Environmental, Social, Legal and Ethical Aspects

of

The Development of Nanotechnologies in Australia

A Report from the National Academies Forum

for

The National Nanotechnology Strategy Taskforce

Department of Industry, Tourism and Resources

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April 2006

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April 2006

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Executive Summary

In March 2005 the Prime Minister's Science, Engineering and Innovation Council received a comprehensive report on nanotechnology. Following the acceptance of the PMSEIC Report, the Australian Department of Industry Tourism and Resources established a National Nanotechnology Strategy Taskforce to develop options for a National Nanotechnology Strategy. In the present study, the National Nanotechnology Strategy Taskforce commissioned the National Academies Forum (through the Australian Academy of Technological Sciences and Engineering) to provide their expert opinions on the environmental, social, legal and ethical issues associated with nanotechnologies and to scope a strategic framework for analysis of real and perceived risks.

In the development of the study, the strategic framework for risk analysis that was used involved the following steps:

- Identification of the opportunities for application of science and technology at the nanometer scale. These arise from molecular engineering inspired by biotechnology, electronic technology based on semiconductors, and devices and processes based on new materials;
- Identification and characterisation of hazards of nanomaterials. This involves an analysis of the available data on toxicological properties of nanomaterials, particularly in the form of nanoparticles which are of the same scale as cellular components and larger proteins;
- Identification of the opportunities for exposure in nanotechnologies involving the production, use and disposal of nanomaterials and of devices involving nanomaterials. These were considered for nanoelectronic and nanophotonics, nanobiotechnology, nanomedicine and nanomaterials;
- Combination of these enables a characterisation of real risk posed to human health and the environment. This varies for the type, composition and form of a nanomaterial and its application; and
- In addition to real risks there are perceived risks which arise from the perceptions of society of the potential dangers associated with nanotechnologies and their applications. These were analysed by considering social acceptance and the need for public debate of the ethical, social and legal aspects of nanotechnologies.

Based on a study of the literature a Position Paper was prepared by the Study Leader (Professor G Tegart) in January 2006 for a Steering Committee drawn from the four Academies. After discussion of the Paper, two workshops were held in Sydney and Melbourne in February 2006. These involved Fellows of the Academies and experts nominated by the Academies. The conclusions of these workshops were incorporated into a paper which was then further discussed by the Steering Committee. Discussions were also held with experts from industry and governments.

Based on the study, and as detailed in this report, the Academies formed a number of opinions; these are listed below:

> *The opinion of the Academies is that there is an urgent need to clarify the nomenclature of the topic, from the viewpoint of communication between industry, society and policymakers, particularly on issues of risk. Further, Australia should be strongly involved in international standards activities to protect its interests. (Section 2.1)*
>
> *The opinion of the Academies is that Australia has particular research strengths in nanoelectronics, nanobiotechnology, nanomedicine and nanomaterials and that these need to be at least maintained to give Australia a competitive edge in global science and technology and thus minimise the risk of losing out on the potential benefits of nanotechnologies. (Section 2.2)*

The opinion of the Academies is that nanotechnologies could significantly change a number of industry sectors in Australia such as medicine, energy, water and manufacturing and that strategic planning is needed to manage economic risks and to optimise benefits. (Section 3.2)

The opinion of the Academies is that, while no serious risk is evident at present, potential real risks in the use of nanotechnologies in Australia must be identified so that appropriate risk management strategies can be employed for their safe use. (Section 4.2)

The opinion of the Academies is that nanoelectronics and nanophotonics present little risk in fabrication and use, but regulations for disposal should be examined should nanocomposites and new nanomaterials be used in future equipment and packaging. (Section 5.1)

The opinion of the Academies is that, while risks are generally low, some nanobiotechnology products have the potential to present risks to the environment, and hence to humans and animals. Regulatory agencies need to assess these risks and, if necessary as advocated in the RS/RAE report, limit the use of engineered nanoparticles in environmental applications such as soil remediation until research is undertaken to demonstrate that potential benefits outweigh potential risks. (Section 5.2)

The opinion of the Academies is that, in nanomedicine, the risks are low given that the existing approval and regulation procedures for pharmaceuticals and cosmetic products provide adequate protection for product development and use. However these procedures need to be monitored at regular intervals as new nanoproducts that may challenge the system are developed. (Section 5.3)

The opinion of the Academies is that there appear to be sufficient effective indicators to enable adequate precautions to be taken and to allow production of nanomaterials to go ahead. However, as a basis for continued risk management, there is a need for more detailed information on aspects of nanoparticle production, application and disposal, and on toxicity of nanoparticles to humans when inhaled, ingested or applied to the skin, and on toxicity in the environment stemming from contamination of soils and water supplies. (Section 5.4)

The opinion of the Academies is that medical scientists and bioethicists in Australia need to include in their studies the benefits and risks associated with applications of nanomedicine with a view to enhancing the quality of health care. (Section 6.1)

The opinion of the Academies is that many of the privacy and personal data issues associated with nanotechnologies are not new but will be intensified by their applications. Those issues unique to nanotechnologies which present perceived risks to society need to be identified and managed. (Section 6.2)

The opinion of the Academies is that the potential security risks to Australia presented by misuse of nanotechnologies need to be examined by appropriate agencies. (Section 6.4)

The opinion of the Academies is that, in addition to maintaining their strong links with researchers and markets in Europe and the US, researchers and industries in Australia need to be aware of the development and applications of nanotechnologies in the Asia-Pacific region. (Section 6.5)

The opinion of the Academies is that more attention needs to be paid in Australia to the open public communication of a clear understanding of the possibilities and limitations of nanotechnologies. It is important that researchers in the social and physical sciences engage in dialogue with the community about these emerging technologies and the associated risks. (Section 7.)

1. Background

Nanotechnology is the term given to those areas of science and engineering where phenomena that take place at dimensions in the nanoscale (a nanometer is one billionth of a metre) are utilised in the design, characterization, production and application of materials, structures, devices and systems. Although many technologies have incidentally involved nanoscale structures for many years, it is only in the past two decades that it has been possible to actively and intentionally modify molecules and structures within this size range.

Nanotechnology is increasingly being recognised in Australia as a key emerging technology that will have wide ranging industry and social impacts. Australia has significant research capacity and infrastructure with some 70 public sector research groups and some 50 nanofocussed firms. National research networks in nanotechnology and advanced materials have been formed. Post-graduate and undergraduate courses in nanotechnology and nanoscience have been established in a number of universities. Mainstream industries such as chemical and mining are becoming increasingly aware of the potential of nanotechnology while a nanobusiness network is being created.

In March 2005 the Prime Minister's Science, Engineering and Innovation Council received a comprehensive report on nanotechnology (PMSEIC 2005). The report indicated that total public and private sector R&D investment was estimated at over A$100 million in 2003. It continues to increase rapidly. Research strengths were identified as being in the energy, environmental, electronics, mining and medical applications of nanotechnology.

Following the acceptance of the PMSEIC Report, the Australian Department of Industry Tourism and Resources established a National Nanotechnology Taskforce to develop options for a National Nanotechnology Strategy. The Strategy will look at issues such as science capacity, industry development, health, safety and environment, metrology and standards, infrastructure and public engagement. The Taskforce is working with other Government portfolios and with the States and Territories to develop a Strategy by June 2006. A key theme of the Strategy will be to ensure that Australia engages in international studies and activities designed to support the development of nanotechnology. Thus Australia participated in the inaugural meeting of International Standards Organization TC 229 Nanotechnologies in London on the 20 November 2005 and Standards Australia has formed an Australian committee to liaise with ISO.

However, just as phenomena occurring at the nanoscale may be quite different to those at larger dimensions and thus exploitable for the benefit of mankind, so nanoscale processes and products may expose humans and the environment to new risks and raise new environmental, social, legal and ethical issues. Attention has been focused on the fate of free nanoparticles generated in production and either intentionally or unintentionally released into the environment or actually delivered directly to individuals through the use of a nanotechnology-based product. The PMSEIC report noted that: "There are unknown health risks associated with some types of nanopowders and the OH&S (Occupational Health and Safety) and chemical safety regulations will have to be examined to ensure that they remain effective."

In general, whenever the potential for an entirely new risk is identified it is necessary to carry out an extensive analysis of that risk which can then be used in the processes of risk management. In the present study the National Nanotechnology Taskforce has commissioned the National Academies Forum (through the Australian Academy of Technological Sciences and Engineering) to provide their expert opinions on the environmental, social, legal and ethical issues associated with nanotechnologies and to scope a strategic framework for analysis of real and perceived risks. The conduct of the study is described in Appendix A.

