NANOPARTICLES: REGULATING THE UNDEFINABLE

Karinne Ludlow*

Introduction

Problems arise when trying to regulate a new technology before the actual risks of that technology – including to health and safety and the environment – are known. They are demonstrated by even only a brief study of the literature debating whether the approach taken to risk assessment regarding genetically modified (or GM) food should be science based or based on the precautionary principle.[1] That issue can also be expected to cause debate regarding nanotechnology but it is not the issue to be explored here.[2] This paper concerns a problem arising upstream of the issue of risk assessment –the legal difficulties arising when regulating a new technology where there is no agreement on the definition of the subject matter that is to be regulated and that subject matter cannot even be measured.

What is nanotechnology?

Even explaining what nanotechnology is, is fraught with difficulty. As Hodge and Bowman have pointed out there exists many different definitions of 'nanotechnology' in the current literature.[3] Essentially nanotechnology can be described as molecular engineering. That is, 'the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale'.[4] One nanometre (nm) is one billionth of a meter (10^{-9}).[5] So, for example, a human hair is about 80,000 nm wide and a sheet of paper about 100,000 nm thick. A *nanoparticle* can be defined as a particle with one or more dimensions of 100 nanometres or less.[6] This definition needs clarification though. Whilst nanoparticles are all small – nanosized – they are not all the same. Nanoparticles are certainly not just 'small dots'. They are intricately etched particles with complex spatial dimensions that instruments can barely measure.[7] They can differ in actual size,

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* BSc LLB (Hons) PhD, Senior Lecturer, Centre for Regulatory Studies, Faculty of Law, Monash University, Victoria, Australia. The author would like to express her appreciation to Dr Peter Binks and Nanotechnology Victoria for supporting her attendance at the Frontiers of Regulation Conference (2006), Bath, United Kingdom.

[1] The precautionary principle generally provides that lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

[2] With respect to its' application to nanotechnology see, for example, R Haum, U Petschow and M Steinfeldt, Final Report. *Nanotechnology and Regulation within the framework of the Precautionary Principle* (2004) Institut für ökologische Wirtschaftsforschu.

[3] G Hodge and D Bowman, 'Introduction: Big Questions for Small Technologies', in Graeme Hodge, Karinne Ludlow and Diana Bowman (eds), *New Global Regulatory Frontiers: Evaluating What Will Work for Nanotechnology* (forthcoming 2007) Cheltenham: Edward Elgar.

[4] UK, The Royal Society and The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties* (July 2004), London: The Royal Society and The Royal Academy of Engineering, p 5.

[5] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), p 83.

[6] Publicly Available Specification on the Vocabulary for Nanoparticles of the British Standards Institution (BSI PAS 71:2005).

[7] R Weiss, 'Nanotech Raises Worker-Safety Questions' 8 April 2006 *Washington Post* A01 <http://www.washingtonpost.com/wp-dyn/content/article/2006/04/0...> accessed 13/4/06.

shape (for example, they can be spheres, flakes, fibres or hollow tubes), composition, surface properties (including area, porosity, charge and surface modifications), solubility, agglomeration state and biopersistance (that is, how long is exists in living tissue. Given that we can list their differences, it would seem we should have no problem defining the subject matter that should be regulated if it is decided that nanoparticles should indeed be regulated. But that is not the case.

Possible risks to workers

Due to their size, all nanoparticles have a high surface to volume ratio. This has to be the case because given how tiny the particles are they must be larger on the outside than the inside. That increase in relative surface area has consequences. It means an increase in the percentage of atoms at the surface and therefore more sites for bonding or reacting with surrounding materials.[8] For example, whilst a 30 nm particle has 5% of its atoms on the surface, a 3 nm particle has 50% of its atoms on the surface.[9] Nanoparticles, because of their size and the effect that size has on other properties, can therefore possess different physical, chemical and biological properties compared with their equivalent bulk material, sometimes in ways that are not predicted.[10] This can, for example, result in improved strength or heat resistance allowing engineered nanomaterials to present 'new opportunities to increase the performance of traditional products, and to develop unique new products.'[11] For example, carbon nanotubes are mechanically strong, flexible and conduct electricity but are also nanosized. They are 100 times stronger than steel but only one-sixth the weight.[12] Physically they are typically a few nanometers in diameter but with lengths up to centimeters long.[13] They are therefore useful in reinforced composites, electrical wires, sensors, nanoelectronics and display devices such as LCD displays.[14]

