who is leading in nanoscience and nanotechnologies?

Nanotechnologies have become wide-spread with research and development in this field is being undertaken almost everywhere. Nevertheless, most activity is focussed in four particular regions: Europe, North America, and the Asian countries, (Japan and China in particular). Respondents were asked which of these four regions is the current leader in knowledge production and nanoscience (e.g. in terms of scientific publications), and which is the current leader in transfer of nanotechnology to industry (e.g. in terms of patents and/or bringing products to the market).

The results in figure 7 show that North America is clearly seen as the leader in nanoscience (67%) as well as in the transfer of nanotechnology to industry (66%). Europe obtains a relatively good share in terms of nanoscience (14%) but is rated relatively poorly for nanotechnology transfer. This seems to indicate that the 'European paradox', where excellence in R&D is not translated into wealth generating products and processes, may occur for nanotechnology.

In contrast, Japan has the image of being relatively good in technology transfer (15%). EuropeNorth In accordance with the perceived position

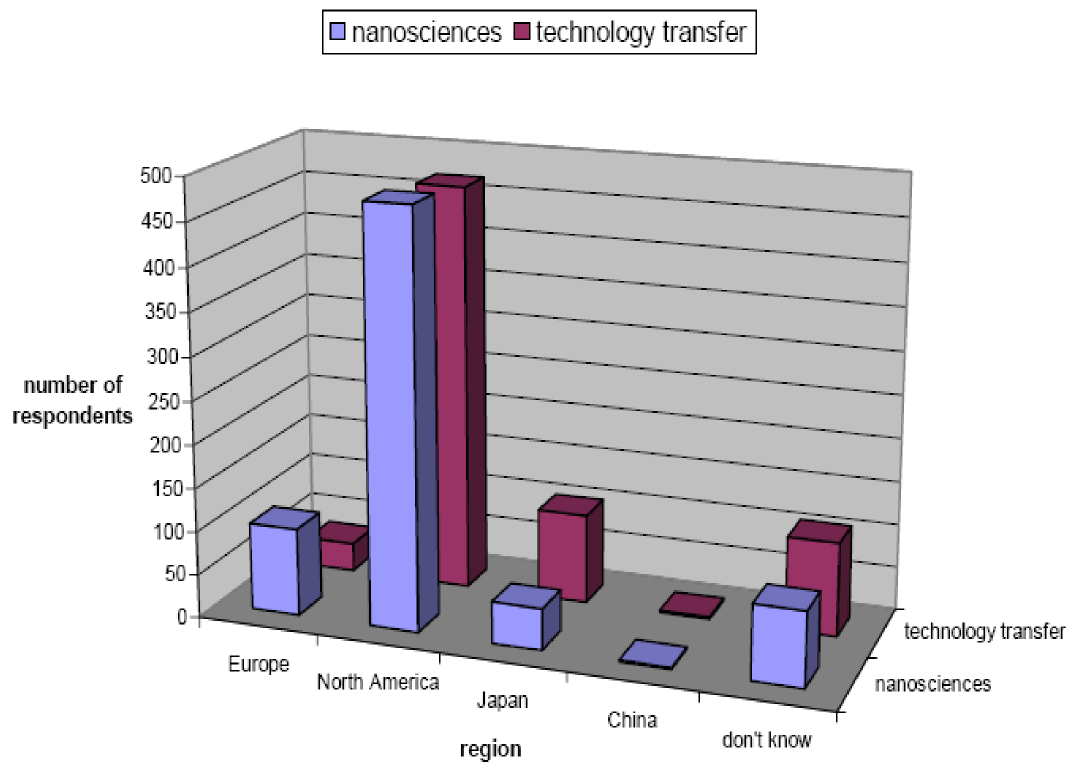

Figure 9 Regions perceived to be leading in nanoscience and the transfer of nanotechnology to industry.

of Europe in nanoscience and nanotechnology, the level of investment in nanosciences and nanotechnology R&D was estimated by the majority of respondents (57%) to be lower than in the USA and Japan (figure 9). Some respondents (13%) even expressed the view that the EU invests much less than the USA and Japan.

No distinction was made between public and private investment.

Which areas of nanotechnology R&D should Europe reinforce?

Nanotechnology can enable developments across a large number of scientific and industrial areas. In this survey, eight main areas of nanotechnology R&D were identified, within which a variable number of sub-areas were provided. The respondents were invited to select areas (multiple areas could be chosen) for which they think Europe should reinforce its R&D capability.

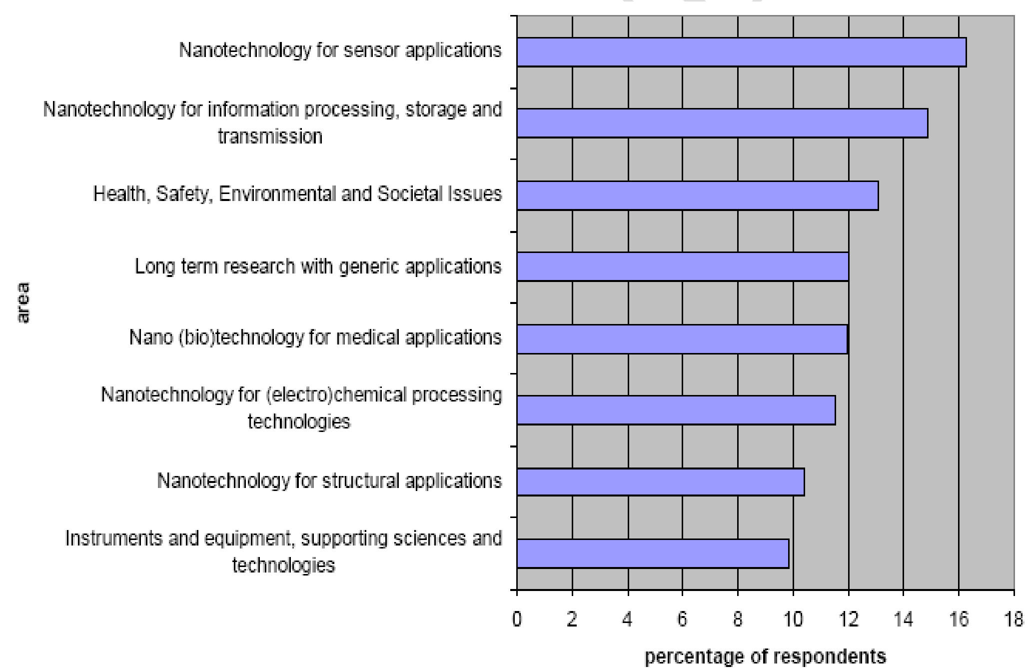

Figure 10 Relative emphasize each main area was given by respondents (the eight areas add up to 100%). The sub-areas "other" were not included here.

The respondents were also given the possibility to highlight areas that were not included in the list of options. Based upon the responses, the weight assigned to each area in terms of selections varied from about 10% to 16%, such that each area was considered to be of almost equal importance . Nevertheless, nanotechnology R&D for sensor applications, IST and health, safety and environmental issues were all rated above 12%. The priorities given to the sub-areas of each of the eight main areas (shown in fig. 10) can be seen in the table below:

Nanotechnology for sensor applications	
1. Nano structured sensors	462
2. Sensors based on biological molecules	409
Other	18

Nanotechnology for information processing, storage and transmission	
1. Nano-electronics, materials and devices	512
2. Opto-electronics / optical materials and devices	426
3. Organic (Opto) electronics	331
4. Magnetic materials and devices	326
Other	12

Health, Safety, Environmental and Societal Issues	
1. Interaction of nanotechnology with living organisms	498
2. Public understanding of nanotechnology	428
3. Risk assessment of nanotechnology	420
4. Interaction of nanotechnology with the environment	415
5. Societal impact of nanotechnology	253

No outliers are seen; each sub-area was checked by at least 20% of the respondents. This indicates that the majority of the respondents are of the opinion that nanotechnology encompasses a broad range of R&D and has an enabling character.As can be seen in table , the option "other" was checked on 98 occasions and respondents were invited to provide a free-text response. Many respondents used the “other” field to generally express their enthusiasm or anxiety about nanotechnology. Several respondents identified two important sectors:

Energy	
1. Efficient lighting	2. Fuel cells
3. Batteries	
4. Thermo-electric sources	
5. Photovoltaic sources	
6. Hydrogen motors	

7. Energy storage
8. Hydrogen storage

Agriculture/Food

1. Food and nutrition processing
2. Encapsulation of nutrients
3. Quality assurance and food safety
4. Packaging and logistics of food
5. Nanosensors to detect pathogen infections (plant science / agriculture)
6. Controlling appearance/touch of food processes.