2. Introduction

2.1 Science and Technology at the Nanoscale

There are numerous definitions in the literature which cover science and technology at the nanoscale. Thus the report of the Royal Society/Royal Academy of Engineering in the UK (RS/RAE 2004) has the following definitions:

> *Nanoscience is the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale.*
>
> *Nanotechnologies are the design, characterisation, production and application of structures, devices and systems by controlling shape and size at nanometer levels.*

These concepts of understanding and application are mirrored in the definition adopted by ISO/TC 229 as the scope of its activities:

Standardisation in the field of *nanotechnologies* that includes *either or both* of the following:

1 Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nm in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications.

2 Utilising the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices and systems that exploit these new properties.

The activities of this ISO Committee will be extremely important in determining the course of global development of nanotechnologies.

The PMSEIC report does not distinguish between nanoscience and nanotechnologies and has a simpler definition as:

Nanotechnology is engineering at the molecular (groups of atoms) level. It is the collective term for a range of technologies, techniques and processes that involve the manipulation of matter at the smallest scale (from 1 to 100 nm).

The significant feature from both approaches is that nanotechnology is a set of tools and processes for manipulating matter at the nanometer level which can be applied to any manufactured product. There is considerable confusion over the concept of a nanotechnology industry. It needs to be stressed at all levels that there is no discrete nanotechnology industry but a set of different industry sectors, each with its discrete set of issues, particularly those relating to real and perceived risks. However there are linkages between them which need to be considered, particularly in the production and use of nanomaterials.

> **The opinion of the Academies is that there is an urgent need to clarify the nomenclature of the topic, from the viewpoint of communication between industry, society and policymakers, particularly on issues of risk. Further, Australia should be strongly involved in international standards activities to protect its interests.**

2.2 Opportunities for Applications of Science and Technology at the Nanoscale

The opportunities can be divided into three main categories:

Molecular engineering inspired by biotechnology

This covers several sectors; firstly, nanobiotechnology and nanomedicine and, secondly, molecular manufacturing. In the first group of *nanobiotechnology* and *nanomedicine*, the scale of living systems involved is in the range from micrometers down to nanometers and it is possible to combine biological units such as enzymes with manmade nanostructures. One of the most significant impacts of nanotechnology is at the bioinorganic materials interface. By combining enzymes and silicon chips it is possible to produce biosensors. These can be implanted in humans or animals to monitor health and to deliver corrective doses of drugs. They have the potential to produce improved health care for humans at lower cost and to improve animal productivity. Development of human biomedical replacements such as artificial skin, smart bandages, pacemakers, etc is also dependent on nanotechnology.

In the longer term there is a vision of making robotic machines, called assemblers, on a molecular scale, that are capable of constructing materials an atom or a molecule at a time by precisely placing reactive groups. This could lead to creation of new substances not found in nature- so-called *molecular manufacturing*. Because the prospect is remote there is little point in discussing risk. However there is the enormous potential for understanding how self-replicating structures with exceptional properties are produced in nature – so-called *biomimetic engineering*.

Electronic technology based in semiconductors

This covers the sectors of *nanoelectronics, nanophotonics* and *quantum computing*. There is potential to increase the capacity of microchips up to 1 billion bits of information per chip. However, the costs of production are increasing dramatically and there is intense study around the world to determine the point in physical scaling where it either becomes physically unfeasible or financially unattractive to continue the trend towards reducing the size and increasing the complexity of microchips. At a size less than about 50 nm particles begin to follow the laws of quantum physics rather than classical physics and properties such as magnetism and electric charge change rapidly. Nanoscale structures such as quantum dots offer a path to a new type of computer – the so-called quantum computer. There is extensive research on the fabrication of electronic structures on the nanometer scale based on entirely new physics. Devices under development include lasers for optoelectronics, ultrafast switches, memory storage devices for computers and, ultimately, devices controlled by single electron events.

Devices and processes based on new materials

Creative materials and surface science is critical to further advancement of nanotechnologies. One of the interesting properties of particles of materials such as metals or ceramics at the nanometer size level is their very high surface area per unit volume which has potential for speeding-up catalytic reactions and biochemical and pharmaceutical separations, and thus improving the efficiency of many processes. Reduction in size to the nanoscale level results in an enormous increase of surface area, so that relatively more atoms or molecules are present on the surface, thus enhancing the intrinsic reactivity. The definition of nanoparticles as being less than 100nm is perhaps too simple since it does not take account of the dramatic size effects in the range below 100nm. For example, a particle of size 30nm has 5% of its atoms on its surface, at 10nm 20% of its atoms and at 3nm 50% of its atoms.

Nanomaterials can be produced from a variety of material classes as:
carbon-based nanomaterials, nanocomposites, metals and alloys, biological nanomaterials, nanopolymers, nanoglasses and nanoceramics. Each covers a wide range of different chemical compositions and of hazardous and non-hazardous forms. Some of these are manufactured and sold in bulk to intermediate companies making specialised products while others are manufactured as part of an integrated production process in the sectors noted above.

Most of the material classes can be produced in a variety of shapes as: nanoscale in one dimension e.g. thin films, layers and surfaces; nanoscale in two dimensions e.g. nanowires and nanotubes ; nanoscale in three dimensions e.g. nanoparticles of regular or irregular shape, fullerenes (spherical molecules about 1nm in diameter, comprising 60 carbon atoms arranged in a cage structure), dendrimers (polymeric molecules) and quantum dots (small nanoscale particles of semiconductors whose optical properties can be controlled by size). Such *nanomaterials* can be produced by either the 'bottom-up' approach, i.e. building-up from individual atoms or molecules, or the 'top-down' approach, i.e. breaking-up bulk materials into nanoparticles. These are discussed in more detail in Section 5.4.

> **The opinion of the Academies is that Australia has particular research strengths in nanoelectronics, nanobiotechnology, nanomedicine and nanomaterials and that these need to be at least maintained to give Australia a competitive edge in global science and technology and thus minimise the risk of losing out on the potential benefits of nanotechnologies.**

3. Applications of Nanotechnologies

3.1 Global Markets

Products based on nanotechnologies are already widely used, e.g. paints, pharmaceuticals, microelectronic devices and composite materials, and the global market is estimated to be worth over US $40 billion. Rapid market growth in these and new areas is anticipated, possibly to US$1 trillion by 2015-2020. Various estimates are available, on different bases, about the likely future global markets for products using nanotechnologies. However it is meaningless to refer to a discrete set of markets, because nanotechnologies can potentially impact on virtually every industry sector and their products, in different ways and at different times. The overall impact will be massive but almost impossible to quantify at this early stage. There will be significant changes to existing industries and new industries will be created. As a result there will be a need for workers with new skills and changes in delivery of services such as health. This process could be disruptive to society depending on the rate of change and its management.

It is possible to look at specific areas and make some estimates of markets based on products that directly and centrally depend on nanotechnologies. The seven largest areas of current demand are: IT peripherals, medical and biomedical applications, automotive and industrial equipment, telecommunications, process control, environmental monitoring and household products.

Three opportunity areas where industry analysts have examined trends are nanoelectronics, nanobiotechnology and nanostructured materials (CSES 2003). In the area of *nanoelectronics*, coatings, particularly for hard magnetic disc drives, are currently around US$24 billion and this could grow substantially in the future. Much depends on the technology developed for sub-100 nm feature sizes for semiconductors. Current devices are approaching the limit for existing technologies. The market for semiconductors, currently about US$140 billion is expected to reach US$ 300 billion in 3 to 4 years. Nanotechnology is anticipated to contribute about US$300 billion to the electronics industry by 2015. In the area of *nanobiotechnology*, about half of all pharmaceutical production (about US$180 billion) is expected to depend on nanotechnologies e.g. microarrays for drug assays and nanomaterials for drug delivery. The market for medical devices and biomedical materials based on nanotechnologies is expected to double in the next 3 years to about US$1 billion and then continue rapid growth. *Nanostructured materials* currently make up a substantial proportion of the global markets for such products (roughly 25 to 20 per cent). Catalysts, for which the market is roughly US$30 billion, are expected to increase to US$100 billion by 2015. Nanoparticles and composites in manufacturing, currently around US$13 billion, are expected to increase toUS$30 billion by 2008.

As noted above there are linkages between these sectors, particularly in nanomaterials. It is instructive to examine estimated production rates of nanomaterials to meet these potential markets. From published data (RS/RAE 2004), these are listed in the table below.

For other products such as skin care, instruments and sensors, and environmental products such as membranes and filters, quantities similar to those for nanoelectronics will be needed. While these appear to be large quantities, they can be put in perspective by noting that the global production rate of all chemicals is about 400 million tonnes/annum so that nanomaterials are thus a fraction of the total currently produced.