Given the sometimes unpredictable effect on properties, particularly biological properties, 'the direct relationship between volume of material and exposure – assumed in most chemical regulation – is not a useful guide for dealing with nanotechnology'.[15] The large surface area and associated increased reactivity of

[8] T Hampton, 'Researchers Size Up Nanotechnology Risks' (2005) 294 (15) JAMA 1881-3, p 1881.
[9] K Mills and C Fleddermann, 'Getting the Best from Nanotechnology: Approaching Social and Ethical Implications Openly and Proactively' (Winter 2005) *IEEE Technology and Society Magazine* 18-26, p 20.
[10] For an explanation of why this is the case, see The Royal Society and The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties* (July 2004), London: The Royal Society and The Royal Academy of Engineering.
[11] Oberdörster et al, 'Review. Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy' (2005) 2 *Particle and Fibre Toxicology* <http://www.pubmedcentral.nih.gov/tocrender.fcgi?iid=116767, p 2.
[12] N Lewinski, 'Nanotechnology Policy and Environmental Regulatory Issues' (2005) 9 *Journal of Engineering and Public Policy*, <http://www.wise-intern.org>, p 8.
[13] Carbon nanotubes can be single walled or multi-walled. EE Knowles III, 'Nanotechnology. Evolving occupational safety, health and environmental issues' (March 2006) *Professional Safety* 20-27, p 20.
[14] EE Knowles III, 'Nanotechnology. Evolving occupational safety, health and environmental issues' March 2006 *Professional Safety* 20-27, p 20.
[15] JC Davies, *Managing the Effects of Nanotechnology*, (2006) Woodrow Wilson International Center for Scholars. Project on Emerging Nanotechnology, p 8.

some nanoparticles may mean different reactions with biological systems.[16] For example, the larger relative surface area seems to mean a greater inflammatory response by the human lungs to the presence of insoluble nanoparticles.[17] It also may mean that nanoparticles take longer to settle from the air and so have greater opportunity to travel and spread in the environment and to come into contact with humans. The smaller size also means nanoparticles can deposit deeper in the respiratory tract than larger particles.

The new properties brought about by their size raise questions about the safety of engineered nanoparticles. The term 'engineered nanoparticles' refers to intentionally engineered nanoparticles rather than naturally or incidentally occurring particles. Nanoparticles already occur in the natural environment, such as the nanosized specks of salt that beachgoers are exposed to. Many traditional industrial processes such as welding and smelting also cause the production of airborne particles in the nanometre size range.[18] This paper focuses on the newer phenomenon of deliberately created nanoparticles. Workers could be exposed to these through, for example, inhalation or adsorption through the skin. For some nanoparticles, such as carbon nanotubes referred to above, the fibre shape and small size has lead to speculation that carbon nanotubes may have health effects similar to asbestos fibres.[19] Further, as Maynard and Kuempel have noted, 'concern has been expressed that [nanostructure-dependent] properties may present unique challenges to addressing potential health impact'.[20] Nanoparticles' large surface area and the effect of that also raise suspicions that nanoparticles could be potential catalysts for reactions that would otherwise proceed slowly.[21] Bioavailability may also increase as the particles decrease in size. The US National Institute of Environmental Health Sciences (US NIOSH)[22] has stated that generally the smaller the particles, the more reactive and toxic are their effects.[23]

Unfortunately though much of this is still only speculation. Much more work needs to be done to measure the actual risk that nanoparticles pose to workers. But workers are currently being exposed to nanoparticles. In Australia, it seems there are about 50

