CHAPTER 7

NANOTECHNOLOGY

7.1 With scientists now able to manipulate atoms one at a time, new atomic structures are available. These new structures sometimes have unique and novel properties, far removed from those of the material at normal scale. The control of individual atoms and molecules is known as nanotechnology. The technology is already being used in some sectors of industry: in manufacturing ultra-fine powders are used for electronics and metal composites and corrosion and wear resistant coatings. Consumer goods incorporating nanoparticles are now also available including sunscreens and cosmetics.

7.2 Many consider that the further development of nanotechnology and nanoscience will have enormous potential in research and industrial applications with some suggesting that nanotechnology has the potential to change lives as much as the discovery of electricity or the microchip. The Prime Minister's Science, Engineering and Innovation Council (PMSEIC) Working Group on Nanotechnology stated:

> [Nanotechnology] could give rise to a whole new set of industries as well as transform current technologies in manufacturing, healthcare, electronics and communications.[1]

7.3 Investment in nanotechnology is expanding rapidly and has more than quadrupled between 2001 and 2005.[2] Given its potential application to many fields, nanotechnology will have significant economic, environmental and social implications and will create new challenges for safety and regulatory regimes.

Nanoscience and nanotechnology

7.4 Nanoparticles are ultrafine particles with aerodynamic diameters less than 100 nanometres. A nanometre (nm) is one billionth of a metre. For comparison, a single human hair is about 80 000 nm wide and a water molecule is almost 0.3 nm across. Nanoparticles can comprise a range of different morphologies including thin films, nanotubes, nanowires, nanodots and a range of spherical or aggregated dendritic forms. Nanotechnology involves structures in the range 1 to 100 nanometres.[3]

7.5 Interest in nanoparticles is increasing significantly as the properties of materials in nanoparticle form can have very different or enhanced properties

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1 Prime Minister's Science, Engineering and Innovation Council Working Group, *Nanotechnology: Enabling technologies for Australian innovative industries*, 11.03.05, p.3.

2 PMSEIC, p.9.

3 PMSEIC, p.8; for more detailed information on examples of nanotechnology, see PMSEIC, p.13-17.

compared with the same material at a larger scale. Advances in technology have also allowed atoms and molecules to be examined and probed with great precision leading to the expansion and development of nanoscience and nanotechnologies.

7.6 The properties of materials at nanoscale vary significantly from those at bulk size for two main reasons. First nanomaterials have a relatively larger surface area when compared to the same mass of material produced in a larger form. This can make materials more chemically reactive 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.[4]

7.7 Nanoscience is concerned with understanding these effects and their influence on the properties of materials. Nanotechnologies aim to exploit these effects to create structures, devices and systems with novel properties and functions due to their size.

7.8 These materials have application in a wide range of industries including electronics, pharmaceuticals, chemical-mechanical polishing and catalysis. For example, very thin coatings are used in electronics and active surfaces (self-cleaning windows). Carbon nanotubes have great tensile strength and are considered to be 100 times stronger than steel whilst being only a sixth of its weight thus making them potentially the strongest, smallest fibre known.[5] Titanium dioxide is used in sunscreens and self-cleaning glass and as a photo catalyst. Nanoscale silicon is used in semiconductor manufacturing while metal core coated particles are used to create quantum nano-dots that allow high sensitivity labelling in a range of chemical or environmental settings.[6] Stain and wrinkle-free fabrics incorporating 'nanowhiskers' and longer lasting tennis balls using butyl-rubber/nanoclay composites are now being marketed.[7]

7.9 Nanoparticles are mostly fixed or embedded in nanoscale components. In some instances, free nanoparticles are used, for example in cosmetics.

7.10 Certain industrial by-products can be considered to contain nanoparticles, for example from combustion engines (diesel particulate material), furnaces and welding. There are also naturally occurring nanoparticles associated with sand storms and forest fires. Most debate centres around the new field of engineered nanoparticles.

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4 The Royal Society & The Royal Academy of Engineering, *Nanoscience and Nanotechnologies: opportunities and uncertainties,* London, July 2004, p.2.

5 Institute of Occupational Medicine for the Health and Safety Executive, *Nanoparticles: An occupational hygiene review,* Research Report 274, 2004, p.10. www.hse.gov.uk/research/rrhtm/rr274.htm

6 *Hazards Magazine*, 'Dangers come in small particles', Issue 87. www.hazards.org/nanotech/safety.htm

7 NIOSH, *Nanotechnology and Occupational Safety and Health Research* www.cdc.gov/niosh/topics/nanotech/faq.html

Investment in nanotechnologies

7.11 Worldwide the investment in nanotechnology research and development has increased dramatically over recent years. Governments in many countries are funding research and manufacturers are already marketing a wide range of products. The United States invests approximately US$3 billion annually in nanotechnology research and development, which accounts for approximately one-third of the total public and private sector investments worldwide.[8]

7.12 In the United Kingdom there are some 370 companies currently involved in nanotechnologies.[9] Some 1500 companies internationally have announced nanotechnology research and development plans, 80 per cent of which were start-up companies.[10]

7.13 The Woodrow Wilson International Centre for Scholars in the USA has established the Project on Emerging Nanotechnology to encourage discussion about nanotechnology's benefits as well as its safety and environmental impacts. As part of this project it has established the Nanotechnology Consumer Products Inventory which, at March 2006, contained more than 200 manufacturer-identified nano products.[11]

7.14 In Australia, there are over 50 Australian companies focussed on nanotechnology. Australian nanotechnology research spans materials, biotechnology, energy, environment, electronics, photonics, computing and surveillance. The Australian Research Council currently funds more than 200 nanotechnology research projects. Australian universities, CSIRO, the Australian Nuclear Science Technology Organisation and the Defence Science Technology Organisation are also active in nanotechnology research and development.[12] The PMSEIC Working Group estimated that at 2003, government and the private sector were investing up to A$100 million per annum in nanotechnology, with at least half from government sources.[13]

7.15 It has been estimated that the sales of products incorporating emerging nanotechnologies will rise from 0.1 per cent of global manufacturing output in 2004 to 15 per cent in 2014, totalling US$2.6 trillion.[14]

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8 Woodrow Wilson International Centre for Scholars, *New Nanotechnology Consumer Products Inventory*, www.wilsoncenter.org

9 The Royal Society-Science Council of Japan, *Report of a Joint Workshop on impacts of nanotechnologies,* July 2005, p.2.