Nanotechnology for information processing, storage and transmission

1. Integration of Micro (MEMS) and Nano Technology
2. Hybrid media
3. Information storage by using water molecules
4. Quantum Information Computing/Processing

Health, safety, environmental and societal issues

1. Measuring physicochemical properties contributing to both hazard assessment and environmental fate modelling,
2. Novel toxicology methods; and environmental exposure monitoring in support of risk assessment and management

3. International research cooperation with emerging markets and developing countries.

4. Diffusion and adoption processes within general innovation processes

5. Techno-starters

6. Nanotechnology for environmental remediation

7. Utilisation of renewable resources

8. Analysing the life cycle of nanotechnology-based products

Long-term research with generic applications

1. Generic research: contamination control

Nano (bio)technology for medical applications

1. Delivery of DNA fragments for gene therapy

2. Brain/machine interfaces

3. Neural implants; neuroelectronics

4. Interface between electronic and living tissue

Nanotechnology for (electro)chemical processing technologies

1. Pulping process equipment

2. Micro reactor and separation technology

3. Separation / membranes

Nanotechnology for structural applications

1. Structural applications: paper and packaging

2. Glasses and ceramics

3. Structuring of surfaces through supramolecular

polymer/nanoparticle chemistry

4. "Smart"/"triggered" colloids and arrested matter.
5. Polymer nanotechnology (in context of medical applications, plastic electronics and nanoelectronics, and smart and functional structural materials)
6. Fibres, notably nanotube based fibres.

Instruments and equipment, supporting sciences and technologies

1. Equipment for nanohandling, i.e. robots, manipulators and application-specific end-effectors
2. Production up-scaling (including safety or time-to-market aspects)
3. Equipment for new coating and printing methods

Several respondents commented on the interdisciplinary nature of nanotechnology and the overlap between the mentioned areas. "Due to complexity of the subject interdisciplinary research/networking is required but more funding is required for developing a network." It made some respondents tick all of the available area boxes. One respondent clearly stated that "it is almost impossible to prioritise the R&D issues", an opinion that is well reflected by the evenness in the total response. A different respondent stated: "If we are to be competitive, ALL these things have to be investigated in a balanced manner. Furthermore, neglecting some areas can have unpredictable influence on others. One can decide if something is worth producing only when it is invented, made and tested!"

One respondent expressed the opinion that a "clear EU communication strategy why nanotechnology is necessary and how Europe and its citizens benefit from nanotechnology is absolutely mandatory…." Others wanted emphasis on the socio-economic aspects/influence of nanotechnology, to pay more attention to risk perception, and to take care to minimize the hype. A respondent stated "the philosophical issues and especially issues regarding the philosophy of science should be included. It is very important that one introduces standards from "normal" and "post-normal" science into nanotech since it is one of the easiest ways of getting both sound science and public acceptance." Regulatory aspects were also touched on, ranging from stating the issue to calling for a moratorium.

An American representative (who explicitly presented him/herself as such), said: "We believe that Europe should pick specific technologies (for funding) in each of the areas listed (e.g., nanotechnology for structural applications) rather than provide monies for all the technologies (thereby spreading the investment thinly). Furthermore, this can only be done by understanding the needs of the market place before allocating European R&D funds. The key question must be: How can Europe derive the greatest impact its research investment in nanotechnology? We also feel that investment in instrumentation, equipment; metrology, HSE and societal issues underpin any research and development activities undertaken in nanotechnology. These aspects must be adequately funded if Europe is to derive value (i.e. generate profits) from this burgeoning field. Hence, all the categories have been ticked."

EU Research Activities and the Framework Programmes

Since the consultation was initiated by the European Commission, one part of the questionnaire was devoted to gathering the opinion of the respondents on current research activities in the EU, namely the Framework Programmes (FP) and to obtain their views on future wishes. Of the respondents, 328 (46%) had already participated in one or more EC funded projects under the Framework Programmes.

Type of project	*Number of participants*
STREP	145
IP	125
NoE	117
SSA	58
CA	42
IP-SME	22

Desired amount of attention to nanoscience and nanotechnology in the next Framework Programme with respect to current FP6**.**

When the respondents were asked to estimate the balance between basic and applied research in Europe, their reactions were almost equally divided over the two categories. On the whole, this would appear to indicate that there is a balance in the community.

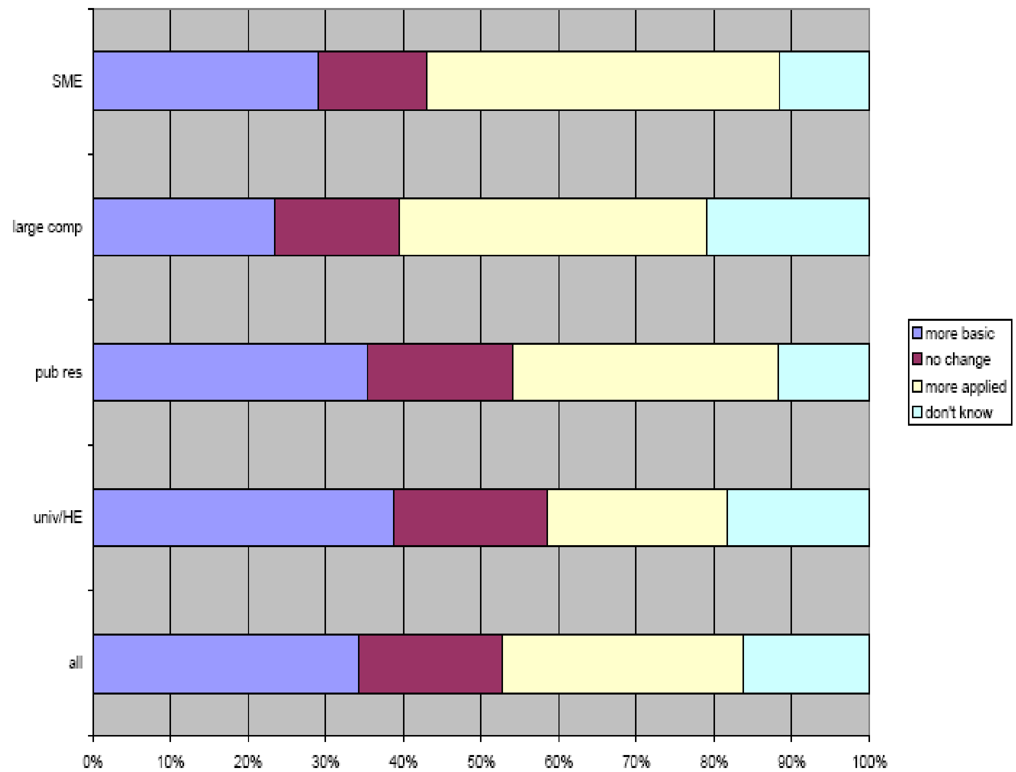

Figure 11 Perceived balance between basic and applied R&D in Europe.
Closer analysis of the question 'basic vs. applied' in terms of the profile of the respondent reveals that the responded depending upon whether the respondent was active in a research organisation/university or in industry. More basic research is requested by 39% of people in university or higher education compared to only 23% of respondents in large companies. On the contrary, 45% of SME-respondents wanted

more applied research, compared to 23% of respondents in universities. Figure 11 above shows the responses for all respondents and those from University/Higher Education; Public Research institutes; large companies and SMEs.

Views on Future EU R&D activities in nanotechnology?