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[16] MP Holsapple, et al, 'Forum Series. Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs' (2005) 88(1) *Toxicological Sciences* 12-17, p 12.
[17] T Hampton, 'Researchers Size Up Nanotechnology Risks' (2005) 294 (15) JAMA 1881-3, p 1881.
[18] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 588.
[19] EE Knowles III, 'Nanotechnology. Evolving occupational safety, health and environmental issues' Professional Safety March 2006 20-27, p 23; CW Lam, JT James, R McCluskey and RL Hunter, 'Pulmonary toxicity of single wall carbon nanotubes in mice 7 and 90 days after intratracheal instillation' (Jan 2004) 77 (no 1) *Toxicological sciences* 126-134.
[20] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 587.
[21] UK, Health and Safety Executive (HSE) 'HSE Information Note: Nanotechnology' no HSIN1. (2004) London: HSE, p 2.
[22] NIOSH is part of US Centers for Disease Control and Prevention (CDC) in US Dept of Health and Human Services and is the US federal agency that conducts scientific research in field of occupational safety and health and makes recommendations for preventing work-related injuries, illnesses and deaths. In 2005 NIOSH embarked on a five year study of the toxicity and health risks associated with occupational nanoparticle exposure. T Hampton, 'Researchers Size Up Nanotechnology Risks' (2005) 294 (15) JAMA 1881-3, p 1882.
[23] US, National Institute of Environmental Health Sciences (NIEHS) 'Nanotechnology Safety Assessment' OPPE Factsheet #03. (2003) Washington DC: NIEHS.

companies using or researching nanotechnology.[24] Both the Australian Council of Trade Unions (ACTU) and the Australian Manufacturing Workers Union have called for research into risks to workers, with the ACTU also calling for regulation of nanoparticle exposure levels.[25] Given the horrendous experiences with asbestos, this is understandable and justifiable.

So why don't we 'regulate'? Certainly it seems those advising the Australian government consider such regulation necessary. A working group report in March 2005 to the Prime Minister's Science, Engineering and Innovation Council[26] said the Australian national nanotechnology strategy that is currently being developed should provide a framework to ensure Australia has 'an appropriate regulatory framework which safeguards the health and safety of Australians'.[27] A Senate committee inquiry into workplace exposure to toxic dust, which reported in May 2006, said that it 'considers a responsive regulatory system will be imperative as workers are exposed to new hazards through emerging technologies such as nanotechnology'.[28]

Measuring nanoparticles

If it is accepted that regulation is required to protect workers, the issue becomes what should be regulated? It is not just a problem with defining the technology. That problem arises with all new technologies such as cloning and stem cell research. Nanoparticles pose an additional difficulty – characterisation and measurement.

Regulation of nanoparticle exposure requires the ability to accurately describe and to measure the thing being regulated. The ETC Group says at least 44 of the 113 elements in the periodic table are commercially available in nanoscale form.[29] It may seem to follow that we could define these 'new chemicals' as the nanoscale form of the bulk equivalent. So, for example, 'nanoscale carbon' to distinguish it from macroscale carbon. But even at the most simplistic level 'nanoscale carbon' comes in an array of forms including tubes (which themselves can be single or multi walled) and sphere shapes. Even within one form, there will be significant differences in the surface properties of the particles depending on the method of manufacture. For example, some particles may have internal voids and therefore be more porous than others. Difficulties in description will be important not only to regulation but to risk assessment necessary for regulation. If nanoparticles cannot be accurately named, it will be difficult if not impossible to be sure two investigators are considering the same

[24] W Birnbauer, 'Nano could be a huge future health crisis' 30 October 2005 *Sunday Age*, p 4.
[25] W Birnbauer, 'Nano could be a huge future health crisis' 30 October 2005 *Sunday Age*, p 4.
[26] *Nanotechnology: enabling technologies for Australian innovative industries*.
[27] Prime Minister's Science, Engineering and Innovation Council, *Nanotechnology: enabling technologies for Australian innovative industries* (2005), p 5.
[28] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), p 71.
[29] ETC Group, *No Small Matter II: The case for a global moratorium, Size Matters!* Occasional Paper Series, (April 2003) Vol 7, no 1, Action Group on Erosion, Technology and Concentration, <http://www.etcgroup.org>.

material.[30] Because of this concern, there is an urgent need for the development of standard reference nanomaterials for use by the toxicology research community.[31]

In June 2005, the International Standards Organisation (ISO) established a technical committee on nanotechnologies of which Australia is a participating member.[32] That committee is to develop standards for 'terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety and environmental practices.'[33] Standards Australia in March 2006 established a committee[34] to coordinate Australia's contributions to the ISO work and perhaps produce Australian standards.[35] With the scope of the ISO committee having only been finalised in June 2006, standards themselves may still be some way off.