10 PMSEIC, p.11.

11 Project on Emerging Nanotechnologies, *A Nanotechnology Consumer Products Inventory,* www.nanotechproject.org/consumerproducts

12 *Submission* 10, p.7 (Friends of the Earth).

13 PMSEIC, p.11.

14 PMSEIC, p.9.

7.16 The United States National Institute for Occupational Safety and Health (NIOSH) reported that there is no current comprehensive data from official survey sources on the number of people employed in the US in occupations or industries in which they might be exposed to engineered nano-diameter particles in the production or use of nanomaterials. However, a 2004 survey estimated that some 24 300 people were employed in companies engaged in nanotechnology (this included all people employed in the company).[15]

7.17 Friends of the Earth estimated that there are as many as 700 people in Australia who are currently employed in activities in which they may be regularly exposed to synthetic nanoparticles in some form. Friends of the Earth commented that this figure 'seems reasonable' as there are now over 50 Australian companies focussed on nanotechnology and the Australian Research Council is currently funding more than 200 nanotechnology research projects. It was estimated that this number is likely to at least double over the next five years.[16]

7.18 The National Science Foundation estimated that in 2015 there will be 2 million workers employed in nanotechnology-related industries worldwide; the number of people in secondary industries using nanotechnology-related materials and devices will be orders of magnitude greater.[17]

Health and safety concerns

> …nanotechnology presents new and very serious risks that are currently affecting workers and the public and, as industrial expansion continues, will impact further upon the environment. There is early evidence of serious harm and there are warnings from the world's most eminent scientific body in relation to nano risks. We also have warnings from the world's second-largest reinsurer that, in order to prevent a repeat of the asbestos experience, we need conservative regulation that puts safety first now and that catches up to the industry expansion.[18]

7.19 Various studies and reports point to the lack of information concerning the human health and environmental implications of manufactured nanomaterials. However, it is generally considered that there is an inverse relationship between toxicity of insoluble materials and particle size, irrespective of parent material.[19] The UK Health and Safety Executive noted that 'the toxicity of insoluble materials increases with decreasing particle size, on a mass for mass basis'.[20] It was also noted

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15 NIOSH, *Nanotechnology and Occupational Safety and Health Research*, http://www.cdc.gov/niosh/topics/nanotech/faq.html

16 *Submission* 10, p.12 (Friends of the Earth).

17 *Submission* 10, p.6 (Friends of the Earth).

18 *Committee Hansard* 29.9.05, p.58 (Friends of the Earth).

19 *Submission* 10, p.8 (Friends of the Earth).

20 UK Health and Safety Executive, p.12.

that unlike larger microparticles, nanoparticles are highly mobile and readily enter the blood stream following inhalation or ingestion. Nanoparticles may also penetrate human skin.[21]

7.20 It is generally believed that the principal determinants of toxicity of nanoparticles are:

- chemical reactivity of the surface (including any surface components such as transition metals or coatings and particularly any ability to take part in reactions that release free radicals);
- total surface area presented to the target organ;
- physical dimensions (which could influence penetration and removal in the body); and
- solubility (soluble particles may disperse before initiating a toxic reaction).[22]

7.21 The Minerals Council of Australia noted that significant research has identified that inflammation is a primary health effect and oxidative stress can be identified as a dominant mechanism in the production of this inflammation.[23]

7.22 Friends of the Earth also cited a research report which showed that inhaled nanoparticles penetrate the protective mucus lining of human lungs and have high rates of deposition in the deeper lungs. Scavenger cells usually intercept foreign bodies and larger sized particles that make it past the mucus lung lining and into the deeper lung. However studies have shown that these cells have difficulty recognising nanoscale particles, they are readily overloaded, and their action is impaired.[24] Reports also indicate that nanoparticles are associated with inflammatory lung injury and laboratory studies have shown that nanoparticles are transported around the body and are absorbed by organs and tissues including the brain, heart and liver. Ingested nanoparticles can be absorbed into the lymphatic system.[25] Friends of the Earth commented:

> The effect of [the] characteristics [of nanoparticles] is that nanomaterials have an unprecedented access to the body through inhalation, ingestion and dermal contact, so all the ways that material can have access into our bodies, and also to the bloodstream by other dermal contact. Once in the body, nanomaterials have unprecedented access to vital organs and tissues, including the heart and liver, bone marrow and reproductive organs. They even have access to the brain along the olfactory nerve and across the

21 UK Health and Safety Executive, pp.12-14.

22 The Royal Society-Science Council of Japan, p.3.

23 *Submission* 23, p.4 (MCA).

24 *Submission* 10, p.8 (Friends of the Earth) citing Wichmann HE and Peters A, 'Epidemiological evidence of the effects of ultrafine particle exposure', *Philosophical Transactions of the Royal Society*, London, 2000, A 358:2751-2769.

25 *Submission* 10, p.9 (Friends of the Earth).

