

**A Review of the Adequacy of New Zealand's Regulatory
Systems to Manage the Possible Impacts of Manufactured
Nanomaterials**

Final Report

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Nanomaterials*

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ABBREVIATIONS

Abbreviation	Full Name
CNTs	Carbon nanotubes
DoL	Department of Labour
DHBs	District Health Boards
ERMA	Environmental Risk Management Authority
EU	European Union
FDA	US Food and Drug Administration
FSANZ	Food Standards Australia New Zealand
HRC	Health Research Council
mNMs	Manufactured Nanomaterials
MedSafe	New Zealand Medical and Medical Devices Safety Authority
MfE	Ministry for the Environment
MCA	Ministry of Consumer Affairs
MOH	Ministry of Health
MoRST	Ministry of Research, Science and Technology
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
Nm	Nanometre
NMs	Nanomaterials
NZCS	New Zealand Customs Service
NZFSA	New Zealand Food Safety Authority
OSH	Occupational Health and Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
TGA	Therapeutic Goods Administration

EXECUTIVE SUMMARY

This report presents an independent review of the adequacy of New Zealand's regulatory frameworks in dealing with manufactured nanomaterials (mNMs). In particular, it considers how regulatory oversight is triggered for mNMs, and identifies the existence of some potential regulatory gaps (a somewhat contested term which we discuss below). This project was completed by staff of the New Zealand Law Foundation Centre for Law and Policy in Emerging Technologies, Otago University, over the period March to December 2010. Our approach has closely followed that adopted in the report conducted by staff at Monash University in 2007, regarding Australia's regulatory frameworks.

In many ways, our overall conclusions are similar to those of the Monash Report, and indeed to other reports in this area.³ None of the areas of the New Zealand regulatory system that we have considered require wholesale changes in order to be applicable to mNMs. The regulatory mechanisms applicable to conventional products will, in broad terms, apply to mNMs, and to products containing and incorporating such products (though a possible gap was identified where the product actually *creates* nanoparticles, subsequent to sale.)

In those areas where regulatory coverage is comprehensive for conventional products, it will usually be comprehensive for mNMs. The corollary, of course, is that areas of weakness in the regulatory frameworks will provide areas of weak regulation for mNMs too. We have, however, identified a number of possible regulatory gaps or weaknesses that are more specific to products containing mNMs. Our approach has distinguished between gaps that appear to occur at different levels: respectively, at the level of legislation, at the level of regulatory policy, and at the level of compliance and enforcement. The options for addressing those gaps will often depend upon which of these categories they are considered to fall within.

We have also followed the methodology of the Monash Report in grouping the gaps under six headings, though our headings do not map precisely onto those utilised in the earlier report.

Is a nanoform 'new'?

Identified by the Monash Report as 'possibly the most significant potential gap', we have also found points within New Zealand's regulatory framework where the identification of nanoforms of existing products as new or 'novel' is potentially uncertain. A safety assessment under the HSNO Act, for example, will only be triggered if 'the hazards differ between the "conventional" substance and the nano substance'. Similarly, in many circumstances a food will be subject to a pre-market safety assessment only if it satisfies the criteria for a 'novel food' set out in Standard 1.5.1 of the FS Code.

We have suggested that, with regard both to the HSNO and FSANZ Acts, these gaps could potentially be addressed by the regulators, without need to amend the legislation. ERMA could, for example, modify its Group Standards to require that nano-forms of existing

³ "Regulatory gap" analyses have tended to conclude that the existing framework is capable of adaptation to make it fit for purpose in dealing with nanomaterials ... After careful consideration, we agree.' Royal Commission on Environmental Pollution, *Novel Materials in the Environment; Then case of nanotechnology* (2008), at paras 4.43 and 4.44. 'We believe that for the foreseeable future, the present regulatory frameworks for protecting humans and the environment are sufficiently broad to encompass nanotechnologies and that a separate regulator or regulatory framework is unnecessary.' The Royal Society and The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties* (2004) at 8.5.
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substances could be subject to new assessments, or at least that they must be notified to ERMA. A partial precedent already exists in the form of the Cosmetic Products Group Standard, which requires notification of any cosmetic product containing nanomaterials. With regard to food, we have suggested that the least burdensome step for the regulator would be to stipulate unambiguously that all foods containing manufactured NMs should be submitted either to the Advisory Committee on Novel Foods for a recommendation as to novelty, or to FSANZ for an approval.

Regulatory scope

Some questions have also arisen with regard to the remit of some of the regulatory bodies. For example, the applicability of the HSNO Act to nano-silver washing machines, and – in future – other items such as nano-silver fridges is an area of uncertainty, in view of the likely designation of such items as ‘manufactured articles’, which may render them ultra vires of the HSNO Act and of ERMA.

The existence of such gaps is not attributable to the presence of mNMs; ERMA’s regulatory remit does not extend to manufactured items, whether or not they contain mNMs. However, the presence of mNMs may be thought to present new hazards, of a nature that would render greater regulatory oversight desirable. Furthermore, some of the potential gaps we have identified result in fairly arbitrary distinctions, e.g. between items designed to *produce* potentially hazardous substances, and items which already *contain* such substances.

We have indicated that the potential solutions to such gaps may lie at the level of regulatory policy; as discussed below, for example, it may be open to ERMA to extend its remit to nano-silver white goods by utilising s.96B(2)(d) of the HSNO Act. There may, however, be instances where the regulator’s remit can only be extended to certain items by means of amending the statute.

Appropriateness of quantity-based triggers and conditions

The existence of quantity-based regulatory triggers was identified in the Monash Report as a significant regulatory gap, and its conclusions have led NICNAS, the Australian industrial chemicals regulator, to revise some of its mass-based exemptions. As no analogous exemptions exist in New Zealand, this particular proposal is not applicable to the New Zealand regulatory framework.

Quantity-based *conditions*, however, are present in the New Zealand regulatory scheme. For example, in terms of food regulation, some additives and contaminants are permitted only subject to quantitative restrictions. Doubts have been raised regarding the suitability of such limits to nanoforms. Again, it appears to us as though the regulator – in this case, FSANZ – has the capacity to vary these limits, either with regard to nanoforms of existing materials or new/novel nanoscale materials (see Section 3.7). It is to be hoped that regulators will keep the appropriateness of such quantitative restrictions under review if – as we strongly suspect – more products containing mNMs enter the market.

Nano-specific labelling

The European Union recently legislated for compulsory labelling of cosmetics containing NMs, 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. At present, there are no nano-specific labelling requirements in New Zealand, either for

cosmetics or for any other products containing mNMs. This could be argued, in some contexts, to be a regulatory gap. In relation to food regulation, for example, we have noted that one of FSANZ's objectives, as laid down in the FSANZ Act, is 'the provision of adequate information relating to food to enable consumers to make informed choices'. On the other hand, as discussed later, the view has been expressed quite forcefully that the decision not to require nano-specific labelling is not a regulatory gap, but rather, a considered and appropriate decision made within the regulatory framework.

Perhaps more than any other, we found this issue to be one that divided, even polarised, opinion. Clearly, before offering an opinion on the normative question as to whether food or other products containing mNMs should be labelled as such, a great many considerations would need to be weighed that we have not had the opportunity to evaluate here. We have therefore confined ourselves to the observation that *some* commentators view the status quo as inadequate, and as such, we consider it a suitable subject for inclusion in our report. Our suggestions as to *how* a labelling requirement *could* be introduced should, however, be read in that context, and should be taken to imply nothing either way about the quite separate question of *whether* it *should* be introduced.

Insofar as this is properly seen as a regulatory gap, it may be one that could be addressed at a regulatory, as opposed to statutory level. FSANZ could, for example, vary the FS Code to require nano-specific labelling, while it would seem to be open to ERMA to use Group Standards to impose a similar condition on manufacturers of, e.g., cosmetics containing NMs. We note, finally, that due consideration would have to be paid to the appropriate wording of any such labels, if they are to impart genuinely useful information to prospective consumers without causing unjustified alarm.

Regulating uncertainty

The limited state of current knowledge about the risks posed by some mNMs presents a number of obstacles to any attempt to regulate in this area. In some cases, regulatory triggers require the identification of a product as being likely to present a risk. Under the Waste Minimisation Act, for example, the absence of documented cases of adverse environmental effects directly attributable to mNMs may mean that products containing mNMs may not be singled out as products likely to harm the environment when disposed of as waste.