The respondents were given the opportunity to comment on the question "What would you like to see for nanotechnology R&D in future Europe research activities? (E.g. key issues to address, new areas, new instruments, special measures for SMEs/industry, practical operation of the programme, etc.)" Two-third of the respondents (481 people) used this opportunity to express their desires. Many subjects were addressed and lengthy comments were frequently provided.

In all categories except for the first, the comments of the respondents were tallied. It should be noted that the answers of many respondents were guided by the examples that were given between brackets in the question. For example, "new instruments" and "special measures for SME" were often mentioned as such, without further commenting. One should bear in mind, therefore, that the comments on this open question might be somewhat unbalanced in quantitative respect.

Ethical, legal and social impacts of nanotechnology

Within this category, five main topics were addressed by the respondents:

1. Social impact of nanotechnology

Attention was requested for the social impact for nanotechnology, and more emphasis on addressing societal needs was desired. In particular, issues such as the ethics and philosophy of science, more attention for the impact on the economic situation, and creation of jobs, were highlighted. In addition, attention should be paid to the evaluation of economical efficiency compared to the conventional macro technologies. (9 respondents)

2. Risks and regulation

Health and safety issues, toxicology, risk management/assessment, and establishing regulation were highlighted as crucial issues for which more R&D is needed. A wide span of views were

27given include one respondent who asked for "A complete moratorium on lab-research until compulsory safety protocols are introduced; and a strict "no patents" policy on new molecules." Among those who are positively minded towards nanotechnology, the patenting issue was addressed by asking for "one EU patent". (37 respondents)

3. Environmental impact

Sustainability and environmental impact issues were stressed by respondents that they should be more pronounced on the EU agenda (24 respondents). It was advised to "incorporate with Technology Platform for Sustainable Chemistry". Several respondents took the opportunity to reiterate calls for a moratorium on nanotechnology.

4. Public communication

Public communication concerned the issue of making the link between researchers and the public to raise public awareness. Well coordinated activities to foster public awareness and information were recommended, as well as to "address areas that will realise benefits that the public will notice, understand and embrace" (14 respondents)

5. Education

As part of public communication, science communication was considered as important to be stimulated, such as science education to young children, specific educational programs at European level, promotion of interdisciplinary education. Simplification of the science language was recommended. (13 respondents)

"Finding of information was easy, CORDIS offers good service, and support of the national contact point was excellent."

"Finding information was easy."

Current situation for nanotechnology infrastructure

Infrastructure is widely viewed as crucial for carrying top quality R&D in nanotechnologies and bringing together researchers and entrepreneurs. We therefore asked respondents about the availability of such an R&D

infrastructure in Europe for nanotechnology. To gain an overall picture, the question was posed: "Is there a coherent system of infrastructure for nanotechnology R&D ("poles or centres of excellence") in Europe that is competitive at world-level?" Very few respondents (4%) answered positively indicating that there is no European system of nanotechnology infrastructure.

Many respondents believe there is a coherent system of such R&D infrastructure in some countries or disciplines (27% of all respondents), and 5% believed it exists for some disciplines. There are no significant differences in the responses per profile of employing organisation. One could infer that there are 'hotspots' for infrastructure in Europe for certain disciplines and/or countries and this will be analysed in more detail below.

In fact, the largest group of respondents (29%) did not know the answer which is either indicative of the number of non-specialists that participated in the open consultation or that there is a lack of awareness about nanotechnology. In any case, there is clearly a need to identify the available R&D infrastructure for nanotechnology in Europe and to assess whether this meets the need of the various stakeholders.

Is there a coherent system of infrastructure for nanotechnology R&D in Europe that is competitive at world level?

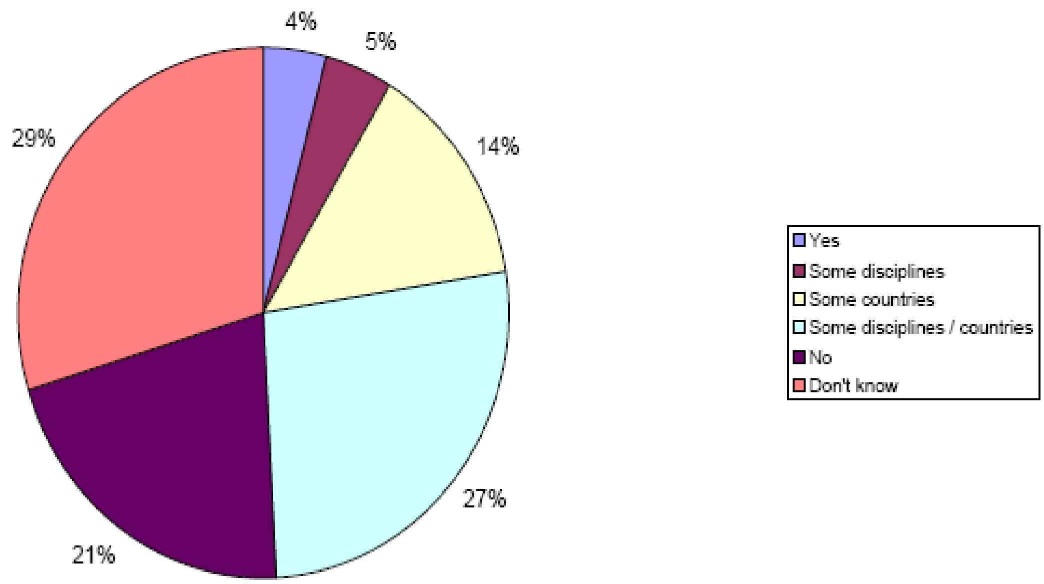

Figure 12: Opinions on the existence of a coherent system of infrastructure for nanotechnology R&D in Europe that is competitive at world level.

Different views on available infrastructure between Germany and the UK

To investigate the situation perceived by those in certain countries, we compared the responses originating from the UK (133) and from Germany (150). There were sufficient responses from these two countries to make a statistical analysis meaningful. The German respondents were more optimistic than the British. This may be related with the different national situation. If Europe is to invest in new R & D

Infrastructure, it appears unlikely that a "one Size fits all" approach would be successful since the situation appears to be quite varied according to the country and/or discipline.

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Different views on available infrastructure between Germany and the UK Panel

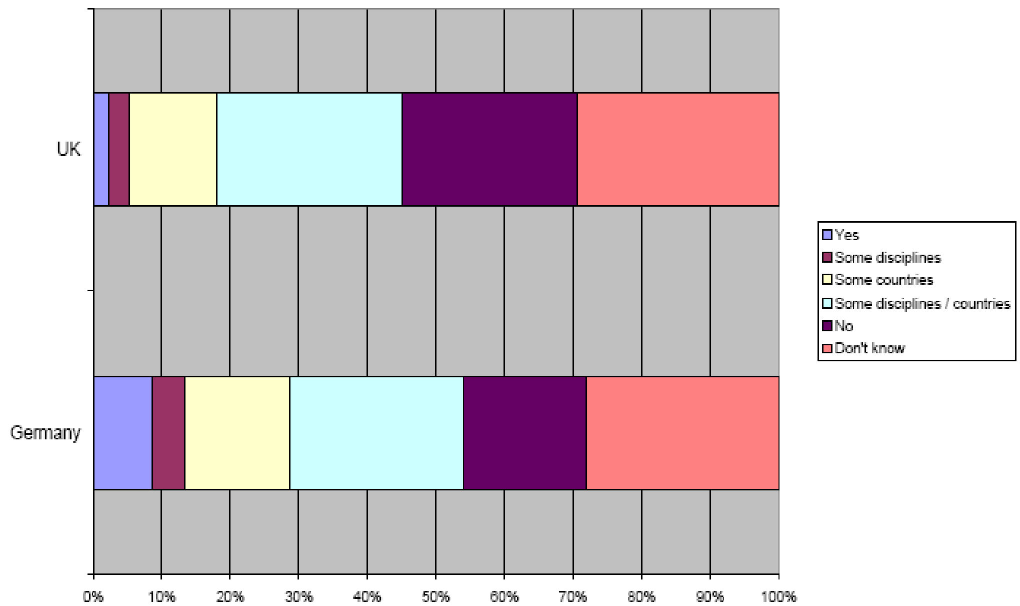

Figure 13: Different views on the availability of a nanotechnology R&D infrastructure from British and German respondents.