It will need to be decided whether the definition of a nanoparticle should be based on physical dimensions (such as length, diameter, surface area) or some behavioural property such as diffusivity and any definition will need to take into account that nanoparticles agglomerate and that this also effects their properties.[36] This decision will be made more difficult by the fact that it is still unsettled how biologically active or available surface areas should be defined.[37]

Once it is determined what characteristics are important, we then need to be able to measure such characteristics. The measurement techniques used will generally need to be robust, compact, inexpensive and relevant to appropriate exposure standards.[38] Asbestos is a clear example of difficulties caused by measurement. The use of asbestos is banned in Australia and the UK.[39] However, it took far too long to get there. Whilst there were many reasons leading to the regulatory failure regarding the health risks of asbestos,[40] one practical problem was the inability to 'measure' (by counting) asbestos fibres. This requires a specialised optical microscope (a phase

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[30] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 602.
[31] MP Holsapple, et al, 'Forum Series. Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs' (2005) 88(1) *Toxicological sciences* 12-17, p 16.
[32] ISO TC 229- nanotechnologies.
[33] John Miles, 'Current situation with nanomanufacturing standards and the International Organization for Standardization' in Graeme Hodge, Karinne Ludlow and Diana Bowman (eds), *New Global Regulatory Frontiers: Evaluating What Will Work for Nanotechnology* (forthcoming 2007) Cheltenham: Edward Elgar.
[34] NT-001 Nanotechnologies.
[35] John Miles, 'Current situation with nanomanufacturing standards and the International Organization for Standardization' in Graeme Hodge, Karinne Ludlow and Diana Bowman (eds), *New Global Regulatory Frontiers: Evaluating What Will Work for Nanotechnology* (forthcoming 2007) Cheltenham: Edward Elgar.
[36] Texas A&M Engineering, 'Interim Guideline for Working Safely with Nanotechnology'.
[37] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 599.
[38] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 602.
[39] Asbestos (Prohibition) Regulations 1992 (UK).
[40] See D Gee and M Greenberg, 'Asbestos: from 'magic' to malevolent mineral', in P Harremo, D Gee, M MacGavin, A Stirling, J Keys, B Wynne, S Guedez Vaz (eds), *Late Lessons from early warnings: the precautionary principle 1896-2000*, (2002) Copenhagen: European Environment Agency; L Bruan, A Green, M Manseau, R Singhal, S Kisting, N Jacobs, 'Scientific controversy and Asbestos: Making Disease Invisible' (2003) 9 *International Journal of Environmental Health* 194-205.

contrast microscope with a specially designed eyepiece graticule) to check air samples. The phase contrast optical microscope was only first described in 1934 and practical microscopes were not created until some time later. Dust control regulations for asbestos dust were introduced in the UK for the first time in 1931.[41] These simply required adherence to a short series of legal requirements to prevent 'the escape of asbestos dust into the air of any room in which persons work'.[42] Understandably, there was no attempt in 1931 to address what level of dust was needed before the prohibition would be breached because there was no equipment to measure it. The adoption of better control standards once measurement was possible was obviously disgracefully slow. (UK Regulations only reflected a need to limit exposure to air contamination when amended in 1969 when exposure was limited to 2 million fibres/ m^3.[43] This was decreased again in 1984.[44]) But the initial lag between regulation by general 'prohibition' to the more precise regulation through limits on exposure can for some period be explained by the inability to actually measure the thing being regulated. Australia now has a Code of Practice for the Management and Control of Asbestos in Workplaces[45] which provides a national exposure standard for asbestos (that is, airborne concentration of asbestos within workers breathing zone) of 0.1 fibres/mL of air.[46]

The use of a technology can of course be banned where there are difficulties in measuring a technology or its outcomes but monitoring and enforcement of that regulation will be very difficult. History clearly shows the importance of proper enforcement of any regulations, something not done with the earlier asbestos regulations.[47] Unfortunately the Senate committee inquiry into toxic dust exposure noted that monitoring and enforcement of exposure standards is still poor for toxic dusts generally even where there is no difficulty with measurement.[48] Recognition of a need to consider regulation in whatever form does though provide an impetus for developing characterisation and measurement capabilities as is happening with nanotechnology.