> blood-brain barrier. Unlike larger particles, because nanomaterials are very small particles, they gain access to individual cells. The toxicological impact on organs and individual cells is still poorly understood, but some preliminary research has come out in the last couple of years, the results of which we believe are very concerning.[26]

7.23 Friends of the Earth also noted that the duration of deposits of nanoparticles in vital organs is unknown, 'although there is some evidence to suggest they may accumulate in organs such as the liver'.[27]

7.24 The Australian Council of Trade Unions (ACTU) informed the Committee that there are concerns that nanoparticles may possibly cause Alzheimer's disease. *Rachel's Environmental and Health News* in 2003 reported that nanoparticles combined with metals can pass directly into the brain where they can promote the formation of waxy amyloid plaques which are the signature feature of Alzheimers. *Rachel's Environmental and Health News* has also warned of the risks of industrial production of nanoparticles 'similar to those old-style ultrafines already established to be prolific killers'. Rachel's concluded 'clearly, in the case of nanoparticles, we have reasonable suspicion of harm, and we have some remaining scientific uncertainty. There we have an ethical duty to take preventive (precautionary) action. If there ever was a proper time to invoke the precautionary principle, this is it.'[28]

Occupational health and safety issues

7.25 A number of key concerns with the developments in nanotechnology have been identified in evidence:

- lack of knowledge about key aspects of how nanoparticles impact on health;
- lack of effective methods to measure and assess workplace exposure to nanoparticles;
- poor understanding of existing workplace exposure;
- lack of consistent nomenclature and terminology for describing nanoparticles (for example whether to define nanoparticles by physical dimensions or behavioural properties);
- no effective control methods to safeguard against exposure to nanoparticles and other nanomaterials;
- problems with regulatory regimes unable to meet the demands of a rapidly emerging new field of products and technologies; and
- the small investment in occupational health and safety aspects of nanotechnology.

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26 *Committee Hansard* 29.0.05, p.55 (Friends of the Earth).

27 *Submission* 10, p.10 (Friends of the Earth).

28 *Submission* 28, p.9, Additional Information, p.2 (ACTU).

Impact on health of workers

7.26 As noted above, nanoparticles appear to have the potential to cause harm. The US National Institute for Occupational Safety and Health (NIOSH) noted potential health concerns including exposure routes; effects seen in animal studies indicating adverse health effects; and observations from epidemiological studies involving fine and ultrafine particles indicating adverse lung and respiratory outcomes.[29]

7.27 The Australian Institute of Occupational Hygienists (AIOH) noted that reports by the UK Health and Safety Executive indicated how limited the available data was and the difficulty of reading across from existing data and that the hazards from nanoparticles and fibres are sufficiently different from bulk materials to require further careful study. They also indicated that the areas of initial occupational health concern should be:

- potential for enhanced toxicity;
- potential to cross the skin barrier;
- existing control measures are unproven; and
- possible persistence in the workplace.[30]

7.28 Witnesses drew parallels between nanoparticles and asbestos. The Australian Manufacturing Workers Union (AMWU) commented that asbestos had exacted a very high toll in Australia, as we now have the 'unenviable distinction of having the highest mesothelioma rate in the industrialised world'. Furthermore:

> It would be an act of negligence to future generations if we did not heed the concerns now being raised in the research community about the health effect of nanotechnology.[31]

7.29 Friends of the Earth also commented on the parallels between workplace exposure to asbestos and nanoparticles in that exposure to nanoparticles has the potential to cause serious pulmonary disease. Friends of the Earth commented further:

> We are not just talking one asbestos; we could be talking five, 10, 100, 1,000, 10,000. No-one knows, because serious harm to health will only manifest over the long terms and it is an omnipresent risk. As I mentioned earlier, nanomaterials are already in the environment.[32]

7.30 Friends of the Earth noted that the international insurer, Swiss Re has stated that the most important similarity between asbestos and nanoparticle exposure may be the lag time before the potential onset of serious harm to health – resulting in

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29 NIOSH, *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH* www.cdc.gov/niosh/topics/nanotech/nano_exchange.html

30 *Submission* 20, p.24 (AIOH).

31 *Submission* 15, p.2 (AMWU).

32 *Submission* 29.9.05, p.55 (Friends of the Earth).

significant human and financial cost. To safeguard against a repeat of the asbestos experience, Swiss Re has advocated a strict application of the precautionary principle in the regulation of nanotechnology and that health and safety first must be foremost in any regulatory regime:

> Swiss Re emphasised that there is a really clear economic impetus to pursuing a precautionary approach to the regulation of nanotechnology. It warned that delayed action and inadequate regulation of workplace risk will result in a repeat of the asbestos experience. It is particularly concerned about liability for the insurance sector.[33]

Measurement and monitoring of nanoparticles

7.31 The AIOH raised concerns about how dust samples are collected and measured:

> …we have a 21st century technology there but we are still thinking in 20th century terms about how we collect dust samples, how we measure them and how we use things like respirators and ventilation or enclosures to contain the dust. These nanoparticles are so fine that we cannot use existing monitoring methods to assess how much exposure a worker is receiving. If we do tell workers to wear a respirator, we have no real means of telling if the respirator can protect them, because if these particles are so fine they will just go straight through any filter or around the side of the face seal. We do not know if ventilation is going to capture dusts containing nanoparticles. We really are in the dark at the moment about the hazards and the means of controlling the hazards, if there are any, from nanotechnology.[34]

7.32 Friends of the Earth also echoed these concerns and noted for example that at the moment 'we are in a situation where, for instance, you look at zinc dioxide and five different measuring instruments come up with five different sizes. One will say it is 10 nanometres, the next one will say it is 100 nanometres. Which one is it? And the size will have a very important effect'.[35] There is also no internationally agreed nomenclature: 'If you cannot describe nanoparticles, how can you measure them? How can you do the safety assessments and how can you set the workplace exposure standards?'[36]

7.33 NIOSH has also pointed to the difficulties of measuring nanoparticles in the workplace:

> …nanomaterials differ in significant ways from traditional materials for which established measurement procedures and equipment exist. One factor involves instrumentation: in general, available devices and methods are not

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33 *Committee Hansard* 29.0.05, p.56; *Submission* 10, p.4 (Friends of the Earth).

34 *Committee Hansard* 29.9.05, p.31 (AIOH).

35 *Committee Hansard* 29.9.05, p.60 (Friends of the Earth).

36 *Committee Hansard* 29.9.05, p.57 (Friends of the Earth).