It is obviously important that regulators remain apprised of the most recent reliable information with regard to the possible hazards presented by mNMs; indeed, we are reassured that many of the regulators had already acknowledged this obligation. 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 the contrary assumption: that a new product is unsafe until the contrary can be demonstrated?

Some of the regulatory frameworks we have examined 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'. 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.' 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.’⁴ On one view, it seems inevitable that, when dealing with NMs about which the evidence of hazard is still uncertain, particular mNMs must either be presumed to be safe or unsafe. It is unclear what an approach avoiding either of those presumptions might look like, even in theory. However, it is also possible that more nuanced options may exist within those broad presumptions. For example, an approach could perhaps be adapted from criminal law, whereby anyone objecting to an NM would bear an *evidentiary burden* of demonstrating *some* risk of harm – of ‘putting the issue into play’, as it has been described – but having passed that threshold, the burden of proof would then transfer to the manufacturer to prove that the risk was unfounded or adequately managed. This could potentially avoid the possibility of an NM being banned because of a mere *suggestion* of hazard, but would perhaps avoid the danger of regulatory paralysis until some harm has actually occurred.

The question of *standard* of proof has also been identified as an area of possible uncertainty, for example, the ‘likelihood’ trigger in Standard 1.4.3 of the FS Code, or the designation as ‘hazardous’ in terms of the HSE or HSNO Acts. 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.⁵ For some of those with whom we have spoken, 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.

Insofar as existing regulations are not specific about the level of proof that would be required to trigger regulatory action, we agree with the Monash Report that these may be seen as potential regulatory gaps.

Successive Generations of mNMs and Combination Products

This report focuses on presently existing nano-products, and to an extent, on those which are foreseen as likely to enter the market in the near future. Therefore, we are primarily concerned with the first and second generation nanotechnologies and mNMs.⁶ We suspect that the conclusions that we offer here will require revision as and when successive generations of mNMs enter the market.

Some reviews of this topic have suggested that subsequent generations of nanotechnologies are likely to present a much more significant challenge to existing regulatory structures.⁷ This report concludes that the second, and successive generations, of nanomedicines do, and will continue to, present challenges to the Medicines Act 1981. Many of the new generation nanomedicines combine medicines and devices into a single product. These ‘combination products’ are therapeutic or diagnostic products that combine a drug, device and/or biological

⁴ Roger Brownsword, *Rights, Regulation, and the Technological Revolution*. Oxford: Oxford University Press, 2008, at p.106

⁵ As per correspondence with Sustainability Council, 30 November 2010, and ERMA, 21 December 2010.

⁶ J. Clarence Davis ‘Oversight of Next Generation Nanotechnology’ (Project on Emerging Nanotechnologies, April 2009) at p. 8, available at <http://www.nanotechproject.org>

⁷ *Id.*

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product into a single entity. ‘Cosmeceuticals’, which combine cosmetics with medicines, may also present regulatory challenges.

These next generation and combination nano-products (which may sit at the border or regulatory agencies and regulatory regimes) will require regulatory review as more such products are released onto the market.

Compliance and enforcement

Finally, it should be borne in mind that even the most comprehensive regulatory framework will be an ineffective safeguard of public health if no effective mechanism exists to monitor and enforce compliance with it. This is what we identified as a third level regulatory gap. For example, the notification requirement of the presence of NMs in cosmetics relies upon the voluntary compliance of manufacturers. It appears, however, that this requirement has, at least until recently, been widely ignored. This gap is far from unique to New Zealand; in Australia, a voluntary call for data by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) produced ‘disappointing’ results, while a voluntary reporting scheme operated by the UK’s DEFRA has yielded a similarly low number of reports.⁸

We therefore make the general observation that, before implementing any rule or measure to address nano-safety concerns, consideration should perhaps be given to the practical necessity of monitoring, and where need be, enforcing compliance with that rule or measure. This may involve a range of measures, from merely reminding manufacturers in clear terms of their obligations, to invoking such legal sanctions as are considered appropriate. Where regulators are not empowered to conduct such monitoring and enforcement roles, amendment of their foundation statutes may be required. More often, we suspect, lack of monitoring and enforcement will result from policy decisions by the regulators themselves, and the resource realities within which they operate.

Conclusion

It may be seen, then, that some of the potential gaps we have identified are quite specific to a particular regulatory area. Others – such as the challenge of deciding what burden and standard of proof is most appropriate in the face of uncertain evidence – are likely to be common to all regulators, and probably in all jurisdictions. Insofar as specific gaps have been identified, we have tried where possible to consider some possible strategies whereby they could be closed, or at least narrowed. Where we have done so, these should be seen merely as options for further consideration, rather than explicit recommendations on our part.

As the Monash Report concluded, it is now for each of the regulatory agencies to consider in detail the potential gaps we have identified, and to consider whether these potential gaps require some action on their part. If some action is regarded as appropriate, detailed consideration should then be given to what form of action would be most appropriate to the gap in question, giving consideration to the scale and urgency of the possible problem, and to issues of proportionality.

⁸ Royal Commission on Environmental Pollution *Novel Materials in the Environment*, op. cit., at para. 4.74.

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This report, then, in no ways purports to be the last word on the subject of regulation of nanoproducts in New Zealand. It is hoped, however, that it will make a worthwhile contribution to clarifying the terms of the discussions that must follow.

1 INTRODUCTION

1.1 Background

The origins of this review lie with a Nanotechnology Workshop, hosted by MORST and others, in April 2009. The aim of that Workshop was to ‘raise awareness of opportunities and challenges that nanotechnologies are creating, identify what are the most important nanotechnology-related issues for New Zealand, and discuss appropriate ways to address them.’⁹ One outcome of this Workshop was an undertaking by MoRST to commission ‘a study to review New Zealand’s regulatory landscape with respect to nanotechnologies ... identifying potential regulatory gaps or weaknesses.’ Similar studies had already taken place in the UK,¹⁰ EU¹¹, Australia,¹² and the US.¹³ The stated intention was that the New Zealand study would follow a similar approach to that adopted in the Monash Report.

In March 2010, responsibility for conducting this study was given to members of the newly established New Zealand Law Foundation Centre for Law & Policy in Emerging Technologies, at the University of Otago. An interim report, representing the results of the researchers’ meetings with regulators and provisional conclusions, was presented in September 2010. Following a teleconference meeting with regulators in October 2010, at which responses and suggestions were offered and discussed, a Final Report was prepared and submitted in January 2011.

Although we are grateful for the contributions that various regulators, academics and other stakeholders have made to our understanding of this area, we stress that the content, and particularly the conclusions, of this report are our own, and not necessarily shared by any of those parties.

1.2 Project aims

The aims of this project are to produce a review of how regulatory oversight is triggered for mNMs in New Zealand, as well as to conduct an analysis of Australia’s proposed response to a similar review of their regulatory framework. More specifically, the objectives set out by the Ministry of Research, Science and Technology in the Statement of Work document were to:

Assess New Zealand’s existing regulatory framework to determine if potential risks of manufactured nanomaterials are covered by existing regulatory frameworks;

⁹ <http://www.morst.govt.nz/current-work/roadmaps/nanotech/workshop-2009/>

¹⁰ The Royal Society & The Royal Academy of Engineering, *Nanoscience and nanotechnologies*. (July 2004), Chapter 8; Chaudhry Q.; Boxall, A.; Aitken, R.; Hull, M. *A Scoping Study into the Manufacture and Use of Nanomaterials in the UK*. Sand Hutton, York: Central Science Laboratory, 2005; Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology* (November 2008), Chapter 4.

¹¹ 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); European Commission *Regulatory Aspects of Nanomaterials* (Commission of the European Communities, Brussels, 2008).

¹² Karinne Ludlow, Diana Bowman and Graeme Hodge. *A Review of Possible Impacts of Nanotechnology on Australia’s Regulatory Framework*. September 2007, henceforth referred to as the Monash Report.

¹³ 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).

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Identify where manufactured nanomaterials may not be adequately covered by any existing regulatory framework; and

Analyse whether the changes to the regulation of industrial nanomaterials proposed by NICNAS in Australia are relevant to provisions under the HSNO Act.

