

An Evaluation of Whether New Zealand's Occupational Health and Safety Law Adequately Addresses the Risks to Workers Exposed to Nanotechnology and Nanoparticles

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Introduction

Nanotechnologies use processes to create novel materials and particles sized between one to 100 nanometers, although this metrology is not uncontested.¹ Nanoparticles (NPs) have different physical, chemical and biological properties from their equivalent macro counterparts. There is concern that the special properties of some nanoscale materials will present unforeseen human and environmental health and safety risks.² Nanoparticles can be categorised as natural or engineered/manufactured. Naturally occurring NPs include particles in our atmosphere such as salt at the beach. Engineered NPs are the newer phenomenon of intentionally/deliberately created manufactured nanomaterials (mNMs). This article is concerned with mNMs.

The key issue explored in this paper is whether New Zealand (NZ) occupational health and safety (OHS) legislation provides adequate protection for workers who are exposed to NPs. I evaluate the suitability of NZ regulation of NP exposure in the workplace and the current scientific data on occupational disease attributed to NPs.

Approximately NZ\$6 million of public money per annum is invested in nanotechnology research and development.³ Nanoparticles are used in a broad range of consumer products (nanoproducts) such as cosmetics, sunscreens, food packaging, paints, textiles and herbal remedies.⁴ There are over 1000 manufacturer-identified nanoproducts currently on the market and new nanoproducts are entering the market at a rapid pace.⁵ An estimated US\$2.6 trillion worth of manufactured goods are expected to incorporate manufactured nanomaterials (mNMs) by 2014.⁶ The increasing numbers of nanoproducts are creating occupational exposures, some of which may be harmful to human health.

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Dr Moore and Associate Professor Colin Gavaghan co-authored the New Zealand government commissioned report on the ability of New Zealand's regulatory systems to manage the possible impacts of manufactured nanomaterials. This paper is based on that report.

¹ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) *Risk Assessment of Products of Nanotechnologies* (SCENIHR, EU, January 2009) at 7; Melanie Auffan and others "Towards a Definition of Inorganic Nanoparticles from an Environmental, Health and Safety Perspective" (2009) 4 *Nature Nanotechnology* 634.

² Milind Kandlikar, Ramachandran Gurumurthy and Andrew Maynard "Health Risk Assessment for Nanoparticles: A Case for Using Expert Judgment" (2007) 9 *Journal of Nanoparticle Research* 137; Andrew Maynard "Nanotechnology: The Next Big Thing or Much Ado About Nothing?" (2007) 51 *Annals of Occupational Hygiene* 1; Andrew Maynard "Safe Handling of Nanotechnology" (2006) 444 *Nature* 267; Eva Oberdorster and others "Nanotoxicology: An Emerging Discipline Evolving from Study of Ultrafine Particles" (2005) 113 *Environmental Health Perspectives* 823.

³ Ministry of Research, Science and Technology *Nanoscience and Nanotechnology Roadmap* (MORST, Wellington, 2006) at 28.

⁴ For further examples of products containing nanomedicines see Nanotechnology Project "Consumer Products: An Inventory of Nanotechnology-based Consumer Products Currently on the Market" (2011) Woodrow Wilson International Centre for Scholars <www.nanotechproject.org>.

⁵ *Ibid.*

⁶ Lux Research *The Nanotechnology Report* (4 ed, 2006).

Given the potential market for nanoproducts, the occupational exposures and the growing evidence that “certain applications of nanotechnology will present risks unlike any we have encountered before”,⁷ it is important to have adequate regulation of NP exposure in the workplace in order to prevent or minimise adverse public health ramifications.

Workers involved at any point throughout the lifecycle of nanoproducts (from laboratories to manufacturing facilities) are potentially being exposed to NPs. The exact size of the exposed workforce in NZ, Australia or the United States (US) is currently unknown, but studies are being conducted.⁸ Numerous organisations have highlighted the OHS concerns raised by NPs. For example, the European Agency for Safety and Health at Work recently identified NPs among the top ten emerging risks from which workers need protection.⁹ The US National Nanotechnology Advisory Panel concluded that OHS is the most serious and immediate health and safety concern raised by mNMs.¹⁰ The NZ Council of Trade Unions,¹¹ the Australian Council of Trade Unions¹² and the Australian Manufacturing Workers Union¹³ have demanded nano-specific regulation of NP exposure and more research into the health risks of NP exposure. Non-government organisations such as the Friends of the Earth (FoE) have called for a moratorium on the research, development and manufacture of NPs.¹⁴

FoE has warned that nanotechnology could present “a repeat of the asbestos tragedy”¹⁵ and, specifically that carbon nanotubes (CNTs), a new form of carbon molecule, may be the new asbestos.¹⁶ The Department of Labour’s annual report on OHS identifies asbestos related cancer as one of the most prevalent occupational diseases with the highest toll.¹⁷ The similarity between some NPs and asbestos fibres could, therefore, present a significant potential OHS burden.

Despite these potential risks, NZ regulation of workers’ exposure to hazardous materials does not address the specific risks associated with NP exposure in the workplace. Other jurisdictions such as Australia and the United States face similar regulatory challenges. Reviews initiated by governments

⁷ Andrew Maynard and ED Kuempel “Airborne Nanostructured Particles and Occupational Health” (2005) 7 *Journal of Nanoparticle Research* 587.

⁸ Paul Schulte “Progress in Understanding and Preventing Work Related Disease and Injury from Nanomaterials” (paper presented to the Global Regulation of Nanotechnologies Conference, Northeastern University United States, 7 May 2010); Michael Methner and others “Nanoparticle Emission Assessment Technique (NEAT) for the Identification and Measurement of Potential Inhalation Exposure to Engineered Nanomaterials – Part B: Results from 12 Field Studies” (2010) 7 *Journal of Occupational and Environmental Hygiene* 163; Kaspar Schmid and others “Nanoparticle Usage and Protection Measures in the Manufacturing Industry – A Representative Survey” (2010) 7 *Journal of Occupation and Environmental Hygiene* 224.

⁹ European Agency for Safety and Health at Work “Report: Expert Forecast on Emerging Chemical Risks Related to Occupational Safety and Health” (Belgium, 2009) <<http://osha.europa.eu>>.

¹⁰ President’s Council of Advisers on Science and Technology (Podcast) “The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel” (2005) <www.nano.gov>.

¹¹ Letter from the NZ Council of Trade Unions to Jennifer Moore regarding the regulation of workers’ exposure to NPs (12 October 2010).

¹² Australian Council of Trade Unions “Factsheet: Nanotechnology – Why Unions are Concerned” (2009) <www.actu.org.au>; Hall Ashley “Nanotechnology is the Next Asbestos, Union Says” (2009) ABC News <www.abc.net.au>.

¹³ W Birnbauer “Nano Could be a Huge Future Health Crisis” *Sunday Age* (Melbourne, Australia, 30 October 2005) at 4.

¹⁴ Friends of the Earth Australia and Friends of the Earth United States *Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks* (Friends of the Earth, Sydney, 2006) at 5.

¹⁵ Georgia Miller “Nanotechnology Risks a Repeat of the Asbestos Tragedy” Friends of the Earth Australia <www.foe.org.au>.

¹⁶ Friends of the Earth Australia *Mounting Evidence that Carbon Nanotubes may be the New Asbestos* (Friends of the Earth, Melbourne, Australia, 2008).