> designed to take and analyse samples at the nano-scale. Another factor involves uncertainties regarding the appropriate parameters for sampling and analysis. Procedures for measuring traditional materials are based on the particles' mass and bulk chemistry as characteristics that most determine whether the material is likely to have adverse effects. For nanomaterials, current research suggests that mass and bulk chemistry may be less important than particle size, surface area and surface chemistry (or activity) as the most relevant parameters for measurements.[37]

7.34 In November 2005, the International Organisation for Standardisation (ISO) established the Nanotechnologies Technical Committee. The national standards institutes of 24 member countries are participating, while another eight have observer status. Specific tasks for the Technical Committee include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; and science-based health, safety and environmental practices.[38]

Regulatory regimes

7.35 GeneEthics pointed to the novel features of nanoparticles and the need for these to be addressed in regulatory regimes:

> Nanoparticles…are largely unresearched at this point. Our regulators are assuming that nano sized particles of minerals and chemicals that are already approved by them are going to behave in the same way as the approved substances. It is now becoming clear that those assumptions are incorrect and yet there is no mechanism for ensuring that the nano sized particles of those substances are re-evaluated, that new scientific data be generated and available for assessment when there are applications for its use. The use of nanoparticles in cosmetics, for example, logically ought to be regulated by the Therapeutic Goods Administration but, as it is cosmetics, is not regulated by anybody.[39]

7.36 Workplace Health and Safety Queensland (WHS), noted that some nanoparticles exposures already occur from aerosols in existing Queensland industries such as pharmaceutical manufacturing, aluminium smelting, welding processes, soldering, metal grinding and thermal coating. However, WHS went on to state that it 'possesses no capacity to assess accurately the health impacts from particle sizes specifically in the nanometre range or the possible preponderating influence of their massive numbers'.[40]

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37 NIOSH, www.cdc.gov/niosh/topics/nanotech/faq.html

38 ISO, *ISO launches work on nanotechnology standards*, 16.11.05, www.iso.org/iso/en/commcentre/pressreleases/archives/2005/Ref980.html

39 *Committee Hansard* 29.9.05, p.8 (GeneEthics Network).

40 *Submission* 26, p.25 (WHS).

7.37 Friends of the Earth also commented on the difficulties of regulatory regimes addressing the particular characteristics of nanoparticles:

> Each and every nanomaterial is different from the next one, so there is a nanomaterial that is zinc oxide, titanium dioxide, various carbon formations, and the list goes on and on. There will be literally tens of thousands of different nanomaterials. Each and every one of them is going to be different from the next one because each and every one will be manufactured in a slightly different way. It will have a different shape, different surface properties, different surface areas.
>
> While we have a general indication that they have particular characteristics in common, some of them will be just fine and others will not be nice at all.[41]

7.38 Friends of the Earth also informed the Committee that the European Union and the US have decided not to require new safety testing for certain products that are now used in nanoscale, based on the known safety of those substances at a macroscale. These products included titanium dioxide and zinc oxide which at the nanoscale are used in sunscreen: 'that same sunscreen has been shown to cause DNA damage and to have a carcinogenic impact in human skin cells in in-vitro studies, and in human colon cells as well'.[42]

7.39 The lack of regulatory activity 'is in no small part related to the huge gaps in knowledge that still exist around nanotechnology and that confound our ability to adequately assess risk and to bring in regulations that will guarantee workplace safety'. Friends of the Earth commented that there are no mechanisms in place to enable risk assessment to be undertaken and regulations to be developed to protect workers in the workplace 'yet we have many thousands of workers…in Australia who may be exposed to nanoparticles, who are working in a wholly unregulated environment'.[43]

Occupational health and safety research funding

7.40 GeneEthics proposed that a minimum of 25 per cent of the budgets of all nanotechnology research and development, both privately and publicly funded, be allocated to experiments on worker, public and environmental health and safety.[44] In support of this view, GeneEthics stated:

> There is some small research being done [on safety] but, in our view, a substantial amount – and we have suggested a quarter, though it is really quite an arbitrary figure – should be expended on finding out in advance what the impacts are likely to be. The behaviour of each kind of

41 *Committee Hansard* 29.9.05, pp.59-60 (Friends of the Earth).

42 *Committee Hansard* 29.9.05, p.61 (Friends of the Earth).

43 *Committee Hansard* 29.9.05, p.57 (Friends of the Earth).

44 *Submission* 31, p.1 (GeneEthics Network).

> nanoparticle, though it will be different from larger particles of the same substance, will vary, and so there is a substantial amount of research that needs to be done to understand where these things bioaccumulate, if they do, and how mobile they are in the environment.[45]

7.41 Friends of the Earth also noted that there was a very small amount of investment in research on occupational health and safety compared with the amount invested in other research:

> The amount of money that has been invested into looking at its potential health and safety implications, its toxicological impacts and its environmental implications is extremely small. There is a dearth of peer reviewed toxicological literature looking at this stuff, and yet, of the stuff that has been published, the overwhelming majority of the studies have rung serious alarm bells. There are very few studies that have been undertaken into the impact of nanotechnologies that have not pointed to serious problems.[46]

Response to concerns

7.42 The AIOH concluded that the lack of knowledge about the possible health impacts of nanotechnology placed a great responsibility on those involved in the development, import, marketing and distribution of emerging technology products to ensure that workers will not suffer any adverse response from being exposed to these products in their workplaces. AIOH saw a need for those involved in the development of products to ensure that adequate information is provided to users to ensure they are able to use the technology safely. AIOH considered that further product testing may be required and there are parallels with existing schemes for controlling the introduction of new chemicals, such as the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). AIOH recommended that nanoparticles should be referred to NICNAS for assessment.[47]

7.43 The AMWU identified key areas for action including:

- government needs to ensure that the risks of nanomaterials are identified before they are incorporated into products for commercial production, for example through NICNAS;
- funding for research on health and environmental implications of nanotechnology, including collaborative research ventures with overseas bodies, to ensure that critical research is conducted to identify potential risks;
- comprehensive management of the risks that are identified including identifying changes needed to address current gaps and uncertainties that may be creating regulatory 'nano-loopholes';

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45 *Committee Hansard* 29.9.05, p.5 (GeneEthics Network).