The German respondents were more optimistic than the British. This may be related with the different national situation. If Europe is to invest in new R&D infrastructure, it appears unlikely that a 'one size fits all' approach would be successful since the situation appears to be quite varied according to the country and/or discipline.

Several respondents provided additional information to support the answer to the above question. The majority of the 222 people who gave comments to this question believed there is a nanotechnology infrastructure in some countries (116) while 35 people believed there is an infrastructure for some disciplines, and 33 for some disciplines and some countries. 27 people gave comments on EU infrastructure, and five people commented on the absence of such a coherent system of research infrastructure. Three people criticised the idea of establishing an infrastructure for nanotechnology altogether.

Country	**Yes, there is a nanotechnology infrastructure**	**No, there is no nanotechnology infrastructure**
Germany	59	
France	33	
UK	33	3
Switzerland	15	
Netherlands	9	
Sweden	6	1
Belgium	5	
Italy	5	
Finland	4	
Spain	4	2
Ireland	3	
Austria	2	
Denmark	1	
Romania	1	
Russia	1	
Czech Republic	1	

Of the 116 comments on the existence of a coherent infrastructure in some countries, 16 individual countries were mentioned. In table 6, we list the numbers of comments on the existence of a national research infrastructure per country. Most people only mentioned countries with a good infrastructure or good centres, but some people commented negatively on the existence of such a research infrastructure in a country, suggesting that there is a differing opinion over what constitutes good infrastructure.

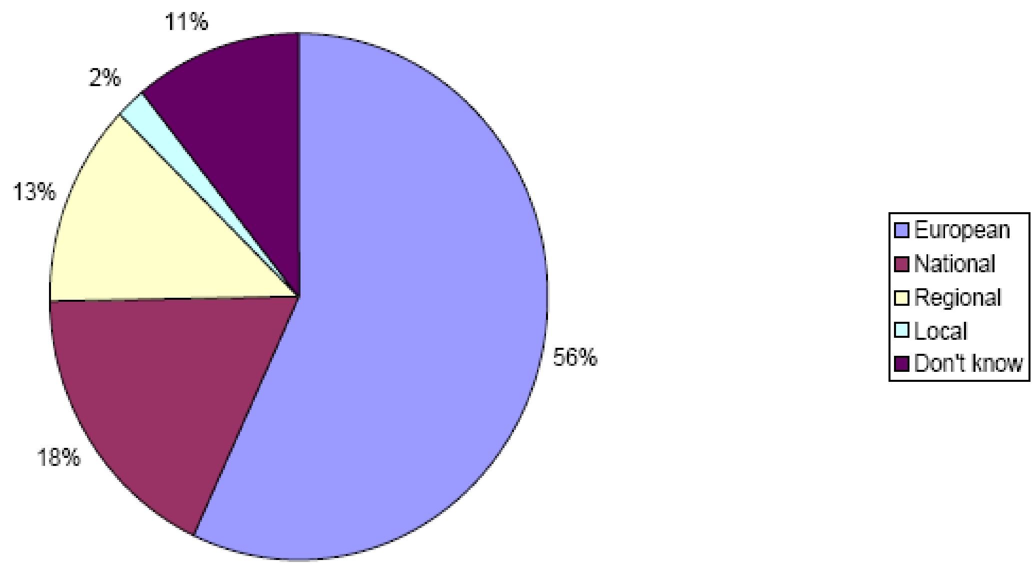

Figure 14: Preferred level for new large nanotechnology R&D infrastructure**.**

Note that the numbers are not representative for all stakeholders, since one third of respondents came from the UK or Germany, and a smaller Numbers from other countries.

Before investing in new R&D infrastructure, the European Commission, governments and other stakeholder need to know what this infrastructure will be used for and the needs of potential users of these new facilities. We therefore asked respondents to rank five possible aims which might be achieved by investing in such R&D infrastructure. All options were considered crucial to important by more than half of the respondents. "To mobilise a critical mass of interdisciplinary researchers", is most popular, over 45% thought it crucial, and another 40% important. "To gain access to unique equipment and facilities" ranked second, followed by "To set up networks of experts around emerging themes in nanotechnology".

While most respondents appear to be viewing infrastructure from the viewpoint of academic research, a good majority also wants new infrastructure "to reduce the time-to-market from R&D to products", or "to establish private-public partnerships". These aims are more focused at technology transfer to industry and SMEs, and the uptake of nanotechnology in real products. As can be expected, the 373 respondents working in University/Higher Education institutes or public research centres were less interested in time to market reduction and private-public partnerships. The 167 respondents from large and small commercial organisations found time to market reduction most important, closely followed by the mobilisation of a critical mass of researchers.

Which issues are important for nanotechnology R&D infrastructure?

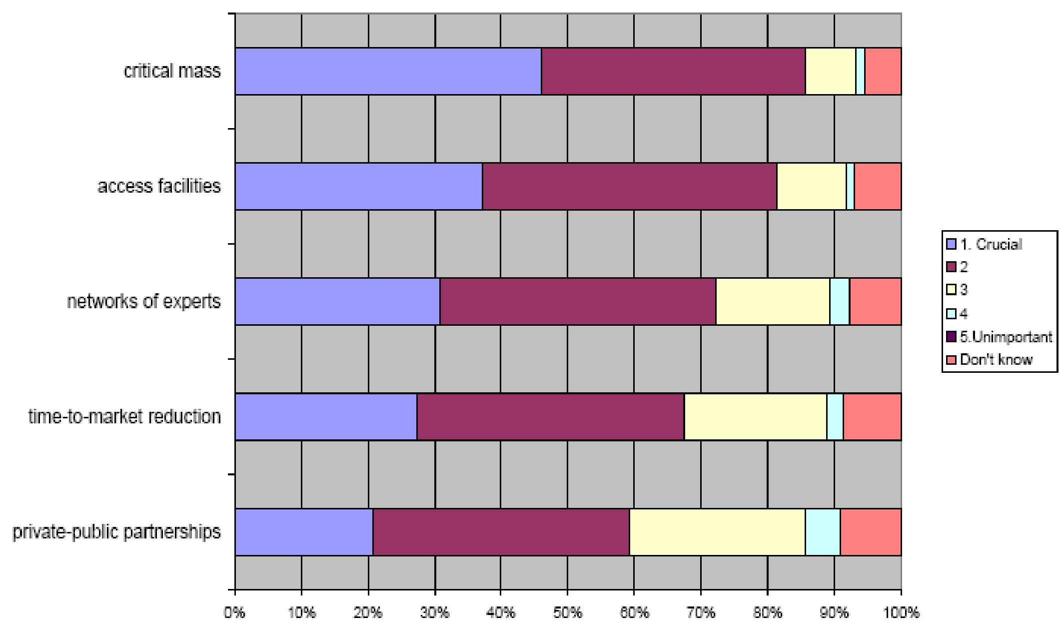

Figure 15: Ranking of the importance of issues for nanotechnology R&D infrastructure according to respondents in commercial organisations.

Access to facilities ranked third and the establishment of private-public partnerships and networks of experts followed last. It is clear that there is more interest in R&D infrastructure relevant for technology transfer to large and small companies among commercial people, than among public sector researchers. To conclude the section on infrastructures, we asked the open question: "Please indicate technological areas and market sectors, for which new nanotechnology-oriented infrastructure is needed, if any. How might these be addressed at European level?" Several technological areas and market sectors were mentioned. These were related to:

- Health/medical (83), - Materials (78), - IT/electronics (77),
- Manufacturing and Instrumentation (31),
- comments on priorities in FP7 (31), - Bio(techno)logy (29),
- Energy (27), - Environmental (19), - Transport (16)
- Chemical (16), - Risk assessment (13), - Telecommunication (13)
- Metrology (11) - Defence (6), - SMEs (6), - Technology transfer (1),
- Construction (4), - Agro food (3), - Consumers (4), - Ethics and science communication (5), - Finance (1), - Optics (1).