Application	Material/Device	Estimated Production Rates (tonnes/annum)		
		Present	2005-2010	2011-2020
Nanoelectronics	Nanotubes, optoelectro materials, organic light emitting diodes	10	10^2	10^3 or more
Nanobiotechnology	Drug delivery, biocompatible quantum dots, biosensors	less than 1	1	10
Structural	Ceramics, catalysts, coatings, thin films, powders, metals	10	10^3	10^4-10^5

3.2 Applications in Australia

Five industry sectors where Australia has significant opportunities based on the applications of nanotechnologies to established industries are: minerals and agribusinesses; medical devices and health; energy and environment; advanced materials and manufacturing; electronics and information and communications technologies (PMSEIC 2005). However, only a relatively small number of large traditional companies are using nanotechnology such as improved separation technologies for the mining industry, better agricultural waste management and food safety, and nanoparticle applications in catalysts and paint additives. These companies are users not drivers of nanotechnology and will assess whether nanotechnologies will present threats or opportunities to existing processes and products and respond accordingly, either by in-company technical development or contracting out. There are economic risks to Australia in not integrating nanotechnologies more widely into traditional industries.

A detailed list of opportunities for the use of nanotechnologies in Australia has not been compiled but an indication can be gained from the opportunities identified for industry in Victoria (CSES 2003). These can be summarised as:

- Human Health – delivery of health services and personalised medicine; health products such as diagnostic devices, drug discovery and delivery, prostheses, implants and other applications of biomaterials;
- Food and Agriculture – food production, food processing and packaging;
- Transport – automotive industry such as monitoring and control systems, composite materials to improve performance and reduce cost; aerospace industry such as materials technology, micromechanical systems, avionics and on-board diagnostics; shipbuilding;
- Energy and Mining – energy such as control systems, transmission and distribution, fuel cells, catalysts, solar cells; mining such as monitoring and control;
- Computing and Communications – thin films; microtechnology and microfabrication facilities;
- Environmental Industries – sensors, membrane filters and water treatment equipment, remediation, waste management;
- Chemicals and Materials – production of nanoparticles of metals, ceramics, polymers for sale to other sectors;
- Building and Construction – composites, sensors, special glass, solar energy systems; and
- Security and Defence – smart textiles, sensors for chemical and biological agents, light weight armour.

Many of these are being pursued in Australia through active research groups but there are concerns about the development of local industries based on this research. However, already there are a number of Australian nanofocussed companies with world leading positions such as Starpharma with dendrimers in drug delivery systems, Cap-XX with carbon nanoparticles in supercapacitors, and Advanced Technology and Micronisers with zinc oxide nanoparticles in sun screens (PMSEIC 2005). A critical factor in the development and application of Australian research outcomes is the creation of technology clusters with adequate infrastructure to enable prototyping of promising products.

> **The opinion of the Academies is that nanotechnologies could significantly change a number of industry sectors in Australia such as medicine, energy, water and manufacturing and that strategic planning is needed to manage economic risks and to optimise benefits.**

3.3 Factors Affecting Application of Nanotechnology Products

The nanotechnology value chain starts with nanomaterials (nanoscale structures in unprocessed form) which then become nanointermediates (intermediate products with nanoscale features) and finally nano-enabled products (finished goods incorporating nanotechnology). There are several factors that will influence whether nanotechnologies will be used routinely within industrial processes-some of these are economic or social, others are technical (RS/RAE 2004). Thus any new process or technology must show major economic benefits to the producer and added value to the consumer. Significant technical barriers stem from a lack of understanding of nanoscale properties and the ability to characterise and engineer them to form useful materials and products. Other barriers are those relating to regulation such as classification and standardization of nanomaterials and processes, and the management of any health, safety and environmental risks. The work of the International Standards Organisation is critical in these areas and active Australian participation in ISO is essential, as noted in Section 2.

4. Risk Aspects of Nanotechnologies

4.1 Risk Framework

As discussed earlier there are a number of nanotechnologies each with its own specific characteristics and its own real risks. *In considering real risks with nanotechnologies we are concerned with the risks posed to human health and the environment.* We need to consider these separately and identify where caution or regulation is needed. There is an Australian standard for risk management which has a general coverage from chemicals to business risk (Standards Australia, 2004). This employs a sequence of activities: risk identification, risk assessment, and risk management. In considering real risks in nanotechnologies we are concerned with the risks posed to human health and the environment. Simply stated:

hazard x exposure = risk.

However all three terms need explanation and definition.

Standard methods exist for assessing and managing such risks. They employ four steps. The first step is to *identify hazard* by answering the question "Is there reason to believe that this process or substance could be harmful to humans or the environment?" The second is to *characterise hazard*, by answering the question "How and under what conditions could it be harmful?" The third is to *assess exposure* by answering the question "How will people and the environment come into contact with this process or substance?" Only when these questions are answered is it possible to *characterise risk*. To conclude that high risk exists, a hazard must exist to which either humans or the environment are exposed in real world conditions.

In the development of the study a strategic framework for risk analysis was used which involved the following steps:

- Identification of the opportunities for application of science and technology at the nanometer scale. These arise from molecular engineering inspired by biotechnology, electronic technology based on semiconductors, and devices and processes based on new materials;
- Identification and characterisation of hazards of nanomaterials. This involves an analysis of the available data on toxicological properties of nanomaterials, particularly in the form of nanoparticles which are of the same scale as cellular components and larger proteins;
- Identification of the opportunities for exposure in nanotechnologies involving the production, use and disposal of nanomaterials and of devices involving nanomaterials. These were considered for nanoelectronic and nanophotonics, nanobiotechnology, nanomedicine and nanomaterials;
- Combination of these enables a characterisation of real risk posed to human health and the environment. This varies for the type, composition and form of a nanomaterial and its application; and
- In addition to real risks there are perceived risks which arise from the perceptions of society of the potential dangers associated with nanotechnologies and their applications. These were analysed by considering social acceptance and the need for public debate of the ethical, social and legal aspects of nanotechnologies.

4.2 Exposure Issues

Many applications of nanotechnologies introduce no new health, environmental or safety aspects, for example where the nanotechnology is in the scale of a node on a computer chip or of nanometer thin films on storage devices such as hard discs. The major concerns that have been expressed strongly in the literature and in political debate relate to nanomaterials, specifically nanoparticles. The fact that nanoparticles are of the same scale as cellular components and larger proteins has led to the suggestion that that they might evade the natural defences of humans and other species and damage cells. The health and safety issues related to nanomaterials are at an early phase and these are further discussed in Section 5.

It is important to recognise that nanomaterials in the form of nanoparticles are present naturally in the atmosphere and that humans have been in contact with them for centuries. Their concentration has increased in line with increased population and industrial activity. The amount of nanoparticles in the air can be surprisingly similar in urban and rural areas, with as much as 10^6 to 10^8 nanoparticles per litre of air depending on conditions. In rural areas, nanoparticles mostly originate from the oxidation of volatile compounds of biogenic or anthropogenic origin. In urban areas, the primary sources of these particles are diesel engines or cars with defective or cold catalytic converters. Photo-oxidation processes of organic vapours can also lead to nanoparticles.

Well known industrial processes produce large quantities of nanoscale materials e.g. synthesis of carbon black by flame pyrolysis produces a powdered form of carbon which is non-uniform but is in the size range of 100nm. Other similar industrial materials include fumed silica, ultrafine titanium dioxide and ultrafine metals such as nickel. Thermal spraying and coating, and welding can produce nanoscale materials as byproducts.

Because of this long industrial history of dealing with ultrafine particles, particle toxicology is a mature science that addresses the mechanism of lung injury by inhaled particles and there are extensive data on ultrafine particles of quartz, asbestos, air pollutants from diesel engines, titanium dioxide and carbon black. All of these can induce pulmonary inflammation, oxidative stress and fibrosis. It has been proposed that available data on ultrafine particles be used as informed, conservative proxies to establish precautionary measures in accord with well-established risk management practices to enable nanoproduct development to proceed but that more research is needed to cover the rapidly developing field of engineered nanomaterials (European Commission 2004, SCENHIR 2005, NIOSH 2005, Nordon and Holman 2005, Nel *et al* 2006).

Such ultrafine particles are usually heterogeneous in size, exist in single or aggregated form and often have a chemical structure consisting of a solid core made of either inorganic material or soot surrounded by a layer of adsorbed constituents. There is some concern that such ultrafine particles are different from the homogeneous composition and controlled size range of engineered nanoparticles, but the important factors of small particle size, chemical composition and the presence of a large reactive surface area are common features which determine their toxicity. Thus, for example, if a bulk material is toxic, nanoparticles of it are likely to be more toxic.

Likely current sources of exposure to engineered nanomaterials are:

- Occupational exposure in the workplace (human);
- Exposure from deliberate environmental releases e.g. remediation of contaminated groundwaters and land (environment and possibly human);
- Exposure from 'unintentional' environmental releases e.g. from fuel additives and in industrial and domestic waste streams (environment and human);
- Exposure from consumer products, such as cosmetics(human);
- Exposure from medical products, including drugs, treatments and devices (human); and
- Exposure during disposal of nanoengineered products e.g. release during breakup of nanocomposite materials (environment and human).