For the purposes of this project, and in accordance with the MORST Statement of Work, nanotechnology has been defined as: ‘the understanding and control of matter at dimensions of roughly 1 to 100 nanometres, where unique phenomena enable novel applications.’ Manufactured nanomaterials are ‘intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 and 100 nanometres’.¹⁴

1.3 Terminology

Though very commonly accepted,¹⁵ the definition of ‘nanotechnology’ set out in the Statement of Work is not uncontested.¹⁶ Indeed, the appropriateness of a size-based definition at all has been called into question.¹⁷ Other commentators seek to restrict the definition of nanotechnology to ‘the control *and restructuring* of matter at 1-100 nm to create materials, devices, and structures.’¹⁸ In view of the current state of technological development, most of what we discuss here would fail to meet that stricter definition; the nanoscale particles of silver or zinc that are found in certain consumer goods have not, after all, been ‘restructured’. Controversies around that definition, however, have little relevance to this report. As the title makes clear, we are concerned here with nanomaterials, rather than nanotechnologies; that is, with manufactured materials with at least one dimension of less than 100nm, regardless of how they were manufactured.

As noted above, and in accordance with the Statement of Work, our report is also limited to consideration of materials ‘*intentionally* produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 and 100 nanometres.’ Our remit, therefore, does not extend to consideration of nano-scale materials that may be produced as an unintended by-product of a manufacturing or other process. Again, that we do not address that issue within *this* report should not be taken to say that it is an issue of no importance.

¹⁴ Statement of Work, at para. 2.

¹⁵ It is, for example, the definition adopted by the US National Nanotechnology Initiative (<http://www.nano.gov/html/facts/whatIsNano.html>), and in reports by, respectively, the UK’s Royal Society and Royal Academy of Engineering, and the Royal Commission on Environmental Pollution.

¹⁶ ‘Currently the definition of what is “nano” is still under debate.’ SCENIHR, *Risk Assessment of Products of Nanotechnologies*, January 2009, p.7. See also Geoffrey Hunt, ‘Nanoscience and Complex Systems: The Case for Nanology’, in Hunt and Mehta, eds. *Nanotechnology: Risk, Ethics and Law* (London: Earthscan, 2006), and the Sustainability Council report, *The Invisible Revolution*.

¹⁷ Auffan, et al. ‘Towards a definition of inorganic nanoparticles from an environmental, health and safety perspective’ *Nature Nanotechnology* 4, 634 - 641 (2009). It has also been noted in one of our predecessor reviews that ‘many believe that “nanotechnology” as a term will cease to exist within the next decade because increasingly researchers will select a material for its functionality, rather than for its size.’ Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology* (November 2008), at para. 2.5.

¹⁸ Mike Treder, ‘Risk Governance Report’, 11 July 2006, at <http://crnano.typepad.com/crnblog/2006/07/irgc.html>, our emphasis.

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Throughout this report, we make frequent reference to ‘regulatory gaps’. This terminology is common in reports of this kind,¹⁹ and indeed, the Statement of Work makes specific reference to it.²⁰ However, as with previous reports on this topic, the use of this expression has at times generated a measure of controversy. It should therefore be made clear from the outset that, in identifying actual or potential regulatory gaps, we intend something analogous to the definition adopted in the Monash Report, i.e. ‘potential regulatory gaps were defined as occurring where the analysis suggested that Australia’s existing regulatory frameworks may not cover, or cover appropriately, nanotechnology-based materials, products and applications.’²¹

In particular, it should be noted that, in identifying the existence of a regulatory gap, we imply nothing about whether such gaps arose as a result of regulatory oversight, or after considered deliberation. Neither do we imply anything about the appropriate response to such gaps; questions of whether, how and when they should be narrowed or closed involve a range of policy and perhaps resource considerations that lie outwith our remit. A regulatory gap is merely an area where it appears to us that existing regulatory frameworks may not apply to mNMs, or may not apply to mNMs in a manner that would generally be agreed to be adequate. Whether a particular gap is troubling enough to justify the cost and effort of closing it is a separate question.

There have also been occasions when we have found the regulatory parameters to be insufficiently certain to enable us to state, with complete confidence, whether or not they would extend to mNMs. This may be because a particular statutory provision is open to a number of alternative interpretations, and has never been definitively interpreted by a court. Or it may be because a particular item that contains or incorporates mNMs has not yet been introduced into New Zealand, leading to a degree of uncertainty as to whether it would trigger particular regulatory mechanisms. In such circumstances, we have flagged up these uncertainties as *potential* regulatory gaps, reflecting the current state of uncertainty as to whether existing regulatory mechanisms will prove adequate.

On other occasions, we have encountered a lack of consensus as to whether something is or is not properly designated a gap. To take one example, the absence of any provision requiring labelling of foodstuffs containing manufactured NMs is, to some observers, a gap in the regulatory framework. To others (including at least some of the regulators with whom we have worked), it is the result of a considered decision within that framework, and should not be designated a ‘gap’ at all. In such circumstances, we have attempted, in our use of language, to indicate this diversity of opinions. However, we hope that consideration of the substantive content of this report does not come to be eclipsed by a debate about semantics.

Our approach identifies three possible levels of regulatory gaps, which seem to require different strategies if they are to be closed. The first is at the **statutory level**. If some of the legislation we have been charged to evaluate does not, for whatever reason, apply to mNMs, then this is a gap that would presumably require to be addressed by amending the relevant statutory provision.

The second level of regulatory gap is at the level of **interpretation and application**; thus, some gaps may be thought to exist because regulators have interpreted a piece of legislation

¹⁹ In addition to the Monash Report, see, for example, The Royal Society & The Royal Academy of Engineering, *Nanoscience and nanotechnologies*. (July 2004); Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology* (November 2008).

²⁰ At paragraph 15.

²¹ Monash Report, at para 1.2

in a particular manner, or because they have adopted a particular policy when applying it or operating within it. A regulatory gap at this level could also be closed by modifying the relevant legislation (so as to render its wording less open to interpretation, or to require a particular course of action by the regulators). Alternatively, it could be altered by a policy change on the part of the regulators.

The third level at which potential regulatory gaps might exist would be with regard to **enforcement and compliance**. Here, we may find that the relevant legislation contains adequate provisions for regulation, and that the regulators charged with implementing it have a policy that encompasses mNMs; however, for whatever reason, compliance with the regulatory framework is inadequate. This may be because importers or manufacturers are neglecting to comply with, or are unaware of, a voluntary reporting scheme. Alternatively, it may be because the regulator is insufficiently resourced to monitor such compliance, or that they have not regarded such monitoring as a priority. The manner in which gaps at this level could be closed will depend ultimately in the reason for their existence, with tighter rules (for example, replacing voluntary with compulsory compliance), more effective monitoring or differing regulatory priorities perhaps being better suited to different situations.

In a recent article, Robert Lee and Elen Stokes pointed out that ‘an analysis of regulatory *coverage* may ignore issues of regulatory *application* and overlook completely the question of regulatory *effectiveness*. The fact that existing regulation can extend to cover nanotechnologies offers little indication of the actual extent of protection.’²² Although we in no way claim that this report addresses all of the areas to which Lee and Stokes refer, we hope that in at least considering these second and third level regulatory gaps, we are addressing some of their concerns about reviews of this nature.

While we may, at times, suggest possible mechanisms by which regulatory gaps could be closed, these should be treated merely as contributions to the range of options available to policy makers. We reiterate that identifying something as a regulatory gap should be taken neither as an attribution of blame for its existence, nor to venture into the realm of policy or resource prioritisation.

1.4 Remit and limitations

As with the Monash Report which we were asked to take as our model, we should make it clear that this report comprises an academic review of the applicability of various regulatory frameworks to manufactured nanomaterials, and should not be regarded as legal advice. It is, to borrow a phrase from that Report, an exercise in ‘regulatory terrain mapping’, and does not purport to be a definitive or wholly comprehensive study of every area of law that could potentially impact upon nanotechnologies and mNMs.

It is also important to be clear from the outset that the remit of this report has limited us to a consideration of whether ‘and under what conditions, nanotechnology-based materials, products or applications, and their manufacture, use and handling, are covered by existing regulatory frameworks’. In particular, it has not been our task to make recommendations regarding the proper policy to be adopted with regard to manufactured NMs, and certainly not to nanotechnology more generally. Where mNMs have been found not to be *covered* by existing regulatory frameworks, we have noted this. Where we have concluded that existing regulatory mechanisms are *triggered* by the presence of mNMs, this should be taken to imply no conclusion either way as to the substantive adequacy of those mechanisms. Whether they

²² Lee, R and Stokes, E. ‘Twenty-first Century Novel: Regulating Nanotechnologies’ *Journal of Environmental Law* (2009); 21(3): 469-482, at pp.472-473

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currently strike the correct balance between, for example, progress and precaution, is an important question, but not one that we were asked to consider in this report.