Regulation of relevant characteristics

Once nanoparticles can be characterised and measured, the challenge moves to ensuring that regulation reflects the properties of nanoparticles that are significant. As the Senate Committee inquiring into workplace exposure to toxic dust warned, nanotechnology 'will create new challenges for safety and regulatory regimes'.[49] At

[41] Asbestos Industry Regulations 1931 SR 40 1931/ 1140 (Rev VII, p 181: 1931 p 410) (UK).
[42] Those persons needed to work in a narrow field of occupations listed in the Preamble to the Regulations.
[43] Asbestos Regulations 1969 SI No 690 (UK).
[44] Asbestos (Licensing) Regulations 1983 came into force in 1984. Asbestos (Prohibition) Regulations were introduced in 1985 and amended 1992.
[45] NOHSC:2018 (2005).
[46] There is also a code for air monitoring, which should be undertaken in accordance with the National Occupational Health and Safety Commission (NOHSC) (2005), Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Fibres [NOHSC:3003(2005)], NOHSC, Canberra, Australia.
[47] NJ Wikeley, 'Asbestos Industry Regulations 1931: A Licence to Kill?' (1992) 19 *Journal of Law and Society* 365.
[48] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), para 5.82.
[49] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), p 83.

present Australian occupational health and safety (OH&S) regulation is very often based on the weight of the substance a worker is exposed to. Classification of chemicals as hazardous substances is done on the basis of health effects criteria evaluated on toxicological data. Those criteria generally use the weight of the test substance and do not refer to the size, number or surface area of the particles. For example, where it is being determined whether a substance is very toxic by inhalation, the evidence required is expressed as –

> 'LC_{50} inhalation, rat, for aerosols or particulates of $\leq$ 0.25/mg/litre/4 hr'.[50]

This evidence, called the median lethal concentration, is the concentration of substance that can be expected to kill during exposure or within a fixed time after exposure in 50% of animals exposed for a specified time. It is expressed as the *weight of test substance* per standard volume of air.[51] In the case of nanoparticles, this may mean that nanoparticles are not accurately assessed in deciding whether they are hazardous substances or not. It may be that the weight of nanoparticles is less important than their size, number or surface area. Unless there is a direct correlation between these characteristics and weight of material (and it seems there is not such a correlation), the use of weight as the relevant metric is not as useful as it should be. If particle size, number or surface area is a more relevant exposure metric, weight (or mass) concentration can only be used as a surrogate measurement when information on particle size distribution or aerosol specific surface area is known.[52] That information is not yet known. As Maynard and Kuempel observe 'the evidence is not yet sufficient to identify a clear general basis for exposure measurement and characterization.'[53]

The difficulties with fitting OH&S regulation to nanoparticles do not end there. If a type of nanoparticle is declared to be a hazardous substance, employers must then ensure no worker is exposed to hazardous substances at levels above the national exposure standards. So, for example, a national exposure standard has been set for titanium oxide of 10 mg/m^3. Titanium oxide, commonly used in sunscreens and cosmetics, has been found to have consumer attractive properties at the nanoscale. Whilst at the macroscale, titanium oxide at even only very low levels produces a white coating, at the nanoscale it is transparent, a more attractive colour for beachgoers. The exposure standard for titanium oxide is determined by the weight (in milligrams) of substance per cubic metre of air. Therefore it is based on the mass of the substance. Yet it seems for nanoparticles that it is the concentration (that is, the number of particles a person is exposed to) *and* the surface area of nanoparticles rather than the mass which is most relevant to the health effects on a person.