These can be categorised in various ways. Firstly, as accidental versus deliberate-in this case there is a need for careful regulation and monitoring at all stages of the value chain. Secondly, as free versus embodied – different regulations may be needed to deal with different circumstances. Thirdly, as environmental versus human concerns – again with differing regulations because of the diversity of species and ecosystems involved in the environment. In considering the form of such regulations it is necessary to examine the foreseeable risks involved (Morgan 2005).

The opinion of the Academies is that, while no serious risk is evident at present, potential real risks in the use of nanotechnologies in Australia must be identified so that appropriate risk management strategies can be employed for their safe use.

5. Real Risks of Specific Nanotechnologies

We will consider several nanotechnologies and their real risks through the value chain as: nanoelectronics and nanophotonics; nanobiotechnology; nanomedicine and nanomaterials.

5.1 Nanoelectronics and Nanophotonics

Identifying and characterising hazards. The information technology industry has been driven for the past 30 years by the need to produce cheaper and cheaper methods for processing, storing and transmitting information. By using silicon as a substrate it has been able to progressively increase the density of transistors on a silicon chip at a doubling rate of about every two years. This has meant the development of lithography, film deposition and etching techniques down to the nanoscale (currently around 65 nm). The technique is potentially capable of reaching 30 nm. Beyond that a switch to quantum computing will open new concepts of computing but much of the technology will be similar. Nanoelectronics draws on the long industry experience of handling of silicon and disposal of chemical wastes and poses low hazards. The use of materials other than silicon may require examination for hazards.

Identifying and characterising exposure. Consider first manufacturing. The fabrication processes for silicon chips and other components such as compact discs and hard drives require extreme standards of cleanliness to maintain quality. A similar high standard is needed for the materials used in the nanophotonics industry where photonic crystals are fabricated at the nanoscale using similar techniques. The industry has developed clean rooms and personal protection to very high standards and there is a very small possibility of accidental escape and worker exposure.

However, as other nanomaterials become used in the information technology industry the situation could change. Thus the use of carbon nanotubes in building field emission displays is not necessarily carried out in clean rooms, although it is desirable to do so, and could expose workers to inhalation of nanotubes in the event of accidental release. The quantities involved would be small.

In use of nanoelectronic products, consumers are not exposed to nanomaterials at present but nanocomposites could be used in future for structures and packaging. There is little cause for concern with such embodied particles except when the composites are accidentally damaged or destroyed.

In disposal of electronic products there are regulations in various jurisdictions with regard to landfill and extraction of precious metals from the integrated circuits. However there could be future problems with disposal of nanocomposites used as product packaging depending on the reinforcing material, e.g. since the nanoparticles in them could reach groundwater and be ingested by animals and humans. The RS/RAE report recommended that until more is known about environmental impacts of nanoparticles and nanotubes that release be avoided as far as possible (RS/RAE 2004).

> **The opinion of the Academies is that nanoelectronics and nanophotonics present little risk in fabrication and use, but regulations for disposal should be examined should nanocomposites and new nanomaterials be used in future equipment and packaging.**

5.2 Nanobiotechnology

Identifying and Characterising Hazards. The pharmaceutical and biotechnology industries are well-established high-technology industries with procedures for designing new chemical and biological compounds as potential products, developing and testing these to determine efficacy and toxicity and then carrying out clinical trials to strict standards. Bionanotechnology deals with molecular scale properties and applications of biological nanostructures. By using nanofabrication techniques, and processes of molecular self-assembly, nanobiotechnology allows production of tissue and cellular engineering products, biosensors combining biological and inorganic materials and drug delivery systems based on nanomaterials. Hazards may arise from new compounds at the nanoscale exhibiting increased toxicity and from new applications of biological molecules. So far the hazards have been low but need to be continuously monitored by appropriate regulatory agencies.

Identifying and Characterising Exposure. Like the electronics industry the manufacture of many pharmaceutical and biotechnology products require extreme standards of cleanliness to maintain quality. These procedures involving clean rooms and high personal protection have extended to nanobiotechnology. For many nanobiotechnology products the quantities are small and the chance of unintentional exposure is low.

However, for applications of nanobiotechnology products such as improved fertilisers and insecticides, the volumes of materials will be higher and production will be on an industrial scale. Here the issues relate to occupational health and safety in manufacturing and handling potentially active ultrafine particles in large quantities. Concerns have been expressed over the impacts of such nano-scale products being dispersed in the environment and thus polluting groundwater and causing damage in the food chain (ETC 2004). This echoes to some extent the concerns expressed in the RS/RAE report regarding the use of treated nanoparticles for soil remediation (RS/RAE 2004).

> **The opinion of the Academies is that, while risks are generally low, some nanobiotechnology products have the potential to present risks to the environment, and hence to humans and animals. Regulatory agencies need to assess these risks and, if necessary as advocated in the RS/RAE report, limit the use of engineered nanoparticles in environmental applications such as soil remediation until research is undertaken to demonstrate that potential benefits outweigh potential risks.**

5.3 Nanomedicine

Identifying and Characterising Hazards. The products used in nanomedicine stem from nanobiotechnology and are manufactured under strict control in clean environments as noted in Section 5.2. Hazards can be high with active compounds but the risk of unintentional exposure is low.

Identifying and Characterising Exposure. The critical issues arise in the use of nanomedicine products. Here we have situations where nanoproducts are deliberately introduced into humans for specific drug delivery or treatment at a cellular level by ingestion or implanting, or applied to the skin for protection. Based on the pharmaceutical industry experience there are clear steps including extensive clinical trials to ensure that only products that meet stringent specifications are released to the public in developed countries. These procedures generally take several years. On the whole these have proved to be adequate and can be applied to nanomedicine but there could be a need for review as new products which do not fit traditional guidelines are developed. Given the strict regulatory procedures employed the risks should be low in application, although somewhat higher during development and testing.

We consider two examples of nanomedical products. The first is the use of dendrimers for drug delivery. The world leader in this field is Starpharma in Melbourne. Dendrimers are polymeric molecules which can be designed to produce a series of small branching molecules around a core molecule. Surface molecules can then be added for specific functions. Dendrimers allow much more precision than conventional drugs in their interaction with cells. Until recently they have been expensive and time-consuming to produce but recent developments (so-called Priostar dendrimers) have dramatically reduced costs. After extensive research Starpharma have produced VivaGel, a dendrimer-based topical microbicide that prevents HIV and other sexually transmitted diseases; this has shown positive results in Phase 1 human trials. It needs to undergo two further trials before it can be approved by the FDA in the US for sale. This is the first drug product based on dendrimers to enter human trials.

Another example is gold nanoshells developed from research at Rice University in the US. These are glass spheres of 100 nm diameter coated with gold. The gold coating can be tuned to absorb near infrared light and can be used for localised medical imaging and for localised heating to kill cancer cells. These gold nanoshells also have the potential for drug delivery by adding antibodies to their surfaces. Clinical trials are now in progress.

An area where there is current debate on safety is sunscreens using nano-zinc oxide. This material has been used in sunscreens for many years at micron sizes but now nano-zinc oxide is being produced by several manufacturers in Australia and is exported for use overseas. The zinc oxide nanoparticles enable production of transparent sunscreens with high levels of UV protection. Concern in Europe and the US has been expressed that that zinc oxide could penetrate into skin cells and react under light to form free radicals which could damage cells. Extensive testing in Australia to cosmetic industry guidelines showed that the products containing nano-zinc, such as ZinClear, were safe (Anon 2005, TGA 2005).

> **The opinion of the Academies is that, in nanomedicine, the risks are low given that the existing approval and regulation procedures for pharmaceuticals and cosmetic products provide adequate protection for product development and use. However these procedures need to be monitored at regular intervals as new nanoproducts that may challenge the system are developed.**

5.4 Nanomaterials

As noted in Section 1.2, nanomaterials can be produced from a variety of materials and in a variety of shape. Some examples have been noted above. Such nanomaterials can be produced by a variety of techniques which fall under two categories:

Top-down manufacturing. One approach involves starting with a larger piece of material and etching, milling or machining a nanostructure into it or from it by removing material as in fabrication of electronic chips. The techniques of etching and machining have been developed by the semiconductor industry over the past 30 years using precision engineering and lithography. Another approach is to break up solids into nanoparticles using grinding or ballmilling; the latter process can be accelerated by the addition of chemicals. Such processes have been widely used in industry but are now refined for controlled production of engineered nanoparticles.