¹⁷ Department of Labour “The State of Workplace Health and Safety in New Zealand” (2011) <www.dol.govt.nz>.

in several jurisdictions (the United States,¹⁸ England,¹⁹ the European Union,²⁰ Australia²¹ and NZ²²) have recommended changes to the existing legislation to ensure that the instruments adequately regulate nanoproducts. Likewise, other commentators have reviewed the suitability of the legislative status quo and called for amendments.²³

In contrast to the “do nothing” regulatory and policy approach,²⁴ I argue that the inadequacy of the current regulatory regimes for safeguarding human health has been demonstrated. Existing regulations will “function only as a filter – allowing particles smaller than the relevant pore size to escape through the regulatory process”.²⁵ This often occurs because some legislative triggers fail to fire when applied to workers’ exposure to NPs.

What are NPs and their potential risks?

Nanoparticles

A NP is a particle with all three external dimensions in the nanoscale: 1-100 nanometers. One nanometre is one billionth of a metre. Scientists have been working with nanoscale materials for centuries but the relatively recent development of special microscopes, capable of displaying tiny particles, has improved researchers’ ability to work with these materials.

Due to their tiny sizes, NPs have a high surface area to volume ratio. There is an increase in the percentage of atoms at the surface and, therefore, more sites for bonding or reacting with surrounding materials. The considerably larger surface area per unit mass increases their potentials for biopersistence (how long it exists in living tissue) and reactivity. All nanoparticles are ‘nanosized’ (small) but they are not all the same. They can differ in actual size, shape (some are tubes, others spheres etc), surface properties (e.g: charge and porosity) and biopersistence. The nano features of these particles include not only size, but also other parameters such as shape, surface chemistry, composition, solubility and aggregation.

Approximately 44 elements in the periodic table are commercially available in nano form.²⁶ Nanoparticles, because of their size and the effect that size has on their other properties, exhibit different properties from their bulk counterparts. In science, a ‘property’ describes how a material acts

¹⁸ Food and Drug Administration *Nanotechnology – A Report of the US Food and Drug Administration Nanotechnology Task Force* (FDA, Washington DC, 2007); Environmental Protection Agency *EPA Nanotechnology White Paper* (EPA, Washington DC, 2007).

¹⁹ Quasim Chaudhry and others *Final Report: A Scoping Study to Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies* (Department for Environment, Food and Rural Affairs, London, 2006).

²⁰ European Commission *Regulatory Aspects of Nanomaterials: Summary of Legislation in Relation to Health, Safety and Environment Aspects of Nanomaterials, Regulatory Research Needs and Related Measures* (Commission of the European Communities, Brussels, 2008).

²¹ Karinne Ludlow, Diana Bowman D and Graeme Hodge *A Review of Possible Impacts of Nanotechnology on Australia’s Regulatory Framework (The Monash Report)* (Monash Centre for Regulatory Studies, Melbourne, Australia, 2007).

²² Colin Gavaghan and Jennifer Moore *A Review of Possible Impacts of Manufactured Nanomaterials on New Zealand’s Regulatory System* (Faculty of Law University of Otago, New Zealand, 2011) <www.msi.govt.nz>.

²³ George Kimbrell “Nanomaterial Consumer Products and FDA Regulation: Regulatory Challenges and Necessary Amendments” (2006) 3 *Nanotechnology Law and Business* 329; JC Davies *Managing the Effects of Nanotechnology* (Woodrow Wilson International Center for Scholars, Washington DC, 2006).

²⁴ Joel D’Silva and Diana Megan Bowman “To Label or Not to Label? – It’s More than a Nano-Sized Question” (2010) 4 *EJRR* 420 at 427. See also LB Moses “Regulating Beyond Nanotechnology: Do Nano-specific Problems Require Nano-specific Solutions?” (2010) *IEEE International Symposium on Technology and Society* 68, for arguments against enacting nano-specific legislation.

²⁵ Karinne Ludlow “Nanoregulation – Filtering Out the Small Stuff” (2008) 2 *Nanoethics* 183 at 184.

²⁶ ETC Group “No Small Matter II: The Case for a Global Moratorium, Size Matters!” 7(1) *Occasional Paper Series*, (Action Group on Erosion, Technology and Concentration, Canada, April 2003) <www.etcgroup.org>.

under certain conditions. Examples of properties are: optical (e.g: colour transparency), electrical (e.g: conductivity), physical (e.g: hardness, melting point), chemical (e.g: reactivity). For instance, in terms of optical properties, bulk gold appears yellow whereas nanosized gold appears red. Also, gold as a bulk material is nontoxic, but gold particles below two nanometres have shown unexpectedly high toxicity in a variety of cell lines.²⁷

Examples of mNMs include fullerenes (C₆₀ or Buckyballs), carbon nanotubes and metal oxides. These are examples of first generation nanoproducts.²⁸ Subsequent generations of nanoproducts may change in response to electric fields, light or in the presence of specific molecules. Subsequent generations of mNMs will create further regulatory challenges because the OHS regulations are not designed to deal with the novel properties of these new particles, nor are the standard methodologies adequate for testing nanotoxicity in the workplace.

Defining Nanotechnology – Legislative Drafting Difficulties

Nanotechnology has been touted as the “next industrial revolution”.²⁹ Defining nanotechnology is difficult³⁰ but most commentators describe ‘nanotechnologies’ as a multidisciplinary and heterogeneous field involving molecular engineering. It can have many applications in, for example, medicine, food, and electronics.

Definitions are crucial to the operation of legislation as they assist in establishing the subject matter to be regulated and the regulatory scope. The heterogeneity of nanotechnology and NPs has presented problems for the drafters of legislation. There is no generally accepted definition within the international community. No jurisdiction has a definition for nanotechnology or NPs in OHS legislation.

The EU is one of the few jurisdictions that include a legislative provision that defines nanomaterials, but this does not appear in OHS law. The EU is attempting to regulate particular product areas in which mNMs are used; specifically, foods and cosmetics. The EU’s Regulation on Novel Foods proposes a nano-specific provision which states that “novel food should include foods derived from plants and animals, produced by non-traditional breeding techniques, and foods modified by new production processes, such as nanotechnology and nanoscience, which might have an impact on food.”³¹ The EU Cosmetics Directive 2009 defines NM as “an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure from 1-100 nanometres”.³²

²⁷ Willi Jahnhan-Dechent and Ulrich Simon “Function Follows Form: Shape Complementarity and Nanoparticle Toxicity” (2008) 3 *Nanomedicine* 601 at 602.

²⁸ MC Roco “Nanoscale Science and Engineering: Unifying and Transforming Tools” (2004) 50 *AICHE Journal* 890. Roco’s conceptualization of nanotechnologies as generations has been influential.

²⁹ Robert Sparrow “Talkin’ ‘Bout a (Nanotechnological) Revolution” (2008) 2 *IEEE Technology and Society Magazine* 37.

³⁰ Reaching agreement on fundamental terms such as ‘nanotechnology’, ‘nanoscale’, ‘nanomaterial’ and ‘nanoparticle’ is complex and contested. For example, see Graeme Hodge, Diana Bowman and Karinne Ludlow “Introduction: Big Questions for Small Technologies” in Hodge, Bowman and Ludlow (eds) *New Global Regulatory Frontiers in Regulation: The Age of Nanotechnology* (Edward Elgar, Cheltenham, 2007) at 10; Graham Hunt “Nanomaterials: Nomenclature, Novelty and Necessity” (2004) 56 *Journal of Materials* 13; Diana Bowman, Joel D’Silva and Geert van Calster “Defining Nanomaterials for the Purpose of Regulation within the European Union” (2010) 2 *The European Journal of Risk Regulation* 115; WG Kreyling, MK Semmler-Behnke and Qasim Chaudhry “A Complementary Definition of Nanomaterial” (2010) 5 *Nano Today* 165.