In general, there were many comments in favour of new infrastructure, giving suggestions on organisational issues for future European research activities. These include:

- The introduction of any new nanotechnology-oriented infrastructure must ensure that it is easily accessible and responsive to industrial needs, helps to accelerate the R&D process, and reduces time to market. Business intensification is a crucial if European companies are to engender innovative enterprise, and beat the competition at delivering products/processes to the market place.

- Infrastructure is important but some fields do not require the same infrastructure as others. Some require clean rooms while others large computer connections. The policies implications are very different.
- Advancement could be achieved by creating European (Intra-national) Centres of Excellence, which include both basic and applied research capabilities and experts, with a high interaction level and access to direct implementation of basic research into small scale pilot/ testing programs. Such Centres could be funded and coordinated in collaboration with private European partners capable to apply in relatively short time the results of R&D first in small production lines, followed by mass production and distribution.
- Set up hub-and-spoke networks in individual countries that give rapid access to experts and facilities and then network the hubs at a European level.
- Big European Centres are good for the strength of some regions however the added value of these centres are stopped in their region, for that it is necessary to create smaller regional or national R&D centres.
- The interdisciplinary approach of nanotechnology needs scientist from all different disciplines to work together from the start. This cannot be provided on a standard university level. Institutes for integrated nanosciences should be necessary.

- Set up clearly identifiable centres of excellence within Europe which are networked together through projects. (and not connected for the sake of coordination) It must be project driven.
- Infrastructure is needed for university research groups in the fields of biomedical engineering and development of medical sensors/diagnostic devices. On the European-level, additional travel expenditures on a single journey base could provide valuable support.
- Development of mimickers of biological tissue in a European data bank to be used for implants.

The following comments related to the organisation of nanotechnology for **IT** applications at EU level:

- Interdisciplinarity and project-oriented approach are key. See US "Nanotechnology Initiative" (nano.gov) / NSF as a model. Huge need for Private/public partnerships (ex: CNRT label in France, to develop exchanges between public basic research and private applied research in an attractive manner for students/researchers), and clusters (both network of excellence + SME/industries & investment funds)
- Networking regional nodes with pronounced and successful nanotechnology R&D and possibly industrial transfer.
- For basic research of non-silicon based Nanoelectronics and Nanoelectronic hybrids for Microelectronics. They might be

addressed as service centers at national level for equipment and technology (like in the US).

Some respondents asked for infrastructure for more fundamental Research in IT:

- Nanoelectronics will require increasing investments in infrastructures. Alternative technologies could benefit from common infrastructures to help synergy among researchers.
- Europe should aim for a few large nodes in nanoelectronics (LETI, IMEC) surrounded by a limited number of high-quality university labs.
- Molecular electronics the infrastructure needed is mostly new lithography methods at the nanoscale and analysis techniques like HRTEM. International cooperation should be increased with ``new instruments" which could complement the NoE.
- Information processing and storage -the silicon-to-carbon interface: interaction between micro/nanoelectronics and the human body -micro/nanosensors and actuators in the widest meaning -addressing should be done in concerted actions between leading universities, institutes and the industry.

Respondents highlighted the need for infrastructure to enable **environmental** applications of nanotechnology for remediation and environmental protection (e.g. in the domestic environment). Regarding organisation of this infrastructure, they asked for “Support for SMEs in the field’, and someone thought that these issues “could be best addressed by small STREPs.”. A topic for such new infrastructure could be “Environment protection by substituting more and more macro technologies with well designed nano ones.”

The following comments related to the organisation of **nanobiotechnology** applications at EU level:

- In general nanobiotechnology is a true multidisciplinary area that requires the non traditional grouping of biologists, chemists, physics, etc.
- The infrastructure’s administrative centre should be located at a specific research centre where major resources should be delivered. In addition the structure should include a net of satellite labs in different countries and a programme of mobility for those researchers adhering to the initiative.

Comments on topics that require new **nanobiotechnology** infrastructure at European level include:

- Nanobiotechnology basics
- Medicine and Biology need centres that coordinate systems biology and computational biology approaches. One kind of European support centres should be "Nanosystems Biology" that focuses on novel (nano) techniques required for systems biology
- Pan-European centre for biological samples examination and manipulation - using the most advanced instruments and expertise. This could be achieved with the collaboration with the manufacturers who clearly have an interest in it.

- In the area of nanobiotechnology a lasting infrastructure is needed to ensure a critical mass in interdisciplinary research.
- Infrastructure for nanotechnology for **chemical industry/ chemistry** should focus on:

  Catalysis - Filtration - Surface chemistry

  Nanochemistry - Self assembly

The following comments dealt with technological topics of infrastructure for **chemistry**:

- More fundamental understanding of catalyst structures and catalysis mechanism in chemistry is essential. The use of molecular modelling for the design of catalyst molecules is paramount important and needs to be better addressed at a European level
- Surface chemistry groups integrated with biological / biochemical / cell biological groups. This can be achieved by providing support for specific local collaborative projects and expanding those that prove successful.
- Self - assembly of materials fabrication of micromechanical/nanomechanical probes handling and manipulation on the 1-10nm scale.

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IV.

NANOTECHNOLOGY :

RISK ANALYSIS-I

IV. Nanotechnology : Risk Analysis-i

Asbestos, PCBs and other “wonder” products were once hailed for their benefits. Decades later, the claims for environmental cleanup and for personal injuries are enormous. For asbestos alone, experts estimate that pending and already-paid claims will cost industry $265 billion. Already, these claims and payments have contributed to the bankruptcy of over 70 companies. For the plaintiffs’ bar and environmental activists, pursuing these companies has been a cottage industry. The same excitement that surrounded the introduction of asbestos and PCBs now surrounds the introduction of nanotechnology. Yet, once again, some scientists are issuing warnings about potential environmental and health impacts – warnings that are eerily similar to earlier questions about asbestos and PCBs. If the past could be prologue, is it time to consider some type of nanotechnology liability protection plan?

Nanotechnology involves creating or improving products by manipulating molecules and atoms. The U.S. National Nanotechnology Initiative defined nanotechnology as using matter sized “at dimensions of roughly 1 to 100 nanometers.” One nanometer is one billionth of a meter, about a thousand times smaller than a red blood cell. A single human hair is 80,000 nanometers wide. Society is already seeing the benefits of nanotechnology as nanoparticles are incorporated into a broad spectrum of products to improve their performance. For example,