Specifically, we have not addressed the question of whether a separate regulatory strategy or regulatory body should be set up to deal with mNMs or nanotechnologies. We note, however, that while some jurisdictions may be moving towards closer scrutiny of mNMs,²³ there does not seem to have been a move towards the creation of nano-specific regulatory bodies; indeed, some reviews of this area have expressed skepticism as to the utility of a nano-specific regulatory approach.²⁴

Finally, we note that our report has focused on presently existing nano-products, and to an extent on those which are foreseen as likely to come 'on-stream' in the near future. Essentially, then, we are concerned with the products of what have been described as first and second generation nanotechnologies.²⁵ Our research has revealed highly disparate estimates as to how nanotechnologies are likely to evolve in the medium and long term, and it may be that the conclusions that we offer here will require to be revised as and when more is learned about successive generations of nanotechnologies (a caveat that the authors of the Monash Report have also been careful to emphasise). It should perhaps be noted that some reviews of this topic have suggested that subsequent generations of nanotechnologies are likely to present a much more significant challenge to existing regulatory structures.²⁶

In all, though it is hoped that this report makes a valuable contribution to decisions as to 'whether changes to the current regulatory frameworks are required', it was neither asked to, nor does it purport to, provide exhaustive coverage of the sort of information and evidence that should inform such decisions.

Nanotechnologies: an overview

As noted above, the definition of 'nanotechnologies' is contested. Most commentators, however, agree that the term refers to a multidisciplinary and heterogeneous field involving nanostructures and devices which are generally sized between 1 to 100 nanometers.²⁷ One nanometre is one billionth of a metre. A human hair is approximately 80,000 nanometres wide. It would take eight hundred 100-nanometer particles side by side to match the width of a human hair.²⁸ Scientists have been working with nanoscale materials for centuries, but the

²³ 'Nanomaterials: MEPs call for more prudence', 24 April 2009, <http://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20090422IPR54260&format=XML&language=EN>

²⁴ 'We have not seen convincing evidence of the need for a special regulatory regime for nanomaterials ... There is no logical reason why size of particle should in itself provide the basis for new regulatory controls.' Royal Commission on Environmental Pollution, *Novel Materials in the Environment: The case of nanotechnology* (November 2008), at para. 4.44.

²⁵ J. Clarence Davis, 'Oversight of Next generation Nanotechnology' (Project on Emerging Nanotechnologies, April 2009), at p.8, Available at <http://www.nanotechproject.org/process/assets/files/7316/pen-18.pdf>,

²⁶ 'nothing less than a completely new system will suffice to deal with the next generations of nanotechnology.' 'Oversight of Next generation Nanotechnology', *ibid*, at p.8,

²⁷ We say 'generally' because although 1 to 100 nanometers is the commonly accepted metrology, it is not uncontested. For example, see SCENIHR, *Risk Assessment of Products of Nanotechnologies*, (SCENIHR, EU, January 2009) 7; Melanie Auffan and others 'Towards a Definition of Inorganic Nanoparticles from an Environmental, Health and Safety Perspective' (2009) 4 *Nature Nanotechnology* 634.

²⁸ Understanding Nano: Introduction to Nanotechnology <http://www.understandingnano.com/introduction.html> viewed 16 October 2010.

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relatively recent development of special microscopes,²⁹ capable of displaying small particles such as atoms, has improved researchers' ability to work with these tiny materials.

NMs can be categorised as natural or engineered/manufactured. Naturally occurring NMs include particles in our atmosphere such as volcanic ash. Manufactured NMs are manufactured to have regular shapes which may contribute to their toxicity. As we explain in the Introduction, this report is concerned only with manufactured NMs.

A broad range of applications, materials and products fall under the term 'nanotechnologies'. Details of the various 'nanotechnology families' can be found in the Monash Report.³⁰ Therefore, this report does not repeat that discussion, but provides a brief explanation of nanotechnology applications, materials and products. Nanotechnology allows manipulation of properties at the nanoscale and it can have many applications in, for example, medicine, energy, food, environmental air and water quality, and electronics.

Examples of mNMs include metal oxides, nanotubes, quantum dots and fullerenes (C₆₀ or Buckyballs). Engineered NMs have greater surface area to volume ratios than at larger sizes. The considerably larger surface area per unit mass increases their potential for biopersistence and reactivity. The nano features of these materials include not only size, but also other parameters such as shape, surface chemistry, composition, solubility and aggregation.

NMs exhibit different physical, chemical and biological properties from their equivalent macro counterparts. For instance, gold as a bulk material is nontoxic, but gold particles below 2 nanometres have shown unexpectedly high toxicity in a variety of cell lines.³¹

Not all NMs are the same, nor are they all potentially harmful to human and environmental health and safety. There are deficiencies in our scientific understanding of nanotoxicity, but there is growing evidence that the novel properties of *some* NMs may bring unforeseen human and environmental health and safety risks.³² Research on carbon nanotubes, for example, suggests that their size and fibre shape may lead to health effects similar to asbestos.³³ Detailed discussions about the health risks, toxicity³⁴ and exposure routes³⁵ of NMs have been conducted in the academic literature.

²⁹ The Scanning Tunnelling Microscope was invented in 1981

³⁰ Monash Report, at pp.13-20.

³¹ Jahnhan-Dechent, W. and Simon, U. 'Function Follows Form: Shape Complementarity and Nanoparticle Toxicity' (2008) 3 *Nanomedicine* 601, 602.

³² Kandlikar, M.; Ramachandran, G. and Maynard, A. 'Health Risk Assessment for Nanoparticles: A Case for Using Expert Judgment' (2007) 9 *Journal of Nanoparticle Research* 137; Maynard, A. 'Nanotechnology: The Next Big Thing or Much Ado About Nothing?' (2007) 51 *The Annals of Occupational Hygiene* 1; Andrew Maynard and others 'Safe Handling of Nanotechnology' (2006) 444 *Nature* 267; Oberdorster, G., et al 'Nanotoxicology: An Emerging Discipline Evolving from Study of Ultrafine Particles' (2005) 113 *Environmental Health Perspectives* 823.

³³ Poland, C. and others, 'Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study' (2008) *Nature Nanotechnology* 423; Knowles, EE. 'Nanotechnology: Evolving Occupational Safety, Health and Environmental Issues' (2006) *Professional Safety* 20, 24; Service, R. 'Nanotechnology's Public Health Hazard?' (2008) *Science Now* <http://news.sciencemag.org/sciencenow/2008/05/20-01.html> viewed 11 August 2010.

³⁴ Aitken, RJ; Creely, KS; Tran, CL. *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); Donaldson, K and others 'Nanotoxicology' (2004) 61 *Occupational Environmental Medicine* 727; Oberdorster, E. 'Manufactured Nanomaterials (Fullerenes, C60) Induce Oxidative Stress in the Brain of Juvenile *A Review of the Adequacy of New Zealand's Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials*

The ability to use nanotechnologies across many industry sectors has ensured the rapid commercialisation of products produced by nanomanufacturing processes or incorporating manufactured NMs. NMs are used in a broad range of consumer products such as cosmetics, sunscreens, food packaging, paints, textiles, herbal remedies, medical devices and pharmaceuticals.³⁶

Mike Roco's influential approach conceives of nanotechnologies in terms of generations. **First generation** nanoproducts are 'passive nanostructures, illustrated by nanostructured coatings, dispersion of nanoparticles, and bulk materials - nanostructured metals, polymers, and ceramics.' **Second Generation** nanoproducts are 'active nanostructures', such as 'nanobiosensors and devices, tools for molecular medicine and food systems, multiscale hierarchical modeling and simulation, energy conversion and storage, nanoelectronics beyond CMOS, 3-D nanoscale instrumentation and nanomanufacturing, R&D networking for remote measurement and manufacturing, converging technologies (nano-bio-info-cogno) and their societal implications.'