³¹ Regulation (EC) 258/97 concerning Novel Foods and Novel Food Ingredients.

³² EU Cosmetics Directive 2009 76/768/EEC, Article 2(1)(k).

In November 2011, the New Zealand Environmental Protection Authority (NZEPA) released its Proposals for Amendments to the Cosmetic Products Group Standard (the Standard).³³ The NZEPA may issue group standards under section 96B of the New Zealand Hazardous Substances and New Organisms Act 1996 (HSNO). The Standard follows the definition of NM that is used in the EU Cosmetics Directive. Proposal 3 proposes introducing a labelling requirement for nanomaterials which is in line with Article 19 of the EU Cosmetics Directive (76/768EEC).³⁴ These definitions of NM are not perfect; for example, they focus on size instead of including other physio-chemical characteristics such as shape, charge and surface properties. These provisions represent the first attempt by a Parliament to define nanotechnology or mNMs. It is possible that legislative instruments in other jurisdictions will be similarly amended to include nano-specific provisions. In my opinion, nano-specific legislative provisions should be drafted to help protect NZ workers from the risks of exposure to NPs.

Characterisation and Measurement of NPs Pose Regulatory Challenges

In addition to the regulatory difficulties in defining NPs, these tiny particles also present other hurdles in terms of characterisation and measurement. Effective regulation of NP exposure involves the ability to accurately describe and measure the matter being regulated. Under NZ's Hazardous Substances and New Organisms Act 1996, hazardous substances such as chemicals are conceptualised as 'new' or 'existing'.³⁵ How should the nanoscaled version of a chemical be categorised? For example, should nanoscaled carbon be distinguished from macroscale carbon? The nanosized version exhibits different properties from its macro counterpart; therefore, in my opinion, it should be considered 'new'.

However, the difficulty is that even within one form of nanoscale carbon, there are an array of forms and shapes including tubes and spheres. These different surface properties can generate different behaviours. To what extent can and/or should any legislative definition include these finer distinctions? There is an urgent need for the development of standardised reference NMs. These persistent difficulties in the description and definition of NPs will continue to hinder effective regulation and risk assessment.

Another regulatory challenge is the difficulties in measuring NPs. The story of asbestos regulation also includes difficulties caused by measurement. Inadequate measurement devices should not delay the introduction of nano-specific OHS provisions. It is preferable to prevent harm to workers rather than to wait for measurement techniques to become available. Also, like asbestos-related disease, there may be a long latency (possibly of many decades) before disease symptoms appear.

NPs and Potential Risks to Workers' Health

Detailed discussions about the health risks and toxicity³⁶ of NPs have been undertaken in the academic literature. Not all NPs are the same, nor are they all potentially harmful to human and

³³ NZEPA "Proposed Amendments to the Cosmetic Products Group Standard" (2011) <www.epa.govt.nz>.

³⁴ NZ Environmental Risk Management Authority "Group Standards" <<http://archive.ermanz.govt.nz>>.

³⁵ HSNO Act, ss 28 and 28A(2)(a).

³⁶ Andrew Maynard *Nanotechnology: A Research Strategy for Addressing Risk* (Woodrow Wilson Project on Emerging Technologies, Washington DC, 2006); RJ Aitken, KS Creely and CL Tran *Nanoparticles: An Occupational Hygiene Review* (Institute of Occupational Medicine for the Health and Safety Executive, London, 2004); Therapeutic Goods Administration *A Review of the Scientific Literature on the Safety of Nanoparticulate Titanium Dioxide and Zinc Oxide in Sunscreens* (Therapeutic Goods Administration, Canberra, 2006); Ken Donaldson and others "Nanotoxicology" (2004) 61 *Occupational Environmental Medicine* 727; Eva Oberdorster "Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile Largemouth Bass" (2004) 112 *Environmental Health Perspective* 1058; MC Powell and MS Kanarek "Nanomaterial Health Effects – part 1: Background and Current Knowledge" (2006) 2 *Wisconsin Medical Journal* 16; MC Powell and MS Kamarek "Nanomaterial Health Effects – part 2: Uncertainties and Recommendations for the Future" (2006) 2 *Wisconsin Medical Journal* 18; Joel D'Silva and Geert van Calster "Taking

environmental health and safety. There is growing evidence that the novel properties of some NPs will bring unforeseen human and environmental health and safety risks.³⁷ The large surface area and related increased reactivity of some NPs may mean unpredictable and different reactions with biological systems. Generally, the smaller the particles, the more reactive and toxic are their effects.³⁸ The smaller size of NPs means that they can deposit deeper in the respiratory tract than larger particles. Nanoparticles may take longer to settle in the air and, therefore, have more chance to travel and spread in the workplace, thereby coming into contact with workers.

Carbon nanotubes have been identified as a particularly troubling type of mNM. There are many variants of CNTs but they have been broadly categorised as single-walled (consisting of a single layer of carbon atoms arranged in a cylinder) and multi-walled (comprising multiple concentric layers of single walled tubes with diameters up to tens of nms).³⁹ Although further evidence is required, preliminary research on CNTs suggests that their structural similarity and low solubility may exhibit similar pathology to asbestos.⁴⁰ CNTs are increasingly used in industry because they are 100 times stronger than steel but very light. They are, thus, useful in electronics and display devices such as LCDs. The size and fibre shape of CNTs may lead to health effects similar to asbestos.⁴¹ CNTs can cause adverse health effects such as inflammation and fibrosis (scarring).⁴² However, the lack of data on exposure pathways of certain NPs, combined with uncertainty about the suitability of some existing testing methods, is widely recognised as a barrier to the effective implementation of regulations.⁴³

NZ OHS Regulation

The Legislative Framework

NZ workers' OHS is regulated by the Health and Safety in Employment Act 1992 (HSE Act), the Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work 1997 (the Code) and the Hazardous Substances and New Organisms Act 1996 (HSNO Act). The HSE Act applies to places of work. Duties are imposed on employers (and others) to take all practicable steps to ensure healthy and safe workplaces. The concept of 'hazard' is central to the Act. Employers must identify hazards and eliminate, isolate or minimise them. Employers must follow this

Temperature – A Review of European Union Regulation in Nanomedicine” (2009) 16 European Journal of Health Law 249.

³⁷ Milind Kandlikar, Ramachandran Gurumurthy and Andrew Maynard “Health Risk Assessment for Nanoparticles: A Case for Using Expert Judgment” (2007) 9 Journal of Nanoparticle Research 137; Andrew Maynard and others “Safe Handling of Nanotechnology” (2006) 444 Nature 267; Eva Oberdorster and others “Nanotoxicology: An Emerging Discipline Evolving from Study of Ultrafine Particles” (2005) 113 Environmental Health Perspectives 823.

³⁸ US National Institute of Environmental Health Sciences research presented in a paper by T Hampton “Researchers Size Up Nanotechnology Risks” (2005) 294 JAMA 1881 at 1882.

³⁹ Robert J Aitken and others “Regulation of Carbon Nanotubes and Other High Aspect Ratio Nanoparticles: Approaching this Challenge from the Perspective of Asbestos” in Hodge, Bowman and Maynard (eds) *International Handbook on Regulating Nanotechnologies* (EE, 2010) 205.

⁴⁰ CA Poland and others “Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study” (2008) Nature Nanotechnology 423.