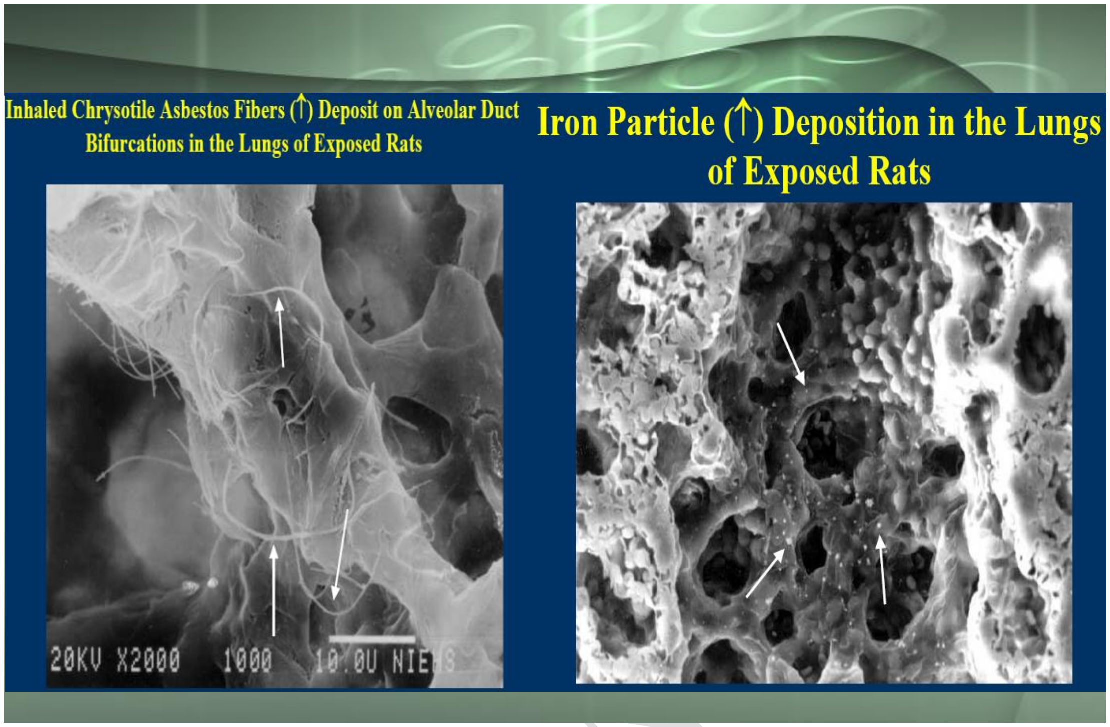

Fig. 16. Asbestos and Iron Particles' Deposits in the Lungs of Exposed Rats

nanotechnology is now being used in electronic products, pharmaceutical products, medical equipment, cameras, sunscreens, razor blades, clothing, product coatings, cosmetics, sports equipment, car products, and food packaging. Nanosized particles have been developed which decrease diesel fuel emissions. Other nanoparticles make hazardous waste cleanups more effective by removing contaminants from soil and groundwater.

Pants, made stain resistant by nanoparticles, are being marketed. Some car manufacturers are using nanotechnology to make exterior plastic parts and paint more durable. Carbon nanotubes, an elongated nanoproduct, are valued because they are among the strongest materials

Fig.17. Some Nanoproducts sold in market.

known to exist. Altogether, nanotechnology is used in about 700 products manufactured at about 800 facilities in the U.S. alone. It is estimated that $32 billion in products containing nanomaterials were sold in 2005.

According to the National Science Foundation, global sales of nanomaterials could exceed $1 trillion within ten years. Some observers place that number at over $2.5 trillion. Looking toward the future, hundreds of research projects are underway. In the agriculture sector alone, there is extensive research into using nanotechnology for food packaging and pathogen suppression. Research on reducing agricultural waste and runoff also shows promise. Some experts see a nanotech food market of $20 billion in the next four years. In the energy sector, researchers are exploring nanofluids which improve heat transfer rates, thereby improving the efficiency of home water heaters and central heating systems. Other researches have developed nanobased filtration membranes that might curb harmful power plant emissions.

Although nanotechnology is ripe with promise and potential, some researchers are raising cautionary flags, finding that nanoparticles, because of their size and configuration, may behave differently than larger particles of the same substance.

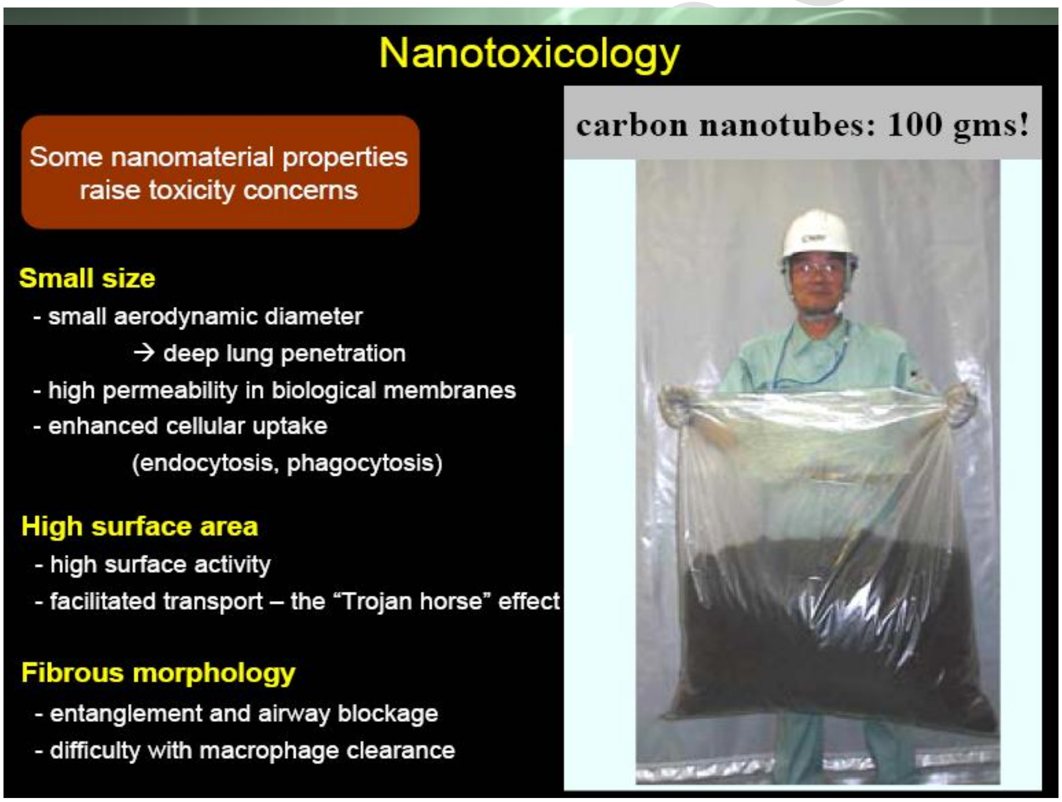

Fig.18. Nanotoxicology

For example, in September 21, 2006 testimony before the House of Representatives' Committee on Science, representatives of the National

Science Foundation noted that gold is a well known, oft used inert substance. But, on a nanoscale, gold behaves differently. Its color changes to a striking red, and under certain circumstances, it may be very reactive, may penetrate the brain/blood barrier, and may enter cells. On the other hand, the Environmental Protection Agency recently reviewed fifteen chemicals produced on a nanoscale and found that only one had unique properties causing it to act differently than the larger form of the same chemical. However, certain nanoparticles are specially engineered and have no bulk equivalent.

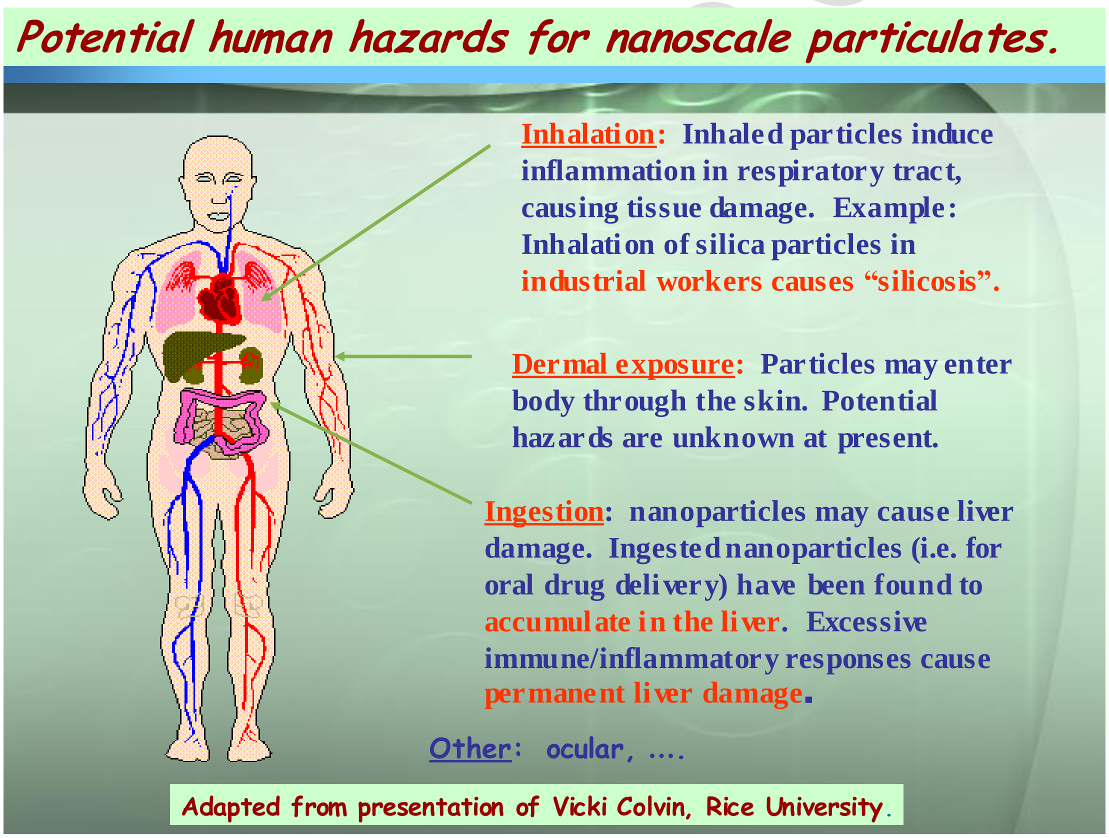

Fig. 19. Potential Hazards for Nanoparticles.