46 *Committee Hansard* 29.9.05, p.60 (Friends of the Earth).

47 *Submission* 20, p.25 (AIOH).

- urgent investigation and regulation of nanoparticle exposure levels to the lowest possible level, until a safe and healthy exposure standard can be adopted particularly in scientific research and commercial research and development departments;
- industry itself needs to develop and drive widespread adoption of 'standards of care' for responsible nanotechnology development; and
- engagement of stakeholders outside government and industry whose constituencies stand to be both beneficiaries of this technology and those most likely to bear any risks that arise.[48]

7.44 The ACTU also echoed these concerns and recommended that urgent research be undertaken into the risks posed to workers and the public by nanomaterials and into techniques to eliminate the risk of exposure.[49] It also called for a national conference on nanotechnology at which regulators, hygienists, scientists, lawyers, researchers, unions, business, medicos, and community groups could be brought together to discuss the impact of nanotechnology. In particular it could look at regulating the exposure levels of workers to nanoparticles; how to label products that contain nanoparticles; monitoring the workplaces that expose workers to nanotechnology and nanoparticles; and screening workers. The ACTU commented that workers and consumers are already being exposed to nanoparticles:

> These products are out there at the moment. They are currently being used potentially by millions of Australians. We use a lot of sunscreen. We need to know what impact these products are having on consumers and we also need to look at who is producing these things and how prevalent they are. There is no regulation about what products are being produced using nanotechnology. We do not know. It is a minefield. If – a worse case scenario – nanotech and nanoparticles cause serious harm to people, we are sitting on a bit of a time bomb. Let's face it! We do not know enough.[50]

7.45 Friends of the Earth, supported by the GeneEthics Network, called for a moratorium on all research, development, commercial production and sale of synthetic nanotechnologies, nanoparticles, and other nanomaterials and products that contain them. The moratorium should remain in force, at a minimum, until new laws and a regulatory system are developed and implemented. This should include a nomenclature, a way of measuring risk, a way of assessing risk and until safety assessments have been undertake so that there is a better understanding of the toxicological interaction between nanoparticles in the body; and until there is a

48 *Submission* 15, pp.2-3 (AMWU).

49 *Submission* 28, p.10 (ACTU).

50 *Committee Hansard* 29.9.05, p.90 (ACTU).

regulatory framework for assessing risk and protecting health and safety.[51] Friends of the Earth concluded:

> The need to regulate workplace exposure is particularly urgent. There are tens of thousands of Australian workers who are likely to be exposed to synthetic nanoparticles, hundreds of thousands of workers exposed to incidentally produced nanoparticles, and a growing body of evidence that such exposure may relate in serious harm. Given the many uncertainties that continue to plague the development of adequate nanotechnology regulation, a moratorium on the research, development and manufacture of synthetic nanoparticles is essential until a comprehensive regulatory regime is developed and implemented.[52]

7.46 GeneEthics Network also proposed the development of a comprehensive, innovative regulatory framework including the establishment of an Office of New Technology Assessment and Regulation with responsibility for the registration, assessment, licensing and monitoring of all new technologies. This office would be established under a Council of Australian Governments agreement and be responsible to a New Technology Ministerial Council, composed of Commonwealth, State and Territory health ministers.[53]

7.47 The Department of Employment and Workplace Relations (DEWR) stated:

> DEWR's view is that a full picture of the potential health and safety implications and risks of nanotechnology, if any, remain unknown. The office will closely monitor international research on this topic and ensure that key government agencies are kept informed of relevant developments. DEWR is of the view that the current OHS regulatory framework is appropriate for dealing with the potential risks associated with nanotechnology.[54]

Studies and reports into the potential impact of nanotechnology

7.48 Interest in the potential impact of nanotechnology has increased over the last two to three years with the release of major reports by international organisations. Studies into the implications of current and future developments in nanoscience and nanotechnologies and their impacts have been undertaken overseas. The following provides an overview of some of the major reports and studies.

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51 *Submissions* 10, p.17 (Friends of the Earth); 31, p.1 (GeneEthics Network); seel also *Committee Hansard* 29.9.05, p.61 (Friends of the Earth).

52 *Submission* 10, p.17 (Friends of the Earth).

53 *Submission* 31A, p.2 (GeneEthics Network).

54 *Committee Hansard* 10.11.05, p.2 (DEWR).

The Royal Society and Royal Academy of Engineering – United Kingdom

7.49 In July 2004, the Royal Society and Royal Academy of Engineering reported on current applications of nanotechnologies and examined the health, safety and environmental implications and uncertainties that may arise from nanotechnologies.[55]

7.50 The Royal Society examined evidence from exposure to quartz, asbestos, air pollution and medical applications of nanoparticles to understand the toxicity of nanoparticles and fibres. It stated that the understanding derived from this evidence had led it to the general conclusion that the principal determinants of the toxicity of nanoparticles were the surface area, chemical reactivity of the surface, the physical dimensions of the particle that allow it to penetrate to the organ or into cells or that prevent its removal; and possibly, its solubility.[56]

7.51 The Society concluded that whilst many applications of nanotechnologies pose no new health or safety risk, manufactured nanoparticles and nanotubes in a free form may pose health and safety risks. The Society saw the main risk of human exposure to manufactured nanoparticles and nanotubes as being in a few work places (including academic research laboratories) and through the use of a small number of skin care preparations which contain free nanoparticles. It commented however that 'the current lack of available research means that the scale of this risk cannot be fully determined'. [57] In addition, the Society stated:

> There is virtually no evidence available to allow the potential environmental impacts of nanoparticles and nanotubes to be evaluated. With the exception of some experiments on laboratory animals…and one small study on one species of fish, little information is available about the toxicity of nanoparticles to non-human species.[58]

It was concluded that:

> There are uncertainties about the risk of nanoparticles currently in production that need to be addressed immediately to safeguard workers and consumers and support regulatory decisions.[59]

7.52 The Society made 21 recommendations. These included, that given the lack of evidence about the risk posed by manufactured nanoparticles and nanotubes is resulting in considerable uncertainty, that:

- an interdisciplinary centre be established to research nanoparticles and nanotubes including toxicity and exposure pathways, and to develop

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55 The Royal Society & The Royal Academy of Engineering, *Nanoscience and Nanotechnologies: opportunities and uncertainties,* London, July 2004.