⁴¹ EE Knowles “Nanotechnology: Evolving Occupational Safety, Health and Environmental Issues” (2006) Professional Safety 20 at 24; Robert Service “Nanotechnology’s Public Health Hazard?” (2008) Science Now <<http://news.sciencemag.org>>; CL Tran, SM Hankin, B Ross *An Outline Scoping Study to Determine Whether High Aspect Ratio Nanoparticles (HARN) Should Raise the Same Concerns as do Asbestos Fibres* (Institute of Occupational Medicine, Edinburgh, 2008).

⁴² CW Lam and others “Pulmonary Toxicity of Single-Wall Carbon Nanotubes in Mice 7 and 90 days after Intratracheal Instillation” (2004) 77 Toxicological Science 126.

⁴³ Robert Falkner, Linda Breggin, Nico Jaspers, John Pendergrass and Read Porter “International Coordination and Cooperation: The Next Agenda in Nanomaterials Regulation” in Graeme Hodge, Diana Bowman and Andrew Maynard (eds) *International Handbook on Regulating Nanotechnologies* (Edward Elgar, Cheltenham, 2010) at 513.

process for hazards, whether or not the hazards involve NPs. The Code applies to all workplaces in which hazardous substances are being used or produced, whether or not they contain NPs.

The HSE Act and the Code are administered by the Department of Labour (DoL). Under section 20 of the HSE Act, the Minister may approve codes of practice. Compliance with codes is not mandatory but they have “powerful persuasive authority”.⁴⁴ One of the DoL’s roles is to ensure that the HSNO Act is complied with in workplaces. The HSNO Act’s stated purpose is “to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms”.⁴⁵ The Act applies to everyone who imports, manufactures, uses or stores hazardous substances. The HSNO Act’s provisions relating to hazardous substances have the most significance for OHS.

Section 14 of the HSNO Act provides for the establishment of the Environmental Risk Management Authority (ERMA). However, following the recent introduction of the Environmental Protection Act 2011 (EPA Act), ERMA was disestablished and the Environmental Protection Authority (EPA) was established.⁴⁶ The EPA will now administer the HSNO Act.

Regulating ‘Hazard’, ‘Risk’ and ‘Exposure’

Various workplace tasks, such as working with NMs in liquids without adequate protection, will increase exposure to NPs. Seven young female Chinese workers developed severe lung damage (and two died) after inhaling nanoparticles produced in their factory.⁴⁷ However, the US National Institute for Occupational Safety and Health contended that the tragedy could have been avoided by the use of proper industrial hygiene procedures.⁴⁸ Debate continues about whether the deaths of the workers can be directly linked to their exposure to nanoparticles.

Such incidents have generated increasing debate about the risks to human health posed by NPs and how they should be regulated.⁴⁹ In NZ, the regulation of occupational exposures involves quantifying and evaluating scientific risk by assessing the relationship between a person’s exposure and the harm caused by that exposure. Risk management involves identifying hazards, assessing exposure and risk, and managing those risks.

Hazard identification and characterisation refers to the toxicology of NPs. Although there is limited information about the adverse occupational human health effects of NPs, there is cause for concern about the health effects of NMs on the basis of three main streams of evidence. Firstly, research on inhaled dusts and fibres recognises their potential respiratory toxicity.⁵⁰ There is a difference between large and nano-sized particles. Air pollution epidemiological studies show that particles less than 2.5 µm are responsible for respiratory and cardio effects. Research on industrial fibres, such as asbestos has established that fibres longer than 15-20 µm with diameters less than 3µm and are biopersistent in

⁴⁴ Richard Rudman *New Zealand Employment Law Guide* (CCH, Auckland, 2009) at 234.

⁴⁵ HSNO Act, s 4.

⁴⁶ Environmental Protection Authority Act 2011, s 7.

⁴⁷ See Y Song, X Li and X Du “Exposure to Nanoparticles is Related to Pleural Effusion, Pulmonary Fibrosis and Granuloma” (2009) 34 *European Respiratory Journal* 559; Alok Dhawan and Vyom Sharma “A Cautious Approach to Nanotechnology” *Cosmos Online* (2011) <www.cosmosmagazine.com>; Reuters “Deaths, Lung Damage Linked to Nanotech” (2009) *Stuff* <www.stuff.co.nz>.

⁴⁸ Reuters “Deaths, Lung Damage Linked to Nanotech” (2009) *Stuff* <www.stuff.co.nz>.

⁴⁹ Royal Commission on Environmental Pollution *Novel Materials in the Environment: The Case of Nanotechnology* (London, RCEP, 2008); Royal Society and Royal Academy of Engineering *Nanoscience and Nanotechnologies: Opportunities and Uncertainties* (London, RSRAE, 2008).

⁵⁰ Robert Aitken and others “Regulation of Carbon Nanotubes and Other High Aspect Ratio NPs: Approaching this Challenge from the Perspective of Asbestos” in Graeme Hodge, Diana Bowman and Andrew Maynard (eds) *International Handbook on Regulating Nanotechnologies* (Edward Elgar, Cheltenham, 2010) 205.

the lungs, are hazardous to human health.⁵¹ Hazard identification and assessment needs to consider the role of particle size, chemical properties, shape and dose. Secondly, some familiar materials, when nanoscaled, demonstrate heightened biological reactivity. The United States National Institute for Occupational Safety and Health (NIOSH) has indicated that low solubility NPs are more toxic than larger particles on a mass for mass basis.⁵² Thirdly, initial animal inhalation studies of engineered NPs have shown findings of pulmonary fibrosis, granulomas, inflammation, lung cancer, mesothelioma-like effects and cardiovascular effects.⁵³ In these studies, NPs have been shown to translocate from the nose to the brain and from the lungs to other organs.⁵⁴

This research provides evidence of the potential occupational hazards of some NPs, but there will only be risks to human health if there is exposure at levels in which harm can occur. The most likely route of exposure to NPs is through inhalation,⁵⁵ but ingestion and dermal penetration may also occur.⁵⁶ Detailed discussion of exposure routes has been outlined elsewhere.⁵⁷ There are currently no occupational exposure limits governing workplace exposure to NPs. Therefore, NPs present new challenges to understanding, predicting and managing potential health risks to workers. It is likely, for example, that current personal protective equipment will be of limited effectiveness in reducing dermal exposure to NPs because NPs will “more readily be able to penetrate the material from which the protective clothing is made than macro-sized particles.”⁵⁸

Studies are being conducted to establish the workforce’s exposure.⁵⁹ It is possible that workers are currently experiencing relatively low levels of exposure, but because the toxicity of all NPs is unknown, even low exposure could be potentially harmful to human health. Dose metrics besides mass concentration may be a better measure when evaluating the health effects of exposure to NPs. Currently commercially available air sampling instrumentation can characterise nanoscale aerosols based on a number of metrics, but none are sufficiently small to be worn by workers to allow the estimation of NP concentration in their personal breathing zone.⁶⁰ Information on exposure remains basic and there are many outstanding knowledge gaps.⁶¹

What are the procedures to minimise exposure? At present, there are no standardised or validated methodologies or equipment to enable routine measurement of NPs in the workplace. However, it is good public health practice to keep exposures to new and uncharacterised particles as low as possible. The NIOSH recently published the results of 12 field studies using the Nanoparticle Emission

⁵¹ National Institute of Occupational Safety and Health (NIOSH) “Workplace Safety and Health Topics: Nanotechnology” Centres for Disease Control and Prevention (CDC) <www.cdc.gov>.