Some laboratory studies have shown certain carbon-based nanomaterials cause inflammation and damage kidneys, livers and spleens in lab animals. Sometimes the damage was fatal. Agricultural researchers found some nanoparticles can stunt plant growth and cause cells to die.

Other researchers have found that chemicals in sunscreens biologically accumulate in fish and questions are now being raised as to whether nanoparticles in sunscreens which increase the absorption rate also increase bioaccumulation rates. Some researchers say the minute size of nanoparticles makes it easier for those particles to penetrate cells and to evade host defenses. Other researchers suggest the nanomaterial itself may be benign but, given its size and configuration, may catalyze other chemical reactions which may be harmful.

While these studies do not prove that problems exist, they suggest the possibility. Largely because of that possibility, everyone agrees we need to know more about the behavior and effects of nanoparticles. Because of the uncertainty about the effect of nanoparticles, there is a steadily rising chorus of calls for more research. In 2003, the Nanotechnology Environmental and Health Implications Working Group was established within the Federal government. The National Science Foundation is spending about $25 million annually to assess the environmental health and safety implications of nanotechnology.

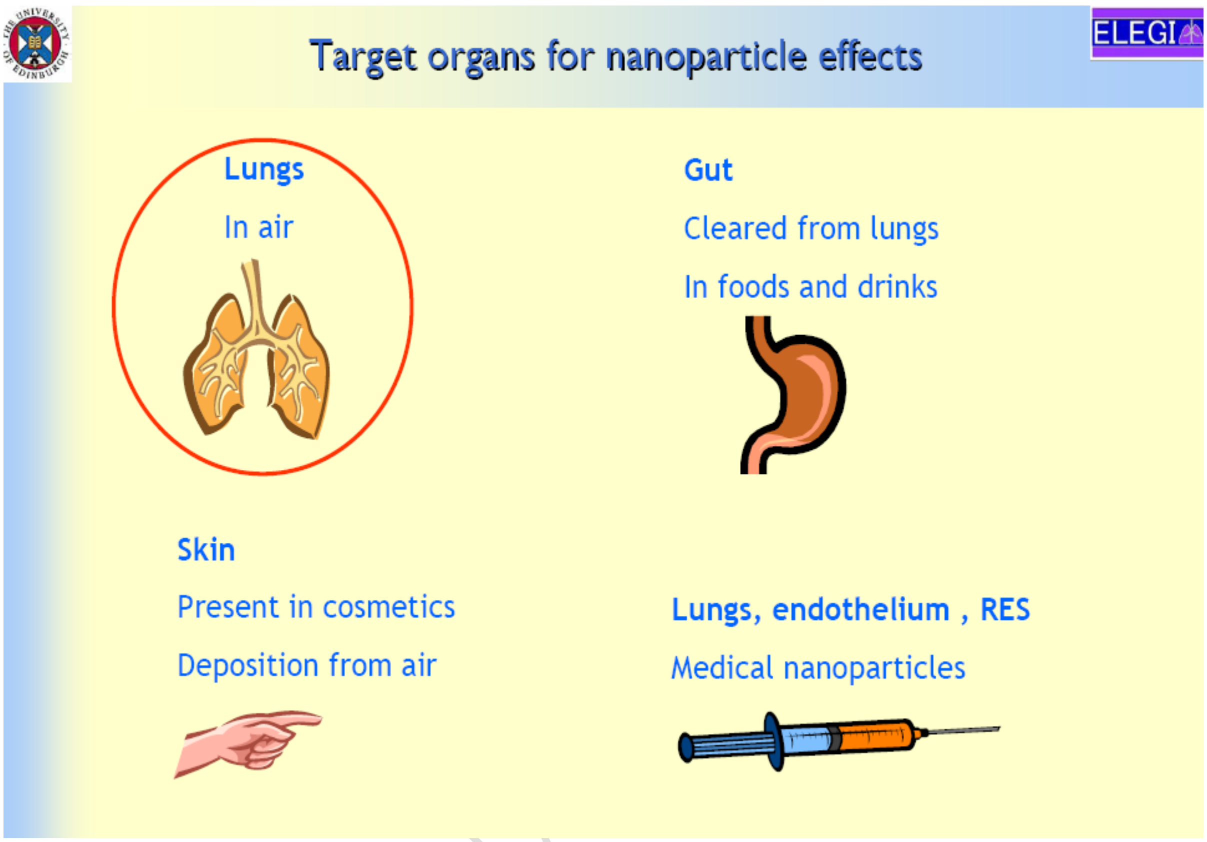

Fig.20.Target Organs for Nanoparticle effects

As more research dollars are spent, and as time passes, the answers about whether nanotechnology presents environmental or health concerns will come. However, some groups have already concluded that nanoparticles may be a threat. In 2006, Friends of the Earth called for a ban on the use of nanoparticles in sunscreens, calling the purchasers of these products human guinea pigs. Although no one can predict the future, the April 8, 2006 edition of *The Washington Post* contained an article by a reporter who toured a nanotechnology plant to observe production methods. The *Post* reported that from a production standpoint the future looks much like the past.

Workers were seen walking atop two-story spray and drying machines while forklift operators and other workers wrestled 55-gallon chemical drums into place. Workers with face masks were reported to be covered by a film of dust. If studies ultimately find adverse environmental and health impacts from some or all applications of nanotechnology, fixing the problem will not be easy, or inexpensive. Nanoparticles, once in the environment, will prove very difficult to remove because of their size and durability, particularly if they enter and accumulate in the human body. If nanoparticles become the next asbestos or PCB-like crisis, the cost to industry will be huge. In fact, some observers are already pointing to decisions by smaller companies, and even some larger companies, to not pursue nanotechnology because these companies do not want to be exposed to nanotech liability if potential risks become actual problems.

Other companies have been reluctant to pursue nanotechnology because they lack the resources to undertake expensive toxicity and safety tests, without which they fear they cannot guard against potential liabilities.

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.

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.

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;
To 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
to 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).

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.

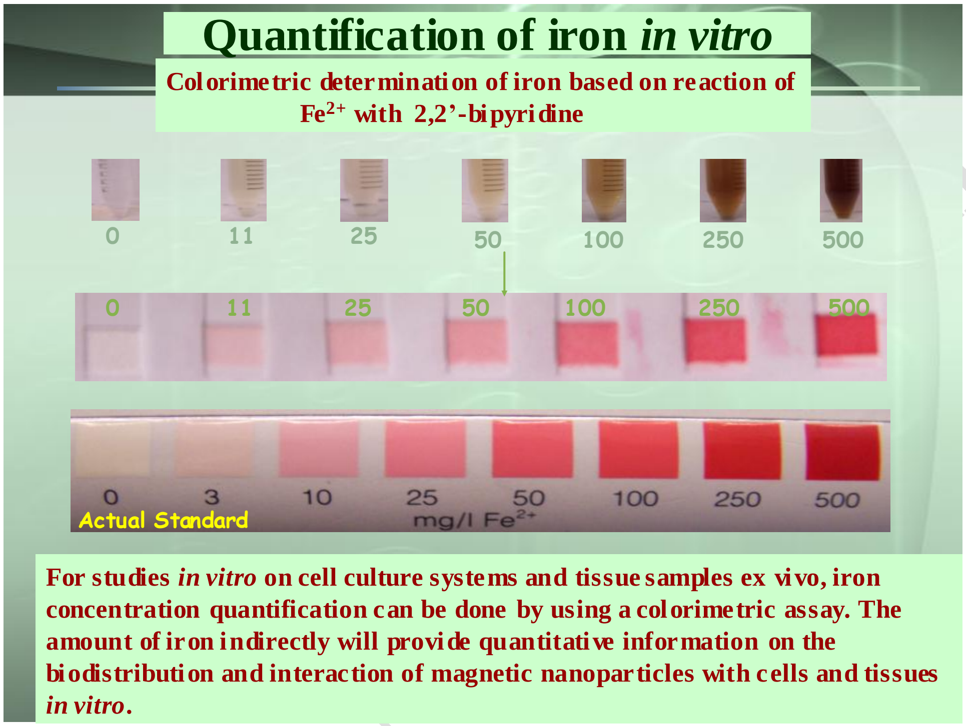

Fig.21. Quantification of Iron in vitro

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.