The **Third Generation** will involve '3-D nanosystems and systems of nanosystems with various syntheses and assembling techniques, such as bioassembling; networking at the nanoscale and multiscale architectures,' while the **Fourth Generation** of nanotechnologies will see the development of 'heterogeneous molecular nanosystems, where each molecule in the nanosystem has a specific structure and plays a different role. Molecules will be used as devices and from their engineered structures and architectures will emerge fundamentally new functions.'³⁷

We will provide a brief explanation of one group of products, nanomedicines, in order to provide readers with a case study example of one nanotechnology family. We have chosen nanomedicines as our case study because research and development on nanotechnologies for medical products is one of the fastest growing areas. Commentators predict that by 2014, the market for health applications of nanobiotechnology will be US\$18 billion per year.³⁸ 'Nanobiotechnology' is a narrower application of nanotechnology in which nanotechnology and biotechnology converge. There is no legislative definition, but academic literature defines nanobiotechnology as:³⁹

Largemouth Bass' (2004) 112 *Environmental Health Perspective* 1058; Powell, MC and Kanarek, MS. 'Nanomaterial Health Effects – part 1: Background and Current Knowledge' (2006) 2 *Wisconsin Medical Journal* 16; Powell, MC and Kamarek, MS. 'Nanomaterial Health Effects – part 2: Uncertainties and Recommendations for the Future' (2006) 2 *Wisconsin Medical Journal* 18; D'Silva, J and van Calster, G. 'Taking Temperature – A Review of European Union Regulation in Nanomedicine' (2009) 16 *European Journal of Health Law* 249; Maynard, A. *Nanotechnology: A Research Strategy for Addressing Risk* (Woodrow Wilson Project on Emerging Technologies, Washington DC, 2006); Maynard, A and Kuempel, ED. 'Airborne Nanostructured Particles and Occupational Health' (2005) 7 *Journal of Nanoparticle Research* 587.

³⁵ For example, see Karinne Ludlow 'One Size Fits All? Australian Regulation of Nanoparticle Exposure in the Workplace' (2007) 15 *JLM* 136, 140-142.

³⁶ For further examples of products containing NMs see Woodrow Wilson International Center for Scholars *Consumer Products: An Inventory of Nanotechnology-based Consumer Products Currently on the Market* <http://www.nanotechproject.org/inventories/consumer/> viewed 17 September 2010.

³⁷ Roco, MC. 'Nanoscale Science and Engineering: Unifying and Transforming Tools', *AICHE Journal* (2004); 50(5): 890–897

³⁸ Drew, H and Raj, B. 'The Carbon NanoTube Patent Landscape in Nanomedicine: An Expert Opinion' (2007) 17 *Expert Opinion Therapeutic Patents* 1.

³⁹ Roco, MC. 'Nanotechnology: Convergence with Modern Biology and Medicine' (2003) 14 *Current Opinion in Biotechnology* 337, 337.

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a field that applies the nanoscale principles and techniques to understand and transform biosystems (living or non-living) and which uses biological principles and materials to create new devices and systems integrated from the nanoscale.

Examples of products currently on the US and EU markets, and which are produced by nanobiotech manufacturing processes or incorporating manufactured NMs, include Rapamune® immunosuppressant for prevention of organ rejection in renal transplant patients,⁴⁰ Epaxal® Hepatitis A vaccine,⁴¹ Estrasorb topical estrogen therapy,⁴² Vitoss® bone graft substitute,⁴³ TiMesh tissue reinforcement, EnSeal™ tissue sealing system for laparoscopic surgery,⁴⁴ and CellTracks® Analyser II *in vitro* diagnostic device,⁴⁵ and Abraxane®. NZ has approved two nanomedicines: Rapamune⁴⁶ and Abraxane.⁴⁷ Rapamune is an immunosuppressant for prevention of organ rejection in renal transplant patients. Abraxane is a nanoparticle albumin-bound paclitaxel which is indicated for the treatment of metastatic breast cancer.

Many nanomedical products are currently in the third phase of clinical trials. Many of the new generation nanomedicines combine medicines and devices into a single product. These 'combination products' are therapeutic or diagnostic products that combine a drug, device and/or biological product into a single entity.

Another type of combination product is the cosmeceutical. 'Cosmeceutical' is a term used by the cosmetics industry to refer to cosmetics that have medicinal benefits. They are typically products that combine cosmetics and medicines. Legislation in the US, EU and NZ does not use the term 'cosmeceutical'. 'Nanocosmeceutical' refers to cosmeceuticals which contain materials at the nanoscale.

These next generation combination nanoproducts (which may sit at the border of regulatory agencies and regulatory regimes) will require regulatory review as more such products are released onto the market.

⁴⁰ See Wyeth Pharmaceuticals (which is now part of Pfizer) www.wyeth.com/products viewed 18 October 2010

⁴¹ See Crucell-Berna Biotech www.crucell.com/Products-Epaxal viewed 1 November 2010

⁴² See Espirit-Pharma www.estrasorb.com viewed 1 November 2010.

⁴³ See Orthovita <http://www.orthovita.com/vitoss/> viewed 1 November 2010.

⁴⁴ See Project on Emerging Technologies

http://www.nanotechproject.org/inventories/medicine/apps/medical_tools/enseal_laparoscopic_vessel_fusion_system/ and <http://www.surgrx.com> viewed 1 November 2010.

⁴⁵ The Project on Emerging Technologies

http://www.nanotechproject.org/inventories/medicine/apps/diagnostic_tests/celltracks/ viewed 1 November 2010.

⁴⁶ See the datasheet information:

<http://www.medsafe.govt.nz/profs/Datasheet/r/Rapamunetaboralsoln.pdf> viewed 25 November 2010.

⁴⁷ Medsafe Product Detail <http://www.medsafe.govt.nz/regulatory/ProductDetail.asp?ID=14039> viewed 18 October 2010; Medsafe Abraxane Product Information

<http://www.medsafe.govt.nz/profs/Datasheet/a/abraxaneinj.pdf> viewed 18 October 2010.

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2 REGULATORY FRAMEWORKS

This section outlines the relevant regulatory frameworks for seven New Zealand regulatory bodies. Following the Monash Report, we conceptualise ‘regulatory framework’ as including a ‘range of activities, from legislation through to relevant regulations, codes, standards and guidelines.’⁴⁸ A summary of the sources of power (the legislative instruments) of the relevant regulatory bodies is shown in the table below.

Regulatory Agency	Legislative Instruments
Department of Labour	Health and Safety in Employment Act. Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work.
MedSafe, Ministry of Health	Medicines Act 1981
Ministry for the Environment & ERMA	Waste Minimisation Act 2008 (MfE). Hazardous Substances and New Organisms Act 1996 (ERMA).
Ministry of Consumer Affairs	Consumer Guarantees Act
	Fair Trading Act
New Zealand Customs Service	Customs and Excise Act 1996
New Zealand Food Safety Authority & Food Standards Australia and New Zealand	Food Act 1981 Australia New Zealand Food Standards Code

2.1 DoL

The DoL’s primary role is to improve the performance of the labour market. The DoL administers the HSE Act in most workplaces. The DoL’s roles include coordinating the development of codes of practice, enforcing compliance with the Act and regulations made under it, through inspectors employed by the DoL. The DoL acts as the principal prosecuting authority for offences under the Act.

Under section 20 of the HSE Act, the Minister may approve codes of practice. These codes are the result of consultation between the DoL and affected industry members, including employers and employee organisations. Compliance with codes of practice is not mandatory. However, codes of practice have ‘powerful persuasive authority’.⁴⁹ In any proceedings under the HSE Act, the Court may have regard to the code of practice that was in force at the time of the alleged offending.⁵⁰

The Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work is relevant to nanotechnology. This code of practice and the HSE Act are considered in this review.

⁴⁸ Monash Report, at p.21.

⁴⁹ Richard Rudman *New Zealand Employment Law Guide* (CCH, Auckland, 2009) at ch 11, p.234.

⁵⁰ HSE Act, s 20(9).