56 The Royal Society & The Royal Academy of Engineering, p.41.

57 The Royal Society & The Royal Academy of Engineering, p.80.

58 The Royal Society & The Royal Academy of Engineering, p.80.

59 The Royal Society & The Royal Academy of Engineering, p.81.

methodologies and instrumentation for monitoring them in the built and natural environment;

- until more is known about the environmental impacts of nanoparticles and nanotubes, that the release of manufactured nanoparticles and nanotubes into the environment be avoided as far as possible.

In relation to regulatory issues, it was recommended that consideration be given to whether existing regulations are appropriate to protect humans and the environment in relation to nanoparticles and nanotubes.

7.53 As a result of the novel properties of nanoparticles and nanotubes, it was recommended that:

- nanoparticles and nanotubes should be treated as new substances under existing UK and European regulations;
- that the adequacy of regulation of exposure to nanoparticles be reviewed and that in the meantime consideration be given to setting lower exposure levels for manufactured nanoparticles;
- that ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body before they are permitted for use in consumer products;
- that manufacturers publish details of safety tests to show how they have taken into account the novel properties of nanoparticles in consumer products;
- that the list of ingredients of consumer products identify the use of manufactured nanoparticulate materials; and
- that an interdisciplinary research program be funded to investigate the social and ethical issues expected to arise from the development of some nanoparticles.[60]

7.54 The UK Government's response to the report was released in February 2005. The Government indicated that it supported the precautionary stance taken by the Royal Society.[61] As part of its response, it also announced the establishment of a Research Co-ordination Group with a wide-ranging membership to ensure that a comprehensive research program is developed that focuses on regulatory needs. The Government also identified two main priority areas for research:

- the development of robust and reliable measurement and detection technologies for nanoparticles and nanotubes; and

60 The Royal Society & The Royal Academy of Engineering, pp.8-10.

61 HM Government, *Response to the Royal Society and Royal Academy of Engineering Report: Nanoscience and Nanotechnologies: opportunities and uncertainties*, February 2005, p.5.

- work to underpin the robust assessment of potential risks associated with nanoparticles and nanotubes, particularly their toxicology.[62]

7.55 In relation to consumer products, the UK Government agreed that ingredients in the form of manufactured free nanoparticles should undergo a full safety assessment before being used in products and that the use of nanoparticles should be indicated on labels.[63]

7.56 In November 2005, the UK Government produced the first report on on-going and projected research on potential risks posed by engineered nanoparticles as foreshadowed in response to the Royal Society report.[64] Three key areas were identified where further research is needed to develop a risk management framework for nanoparticles:

- properties, characterisation and metrology, including standardisation;
- human and environment exposure; and
- hazard to human health and the environment.

A fourth area is understanding the societal and ethical dimensions of nanotechnologies as they arise. Overarching this is a need for the development of, and international agreement on, nomenclature and definitions.[65]

National Institute for Occupational Safety and Health – United States

7.57 The National Institute for Occupational Safety and Health (NIOSH) has noted that:

> There are still many knowledge gaps to be filled before we fully understand how to work safely with these materials. Until these and other research questions are answered, it is prudent to proceed with caution when working with nanomaterials.[66]

NIOSH has stated that the information gap is 'critical because of the unknown risk that nanomaterials pose to workers'. NIOSH pointed to studies in rats where ultrafine particles caused pulmonary inflammation and lung tumors and commented that 'if

62 HM Government, February 2005, p.10.

63 HM Government, February 2005, p.16.

64 HM Government, *Characterising the potential risks posed by engineered nanoparticles: a first UK Government research report,* December 2005. www.defra.gov.uk/environment/nanotech/nrcg/pdf/nanoparticles-riskreport.pdf

65 HM Government, December 2005, pp.5-6.

66 NIOSH, *Nanotechnology and Workplace Safety and Health,* www.cdc.gov/niosh/docs/2004-175/pdfs/2004-175.pdf

engineered nanoparticles involve the same characteristics that seem to be associated with ultrafine particles, they may raise concerns'.[67]

7.58 NIOSH has formulated strategic goals for its nanotechnology research agenda including the need to understand and prevent work-related injuries and illnesses possibly caused by nanoparticles/nanomaterials. To achieve this goal, NIOSH stated that there is a need to determine the toxicity of nanomaterials, identify possible health effects from the early uses of these materials and monitor the on-going health of individuals working with nanomaterials. There is also a need for research to develop and validate methods of exposure assessment. In order to promote healthy workplaces, there is a need to develop and evaluate engineering controls, personal protective equipment and guidance on safe handling of nanomaterials and to identify and improve safety issues in the workplace.[68]

7.59 NIOSH has identified the following critical occupational safety and health issues arising from nanotechnology:

- exposure and dose;
- toxicity;
- epidemiology and surveillance;
- risk assessment;
- measurement methods;
- controls;
- safety;
- communication and education;
- recommendations including evaluation and updating of occupational exposure limits; and
- applications: identification of uses of nanotechnology for application in occupational safety and health.[69]

OECD – Working Party on Nanotechnology

7.60 The OECD Working Party on Nanotechnology was established under the Committee for Science and Technology Policy (CSTP) in 2005. The Working Party is to identify what member countries are doing in nanotechnology and how members can cooperate to effectively use their nanotechnology investments. The latest meeting of CSTP was held in March 2006 in Sydney.