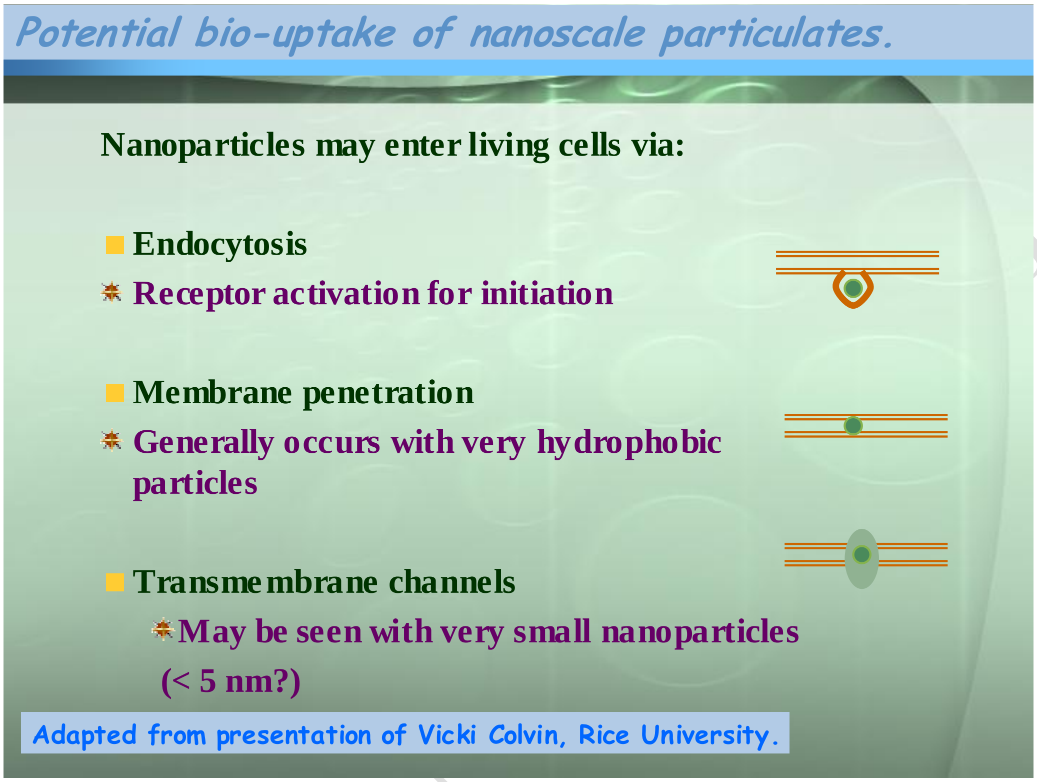

Fig.22. Potential bio-uptake of Nanoparticles.

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, It is recommended 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.

Fig.23. E-Wastes.

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.

Fig.24. Environmental Pollution

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 individualized 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 willtherefore 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.

V. NANOTECHNOLOGY

RISK ANALYSIS-II

IV. NANOTECHNOLOGY : RISK ANALYSIS-II

Health and environmental impacts

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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 it has been recommended 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. It is not expected this to apply to many manufacturers since common understanding is that nanoparticles of zinc oxide are not used extensively in cosmetics in Europe. Based on the recommendation chemicals produced in the form of nanoparticles should be treated as new chemicals, 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 it is recommended 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 it is unlikely to think that nanoparticles or nanotubes will be released from most materials in which they have been fixed, but any risk of such release being greatest during disposal, destruction or recycling.

It is therefore recommended 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.

The review of regulation has not been exhaustive and therefore all relevant regulatory bodies consider whether existing regulations are appropriate to protect humans and the environment from the hazards which have been 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, no case is found 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

- Recommendations are made 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.

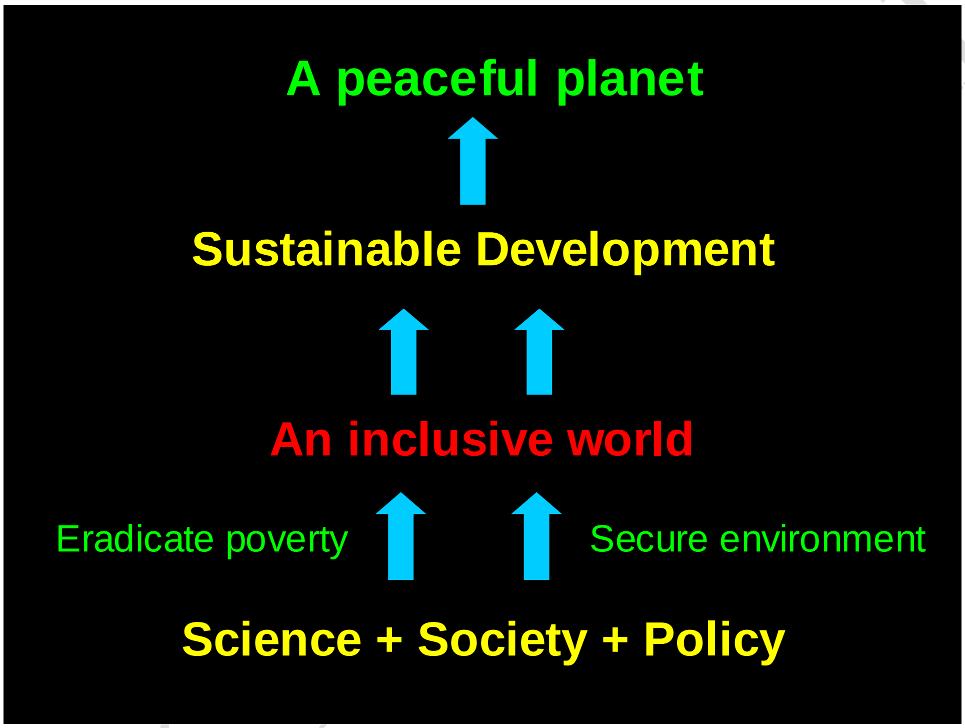

Fig.25. What we need ?

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.

- It is recommended 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,

- Recommendations are made 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.

- It is recommended 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.

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Abbreviations / Glossary AICS Australian Inventory of Chemical Substances DNA Deoxyribonucleic acid Nano 1 part in 109 or one thousand million Nanometre one thousand-millionth of a metre NICNAS National Industrial Chemicals Notification and Assessment Scheme OECD Organisation for Economic Cooperation and Development PMSEIC Prime Minister's Science, Engineering and

Innovation Council USEPA United States Environmental Protection Agency UV Ultraviolet

23] Further information on nanotechnology in Australia can be obtained by contacting the National Nanotechnology Strategy Taskforce at nano@industry.gov.au, or by visiting the Taskforce website at: http://www.industry.gov.au/nano Invest Australia maintains information on Australian nanotechnology capacity at: http://www.investaustralia.gov.au/index.cfm?menuid=0DA5E4E7-B0D0-36D2-5C0BF55FC0AAA99D&setLanguage=AU

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