One of the DoL's roles is to ensure that the HSNO Act is complied with in workplaces. The DoL is working with ERMA and the MfE to identify the best ways to inform employees and employers about their obligations under HSNO Act.⁵¹

2.2 MEDSAFE

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is a business unit of the Ministry of Health (MOH). Medsafe is responsible for the regulation of therapeutic products in New Zealand. Medsafe's mission is 'to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit'.⁵²

Medsafe administers the Medicines Act 1981 and the regulations promulgated under this Act, most notably the Medicines Regulations 1984 and the Medicines (Standing Order) Regulations 2002. The MOH has identified several proposed amendments to these regulations.⁵³ However, changes to the Meds Act itself are not being considered at this stage.⁵⁴

The objective of the medicines legislation is to manage the risk of avoidable harm associated with the use of medicines. The legislation is designed to ensure that:⁵⁵

- medicines meet acceptable standards of safety, quality and efficacy;
- personnel, premises and practices used to manufacture, store and distribute medicines comply with requirements designed to ensure that products meet acceptable standards right up until they are delivered to the end-user; and
- information about the selection and safe use of medicines is provided to health professionals and consumers.

The proposal to establish a joint Australia and New Zealand therapeutic products regulatory agency (ANZTPA) has been postponed.⁵⁶ The Therapeutic Products and Medicines Bill (the legislation that would implement the ANZTPA) has not progressed. The Medicines Act, therefore, remains in force and has been examined for this review.

2.3 MfE

New Zealand's primary agency for protecting the environment is the Ministry for the Environment. The MfE's vision is for a prosperous New Zealand where a healthy environment enhances social and economic wellbeing.⁵⁷ Their mission is environmental stewardship for a prosperous New Zealand.⁵⁸ The MfE was established under the Environment Act 1986. The MfE has specific functions under the RMA and the HSNO Act.

The MfE works on a range of environmental and resource management issues such as waste minimisation. The Waste Minimisation Act 2008 is administered by the MfE. *The New*

⁵¹ DoL, www.osh.dol.govt.nz/about/initiatives

⁵² Medsafe www.medsafe.govt.nz

⁵³ MOH Consultation on Proposed Amendments to Regulations under the Medicines Act (26 February 2010) www.moh.govt.nz

⁵⁴ Id.

⁵⁵ Medsafe www.medsafe.govt.nz

⁵⁶ Australia New Zealand Therapeutic Products Authority <http://www.anztpa.org/> For information about the advantages of establishing a trans Tasman therapeutic products agency see <http://www.anztpa.org/about.htm#why>

⁵⁷ MfE www.mfe.govt.nz

⁵⁸ Id.

Zealand Waste Strategy's vision of 'zero waste and a sustainable New Zealand'⁵⁹ is the background against which the Waste Minimisation Act 2008 was passed.⁶⁰ This Act is relevant because this review is concerned with the possible impact of nanotechnology on New Zealand's regulatory framework across all stages of a product's life cycle.

ERMA

The Hazardous Substances and New Organisms (HSNO) Act 1996 was enacted 'because of the need for a more integrated and consistent approach to managing hazardous substances and new organisms in New Zealand.'⁶¹ The 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.'⁶²

Section 14 of the HSNO Act provides for the establishment of the Environmental Risk Management Authority (ERMA), 'an independent, quasijudicial authority set up by the HSNO Act to decide on applications to introduce hazardous substances and new organisms.'⁶³ ERMA's overall mission is to '[a]chieve effective prevention or management of risks to the environment, public health and safety associated with importing or manufacturing hazardous substances and introducing new organisms, and their use.'⁶⁴

More specifically, it exists to:

- assess and decide on applications to introduce hazardous substances and new organisms into New Zealand
- place controls, where appropriate, on hazardous substances and new organisms
- maintain a publicly available register of applications and approvals
- approve test certifiers and codes of practice.
- monitor compliance with and enforcement of the Act
- where appropriate, enquire into incidents or emergencies involving a new organism or hazardous substance
- report to Parliament annually on incidents caused by inadequate management of hazardous substances or new organisms, and the extent to which the Act has contributed to the health and safety of people and the environment.⁶⁵

2.4 MCA

The MCA is part of the Ministry of Economic Development. The main role of the MCA is to promote information flows between suppliers and consumers so that consumers can transact with confidence.⁶⁶ The MCA has various functions such as investigating unsafe consumer products and developing consumer policy including consumer protection and product safety.

⁵⁹ *The New Zealand Waste Strategy: Towards Zero Waste and a Sustainable New Zealand* (March 2002 with reviews in 2003, 2006) at <http://www.mfe.govt.nz/publications/waste/waste-strategy-mar02/index.html> (accessed 1 June 2010).

⁶⁰ Wagener, H. 'The Waste Minimisation Act 2008 and the Ability of Territorial Authorities to Manage Solid Waste' (2009) *NZJEL* 295 at 299.

⁶¹ ERMA, 'A guide to the Hazardous Substances and New Organisms Act', April 2006, available at <http://www.ermanz.govt.nz.ezproxy.otago.ac.nz/resources/index.html>

⁶² Section 4

⁶³ ERMA, 'A guide to the Hazardous Substances and New Organisms Act', April 2006, p.12

⁶⁴ <http://www.ermanz.govt.nz/about/whatwe-do.html>

⁶⁵ ERMA, 'A guide to the Hazardous Substances and New Organisms Act', April 2006, p.13

⁶⁶ MCA <http://www.consumeraffairs.govt.nz/about-mca/what-we-dont-do-and-who-can-help/about-the-ministry> accessed 27 May 2010

The MCA can:⁶⁷

- investigate unsafe products;
- suggest modifications to make a product safe;
- request that unsafe products be removed from sale;
- give advice to companies recalling unsafe products; and
- help develop self-regulation options.

Where circumstances require this, the Minister of Consumer Affairs can:

- recall unsafe products;
- ban an unsafe product; or
- make mandatory standards.

In addition, misleading conduct and false representations are investigated and enforced by the Commerce Commission.

New Zealand's consumer protection law is contained primarily in the FTA and CGA. Both the FTA and CGA are analysed in this review. Consumer protection law is relevant to nanotechnology. For example, the misleading and deceptive conduct, and safety, provisions in relation to goods can cover goods containing NMs.

New Zealand's consumer protection law overlaps with other areas of law such as contract and tort law. For example, the misleading and deceptive conduct prohibited by the FTA is at the core of the torts of deceit, passing off and negligent misstatement.⁶⁸

The MCA administers the Fair Trading Act 1986 (FTA) and the Consumer Guarantees Act 1993 (CGA). However, the MCA does not investigate breaches of the CGA as it is self-enforcing.⁶⁹ The Commerce Commission is responsible for enforcing the FTA and investigating breaches of the FTA. The Commerce Commission enforces product safety standards and product bans made under the FTA.

The MCA liaises and consults with other government agencies that may have an interest in government intervention.⁷⁰ MCA investigates all product safety issues except those relating to food, medicines, or vehicles.⁷¹ NZFSA and Medsafe deal with product safety issues relating to food and medicine respectively. The New Zealand Customs Service can also enforce the safety provisions under the Customs and Excise Act 1996. Hazardous substances and organisms are dealt with by ERMA and hazardous products and products used in the workplace are dealt with by DoL.

2.5 NZCS

The NZCS is the government agency that facilitates the legitimate movement of goods and people across the border. The focus of the NZCS is protecting the security of New Zealand's borders.⁷² The NZCS has various functions such as enforcing import and export prohibitions

⁶⁷ MCA <http://www.consumeraffairs.govt.nz/about-mca/what-we-dont-do-and-who-can-help/about-the-ministry> accessed 1 June 2010

⁶⁸ *Laws of New Zealand* (online ed) at [1].

⁶⁹ MCA <http://www.consumeraffairs.govt.nz/about-mca/what-we-dont-do-and-who-can-help/what-we-dont-do-and-who-can-help> accessed 27 May 2010

⁷⁰ MCA www.consumeraffairs.govt.nz

⁷¹ *Id.*

⁷² NZCS www.customs.govt.nz/about/Our+history.htm

and restrictions. The NZCS works closely with other agencies such as the NZFSA, Ministry of Economic Development and ERMA.

The primary statute which regulates the movement of goods, craft and people crossing New Zealand's border is the Customs and Excise Act 1996. This Act is administered by the NZCS.

The NZCS also enforces import and export prohibitions and restrictions under other statutes such as the HSNO Act and the FTA.

2.6 NZFSA & FSANZ

The Food Standards Australia New Zealand Act 1991 (FSANZ Act) is intended to 'ensure a high standard of public health protection throughout Australia and New Zealand'.⁷³ The FSANZ Act 'establishes the mechanisms for the development and variation of joint food regulatory measures (a food standard or a code of practice) and creates Food Standards Australia New Zealand (the Authority) as the agency responsible for the development and maintenance of a joint Australia New Zealand Food Standards Code (the Code).'⁷⁴ The Code 'is a collection of individual food standards',⁷⁵ which sets out quality or composition and labelling requirements for food prepared and sold in, or imported into, Australia and New Zealand. It is an offence in New Zealand to supply food that does not comply with relevant food standards.