⁵² NIOSH “Strategic Plan for NIOSH Nanotechnology Research and Guidance: Filling the Knowledge Gaps” <www.cdc.gov>.

⁵³ AA Shvedova and others “Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice” (2005) 289 *American Journal of Physiology* L698.

⁵⁴ Tracy Hampton “Researchers Size Up Nanotechnology Risks” (2005) 294 *JAMA*. 2005 1881.

⁵⁵ CC Daigle and others “Ultrafine particle deposition in humans during rest and exercise” (2003) 15 *Inhalation Toxicology* 539.

⁵⁶ Sally Tinkle and others “Skin as a route of exposure and sensitization in chronic beryllium disease” (2003) 111 *Environmental Health Perspectives* 1202; James Brown and others “Ultrafine particle deposition and clearance in the healthy and obstructed lung” (2002) 166 *American Journal of Respiratory Critical Care Medicine* 1240.

⁵⁷ Karinne Ludlow “One Size Fits All? Australian Regulation of Nanoparticle Exposure in the Workplace” (2007) 15 *Journal of Law and Medicine* 136 at 142.

⁵⁸ *Ibid.*

⁵⁹ Paul Schulte “Progress in Understanding and Preventing Work Related Disease and Injury from Nanomaterials” (paper presented to Global Regulation of Nanotechnologies conference, Northeastern University United States, 7 May 2010); Methner, above n 8; K Schmid, B Danuser and M Riediker “Nanoparticle Usage and Protection Measures in the Manufacturing Industry – A Representative Survey” (2010) 7 *Journal of Occupation and Environmental Hygiene* 224.

⁶⁰ D Brouwer, J Gijsbers, and M Lurvink “Personal exposure to ultrafine particles in the workplace: Exploring sampling techniques and strategies” (2004) 48 *Ann Occup Hyg* 439.

⁶¹ CDC “Strategic Plan for NIOSH Nanotechnology Research and Guidance: Filling the Knowledge Gaps.” <www.cdc.gov>.

Assessment Technique to characterise emissions during processes where engineered nanomaterials were produced or used.⁶² The NIOSH believes that there is sufficient evidence to suggest that it is theoretically possible to control workplace exposure to NPs, but that there will be costs involved.⁶³ A precautionary approach to the prevention and control of workplace exposures should be adopted.⁶⁴ It may be a challenge adopting such an approach because of the way that NZ regulations define and address occupational health risks.

Application of Legislative Instruments to Nanoparticles

HSNO Act

(1) The 'substance' threshold

Before any particular form of mNM or object containing mNMs will require EPA approval, it must satisfy three separate criteria, each of which poses certain challenges with regard to mNMs. The three criteria are: 1) is it a 'substance'? 2) is it 'hazardous'? 3) does it present a 'new' hazard? The HSNO Act applies only to "substances" that are "hazardous" and both of those criteria have been subject to interpretation and controversy. A "substance" is defined as:⁶⁵

- a) any element, defined mixture of elements, compounds or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof;
- b) any isotope, allotrope, isomer, congener, radical, or ion of an element or compound which has been declared by the Authority, by notice in the *Gazette*, to be a different substance from that element or compound;
- c) any mixtures or combinations of any of the above;
- d) any manufactured article containing, incorporating, or including any hazardous substance with explosive properties.

A substance will be considered hazardous if it meets or exceeds one of the thresholds set down in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 for any of the relevant properties. These relate to:⁶⁶

- i. explosiveness;
- ii. flammability;
- iii. a capacity to oxidise;
- iv. corrosiveness;
- v. toxicity (including chronic toxicity);
- vi. ecotoxicity, with or without bioaccumulation.

Where it is possible that a substance may trigger more than one threshold, it should be evaluated against the thresholds established for each hazardous property, e.g. a substance that may have both flammable and toxic properties must be evaluated against both relevant thresholds.

If a substance does not trigger any of the section 2 thresholds, it is not "hazardous" and does not need an approval from the Authority. However, if a substance does trigger a threshold level, then it cannot be imported or manufactured in NZ other than in accordance with an approval from the Authority.

⁶² Methner and others, above n 8.

⁶³ Ibid.

⁶⁴ N Jackson and others "Engineered Nanomaterials: Evidence on the Effectiveness of Workplace Controls to Prevent Exposure" (2009) < <http://nanotech.law.asu.edu/?rgn=cau>>.

⁶⁵ HSNO Act, s 2.

⁶⁶ HSNO Act, s 2.

The manufacture or importation of a hazardous substance without an approval is an offence.⁶⁷ Some nano-chemicals will trigger the legislative thresholds and be deemed hazardous.

However, the existence of quantity-based regulatory triggers is a significant regulatory gap. The Monash Report reached the same conclusion and its opinion has led the National Industrial Chemicals Notification and Assessment Scheme, the Australian industrial chemicals regulator to propose “to administratively exclude nanomaterials which are new chemicals from low volume/low concentration exemptions, thereby shifting a post-market audit activity to a pre-market assessment (i.e. new nanomaterials to be assessed under permit or certificate categories prior to commercialisation).”⁶⁸

The quantity-based exception under the HSNO Act relates to ‘small-scale use of hazardous substances in research and development or teaching’.⁶⁹ The adequacy of training and practice within laboratory environments to ensure safe handling of mNMs is critical. Research conducted by Canterbury University in 2009 suggested that complacency in this regard should be avoided.⁷⁰ The report identified a number of issues of potential concern, specifically:⁷¹

- There is limited information on the effectiveness of engineering controls and personal protective clothing to minimise exposure to unbound NPs.
- Ensuring that researchers have access to best practice safety information for working with nanomaterials and that risk or safety assessments are completed.
- A lack of documented training for new researchers in safe practices for working with nanomaterials.
- Not all nanomaterials research is undertaken in dedicated facilities. A mechanism is needed to ensure that other researchers in shared facilities are aware of any hazards and associated precautionary measures.
- The lack of readily available funding for upgrading research facilities to meet health and safety requirements.

(2) Is the substance ‘new’?

Even if something is agreed to be a “hazardous substance”, an application will only be required if it has not already received approval. The question inevitably arises as to whether a nano-form of a previously approved substance would be regarded as a new substance, requiring its own approval, or alternatively, would be deemed to be covered by the existing approval. The Monash Report referred to this as “possibly the most significant potential gap”, pointing out that “uncertainty exists as to whether the nanoentity would be considered as ‘new’ or ‘different’ from or as the same as its’ [sic] conventional counterpart.”⁷² The Australian toxic dust Senate Committee inquiry recommended that there be an urgent consideration of whether materials already classified as safe at the macroscale should be reassessed to see if they are safe at the nanoscale.⁷³

Similar uncertainty may be said to apply to applications for nanoforms of substances already present in NZ. As ERMA has said:

⁶⁷ HSNO Act, s 25(1).

⁶⁸ NICNAS *Proposal for Regulatory Reform of Industrial Nanomaterials. Public Discussion Paper* (NICNAS, November 2009).

⁶⁹ HSNO Act, s 33.

⁷⁰ Sally Gaw *Identification of Potential Health and Safety Issues Associated with MacDiarmid Institute Funded Nanomaterial Research in University Laboratories* (MacDiarmid Institute, Wellington, 2009).

⁷¹ *Ibid.*

⁷² Ludlow and others, above n 21, at 92.