The US Food and Drug Administration has ruled that titanium oxide is the same ingredient regardless of which form it is in. If that approach is adopted in Australia, the same exposure limit will be used for nanosized titanium oxide as for the

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[50] NOHSC, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], 3rd ed, para 4.9.
[51] NOHSC, *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], 3rd ed, Chap 2.
[52] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 602.
[53] AD Maynard and ED Kuempel, 'Airborne nanostructured particles and occupational health' (2005) 7 *Journal of Nanoparticle Research* 587-614, p 602.

macroscale form despite the fact that it seems it is not the weight of material a person is exposed to that is relevant in nanoparticle safety, but the size, number and surface area. Far more nanoparticles will be present in 10 mg of titanium oxide than macrosized particles in a sample of the same weight.

Therefore even when there is internationally or even Australian agreed terminology that can be used to describe nanoparticles and methodologies and equipment are developed to enable routine measurements of such characteristics,[54] Australian regulations will need to be amended to use the size, number and/or surface area of particles as the relevant metric rather than just the weight. The toxic dust Senate Committee inquiry recommended that there be urgent consideration of whether materials already classified as safe at the macroscale should be reassessed to see if they are safe at the nanoscale.[55] Is that the end of the problem?

'Objective' definition

Definition for the purposes of regulation at least, is not an objective science. Take for example the problem of 'GM'. In mid-July 2005 the media reported that there had been a breach of Victoria's ban on commercial GM crops.[56] Reports claimed that traces of GM material were found in a consignment of canola. The level of contamination was near or below 0.1%. The possible legal consequences of that for farmers are great. It is an offence to cultivate GM canola in Victoria in contravention of the moratorium order if the person knows or is reckless as to whether the crop is a GM crop.[57] Farmers inadvertently contaminated therefore have not committed an offence under the Act.[58] Nevertheless, their contaminated crops can be destroyed against their wishes.[59] Importantly, there is no provision for compensation in such circumstances. In other Australian states, the consequences can be even more onerous including restrictions on the future use of farmers' land. Further, in all States other than Queensland, after a farmer becomes aware of contamination and continues to cultivate the contaminated crop, they will be committing an offence under the legislation and subject to fines and possible jail terms.

Is the presence of an amount of GM material of less than 0.1% (that is, less than 1 g per kilogram) sufficient to make a load of canola 'GM'? There is the problem of measuring such small amounts (at present the current level of scientific detection is about 0.01%) and that, practically speaking, sets the minimum threshold for contamination. But if the problem of actual measuring can be overcome, the next issue is defining what is 'GM'. The Victorian moratorium legislation clearly allows

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[54] US National Institute for Occupational Safety and Health (NIOSH) is attempting to develop cheaper, handheld devices that can test worker exposure. R Weiss, 'Nanotech Raises Worker-Safety Questions' 8 April 2006 *Washington Post* A01 <http://www.washingtonpost.com/wp-dyn/content/article/2006/04/0...> accessed 13/4/06.

[55] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), recommendation 13.

[56] M Marino, 'GM contamination in Victorian grain' 15 July 2005 *The Age* News 3.

[57] *Control of Genetically Modified Crops Act* (Vic) s 17(1). The legislation also restricts dealings with GM crop related material. See s 17(1) and s 3 (definition of 'GM crop related material').

[58] Cf position in South Australia and Tasmania where it would still be an offence even if the farmer was unaware of the contamination. See *Genetically Modified Crops Management Act 2004* (SA); *Genetically Modified Organisms Control Act 2004* (Tas).

[59] *Control of Genetically Modified Crops Act* (Vic) s 15(1). This requires an order by the Magistrates Court.

for the Minister to determine threshold amounts for the presence of GM material in crops.[60] GM amounts less than the threshold can then be disregarded for the purposes of the Act.[61] However, there is no explanation of how such thresholds will be set nor is there provision for public input into setting that threshold. In the case referred to above, it was decided by the government to set the threshold at 0.9% to solve the immediate problem. That means a consignment of canola with more than 9 grams per kilogram of GM material is 'GM' for the purposes of the moratorium legislation.

But that threshold is relevant only for the purposes of that legislation – it is not a threshold applicable to common law litigation or matters arising under other legislation. For example, under Australian law where food is derived or developed from a genetically modified organism ('GMO') it must receive prior approval from the national regulator, after a safety assessment. There is no threshold at all. So presumably any level of GM material makes it a GMO. GM food must also be labelled as GM if it contains any novel DNA and/or novel protein or has altered characteristics. Where, however, a food is accidentally contaminated by a GMO, it only loses its GM free status for the purposes of labelling if that contamination results in a level of 1% (that is, 10 g per kilogram) of GM material or more. Above that level, and the food must be labelled as GM. Regardless of the level though, it must still go through the safety assessment process because it is considered 'GM'.