FSANZ is 'a bi-national Government agency', whose 'main responsibility is to develop and administer the Australia New Zealand Food Standards Code (the Code)',⁷⁶ setting food standards for both countries. Standards or variations to standards developed and approved by the Authority are subject to review by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), which comprises Health Ministers from all Australian States and Territories, the Australian Government and New Zealand.

Interpretation and enforcement of the Code is not the responsibility of FSANZ, but of the relevant departments and food agencies within Australia and New Zealand. In New Zealand, that responsibility falls to the New Zealand Food Safety Authority (NZFSA). NZFSA exists 'to protect consumers by providing an effective food regulatory programme covering food produced and consumed in New Zealand as well as imports and exports of food products.'⁷⁷

⁷³ Section 2A

⁷⁴ http://www.foodstandards.gov.au/_srcfiles/Commentary_v111.pdf

⁷⁵ http://www.foodstandards.gov.au/_srcfiles/Commentary_v111.pdf

⁷⁶ <http://www.foodstandards.gov.au/>

⁷⁷ <http://www.nzfsa.govt.nz/about-us/nzfsa-mandate-15-september-2008.htm>

3 APPLICATION

This section of our report examines each regulatory framework and its adequacy to manage the possible impacts of mNMs. Following the Monash Report, the adequacy of each regulatory framework was analysed with reference to the five criteria adopted in that Report:⁷⁸

1. Trigger and scope;
2. Requirement for regulatory approval;
3. Human safety assessment;
4. Environmental safety assessment and;
5. Post-market monitoring.

A summary of the application of the regulatory frameworks to mNMs can be found in the table below. This table follows the table adopted in the Monash Report,⁷⁹ but we have included the Australian and the New Zealand findings in the table below to enable comparison of the two jurisdictions. A more detailed table summarising the adequacy of New Zealand's regulatory frameworks to mNMs (including a summary of potential gaps) can be found in Section 4 at page 94.

	Is regulatory approval required prior to regulated activity?	Can human safety assessment be required?	Can environmental safety assessment be required?	Does framework provide for post-market monitoring?
AUS:ASCC-HS	0	✓	0	✓
NZ: DoL	0	✓	0	✓
AUS: TGA	✓	✓	0	✓
NZ: Medsafe	✓ (But no pre-market approval process for medical devices)	✓ (But no pre-market safety assessment for medical devices)	0	✓
AUS:DEW	✓	✓	✓	✓
NZ: MfE (WMA)	✓ (limited)	✓ (limited)	0	✓
AUS:N/A	N/A	N/A	N/A	N/A
NZ:MCA	0	0	0	FTA:✓ (limited)

⁷⁸ Monash Report, para 4.1, p.28. A description of the five criteria can be found in the Monash Report at paras 1.4 and 4.1.

⁷⁹ Monash Report, para 4.2, p.29.

				CGA: 0
AUS: Customs	✓	0	0	0
NZ: NZCS	✓	0 (Import prohibitions can take human safety into account)	0 (Import prohibitions can take environmental safety into account)	0
AUS: FSANZ	✓	✓	0	✓
NZSFA & FSANZ	✓	✓	0	✓

3.1 DoL

The Department of Labour’s primary role is to improve the performance of the labour market.⁸⁰ The DoL administers the HSE Act in most workplaces. The DoL’s roles include coordinating the development of codes of practice, enforcing compliance with the Act and regulations made under it, through inspectors employed by the DoL. The DoL acts as the principal prosecuting authority for offences under the Act.

Section 21 empowers the Governor-General to make regulations imposing duties relating to the health or safety of employees. Regulations made under the HSE Act (*The Health and Safety in Employment Regulations 1995* and *The Health and Safety in Employment (Prescribed Matters) Regulations 2003*) extend the scope and detail of the Act itself. The regulations set out the general requirements for all employers and specific requirements for certain industries.⁸¹

Under section 20 of the HSE Act, the Minister may approve codes of practice. These codes are the result of consultation between the DoL and affected industry members, including employers and employee organisations.⁸² Compliance with codes of practice is not mandatory. However, codes of practice have ‘powerful persuasive authority’.⁸³ In any proceedings under the HSE Act, the Court may have regard to the code of practice that was in force at the time of the alleged offending.⁸⁴

The Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work is relevant to nanotechnology. This code of practice and the HSE Act are considered separately below.

Dangerous goods law is also relevant to nanotechnology. The Dangerous Goods Act 1974 was replaced by the HSNO Act. The importation, manufacture and use of explosives are now regulated under the HSNO Act. Both dangerous goods and explosives are now regulated under the HSNO Act and, therefore, they are considered in the analysis of the HSNO Act. The HSNO Act’s provisions relating to hazardous substances have the most significance for

⁸⁰ Department of Labour <www.dol.govt.nz/about>

⁸¹ Rudman, R. *New Zealand Employment Law Guide* (CCH, Auckland, 2009) at ch. 11.

⁸² Rebecca Keenan (ed) *Health Care and The Law* (Brookers, Wellington, 2010) at [14.3.7].

⁸³ Rudman, *New Zealand Employment Law Guide*, op. cit. at ch. 11.

⁸⁴ HSE Act, s 20(9).

occupational health and safety.⁸⁵ The HSNO Act takes an integrated approach to the control of hazardous substances and new organisms. The Act applies to everyone who imports, manufactures, uses or stores hazardous substances.

3.1.1 HSE Act 1992

Scope and Triggers

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.⁸⁶ New Zealand 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.⁸⁷ The Act seeks to achieve this goal by:

- promoting excellence in health and safety management, in particular through promoting the systematic management of health and safety;⁸⁸
- comprehensively defining hazards and harm, including harm caused by work-related stress and hazardous behaviour caused by certain temporary conditions;⁸⁹
- imposing various duties on persons who are responsible for work and those who do the work;⁹⁰
- setting flexible requirements that relate to taking all practicable steps to ensure health and safety;⁹¹
- recognising that volunteers who are engaged in work activities should have their health and safety protected;⁹²
- recognising that successful management of health and safety issues is best achieved through good faith cooperation in the workplace;⁹³
- providing a range of enforcement methods to enable an appropriate response to a failure to comply with the Act;⁹⁴
- prohibiting persons from being indemnified (or indemnifying others) against the costs of these enforcement measures.⁹⁵

The Act covers places of work. ‘Place of work’ is given a broad definition in section 2:

a place (whether or not within or forming part of a building, structure, or vehicle) where any person is to work, is working, for the time being works, or customarily works, for gain or reward; and, in relation to an employee, includes a place, or part of a place, under the control of the employer (not being domestic accommodation provided for the employee), -

- (a) where the employee comes or may come to eat, rest, or get first-aid or pay; or

⁸⁵ Rudman, *New Zealand Employment Law Guide*, op.cit. at p.258.

⁸⁶ Rudman, *New Zealand Employment Law Guide*, op.cit. at ch. 11.

⁸⁷ HSE Act, s 5.

⁸⁸ HSE Act, s 5(a).

⁸⁹ HSE Act, s 5(b).

⁹⁰ HSE Act, s 5(c).

⁹¹ HSE Act, s 5(d).

⁹² HSE Act, s 5(e).

⁹³ HSE Act, s 5(f).

⁹⁴ HSE Act, s 5(g).

⁹⁵ HSE Act, s 5(h).

- (b) where the employee comes or may come as part of the employee's duties to report in or out, get instructions, or deliver goods or vehicles; or
- (c) through which the employee may or must pass to reach a place of work.

This definition applies to places which people move through in the course of their work, and to places which themselves move.⁹⁶ It covers buildings, other structures, mobile plant, vehicles and outdoor workplaces. People are 'at work' if they are 'present, for gain or reward, in their place of work'. A person is in a workplace 'whenever and wherever the person performs work'. Therefore, the HSE Act will apply to places of employment whether or not those workplaces involve employees working with NMs.

The Act binds the Crown.⁹⁷ The HSE Act applies to employers, employees, self-employed people, contractors and subcontractors.⁹⁸ The Act also specifically applies, with some modifications, to persons working on ships or aircraft, volunteers, persons receiving on the job training, persons gaining work experience and loaned employees.⁹⁹ The HSE Act will, therefore, apply to all these people whether or not they work with NMs.