⁷³ Recommendation 13, Senate Community Affairs References Committee *Workplace Exposure to Toxic Dust* (May 2006).

if the hazards of the nanomaterial are the same as the ‘conventional’ substance, then they are covered by the approval for the ‘conventional’ substance. It is only where the hazards differ between the ‘conventional’ substance and the nano substance that the nano substance would need to be treated differently under HSNO.⁷⁴

A question inevitably arises as to how a nanoform of an existing substance will be classified where there is uncertainty about the hazard profile. Should it be assumed that the hazards are identical until data exists to prove otherwise? Or should the default position be that the nano-form may have distinct hazardous properties, meriting a separate approval? These issues raise the question of where the burden of proof should lie and what standard of proof should be required. These regulatory gaps in HSNO may mean that workers exposed to hazardous substances and NPs are not receiving adequate protection. These gaps could potentially be addressed by the regulators without need to amend the legislation. EPA could, for example, modify its Group Standards⁷⁵ to require that nano-forms of existing substances could be subject to new assessments, or at least that they must be notified to EPA.

HSE Act

The HSE Act enacts an extensive statutory regime to ensure the health and safety of employees and other people in the workplace. The Act is less concerned with prescribing how to make workplaces safe and more concerned with putting obligations on employers and employees to ensure that workplaces and work practices meet defined standards of health and safety. NZ has a ‘no fault’ scheme for dealing with accidental injury.

The HSE Act’s object is to promote the prevention of harm to all persons at work as well as others in, or in the vicinity of, a place of work.⁷⁶ The Act covers ‘places of work’ which is given a broad definition in section 2. Therefore, the HSE Act will apply to places of employment whether or not those workplaces involve employees working with mNMs or exposed to NPs. The Act applies to employers, employees, self-employed people, contractors and subcontractors⁷⁷ and will, therefore, apply to all these people whether or not they work with mNMs.

The Act imposes duties on employers to ensure the safety of employees at work. Most duties under the HSE Act are not absolute, but require “all practicable steps”⁷⁸ to have been taken. This phrase recurs throughout the Act. The “all practicable steps” requirement is interpreted strictly.⁷⁹ It is reasonable to expect an employer to do anything that it is practicable to do.⁸⁰ Employers are expected to be proactive in identifying both existing and potential hazards and taking steps to prevent harm to workers. Employers may be expected, therefore, to be proactive in identifying potential hazards associated with mNMs and NPs.

An assessment of whether or not all reasonable steps have been taken analyses:⁸¹

- the nature and severity of the harm that may be suffered if the result is not achieved;
- the current state of knowledge about the likelihood that harm of that nature and severity will be suffered if the result is not achieved;
- the current state of knowledge about harm of that nature;

⁷⁴ Letter from ERMA Chief Executive to Colin Gavaghan and Jennifer Moore regarding HSNO Act (9 July 2010).

⁷⁵ ERMA, Cosmetic Products Group Standard (ERMA, 2006).

⁷⁶ HSE Act, s 5.

⁷⁷ HSE Act, s 2.

⁷⁸ HSE Act, ss 2A and 6.

⁷⁹ Rudman, above n 41, at 242.

⁸⁰ Ibid.

⁸¹ HSE Act, s 2A.

- the current state of knowledge about the means available to achieve the result and the likely efficacy of those means; and
- the availability and cost of each of those means available.

A person required by the Act to take all practicable steps is required to take those steps only in respect of circumstances that the person knows or ought reasonably to know about.⁸² Therefore, a person is required to take all practicable steps to ensure the safety of employees working with NMs or exposed to NPs only in respect of circumstances that the person knows or ought reasonably to know about. The issue is whether a person required by the Act to take all practicable steps would be aware of the presence of NPs and their potential health risks.

There is a potential regulatory gap in that the “current state of knowledge”⁸³ regarding harm attributed to some mNMs is preliminary. Although initial studies indicate that adverse health consequences are possible from some mNMs and NP use and exposure, some of the OHS implications of mNMs and NPs are currently unknown.⁸⁴

The HSE Act sets out specific duties on employers in relation to hazards in the workplace. Employers must identify hazards;⁸⁵ take all practicable steps to eliminate them;⁸⁶ and if they cannot be practicably eliminated, isolate hazards.⁸⁷ If hazards cannot be isolated, they must be minimised.⁸⁸ Employees exposed to them must be monitored.⁸⁹ The general language of the Act requires a broad approach by employers to potential hazards. It is clear that employers must identify specific hazards and then do whatever they can to ensure that the hazards do not cause harm.

The concept of ‘hazard’ is vital to the working of the Act. Hazard means any activity, arrangement, circumstance, event, occurrence, phenomenon, process, situation, or *substance* that is an actual or potential cause or source of harm, whether it arises or is caused within or outside a workplace.⁹⁰ “Substance” means a thing that is an organic material, whether living or not.⁹¹ The definition of hazard in the HSE Act is broad and may be physical, biological or mental.

“Significant hazard” means a hazard that is an actual or potential cause or source of:⁹²

- serious harm;
- harm (that is less than trivial) for which the severity of the effect on a person depends on the extent or frequency of the person’s exposure to the hazard; or
- harm that does not usually occur or that is not easily detectable until a significant time after the exposure to the harm.

“Harm” means illness, injury or both and includes physical or mental harm caused by work-related stress.⁹³ “Serious harm” means death or some other harm declared to be serious harm by the

⁸² HSE Act, s 2A(2).

⁸³ HSE Act, s 2A.

⁸⁴ Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) *Risk Assessment of Products of Nanotechnologies* (European Commission, Brussels, 2009); SCENIHR *Opinion on the Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials* (European Commission, Brussels, 2007); Safety of Nano-Materials Interdisciplinary Research Centre (SnIRC) <www.snirc.org>.

⁸⁵ HSE Act, s 7.

⁸⁶ HSE Act, s 8.

⁸⁷ HSE Act, s 9.

⁸⁸ HSE Act, s 10.

⁸⁹ *Ibid.*

⁹⁰ HSE Act, s 2.

⁹¹ *Ibid.*

⁹² *Ibid.*

⁹³ *Ibid.*

Governor-General.⁹⁴ Any illness, injury, physical or mental harm, or death, whether or not attributable to exposure to NPs may be caught by these definitions, provided that the harm caused is deemed sufficiently serious. The current gaps in public health knowledge about NP hazards and exposure mean that some NPs may not be considered a significant hazard. Also, there may be a prolonged latency period between first exposure to NPs and onset of the first symptoms of the disease, particularly for CNTs with their asbestos-like pathogenicity. If the deficiencies in nanotoxicology prevent a potentially harmful NM from being identified as a significant hazard, this is a significant regulatory gap. However, significant hazard is defined in the HSE Act as an actual or *potential* cause or source of serious harm.⁹⁵ If the mNM is deemed a potential cause of harm, it could theoretically be identified as a significant hazard and, therefore, trigger the hierarchy of action.

This definition of ‘hazardous’ raises the question of standard of proof. How compelling must the evidence be before such triggers are activated? Whether carbon nanotubes, for example, should be deemed “hazardous substances” within the terms of the HSNO Act seems at present to be uncertain.⁹⁶ For some commentators with whom I spoke during the review, existing evidence about CNTs is sufficient to justify a moratorium on their use, or at least on certain uses to which they could be put while for others, the studies published to date are preliminary and inconclusive.