Problems with definition don't end there. Difficulties arise with respect to claims based on matters to which no legislative standards apply. For example, organic farmers in Australia can define GM anyway they chose. There is no legislative definition of 'organic'. Organic standards are set by voluntary certification schemes. The Australian Quarantine and Inspection Service ('AQIS') has implemented a National Standard for Organic and Bio-Dynamic Produce for products labelled as organic or bio-dynamic which are to be exported from Australia.[62] The AQIS Standard does not apply to domestic produce although accredited certifying organisations apply this standard as a minimum requirement to all products produced by operators certified under their inspection systems.[63] Such organisations are, however, free to stipulate additional requirements. Any one of a range of thresholds could apply depending upon the farmer and the certifying organisation they belong to.

Even if the AQIS standard is taken as the domestic standard, significant objections can still be raised by to its use as the definition of GM. Standard 3.1.4 of the AQIS National Standard prohibits the use of products comprised of or derived from GM on any organic farm.[64] Standard 3.1.8b provides that where unintentional GM 'contamination' occurs, the contaminated product cannot be sold as organic. Contamination is not defined. The Organic Federation of Australia claims that AQIS's policy is that only detectable GM contamination renders product

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[60] *Control of Genetically Modified Crops Act* (Vic) s 7(1). See also *Genetically Modified Crops Management Act 2004* (SA) s 4(1).
[61] *Control of Genetically Modified Crops Act* (Vic) s 7(3); *Genetically Modified Crops Management Act 2004* (SA) s 4(2).
[62] Australian Quarantine and Inspection Service, Organic Produce Export Committee, *National Standard for Organic and Bio-Dynamic Produce* (3rd ed, December 2002).
[63] For example, Australian Certified Organic (ACO) is an accredited organisation. It is the certification arm of the Biological Farmers of Australia Co-op Ltd ('BFA'). The BFA, according to its website, is the largest representative group for the organic industry in Australia.
[64] See also Standard 3.1.11.

uncertifiable. As noted above, the current level of detection is about 0.01%. Therefore this is the current threshold for contamination.[65] If that is correct, the tolerance for GM contamination in organic standards is much lower (one hundred times) than that provided for in the food legislation. This will be an important issue when the inevitable litigation concerning contamination of an organic crop by a GM crop occurs. Given that this tolerance is essentially a voluntary one, it is submitted that it inappropriate that it be used as the definition of 'GM' at least for legal purposes.

To return to the asbestos example and the OH&S issues raised by nanoparticles, there can also be problems in defining the outcome of exposure in human terms, that is disease. As Rosenberg has asserted 'a disease is no absolute physical entity but a complex intellectual construct, an amalgam of biological and social definition'.[66] Disease is not defined in the Victorian legislation concerning negligence liability for personal injuries.[67] Returning to the GM context, organic farmers may consider their GM contaminated plants and animals 'diseased' but this is not the case, at least under Victorian legislation concerning plant and animal disease.[68]

But who should be the one to define such things? Can we leave it to the courts? The first difficulty with that is courts will only have the opportunity to consider a matter after a problem has arisen. In the case of nanoparticles and OH&S concerns it is far better to prevent harm to workers than to use them as test cases particularly if, like asbestos-related disease, there is a 30 to 40 year latency period before manifestation of disease. This lag period also means that many claims cannot be brought to Australian courts because they are outside the relevant time limit. A further difficulty for workers injured in such a way is that there are strict limits on the thresholds of injuries needed before there is access to courts in Australia as well as on the amount of compensation available from both the courts and workers compensation schemes. The second difficulty with leaving definition to the courts, and perhaps more importantly for a new technology such as nanotechnology, is that depending on the type of legal proceeding, broader general public or community concerns are of only limited, if any, relevance to a court. Even if such concerns are relevant the material provided to the court to enable it to make such determinations is questionable and in Australia, is ultimately decided by the two private parties involved in the proceedings. Surely having a court balance individuals rights is not the best way to regulate in the public's, rather than private, interests and to ensure that the ethical and socio-economic interests of the community regarding a new technology are taken into account.