Bottom-up manufacturing involves the building of structures, atom-by-atom or molecule-by-molecule. Three approaches can be distinguished: chemical synthesis, self-assembly and positional assembly. In *chemical synthesis*, production occurs through controlled chemical reactions either in the gas or liquid phase leading to nucleation and growth of nanoparticles. The gas phase route is the main route for production of nanoparticles which may be of metals, oxides, semiconductors, polymers and various forms of carbon, and which may be in a wide range of shapes. Chemical vapour deposition methods also have been used to produce controlled nanoparticles and also carbon nanotubes. The liquid phase route produces dispersed colloidal precipitates of controlled size and composition. In *self-assembly*, atoms or molecules arrange themselves into ordered nanoscale structures by physical or chemical reactions between the units. The formation of salt crystals and snowflakes are examples of natural self-assembly processes. The use of self-assembly in industry is relatively new. In *positional assembly*, atoms, molecules and clusters are deliberately manipulated and positioned one-by-one. Special tools are needed and the process is currently extremely laborious. It is currently not suitable as an industrial process.

In the previous sections we have examined limited production of nanomaterials for specific applications. Here we consider the more general case of production of bulk quantities of nanomaterials for a variety of applications. Of particular concern are nanoparticles as noted in Section 4.

Identifying hazards. The major hazards are those involving nanoparticles, either free or embodied, throughout their life cycle from manufacture, use to disposal.

In the case of manufacturing, a recent US study (Robichaud *et al* 2005) has examined the hazards, from an insurance industry context, associated with the production of five specific nanomaterials in terms of the input materials, output materials and waste streams. The five materials were: single walled nanotubes, fullerenes (C_{60}), quantum dots of zinc selenide, alumoxane nanoparticles, and nano-titanium dioxide. In each case a potentially scalable process was examined in detail. The study concludes that there do not appear to be any unusual hazards associated with the production of these five nanomaterials although fullerenes show a higher hazard than the others. Overall the fabrication of nanomaterials may present lower risks than petroleum refining, polyethylene production and synthetic pharmaceutical production.

Characterising hazard. Although there are some data on animals, no hard data exist for characterizing toxicological properties of nanoparticles in humans. Several articles have been published summarizing extensive testing of the effects of nanoparticles in various species which can act as indicators (Hoet *et al* 2004, Oberdorster *et al* 2005, Nel *et al* 2006) and extensive research is continuing in UK (HM Government 2005), the US and Europe.

Free nanoparticles can be inhaled, absorbed through the skin or ingested. Inhaled particles can have two major effects on the human body:

- Their primary toxic effect is to induce inflammation in the respiratory tract, causing tissue damage and subsequent systemic effects. The property that drives the inflammogenicity of nanoparticles is not known but is related to particle surface area and number of particles; and
- Transport through the bloodstream to other vital organs or tissues of the body. This may result in cardiovascular and other extrapulmonary effects. Once in the body, the distribution of the particles is strongly dependent on the size, the shape, the composition and the surface characteristics. It is possible that durable, persistent nanoparticles may accumulate in the body, in particular in the lungs, in the brain and in the liver.

Much of the data on toxicity of nanoparticles has been gathered from studies on rats and small mammals. While there are problems in extrapolating such data to humans (Warheit 2004), there is clearly an increasing body of evidence suggesting that toxicity of certain nanoparticles can present problems if not properly understood.

The available data on engineered nanoparticles can supply some indicators to make initial judgements. Thus the RS/RAE report considered the evidence on inhalation, ingestion and dermal exposure to nanoparticles and noted that nanotubes deserve special attention (RS/RAE 2004). Researchers at Lux Research in the USA have given an analysis of ten nanomaterials based on available results (Nordon and Holman 2005). Their conclusions are:

- Nanoclay particles, nano-titanium dioxide, silicon nanowires and nanocrystalline drug formulations are unlikely to pose danger;
- Dendrimers, nano-zinc oxide and multiwalled carbon nanotubes warrant caution; and
- Single walled carbon nanotubes, cadmium selenide quantum dots and fullerenes should only be used under highly controlled conditions or after surface treatment to reduce their toxic properties.

This is a first attempt at classification and our assessment is that some of these conclusions, for example those relating to dendrimers and nano-zinc oxide, need amendment (see Section 5.3).

There is clearly a need for a systematic approach to the various nanomaterials in the 7 classes noted in Section 1.2. For example, in carbon-based nanomaterials the classification noted above distinguishes between single and multiwalled carbon nanotubes and also fullerenes. However there are other shapes in carbon such as nanohorns, nanowires, nanorods and also carbon foams and carbon gels that have been synthesised but not produced in quantity nor have they been tested for toxicity. While data banks are being developed in the US and Europe, there is need for an Australian focus to examine these data and their relevance in the Australian environment.

Characterising exposure. Likely current sources of exposure have been noted in Section 3. We can consider the steps in the value chain as:

- *Manufacturing* – Workers in plants that manufacture nano-enabled products have an opportunity to come into contact with large volumes of nanoparticles. These may well be in the free form-in the air or in liquids which could enter or touch the body-in contrast to fixed particles which are mixed in a composite or in coatings.

  A recent report for the Health and Safety Executive in the UK (IOM 2004) estimated that the number of UK workers who may be exposed to engineered nanoparticles in the work environment in university and in emerging nanoparticle companies could be about 2 000. This can be compared with about 100 000 workers who may be exposed to ultrafine powders through various powder handling processes. For comparison, in the USA about 2 million workers deal with development, production and use of ultrafine powders on a regular basis.

  In their submission to the current Senate Community Affairs Committee Enquiry into workplace exposure to toxic dust, Friends of the Earth Australia have extrapolated from the UK data based on population comparisons to produce estimates for Australia. They suggest that about 700 people are currently engaged in activities in university research and in nanotechnology companies where they could be exposed to engineered nanoparticles in some form. Further, as many as 33 000 Australian workers may be exposed to fine particles through various powder handling processes. There is a need to collect accurate data for Australia in this area.

  Occupational health and safety procedures are well established in industry for bulk production and handling of ultrafine particles and it has been proposed that these should be applied to engineered nanoparticles until better data are available (see Section 4). In research establishments many nanoparticle production and handling operations take place in clean rooms with small volumes of material. Two effective indicators for exposure of workers are: whether the particles could, intentionally or unintentionally, become airborne during manufacture, and whether large volumes of nanoparticles are used.

- *Use* – Consumers could encounter nanoparticles in the products that they use but are only likely to be exposed to them in small volumes. However the issue is whether they are embodied as in composite materials or free as in sunscreens. Two effective indicators for use are the form of the nanoparticles-fixed or free- and the application.

- *Disposal* – The issue of the environmental and human risks involved in the disposal or recycling of products containing nanoparticles is perhaps the area of greatest uncertainty. The assessment of the environmental impacts of nanoparticles will depend on the assessment of the physico-chemical properties and behaviour of the material, the residence time of nanoparticles in the environment and their environmental fate, toxicity (both acute and long-term) persistence in organisms and bio-accumulation potential. These are areas where there are few data available, particularly on engineered nanoparticles in soils and groundwaters. In the absence of regulations to control disposal of potentially toxic materials, a precautionary approach is needed to treat all such materials as potential hazards (see Section 5.2).

From the available data it is reasonable to conclude that: products employing small volumes of fixed nanoparticles pose little concern at any stage; exposure in manufacturing is directly related to the volume concerned (the larger the volume, the larger the probability of exposure; exposure in use is likely to be highest for products with free, not fixed, nanoparticles, and, exposure at end-of-life is more likely when no appropriate procedures exist.

- *Characterising risk* – Degree of hazard combined with degree of exposure gives a measure of risk. Thus a nanomaterial could have a different degree of risk depending on its production technology and its application. Little work has been done in this area. Researchers at Lux Research in the US have combined the data for the ten nanomaterials noted above with ten applications in nanoproducts to produce a ten-by-ten risk matrix of hazard vs. exposure (Nordon and Holman 2005). There are blank entries because not every nanoparticle has been proposed for every application and some nanoparticles have been proposed for only one application. One interesting example is that, although single-walled nanotubes are rated as hazardous, their use in memory devices raises little concern because of the small quantities involved and the controlled manufacturing conditions. On the other hand, the use of single-walled nanotubes in automotive composites raises concerns because of the large quantities involved in manufacturing and their possible release as a result of damage during use. This is the most detailed assessment yet available. However there is clearly a need for extensive work in this area.

Calls have made in USA and in Europe for the recognition of a new discipline of nanotoxicology (Oberdorster *et al* 2005). In the US strong research support is being provided through the National Institutes of Health and the National Institute for Safety and Health. In Europe several major research projects are operating under the Sixth Framework Programme. In Australia moves are underway in Victoria to set up a collaborative research programme called Nanotox Australia with a view to coordinating Australia's limited resources in this area. Australia would benefit from an interdisciplinary centre (probably comprising several existing institutions) to study the toxicity, epidemiology, persistence and bioaccumulation of engineered nanomaterials as well as their exposure pathways. Two critical aspects of its activities would be to interact with overseas researchers carrying out similar research and producing databases, and to interact with regulators in Australia, particularly on special needs arising from the Australian environment.