The limited state of current knowledge about the risks posed by some NPs presents a number of obstacles to any attempt to regulate in this area. Regulatory triggers requiring “significant hazard” to be demonstrated may fail to fire for some NPs. It is obviously important that regulators remain apprised of the most recent reliable information with regard to the possible hazards presented by NPs. More challenging, however, is the question of how to proceed in situations of uncertainty. With regard to burden of proof, should regulators assume that a nanoform of an existing product is safe until reliable evidence shows otherwise? Or should they operate on the contrary assumption: that a new product is unsafe until the contrary can be demonstrated?

Some regulatory frameworks offer some guidance in this regard. The HSNO Act, for example, adopts a “precautionary approach”, which emphasises “the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects”.⁹⁷ However, a range of opinions can be found as to how ‘caution’ is to be understood. ERMA’s view is that “while the HSNO Act provides for decisions to be precautionary where there is scientific or technical uncertainty ... it does not empower ERMA to act when there are suspicions but little or no evidence.”⁹⁸ This understanding of the precautionary remit is likely to be controversial, not least because it may be thought that many of the situations in which there is ‘scientific or technical uncertainty’ will arise precisely because ‘there are suspicions but little or no evidence’.

This is far from a straightforward matter. As one leading commentator on the regulation of emerging technologies has said, “there is scope for endless argument about just how strong the evidence needs to be before precaution kicks in.”⁹⁹ Insofar as existing OHS regulations are not specific about the level of proof that would be required to trigger regulatory action, this is a regulatory gap which may compromise workers’ health.

“Health” and “healthy” have restricted meanings; they simply mean unharmed.¹⁰⁰ The definition of health under the HSE Act is different from the broad World Health Organisation definition of health.

⁹⁴ Ibid.

⁹⁵ Ibid, my emphasis.

⁹⁶ As per correspondence with Sustainability Council, 30 November 2010, and ERMA, 21 December 2010.

⁹⁷ HSNO Act, s 7.

⁹⁸ Letter from ERMA to Gavaghan and Moore about HSNO Act (10 August 2010).

⁹⁹ Roger Brownsword *Rights, Regulation, and the Technological Revolution* (Oxford University Press, Oxford, 2008) at

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¹⁰⁰ HSE Act, s 2.

Health, according to the WHO, is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.¹⁰¹ The legislative definition of healthy has implications for the level of protection available to workers exposed to NPs. Given the uncertainties, risks assessors and regulators could address the issue by “considering the lowest toxic dose values, and/or a worst-case exposure scenario, to be on the safe side.”¹⁰²

The Code 1997

The Code is a statement of preferred work practices and arrangements. The Code is a practical guide on how to comply with the applicable sections of the HSE Act and Regulations 1995 in order to minimise the risk of occupational illness or injury due to exposure to substances hazardous to health.¹⁰³ The Code applies to all workplaces in which substances hazardous to health are used or produced and to all persons with potential exposure to substances hazardous to health in those workplaces.

The Code does not apply to asbestos and materials containing asbestos because asbestos is covered by other regulatory instruments. Given the potential structural and pathogenic similarity between some NPs and asbestos, and the potential adverse health effects, it may be prudent to draft a nano-specific Code or include nano-specific provisions in the HSE Act, The Code and/or the HSNO Act.

A substance hazardous to health is defined as any substance, or product containing a substance, to be used or produced in a workplace that is known or suspected to cause harm to health.¹⁰⁴ This includes:¹⁰⁵

- Those substances that are classified as hazardous under the HSNO Act, excluding micro-organisms;
- Scheduled toxic substances under the HSNO Act; and
- Those substances that are listed in the Workplace Exposure Standards publication currently applicable in New Zealand.

Therefore, many substances that may be or may incorporate NMs such as paints, heavy metals and solvents will trigger The Code.

Under The Code there is no provision for formal approval of hazardous substances from DoL prior to supply, sale, use or import because such approval is covered by the HSNO Act. In order to achieve compliance with sections 6 and 8 to 10 of the HSE Act, The Code provides a hierarchy of prevention and control measures. Where a significant hazard has been identified, the HSE Act requires that the hazard be managed by considering the following hierarchy of action:

- Elimination;¹⁰⁶ then
- Isolation;¹⁰⁷ and finally
- Minimisation.¹⁰⁸

¹⁰¹ World Health Organisation <www.who.int>

¹⁰² Quasim Chaudhry and others “The Current Risk Assessment Paradigm in Relation to the Regulation of Nanotechnologies” in Hodge G, Bowman D, Maynard A (eds) *International Handbook on the Regulation of Nanotechnologies* (Edward Elgar, Cheltenham, 2010).

¹⁰³ The Code, at 8.

¹⁰⁴ The Code, p 10.

¹⁰⁵ OSH “Workplace Exposure Standards” (1994, revised in 2002) <www.osh.govt.nz>.

¹⁰⁶ HSE Act, s 8.

¹⁰⁷ HSE Act, s 9.

¹⁰⁸ HSE Act, s 10.

If NPs are identified as a significant hazard, they could be eliminated, isolated or minimised. A potential regulatory gap may exist if the deficiencies in nanotoxicology prevent a potentially harmful NP from being identified as a significant hazard.

Minimisation of the risk of substances hazardous to health may be achieved by a variety of practices such as personal protective equipment (PPE). However, it is likely that NPs will be able to penetrate the material from which the protective clothing is made more readily than macro particles.¹⁰⁹ Another regulatory gap is that, under The Code there, is no legal requirement for the supplier of a substance hazardous to health to provide specific health and safety information under the requirements for labelling and SDS under the HSNO Regulations. The Code states that suppliers should have SDS available for all substances hazardous to health that they supply.¹¹⁰

The SDS describes the identity of the substance, relevant health hazard information, precautions for use and safe handling, disposal and emergency response information. Identification of the hazardous substance requires suppliers to detail the chemical identity and CAS Number of the substance. This identification will not necessarily reflect the fact that the chemical is in nanoform. The Code does not expressly distinguish between nano and conventional forms of substances.

The physical and chemical properties of the substance are to be included. The supplier could describe the particle size of the substance in these sections of the SDS, but the supplier is not required to do so. Toxicological information is required but the deficiencies in the toxicological data for NPs, particularly for chronic exposure, may preclude inclusion of such information. In addition to SDS, The Code states that suppliers should ensure that any container supplied for use in a place of work carries sufficient information for the safe use of the product it contains, and is labelled in a way that allows for positive identification of the product. The HSNO Act requirements are now applicable. Labelling requirements will apply to containers of hazardous substances whether or not they incorporate NMs. However, whether users are alerted of the presence of NPs depends on whether the product name, number or identifier used on the label references nano and there are currently no requirements to do so.

Nano-specific labelling is a contentious topic.¹¹¹ The EU recently legislated for compulsory labelling of cosmetics containing mNMs¹¹² while a proposal to require nano-specific labelling of novel foods is currently the subject of conciliation proceedings involving the EU Parliament, Council and Commission.¹¹³ At present, the only potential nano-specific labelling requirement in NZ is the proposed amendment to the NZ Cosmetic Products Group Standard discussed earlier.¹¹⁴ This proposal has not been approved. This lack of labelling could be argued, in some contexts, to be a regulatory gap. In relation to OHS regulation, for example, lack of nano-specific labelling could compromise workers' health and safety. Due consideration would have to be paid to the appropriate wording of any such labels if they are to impart genuinely useful information to workers without causing unjustified alarm.

Challenges in Safety Assessment for NPs

¹⁰⁹ Ludlow, above n 54, at 142.

¹¹⁰ The Code, at 34.

¹¹¹ Joel D'Silva and Diana Bowman "To Label or Not to Label? – It's More than a Nano-sized Question" (2010) 4 EJRR 420.