Suggestions for the definition of nanoparticles

It is not in industry's or Australia's best interests that the courts be left to determine the definition of nanoparticle and how they are regulated. First, leaving the issue to

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[65] S Statham, Organic Federation of Australia Inc, Genetic Engineering Sub-Committee, *Report to the OFA Membership on the Process of Govt Consultation through the Gene Technology Grains Committee* (12 September 2002) (<http://www.bfa.com.au> accessed 5/11/03), text accompanying fns 13 and 14.

[66] C Rosenberg, *The Cholera Years* (1962) 5, quoted by NJ Wikeley, 'Asbestos Industry Regulations 1931: A Licence to Kill?' (1992) 19 *Journal of Law and Society* 365-78, p 374.

[67] *Wrongs Act 1958* (Vic).

[68] *Plant Health and Plant Products Act 1995* (Vic); *Livestock Disease Control Act 1994* (Vic).

the courts creates considerable uncertainty for industry. Such uncertainty is undesirable if nanotechnology is to be encouraged. Legislation on the other hand means regulation and relevant considerations can be explicit and direct.[69] Secondly, private actions between two parties are not the appropriate forum in which to determine whether the ethical, social and economic impacts of nanoparticles are such that the use of engineered nanoparticles should or should not proceed. The interests of the community must be adequately weighed in any balancing process. Such matters are complex in terms of the policy decisions that must be made.[70] They are better determined by the legislature in light of society's best interests and where there is an opportunity for public input. Finally, in most cases the courts will be able to consider the matter only after harm of some sort has occurred and only some cases will be able to be heard by the court.

Whilst industry standards are useful, it is also inappropriate that standards other than legislative and regulatory requirements be used as the standard in these circumstances. In particular using voluntary standards gives competing industries, such as the organic industry in the case of GM agriculture, the power to prevent the development of the new technology. Definitions set by particular industries are arbitrary and although they may be determined by what is in that industry's best interests, they are not necessarily in society's best interests or a fair basis on which to judge the behaviour of others. Further, standards set by industry groups in such cases may be unrealistic.[71] Once again it is submitted that they are not necessarily a suitable standard.

So what should be done? Given there is still uncertainty about whether all or some nanoparticles are hazardous a short-term approach using best management practices to OH&S should have to be adopted until scientific data on exposure and measurement is available. Further, there should be compulsory reporting of any incidence of adverse health effects among those working with nanoparticles. That reporting scheme should be national and adopt consistent identification and assessment mechanisms.[72]

If nanoparticles are hazardous, the question then is whether the benefits of engineered nanoparticles outweigh the risks to those who will be exposed to them. It is submitted that that is a question for Parliament rather than the courts or industry but it essential that the public be involved in answering this question. Given that workers are already being exposed to nanoparticles, it is crucial that Parliament deal with the matter now.

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[69] C H Schroeder, 'Lost in the Translation: What Environmental Regulation Does that Tort Cannot Duplicate' (2002) 41 *Washburn Law Journal* 583, p 598.

[70] For a discussion of whether the courts or government are better suited to making such decisions see D Campbell, 'Of Coase and Corn: A (Sort of) Defence of Private Nuisance' (2000) 63 *Modern Law Review* 197.

[71] For example, there have been international statements that the organic industry standards are not achievable. See Statement by EU Agriculture Commissioner Franz Fischler, 'GM free food is a Garden of Eden fantasy, says Fischler' (23/1/04), *Cordis News* (<wysiwyg://120/http://dbs.cordis.lu/cgi-…S&ACTION=D7SESSION=7RCN=EN_RCN_ID:21489> accessed 12/2/04). See also M Partridge and D J Murphy, 'Detection of genetically modified soya in a range of organic and health food products: Implications for the accurate labelling of foodstuffs derived from potential GM crops' (2004) 106 *British Food Journal* 166.

[72] Cth, Senate Community Affairs References Committee, *Workplace exposure to toxic dust* (May 2006), recommendation 9.