A "whole-of-government" response has been made in the UK to the recommendations of the RS/RAE report to address all these issues (HM Government 2005). This response notes that there are already a wide range of projects covering these areas and that more funds will be made available. There is a need for a similar audit of activities in Australia with follow-up action to address identified gaps.

The opinion of the Academies is that there appear to be sufficient effective indicators to enable adequate precautions to be taken and to allow production of nanomaterials to go ahead. However, as a basis for continued risk management, there is a need for more detailed information on aspects of nanoparticle production, application and disposal, and on toxicity of nanoparticles to humans when inhaled, ingested or applied to the skin, and on toxicity in the environment stemming from contamination of soils and water supplies.

6. Social, Legal and Ethical Aspects of Nanotechnologies

6.1 Medical Aspects

Social and ethical issues rarely arise as a result of the underlying science and technology. More typically, they are associated with specific applications of a technology. Thus, in Europe, medical or "red" uses of biotechnology have raised a different range of concerns from those raised in agricultural or "green" applications. Initially the impact of nanotechnology is likely to be limited to a few products and services where consumers are willing to pay a premium for new or improved performance. As a result it is likely that the evolutionary path will be taken and that nanotechnologies will co-exist with older technologies rather than displacing them.

It appears that the first wave of useful medical technologies is in the area of detection and sensing. When detection outpaces response capability – as it usually does – ethical and policy issues arise. For example it is already possible to identify genetic predispositions to certain diseases there is no known cure, or to diagnose congenital defects in fetuses. Better detection through nanotechnologies will increase the number of these. Nanotechnology-based treatments may develop from the original sensor technologies; these may initially be expensive and hence only available to the wealthy.

Another scenario is that there will be dramatic changes in the national health system as a result of the availability of cheap DNA testing systems and cheap drug delivery systems derived from nanobiotechnology. These possibilities need to be explored, e.g. through foresight studies involving all stakeholders.

The issue of drug delivery systems based on deliberate introduction of nanoengineered particles and devices into humans has been discussed in Section 5.2. Apart from physical risks to humans and the environment which can be identified (and hopefully dealt with) by suitable technology, e.g. strict control of dendrimer production or coating of potentially active nanoparticles, the legitimate concerns of society need to be addressed and different reactions of individuals to drug introduction need to be taken into account.

Another range of medical ethics issues is raised by the potential for enhancement of the capabilities of humans. Conventional implants designed to correct deficiencies have been used to assist humans to achieve normal vision, hearing, and functioning of organs. These are "therapeutic" implants. However the possibility has been raised in discussions in the US and Europe of the possibility of artificially enhancing human performance through the use of specialised implants made possible by nanotechnologies. How can we deal with such "enhancement implants" in the future? There are big questions which need to be addressed in this area (Weckert 2001).

> **The opinion of the Academies is that medical scientists and bioethicists in Australia need to include in their studies the benefits and risks associated with applications of nanomedicine with a view to enhancing the quality of health care.**

6.2 Privacy and Personal Data

Nanotechnologies promise considerable advances in developing small and cheap sensing devices which can be linked to advanced computers to produce networks of surveillance throughout society. On one hand these can be used to achieve greater safety, security and improved healthcare, particularly for an aging population as in Australia. On the other hand such systems can be used for covert surveillance of individuals and groups, for collecting and distributing personal information and for political control. A potentially worrying development is the recent implanting of employees in the US with nanodevices to track their movements in high security areas. This could be readily extended to cover other groups of employees and reduce personal freedom. The ability to rapidly produce personal data such as genetic information through nanotechnologies raises the issue of access to such information and its use in surveillance or in limiting access to health insurance. Public acceptance of nanotechnologies will depend critically on the perceived risks (see Section 7).

> **The opinion of the Academies is that many of the privacy and personal data issues associated with nanotechnologies are not new but will be intensified by their applications. Those issues unique to nanotechnologies which present perceived risks to society need to be identified and managed.**

6.3 Legal Issues

Most of the legal issues associated with nanotechnologies are not new but researchers and policymakers need to be aware of them and the concerns that they raise. Thus the issues of privacy and personal data are linked to civil liberties. Analysis of risks raises issues of liability which are of concern to the insurance companies and to the regulators (Swiss Re 2004, OECD/Allianz 2005, Innovation Society 2006). The International Risk Governance Council whose stakeholders include European insurance companies and European and US government agencies is currently carrying out a major study of risk governance which covers many of the issues raised in this report (Renn and Roco 2005, IRGC 2006). The Council is concerned to ensure that all stakeholders are involved in the development of nanotechnologies and its aim is to set up global and long-term frameworks for research plans and regulations. Although many nanotechnologies are dealt with adequately under existing regulations as discussed in Section 5, it may be necessary to modify some regulations to cope with hazards presented by free nanomaterials, particularly as new materials and shapes are created. Given the international scope of IRGC it would seem desirable for Australia to maintain links with its activities.

A particular issue is that of control of intellectual property rights. The examples of pharmaceuticals and of GM crops, shows how control of a new technology can be gained by multinational companies through control of patents. This does not appear to a problem yet in Australia where the small to medium nanotechnology companies appear to have well controlled patent situations. However it could be a problem for the development of nanotechnology companies in developing countries.

6.4 Military and Terrorism Issues

As with many technologies in the past there are clearly applications of nanotechnologies in military equipment and operations. Some of these will link with civil developments, e.g. sensors for surveillance and for detection of biological activity, while others, e.g. improved body armour or self-healing battle suits, may be specifically developed for military purposes. In this connection we note that the US Army funds an Institute for Soldier Nanotechnologies at Massachusetts Institute of Technology. Some of its outcomes could offer commercial opportunities for the adventure tourism industry.

On the negative side such developments can be accessed by terrorist or criminal groups. Manipulation of biological and chemical agents using nanotechnologies could present entirely new threats that would be hard to detect and counter. An important issue is whether existing arms control programs developed for nuclear, chemical and biological weapons will be effectual for nanotechnologies in the future.

The opinion of the Academies is that the potential security risks to Australia presented by misuse of nanotechnologies need to be examined by appropriate agencies.

6.5 Developing Countries and Economic Risk

In recent years, increased attention has been focused on the potential for application of nanotechnologies to assist in solving the problems faced by many developing countries (Meridian Institute 2004; Meridian Institute 2005). Some areas that have been identified are:

- Energy storage, production and conversion – particularly with cheap solar power and energy storage;
- Agricultural productivity enhancement – particularly improved water usage and pest control through sensor systems;
- Water treatment and remediation – particularly improved filtration systems for drinking water; and
- Disease diagnosis and associated screening – particularly cheaper and rapid diagnostic kits.

Concerns have been raised that such products will be designed and supplied by developed countries and that a "nanodivide" will be produced between developed and developing countries since developing countries will not be able to compete.

On the contrary there is evidence to suggest that, given access to technology and capital, many developing countries will be able to exploit nanotechnologies for their benefit. Already many developing countries have programs, and even national strategies, for the development of nanotechnologies (Maclurcan 2005). Thus in the Asia-Pacific region, the Chinese, South Korean, Malaysian and Thai governments have focused funding for nanotechnologies for 2003 to 2007 on nanomaterials research. China, Thailand and Singapore are strongly supporting health-related technologies. For Australia such developments present both opportunities for research cooperation and access to regional markets but also, in the longer term, potential competition in global markets.

The opinion of the Academies is that, in addition to maintaining their strong links with researchers and markets in Europe and the US, researchers and industries in Australia need to be aware of the development and applications of nanotechnologies in the Asia-Pacific region.

7. Risks and Social Acceptance

Much of the debate about nanotechnologies and their development and use has revolved around perceived risks. Such risks are contextual and depend on the existing social structure. There are thus a range of conceptions of what this emerging technology encompasses and of judgements on what it may mean for society (Wood *et al* 2003). There is a spectrum from at one end a clear-cut revolutionary vision that views nanotechnologies as radical discontinuities from current developments. At the other extreme the nature of the technologies is seen as less novel and it is therefore considered that they will develop in an evolutionary way.

The radical view envisages a goal of molecular manufacturing in which the manufacture of nanotechnology devices occurs through the use of self-replicating nanobots. This concept has led to the idea of uncontrolled self-replication leading to all matter being turned into a 'grey goo' and, although this has been challenged by many reputable scientists, the idea is alive and well in the media and in science fiction. A more useful concept of molecular manufacturing implies that an auto productive system is constructed which is fed by controlled chemical inputs and that this is inherently not self-replicating (Phoenix and Drexler 2004).