¹¹² Council of the European Union "Regulation of the European Parliament and of the Council on cosmetic products" (2009) <www.europa.eu>.

¹¹³ European Union Committee: Environment, Public Health and Food Safety "MEPs flag potentially hazardous substances in electrical and electronic equipment" (press release, 2 June 2010) <www.europa.eu>.

¹¹⁴ See the section on 'Defining Nanotechnology'.

The HSE Act does not specify a particular method of hazard identification. Various hazard identification methods are used in industry. Information from manufacturers, designers, safety data sheets, product labelling should be reviewed as part of the hazard identification process.

Risk assessment, including hazard identification methods, may not be appropriate for NPs. It may be necessary to amend the Safety Data Sheets (SDS) and labelling systems to recognise that NPs have different properties from their bulk counterparts. This presents a challenge to effective risk assessment of NPs because current regulatory requirements for risk assessment are based on knowledge of bulk/conventional particles. The toxicity of NPs is related to properties such as surface area rather than weight. Current processes may not consider the high surface area and increased reactivity of NPs. The relationship between volume of material and exposure (used in chemicals regulation such as the HSNO Act) is not appropriate for assessing the risks of NPs. Therefore, the current methods and procedures will be inadequate for the safety of workers. Hazard assessments for NPs need to consider shape, chemical properties, functionality, and the role of particle size.

There are further difficulties in protecting New Zealand workers from adverse health effects of nanoparticle exposure. Firstly, there is no national or international agreed definition to describe nanoparticles. There are, however, attempts to develop an international terminology for nanotechnology.¹¹⁵ Secondly, equipment and methods to enable routine measurements of nanoparticles are not yet available. The tiny size of NPs poses special challenges of exposure. NPs can penetrate deep into the lungs when inhaled and may circulate throughout the human body when they enter a single part of the body. When NPs get into the environment it “may be impossible to contain them.”¹¹⁶

The HSE Act includes provisions for recording, reporting, reviewing and monitoring hazards in workplaces and workers’ health and safety. For example, Workplace Exposure Standards enable monitoring. When sufficient nanotoxicological and exposure data become available, nano-specific workplace exposure standards should be developed. The HSE Act confers powers on inspectors who may monitor conditions in workplaces.¹¹⁷ It is important that these monitoring and reporting procedures enable the timely and proper collection of information about exposure to NPs which has caused harm, incidents and injuries.

The Code describes an assessment process for employers to meet their duty to manage substances hazardous to health. The assessment aims to achieve compliance with section 7 of the HSE Act. The purpose of an assessment is to gain adequate information on the use of substances hazardous to health in the workplace.¹¹⁸ The assessment process involves:

1. Identifying substances hazardous to health in the workplace;
2. Reviewing the information about the hazards they pose to health;
3. Determining the degree of exposure;
4. Assessing the risk to health; and
5. Reviewing the assessment.

There are currently no effective methods available in the workplace to measure nanoparticles or exposure to nanoparticles, nor are there currently effective methods for assessing particle surface area. Therefore, the assessment process described in The Code will be difficult for hazardous substances that contain NMs or for nanoparticles. The Code describes a process if the outcome of an assessment

¹¹⁵ International Organisation for Standardisation on Nanotechnology <www.iso.org.>

¹¹⁶ Davies J Clarence “A New Approach to Regulating Nanotechnology Products” in Graeme Hodge, Diana Bowman, Andrew Maynard (eds) *International Handbook on Regulating Nanotechnologies* (Edward Elgar, Cheltenham, 2010).

¹¹⁷ HSE Act, s 33(1).

¹¹⁸ The Code, at 16.

is uncertain. If an assessment indicates that harm to health may result from exposure to substances hazardous to health, but there is some uncertainty about the degree and extent of the exposure, then further work such as monitoring, workplace exposure monitoring¹¹⁹ and biological exposure monitoring¹²⁰ is required.

Assessments should be revised at least every two years, or if:¹²¹

- The process, plant or substance related to exposure to the substances hazardous to health is modified;
- New information on the hazards of substances becomes available;
- Monitoring indicates inadequate exposure control...

Hazardous substances containing NPs may trigger a revision if the substance is modified or if new information on the substance becomes available. For instance, new epidemiological information on human exposure and nanotoxicological data may prompt a revision.

The Code also provides for health surveillance as a measure directed at controlling exposure to substances hazardous to health to ensure the health and safety of people at work.¹²² Therefore, monitoring is required, but this depends on the assessment showing that monitoring and surveillance is required. The current deficiencies in public health knowledge about NPs mean it is unclear whether assessments will identify NPs. Further, this limited knowledge means that health surveillance and monitoring processes under The Code may not be suitable or adequate for NPs.

Suggestions for the Nano-specific Regulation

Given that workers are being exposed, it is important that Parliament acts now. There should be compulsory reporting of any incidents of adverse health outcomes experienced by workers exposed to NPs. Such a reporting scheme should be national and use standardised identification and hazard assessment processes. Any OHS legislation provision which defines NP should refer to size and other relevant physio-chemical properties such as shape. The definition should be sufficiently flexible to allow for adaptation as nanoscience develops and new public health data on NPs and their health effects becomes available.

At the time of writing, neither ERMA nor the EPA had formally assessed the potentially hazardous nature of CNTs, as no application involving them has been under the HSNO Act. There is merit in the suggestion that, for the time being, CNTs be classified “as if” they are hazardous, thereby bringing them within the remit of the relevant legislation and regulator.¹²³

Conclusion

Although more work is needed to measure the health and safety risks that NPs pose to NZ employees, workers are currently being exposed. This paper has demonstrated that NZ’s OHS regulation of NPs contains the following specific regulatory gaps:

¹¹⁹ The Code, at 29.

¹²⁰ The Code, at 28.

¹²¹ The Code, at 22.

¹²² The Code, at 27 and 39.

¹²³ Mark Phillbric “An Anticipatory Governance Approach to Carbon Nanotubes” (2010) 30 Risk Analysis 1708.

- Legislative thresholds such as “significant hazard” and “current state of knowledge” may not be triggered because of the current limited public health data on exposure to NPs;
- NZ OHS regulations are not specific about the level of proof that would be required to trigger regulatory action for hazardous substances or particles and this regulatory gap may compromise workers’ health;
- Despite the risks posed by some NPs, there is not necessarily any requirement for the special properties of NPs to be identified in the occupational context;
- The regulatory deficiencies presented by SDS, labelling and PPE pose health risks to workers exposed to NPs;
- The quantity based thresholds under the HSNO Act are inappropriate for NPs;
- The uncertainty about whether a nano-form of a substance will be considered ‘new’ or ‘existing’ may mean that workers exposed to hazardous substances and NPs are not receiving adequate protection; and
- There is no NZ regulatory definition of NP, despite the potential need for a definition to ensure effective oversight of occupational exposure to NPs.

The deficiencies identified in NZ OHS law are particularly troublesome for NPs because of their fundamental differences from standard particles, and due to their unpredictable behaviours when interacting with the human body and (in the case of some CNTs) their structural and pathogenic similarity to asbestos.

There is current uncertainty in the scientific literature and limited occupational exposure data. However, preliminary research does highlight the need to adopt a precautionary approach. NZ’s regulatory risk assessment approach tends to deal retrospectively with well-established occupational hazards. We could learn from the regulatory story of asbestos and, without delay, use the steadily emerging evidence of the potential asbestos-like pathogenicity of some CNTs to enact OHS law to help protect NZ’s exposed workforce.

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