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67 NIOSH, *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH,* www.cdc.gov/niosh/topics/nanotech/nano_exchange.html

68 NIOSH, *Strategic Plan for NIOSH Nanotechnology Research: Filling the Knowledge Gaps,* www.cdc.gov/niosh/topics/nanotech/strat_plan.html

69 NIOSH, *Strategic Plan.*

7.61 The OECD is also considering a proposal to create within the OEDC Environmental Directorate a working group focused on environmental, health and safety risk assessment and the management of nanomaterials.[70]

Royal Society-Science Council of Japan Workshop

7.62 In July 2005 the UK Royal Society and the Science Council of Japan held a joint workshop to consider the potential health, environmental and societal impacts of nanotechnology. The key issues identified by the workshop included:

- the need to develop new measuring technologies;
- the need for further research on exposure routes within the body;
- more research on nanomaterials and carcionogenesis;
- the need to develop internationally recognised standard protocols for toxicology testing of nanoparticles;
- to establish appropriate regulatory regimes funding for research is required and the engagement of stakeholders including the public; and
- international collaboration and coordination of research into toxicology of nanomaterials and the development of standardised safety assessments is needed.[71]

International Risk Governance Council

7.63 The International Risk Governance Council (IRGC) is undertaking a nanotechnology project intended to address the need for adequate risk governance approaches at the national and international levels in the development of nanotechnology and nanoscale products. The project is funded by the Swiss Federal Agency for Development and Cooperation, the US Department of State and the Swiss Reinsurance Company.

7.64 As part of this project, the IRGC conducted a survey on nanotechnology governance across 27 economies (including Australia).[72] A workshop was held in January 2006 to develop strategies and to review the survey. More than 45 recommendations were identified for how risk governance of nanotechnology may be improved in areas such as stakeholder engagement, communication and research. In July 2006, a meeting in Zurich will be held to discuss the recommendations of the survey and workshop.

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70 US Senate Commerce, Science and Transport Committee, *Testimony*, 15.2.06, EC Teague, Director, National Nanotechnology Coordination Office.

71 Royal Society-Science Council of Japan, pp.4-8.

72 IRGC, *Survey on Nanotechnology Governance*, December 2005 www.irgc.org/_cgidata/mhscms/_images/12384-3-2.pdf

Developments in Australia

Prime Minister's Science, Engineering and Innovation Council (PMSEIC)

7.65 In March 2005, the Prime Minister's Science, Engineering and Innovation Council (PMSEIC) working group on nanotechnology presented its report. The working group's terms of reference included:

- outline the importance and potential applications of nanotechnology as an enabling technology to many industries;
- examine what nanotechnology has delivered to date;
- scope Australia's international competitiveness; and
- identify major challenges and opportunities.[73]

7.66 The working group reported that there had been an explosion in technological development worldwide between 2000 and 2005, global investment had quadrupled (and exceeded US$8 billion per year) and important practical applications of nanotechnology are emerging. The working group found that Australia's research base is strong and globally competitive. It stated that:

> To capitalise on the opportunities presented by nanotechnology, the challenge is to enhance the coordination of Australia's nanotechnology effort, concentrate resources and accelerate industry uptake.[74]

Specific needs identified by the working group included:

- the need for a national nanotechnology strategy coordinated across all levels of government, to inform the public debate on social, health and environment issues, and to provide an appropriate regulatory framework;
- the need to address emerging issues concerning community awareness and acceptance of nanotechnology, as well as the considerable ethical, social and safety implications;
- the development of a comprehensive impact and risk analysis framework must be seen as a high priority. This framework must adopt a science-based risk identification, assessment and management process; and
- the development of a substantial Australian skills base in nanotechnology is of fundamental importance to our nanotechnology capability over the next decade.[75]

7.67 The working group made two recommendations:

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73 PMSEIC, *Nanotechnology: Enabling technologies for Australian innovative industries*, 11 March 2005, p.i.

74 PMSEIC, p.4.

75 PMSEIC, p.4.

- That the Australian Government examine the options for implementing a national nanotechnology strategy, with particular emphasis on the framework under which the objectives of a national nanotechnology strategy can be achieved.

This national strategy should provide a broadly based framework to ensure that Australia has a national and coordinated approach to nanotechnology; provision of high level advice to governments; well-informed public awareness activities and debate on social, health and environmental issues; and an appropriate regulatory framework which safeguards the health and safety of Australians.

- That an Australian nanotechnology business alliance be formed with government support whose role is to overcome the current fragmentation evident in the nanotechnology sectors, link business and researchers, and enhance industry application of nanotechnology.[76]

National Nanotechnology Strategy Taskforce

7.68 On 5 February 2006, the Minister for Industry, Tourism and Resources, the Hon Ian Macfarlane, announced the formulation of a National Strategy for the development and regulation of nanotechnology. The aim of the Strategy will be to best capture the benefits of nanotechnology for Australia whilst safeguarding health, safety and the environment. The Minister stated:

> Australia has an opportunity to be part of this world-wide movement towards smaller and greater efficiency in many aspects of our daily lives, no only as developer of the technology, but also as a responsible regulator of the field…
>
> It is hard to imagine areas of our lives that won't be impacted by nanotechnology so it makes sense to have a co-ordinated national approach, with the State and Territory governments, to make sure Australia is 'nanotech ready'.
>
> From an industry perspective we have to capture the commercial opportunities of developing this field but it is just as important that the environment, health and social issues are understood and properly monitored.[77]

7.69 The National Nanotechnology Strategy Taskforce was established to examine options for a coordinated national nanotechnology strategy across Commonwealth and State and Territory Governments by 30 June 2006. A broad array of issues will be examined including:

- community awareness;
- science capacity;

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76 PMSEIC, pp.6-7.

77 Minister for Industry, Tourism and Resources, 'A Big Strategy for Nanotech: The Industry of the Small', *Media Release*, 5.2.06.

- industry development and industry uptake;
- investment and infrastructure;
- regulation and metrology;
- skills and training;
- international engagement; and
- environmental, safety and ethical issues.[78]

7.70 A series of consultations are being undertaken with industry, science and the general community, as well as other Commonwealth government portfolios and State and Territory Governments. A Reference Group representing industry, science and community interests is working with the Taskforce. In addition, the Taskforce released a discussion paper on issues to be considered in a National Nanotechnology Strategy.