However by coupling the idea of a 'grey goo' with concerns about nanoparticles and their potential effects on humans and the environment, various groups have emphasised fears in the community about nanotechnologies that are greater than the real risks discussed above. Such groups have advocated strict regulation, and even a moratorium, on research and development of nanotechnologies.

An expressed concern is that society will not have an opportunity to discuss these perceived fears and that nanotechnologies and their consequences will be thrust upon society. Some writers draw a parallel between the emergence of nanotechnologies today and of genetically modified organisms (GMOs) some 15 to 20 years ago. Thus the lack of democratic consultation certainly keeps the assessment of any risk within the realm of the 'expert'; the public is then considered ignorant, and the authorities attempt to calm any fears with talk of 'sound science', shaped by its political, social, economic and cultural aspect. The strong reaction to GMO foods is still reverberating in Europe for example but such products have found ready acceptance in the US.

The risk analysis discussed in Section 4 is popular with technologists and regulators but does not receive widespread support in the community where it is regarded as an attempt to avoid issues that may be troubling in society. In part this is based on flawed expert assessments of past risks, from which we have learnt that scientists and technologists are often over-confident in accepting overt risk. One suggestion is that we can give expression to community resistance to acceptance of new risks by using a formalization like that developed and marketed by Peter Sandman in the 1980s as:

hazard x outrage= risk

where the outrage term captures the lack of trust that lay members of a community have in the professionals. Thus a small hazard may generate a large outrage in the community and hence suggest a high perceived risk.

Once a certain opinion has become established in a society it is extremely difficult to persuade people to the contrary view. Instead it is easier from the outset for the public to realise that a new technology not only solves problems, but can also create them leading to new risks. How people perceive risk depends on subjective perceptions and a number of so-called "fright factors" has been identified. For example, risks are generally more worrying (and less acceptable) if perceived to be:

- Involuntary rather than voluntary;

- Arising from an unfamiliar source;
- Arising from manmade rather than natural causes;
- Causing hidden and irreversible damage;
- Poorly understood by science; and
- Subject to contradictory statements from responsible sources.

There are cultural differences between, and even within, societies as to the relative weighting put on these perceived risks as shown in surveys of society attitudes to nanotechnologies.

In UK the issue of perceived risk and social acceptance has been discussed in a recent study (RS/RAE 2004). Surveys were made about 1000 people on attitudes to nanotechnologies in the UK. Awareness of nanotechnologies was low and concerns were expressed about possible long-term uncertainties and possible risks. Despite this there was a general feeling that nanotechnologies offered considerable benefits to society.

In the US several studies (Gaskell *et al* 2004, Cobb and Macoubrie 2004, Scheufele and Lewenstein 2004, Macoubrie 2005) have tested the attitudes of samples of up to 1000 people to nanotechnologies. In general the studies indicated that that about half the participants felt mostly or quite positive about nanotechnologies and about a third were neutral. Traditionally the US public is willing to accept risks associated with new technologies if there is evidence of early and significant benefits. With nanotechnologies this is particularly true of medical applications from new diagnostic methods to treatments for cancer and diabetes. The most important message from the studies is that a lack of information – about nanotechnology products, about their possible health and environmental implications, and about the oversight processes to manage risks – breeds public mistrust and suspicion. In the absence of balanced information, people are left to speculate about possible impacts in the light of past, usually unfavourable, technologies.

In Europe, at least in the original EU-15, the public are more skeptical about the ability of nanotechnologies to improve their way of life (Gaskell *et al* 2004; Gaskell *et al* 2005). While the general level of science education and understanding is higher in Europe than in the US, the general level of caution, concern and resistance is much higher. There is greater concern with the impact of the technology on the environment, less commitment to economic progress and less confidence in regulation. However there is some suggestion that the new countries involved in the recent expansion of the EU may have different attitudes to nanotechnologies since they offer new paths to industrial development and economic growth.

In Australia a consortium headed by Nanovic commissioned in 2005 a survey of more than 1000 people across Australia. The results will be published soon but they are generally similar to those in the UK study with a low but increasing awareness of nanotechnologies and generally hopeful attitudes about their potential benefits particularly in health applications. Consumers are still forming their views and generally want to learn more so that they can assess benefits and risks.

While these studies have focused mainly on perceptions and awareness of benefits vs risks of nanotechnologies they also reflect the influence of the media. In the US the emphasis of the media is on scientific and economic benefits and little on risks (Scheufele and Lewenstein 2004). This is likely to change over time as the controversial issues in nanotechnologies are picked up. We will probably see more of a "war of words', i.e. a competition over which issues will dominate public discourse over nanotechnologies. Interest groups, policy makers, researchers and mass media will struggle to get their voices heard and establish their positions. Some of the issues which may emerge are those discussed in Section 6, namely, toxicity of nanoparticles, potential for contamination, security and terrorism.

A better understanding of nanotechnologies at all levels of society is clearly a critical factor in promoting better awareness and debate. At the academic level, universities in Australia have already moved rapidly to introduce new courses in nanotechnologies to provide the trained people needed for the future development and application of nanotechnologies (Tegart 2002). Moves are underway to include an understanding of nanotechnologies in courses for technicians and hopefully for managers in industry. However there is a need to develop a broader educational outreach program, such as that being supported by the National Science Foundation in the US. This is designed to reach the general public through exhibits in museums and to reach middle and high school students through specially designed learning modules. Taiwan is taking a lead in Asia in this regard with special videos on nanotechnologies for junior students. State and Federal education authorities need to be proactive in the teaching of nanotechnologies to provide the framework for the future.

Given the potential economic importance of nanotechnologies in the next decades, a number of academic institutions in the US, Canada and Europe have set up interdisciplinary centres to study the social, legal and ethical issues associated with the development of nanotechnologies in their own social, economic and cultural contexts. At present there is no focal point for such studies in Australia and there is an economic risk that development of nanotechnologies could be slower than desirable, particularly in the light of potential competition from the rapidly developing countries of the Asia-Pacific region. There is a need to set up at least one interdisciplinary centre (and possibly more) to study the social, ethical and legal issues associated with the development of nanotechnologies in Australia. This could be a virtual centre with a central core in one institution and associated researchers across a range of disciplines in other institutions.

> **The opinion of the Academies is that more attention needs to be paid in Australia to the open public communication of a clear understanding of the possibilities and limitations of nanotechnologies. It is important that researchers in the social and physical sciences engage in dialogue with the community about these emerging technologies and the associated risks.**

8. Conclusions

The development of nanotechnologies in Australia will have an impact across many branches of science, technology and industry and, as a consequence, across society in general. Australia's research strengths lie in the areas of nanoelectronics, nanobiotechnology, nanomedicine and nanomaterials. These can be applied to the improvement of traditional industries and to the creation of new industries. However, like any new technology, there is a need for society to examine the benefits and the risks across a number of areas to ensure that balanced development occurs.

In considering the development of nanotechnologies in Australia the Academies have expressed a number of opinions on detailed topics which they see as significant in the formulation of a National Nanotechnology Strategy for Australia. These have been considered under the general headings of environmental, health and safety issues, and social, ethical and legal issues.

Many applications of nanotechnologies introduce no new health, environmental or safety risks, for example in nanoelectronics and nanophotonics where the new technology builds on the established microelectronics industry. Others where engineered nanomaterials or nanostructures are involved such as nanobiotechnology and nanomedicine raise concerns because of the intentional release of nanoproducts into humans and into the environment. Free particles in the nanometre range raise particular environmental, health and safety issues since their toxicology cannot be deduced from that of the same material at the macroscale. This stems from two factors dependent on size, namely the larger surface/volume ratios leading to higher activity, and the potential for nanoparticles to penetrate cells more easily than larger particles.

Currently the knowledge base on the toxicity of nanoparticles is small and there is a need for more research in Australia to ensure that potentially dangerous situations of unintentional release are avoided but that regulations are not over-restrictive. The establishment of an interdisciplinary centre in nanotoxicology, and its application to regulations, would ensure that Australia is not economically disadvantaged in the safe applications of nanotechnologies. Available data suggest that caution needs to be exercised in the manufacture and use of some existing nanomaterials such as carbon nanotubes. However it appears that sufficient effective indicators are available to enable adequate precautions to be taken under existing regulations, and to allow production of nanomaterials to go ahead. Considerable attention is being given to risk governance and the development of appropriate frameworks at national levels in Europe, and at a global level.

Nanotechnologies will have an impact across many branches of science and technology, and industry. Some of these will raise significant ethical, social and legal issues. In the near- to medium-term, issues such as privacy and security of personal data, military uses and terrorism, are not unique to nanotechnologies, but this does not make the concerns any less valid and they need to addressed. In the longer-term, applications of nanotechnologies may raise a completely new set of issues such as control of treatments and devices built around nanomaterials and their exploitation. The establishment of an interdisciplinary centre on social, ethical and legal issues would help ensure that Australia is not economically or socially disadvantaged by the applications of nanotechnologies. The study of attitudes of the community to nanotechnologies and their engagement in the development of nanotechnologies will be vital components of the activities of such a centre.