Office of the Australian Safety and Compensation Council

7.71 The Office of the Australian Safety and Compensation Council (see Chapter 1) currently maintains a watching brief on the OHS developments with respect to nanotechnology and reports to Australian Government (Comcare), State and Territory OHS authorities, ACCI and ACTU. The Office represents DEWR on an interdepartmental committee on nanotechnology, organised by the National Nanotechnology Strategy Taskforce within the Department of Industry, Tourism and Resources. The role of the Office on this committee is to provide input on OHS issues.[79]

National Industrial Chemical Notification and Assessment Scheme (NICNAS)

7.72 NICNAS commenced active consideration of nanomaterials and their regulation in 2004-05. NICNAS is a member of the OECD Steering Group for Nanotechnology.

7.73 In February 2006, NICNAS issued a voluntary call to companies to provide information on uses and quantities of nanomaterials imported or manufactured for industrial uses, or used in cosmetics and personal care products. NICNAS will prepare a report on the extent and scope of the use of nanomaterials in industrial, cosmetic and personal care products in Australia. In its call for information, NICNAS stated:

> It is important and timely that NICNAS considers nanomaterials, their potential health and environmental impacts, and the ability of the [industrial

78 Department of Industry, Tourism and Resources, *Nanotechnology*, www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=E2FE4F8A-4E44-4785-A6A01BE137E0E524#Task_force_established

79 *Submission* 11, p.10 (DEWR).

chemicals national notification] scheme to adequately assess the potential risks of nanomaterials.[80]

7.74 NICNAS also stated that nanomaterials used exclusively as therapeutic goods (such as sunscreens), food or food additives and agricultural or veterinary chemicals, do not fall within the scope of NICNAS.

7.75 To March 2006, no nanomaterials had been assessed by NICNAS.

Therapeutic Goods Administration

7.76 The Therapeutic Goods Administration (TGA) has issued advice on their website about the safety of sunscreens. The TGA is keeping a watching brief on the scientific literature with regard to the safety of nanoparticulate materials used in medicines, for example zinc oxide in sunscreens.

Conclusion

7.77 At the nanoscale, materials exhibit novel properties that affect their physical, chemical and biological behaviour. The Committee considers that the use of nanomaterials has enormous potential in many areas from medicine to computing and electronics. Indeed, nanotechnology may be as significant as the discovery of electricity or the microchip. At the same time, the Committee is mindful that the application of nanotechnology will have implications for workers' health and safety, for individuals through consumer and medical products and for the environment.

7.78 How significant those implications will be, particularly the hazards to human health, is unclear at the present time. The adverse effects of nanoparticles cannot be predicted from their known characteristics at larger scale and there are still major gaps in current knowledge of how nanoparticles enter the human body and how they impact on health including disease-causing effects. There are also problems with how nanoparticle exposure can be measured and assessed in the workplace and the environment.

7.79 The Committee has noted the outcomes of studies and reports from overseas, which have identified areas were further research is required. A key priority for occupational health and safety is the measurement and assessment of nanoparticles so that adequate regulatory frameworks can be developed. For nanoparticles, the use of traditional exposure regimes based on mass concentrations alone are insufficient as the surface area and physical dimension of nanoparticles play a key role in toxicity. These characteristics will require modification of the present regulations on exposure standards, risk assessment and methodologies and equipment needed to undertake measurements to ensure worker safety.

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80 NICNAS, *Nanomaterials – call for information*, Commonwealth of Australia Gazette, No C02 7 February 2006.

7.80 Nanotechnology holds great opportunities but also great responsibilities. The Committee considers that there is a need for continued international cooperation to address concerns raised by nanotechnology and acknowledges the Government's contribution to international forums such as the OECD Working Party on Nanotechnology.

7.81 The Committee also welcomes the establishment of the National Nanotechnology Strategy Taskforce. A national nanotechnology strategy is required as a matter of priority: nanotechnology is a rapidly emerging field attracting more and more investment everyday with workers already being exposed to nanoparticles. Governments overseas have responded to concerns about nanotechnology and a number of authoritative reports and studies are available. Any delays in formulating an Australian national strategy will only impede the consideration of significant regulatory, environmental, safety and ethical issues that must be addressed.

7.82 The Committee does not agree that a moratorium on nanotechnologies is needed but considers that safety of workers and the community must be paramount. This means that the exposure of those workers already working with nanoparticles must be minimised and that new methodologies, means of assessment and equipment being developed in Australia and overseas must be incorporated into the regulatory framework as soon as they are available.

7.83 The Committee also considers that the Australian regulatory framework needs to be flexible to address the novel characteristics of nanoparticles and that mechanisms are required so that all Commonwealth Government regulatory agencies address regulatory developments overseas and their significance for the Australian regulatory framework.

Recommendation 12

7.84 That the National Nanotechnology Strategy be finalised as a matter of priority.

Recommendation 13

7.85 That a working party on nanotechnology regulation consisting of representatives of the Therapeutic Goods Administration, NICNAS and the Australian Safety and Compensation Council be established to consider the impact of the emerging field of nanotechnology on the regulatory framework including:

- **whether existing regulations are appropriate;**
- **how gaps and uncertainties in the regulatory framework can be addressed;**
- **how comprehensive management of risks of exposure to nanoparticles can be incorporated into the regulatory framework;**
- **whether Australia will require materials, already classified as safe at the macroscale, to be reassessed if they are to be used at the nanoscale; and**

- **whether there is a need for the establishment of a permanent body to regulate nanotechnology.**

The working party should consult with stakeholders including consumer groups, State and Territory governments, unions, industry, health organisations and the public and provide a public report on these issues by March 2007.

Recommendation 14

7.86 That Commonwealth agencies including the Office of the Australian Safety and Compensation Council and NICNAS actively pursue links to overseas regulatory and research bodies to ensure that they are kept fully informed of developments in the rapidly emerging field of nanotechnology.

Senator Claire Moore
Chair

May 2006