There is a need for better understanding of the development and application of nanotechnologies in the Asia-Pacific region which could present an economic risk to Australia.

9. Acknowledgements

The National Academies Forum wishes to express its thanks to those Fellows of the four Academies, and those experts nominated by the Academies, who have contributed to the preparation of this report. The two workshops in Sydney and Melbourne provided many new insights. The Steering Committee, comprised nominees from the four Academies, provided many valuable suggestions to steer the report through several iterations to its final format.

The Steering Committee comprised the following members:

- Dr John Byron, FAHA
- Professor Vaughan Beck, FTSE
- Professor Robert Clarke, FAA
- Professor Tony Coady, FAHA
- Professor Sue Dodds, FAHA
- Dr Peter Hudson, FTSE
- Professor Gerard Milburn, FAA
- Professor Ian Rae, FTSE
- Professor Greg Tegart, FTSE
- Dr Terrry Turney, FTSE
- Professor John Weckert,

The Workshops were ably facilitated by Dr John Byron, Executive Director, The Australian Academy of the Humanities.

The project was established and managed on behalf of the National Academies Forum by Professor Ian Rae, FTSE, Technical Director, Australian Academy of Technological Sciences and Engineering (to February 2006) and Professor Vaughan Beck, FTSE, Technical Director, ATSE (since February 2006).

The support provided by the National Nanotechnology Strategy Taskforce and the Manager of the Taskforce, Mr David Gallagher, is kindly acknowledged.

10. References

Anon 2005 *"Commentary on the use of Nanomaterials in Sunscreens",* Advanced Nanaotechnology Ltd., Perth, 5p.

Centre for Strategic Economic Studies 2003 *"Small Scale Technologies: Directions for Victoria"*, CSES, Victoria University.

Cobb, M.D. and Macoubrie, J. 2004 *"Public perceptions about nanotechnology; risks, benefits and trust"*, J. of Nanoparticle Research, Vol.6, No4, pp395-405.

ETC 2004 *"Down on the Farm: the impact of nano-scale technologies on food and agriculture"*, Action group on erosion, technology and concentration, 57p. www.etcgroup.org

European Commission 2004 "Nanotechnologies: a preliminary risk analysis on the basis of a workshop organised in Brussels on 1-2 March 2004", Health and Consumer Protection Directorate General, Brussels.

Gaskell, G., Jackson, J., Ten Eyck, T.A. and Veltri, G. 2005 *"Imagining nanotechnology: cultural support for technological innovation in Europe and the United States"*, Public Understanding of Science, Vol.14, No1, pp81-90.

Gaskell, G., Ten Eyck, T.A., Jackson, J. and Veltri, G. 2004 *"Public attitudes to nanotechnology in Europe and the United States"*, Nature Materials, Vol.3, No8, p496.

HM Government 2005 *"Characterising the potential risks posed by engineered nanoparticles"*, Department for Environment, Food and Rural Affairs, London.

HM Government 2005 *"Response to the RS/RAE Report"*.

Hoet, P.H.M., Bruske-Hohlfeld, I. and Salata, O. 2004 *"Nanoparticles-known and unknown health risks"*, J. Nanobiotechnology, Vol.2, No12, www.jnanobiotechnology.com/content/2/1/12

Innovation Society 2006 *"Nano-Regulation",* The Innovation Society Ltd, St. Gallen, 44p.

IOM 2004 *"Nanoparticles:An occupational hygiene review",* Institute of Occupational Medicine, Edinburgh, 54p.

IRGC 2006 *"Survey on Nanotechnology Governance. Vol.A. The Role of Government",* International Risk Governance Council, Geneva.

D. C. Maclurcan 2005, *"Nanotechnology and Developing Countries - Part A: What Possibilities?"* AzoNano Online Journal of Nanotechnology, http://www.azonano.com/Details.asp?ArticleID=1428

D. C. Maclurcan 2005, *"Nanotechnology and Developing Countries - Part B: What Realities?"* AzoNano Online Journal of Nanotechnology, http://www.azonano.com/Details.asp?ArticleID=1429

Macoubrie, J. 2005 *"Informed Public Perceptions of Nanotechnology and Trust in Government"*, Woodrow Wilson International Center for Scholars, Washington.

Meridian Institute *2004 "International Dialogue on Responsible Research and Development of Nanotechnology"*, Meridian Institute, Colorado and Washington.

Meridian Institute 2005 *"Nanotechnology and the Poor"*, Meridian Institute, Colorado and Washington.

Morgan, K. 2005 *"Development of a Preliminary Framework for informing the Risk Analysis and Risk Management of Nanoparticles"*, Risk Analysis, Vol.25, Dec.,pp1621-1633.

Nel, A., Xia, T., Madler, L. and Li, N. 2006 *"Toxic Potential of Materials at the Nanolevel",* Science, Vol.311, 3 Feb., pp622-627.

NIOSH 2005 *"Approaches to Safe Nanotechnology; An Information Exchange with NIOSH "*, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, USA.

Nordan, M. and Holman,M.W. 2005 *"A prudent approach to nanotechnology environmental, health and safety risks"*, Industrial Biotechnology Vol.1, No.3, pp146-149.

Oberdorster, G., Oberdorster, E. and Oberdorster, J. 2005 *"Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles"*, Environmental Health Perspectives, Vol.113, July, pp823-839.

OECD/Allianz 2005 *"Small sizes that matter: Opportunities and risks of Nanotechnologies",* OECD, Paris/ Allianz AG,Munich, 45p.

Phoenix, C. and Drexler, E. 2004 *"Safe exponential manufacturing"*, Nanotechnology Vol.15, pp869-872.

PMSEIC 2005 *"Nanotechnology: Enabling technologies for Australian innovative industries"*, Prime Ministers' Science Engineering and Innovation Council, Canberra.

Renn,O. and Roco, M. 2005 "Nanotechnology and the Need for Risk Governance", International Risk Governance Council, Geneva.

Robichaud, C.O.,Tanzil, D.,Weilenmann, U.and Weisner, M. R. 2005 *"Relative Risk Analysis of Several Manufactured Nanomaterials: An Insurance Industry Context",* Environ. Sci. Technol. Vol.30 No.22, pp8985-8994.

RS/RAE 2004 *"Nanoscience and nanotechnologies: opportunities and uncertainties"*, Royal Society, Royal Academy of Engineering, London.

SCENHIR 2005 *"Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies",* Scientific Committee on Emerging and Newly Identified Health Risks, European Commission, Brussels.

Scheufele, D.A. and Lewenstein, B.V. 2005 *"The public and nanotechnology: How citizens make sense of emerging technologies"*, J. of Nanoparticle Research, Vol.7, pp659-667.

Standards Australia 2004 *"Risk Management"*, AS/NZS 4360:2004.

Swiss Re 2004 *"Nanotechnology – Small matter, many unknowns"*, Swiss Reinsurance Co., Zurich.

Tegart, G. 2002 *"Nanotechnology: The Challenge to Educators"*, ATSE Focus, No.124, Nov/Dec, pp22-26.

TGA *2005 "Safety of sunscreens containing nanoparticles of zinc oxide or titanium dioxide",* Therapeutic Goods Administration, Australian Government, Canberra.

Warheit, D.B. 2004 *"Nanoparticles: health impacts?",* materialstoday, Feb., pp32-35.

Weckert, J. 2001 *"The Control of Scientific Research: The Case of Nanotechnology",* Aust. J. of Professional and Applied Ethics, Vol.3, No.2, pp29-44.

Wood, S., Jones, R. and Geldert, A. 2003 *"The Social and Economic Challenges of Nanotechnology"*, Economic and Social Research Council, London, 54p.

APPENDIX A - Conduct of the Study

In mid January 2006, a contract for the study was let by the Department of Industry Tourism and Resources to the Australian Academy of Technological Sciences and Engineering acting on behalf of the National Academies Forum. Professor Greg Tegart FTSE was appointed as the Study Leader to carry out the study. He prepared a Discussion Paper which was considered by a Steering Committee drawn from the Academies at a meeting on 30 January. Following this, discussions were held with various individuals and groups interested in the development of nanotechnologies in Australia and the paper was revised.

Two workshops involving Fellows of the Academies and expert persons nominated by the Academies were held in Sydney on 23 February and Melbourne on 27 February, 2006. Wide-ranging discussion at each meeting raised a number of significant issues which were addressed in the draft paper considered at the Steering Committee meeting on 23 March, 2006. A new draft was then produced and after consideration of comments the final draft was produced. After clearance by the Academies this was delivered to the Department in April.