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'¹⁰⁰ to have been taken. This phrase recurs throughout the Act. The 'all practicable steps' requirement is interpreted strictly.¹⁰¹ It is reasonable to expect an employer to do anything that is practicable to do.¹⁰² Employers are expected to be proactive in identifying both existing and potential hazards and taking steps to prevent harm to workers.¹⁰³ Employers may be expected, therefore, to be proactive in identifying potential hazards associated with NMs and nanoparticles.

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

- 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;
- 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.¹⁰⁴

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.¹⁰⁵ Therefore, a person is required to take all practicable steps to ensure the safety of employees working with NMs only in respect of circumstances that the person knows or ought reasonably to know about.

⁹⁶ OSH, *A Guide to the Health and Safety in Employment Act 1992 Including the Health and Safety in Employment Amendment Act 2002* (2nd ed, DoL, Wellington, 2003) at p.12.

⁹⁷ HSE Act, s 3.

⁹⁸ HSE Act, s 2.

⁹⁹ HSE Act, ss 3A-3F.

¹⁰⁰ HSE Act, ss 2A and 6.

¹⁰¹ Rudman, *New Zealand Employment Law Guide*, op.cit. atp.242.

¹⁰² Id.

¹⁰³ Id.

¹⁰⁴ S 2A definition of 'all practicable steps'.

¹⁰⁵ HSE Act, s 2A(2).

There is a potential regulatory gap in that the “current state of knowledge”¹⁰⁶ regarding harm attributed to many NMs is deficient. Although many of the OSH implications of NMs and nanoparticles are unknown, scientific studies indicate that adverse health consequences are possible from NM and nanoparticle use and exposure.¹⁰⁷ For some nanoparticles, such as carbon nanotubes, the small size and fibre shape has led to speculation that carbon nanotubes may have similar adverse health effects to asbestos fibres.¹⁰⁸ Workers in workplaces are potentially being exposed to nanoparticles, hazardous substances and dangerous goods containing NMs. The main exposure routes are inhalation and dermal absorption.

Section 6 requires employers to take all practicable steps to ensure the safety of employees. In particular, an employer must take all practicable steps to:

- provide and maintain a safe working **environment**;
- provide and maintain **facilities** for the safety and health of employees while they are at work;
- ensure that **plant** at work is arranged, designed, made and maintained so that it is safe for the employees to use;
- ensure that while employees are at work they are not **exposed to hazards** arising out of the arrangement, disposal, manipulation, organisation, processing, storage, transport, working, or use of things in the workplace or that are near the workplace and under the employee’s control;
- develop **procedures** for dealing with emergencies that may arise while employees are at work.

These obligations are expressed in general terms. The Act also imposes specific duties on employers in relation to protective clothing and equipment,¹⁰⁹ information for employees,¹¹⁰ and training and supervision.¹¹¹

The HSE Act sets out specific duties on employers in relation to hazards in the workplace. Employers must identify hazards;¹¹² take all practicable steps to eliminate them;¹¹³ and if they cannot be practicably eliminated, isolate hazards.¹¹⁴ If hazards cannot be isolated, they must be minimised.¹¹⁵ Employees exposed to them must be monitored.¹¹⁶

The general language of the Act requires a broad approach by employers to potential hazards.¹¹⁷ It is clear that employers must identify specific hazards and then do whatever they can to ensure that the hazards do not cause harm.¹¹⁸

¹⁰⁶ HSE, s 2A.

¹⁰⁷ 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); Ludlow, K. ‘One Size Fits All?’, loc. cit. at p.137; Safety of Nano-Materials Interdisciplinary Research Centre (SnIRC) <http://www.snirc.org/>

¹⁰⁸ Knowles, E. ‘Nanotechnology, Evolving Occupational Safety, Health and Environmental Issues’ *Professional Safety* (2006) 20; Ludlow, ‘One Size Fits All?’, loc. cit., at p.139

¹⁰⁹ HSE Act, s 10.

¹¹⁰ HSE Act, ss 11, 22.

¹¹¹ HSE Act, s 13.

¹¹² HSE Act, s 7.

¹¹³ HSE Act, s 8.

¹¹⁴ HSE Act, s 9.

¹¹⁵ HSE Act, s 10.

¹¹⁶ Id.

¹¹⁷ Keenan, *Health Care and The Law*, op. cit., at 14.3.1.

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The concept of hazard is vital to the working of the Act.¹¹⁹ 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.¹²⁰ ‘Substance’ means a thing that is an organic material, whether living or not.¹²¹ The definition of hazard in the HSE Act is broad and may be physical, biological or mental.¹²²

‘Significant hazard’ means a hazard that is an actual or potential cause or source of:

- 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.¹²³

‘Harm’ means illness, injury, or both and includes physical or mental harm caused by work-related stress.¹²⁴ ‘Serious harm’ means death, or some other harm declared to be serious harm by the Governor-General.¹²⁵ Any illness, injury, physical or mental harm, or death, whether or not attributable to exposure to nanoparticles, may be caught by these definitions.

‘Safe’ is defined narrowly to mean not exposed to any hazards and free from hazards.¹²⁶ ‘Health’ and ‘healthy’ have restricted meanings; they simply mean unharmed.¹²⁷ The definition of health under the HSE Act is different from the broad World Health Organisation definition of health. 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.¹²⁸

The HSE Act drafters wanted to separate regulating safety at work from general regulation of product liability issues.¹²⁹ Therefore, the regulation of product liability issues (including products containing NMs) falls outside the scope of the HSE Act.

However, the HSE Act applies to places of work in which hazards (which means inter alia, substances) and/or significant hazards are identified, whether or not those hazards and/or significant hazards involve NMs.

Approval Prior to Regulated Activity

There are no provisions for formal approval or authorisation from the DoL prior to the regulated activity. However, there are prevention and control measures in the HSE Act¹³⁰ and

¹¹⁸ Rudman, *New Zealand Employment Law Guide*, op.cit. at p.242.

¹¹⁹ OSH Guide at p.28.

¹²⁰ HSE Act, s 2.

¹²¹ Id.

¹²² OSH Guide at p.30.

¹²³ HSE Act, s 2.

¹²⁴ Id.

¹²⁵ Id.

¹²⁶ Id.

¹²⁷ Id.

¹²⁸ World Health Organisation www.who.int

¹²⁹ We are grateful to John Hughes (who has written extensively on the HSE Act) for making this important point. Email from John Hughes to Jennifer Moore regarding the HSE Act (26 May 2010).

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The Code (see the discussion of The Code below under the heading ‘approval prior to regulated activity’).

Human and Environmental Safety Assessment

Human safety assessment occurs through identifying and managing hazards and monitoring workers’ exposure to hazards. Employers must have effective methods for identifying hazards to employees, if possible before the hazard arises.¹³¹

Employers must regularly assess whether each hazard is significant.¹³² As outlined under ‘scope and triggers’ above, when a hazard is assessed as significant, the employer must take all practicable steps to eliminate it.¹³³ If the hazard cannot be eliminated or isolated, employers must take all practicable steps to minimize the likely harm to employees.¹³⁴

Employers must monitor employees’ exposure to a significant hazard¹³⁵ and, with their informed consent, also monitor employees’ health in respect of their exposure to a hazard.¹³⁶

Pursuant to sections 7 to 10 of the HSE Act, employers must identify and manage hazards and monitor workers’ exposure to hazards, whether or not those hazards contain, or are attributable to, NMs. Nanoparticles and NMs may be covered by the hazard identification process. However, the identification of hazards may require the employer to know or suspect nanoparticles are a potential risk to human health. Deficiencies in current knowledge may preclude the identification of nanoparticles as a hazard. These potential statutory gaps may be covered by the language in section 7 in that hazards may be: previously existing,¹³⁷ new,¹³⁸ or potential.¹³⁹

The HSE Act does not specify a particular method of hazard identification. Various hazard identification methods are used in industry.¹⁴⁰ Four commonly used hazard identification methods are:¹⁴¹

1. Physical inspections: walking around the workplace with a checklist to identify hazards.
2. Process analysis: following the production or service delivery process from start to finish and identifying hazards at each stage.
3. Task analysis: examine the tasks in each job and observe the actions of employees while identifying the hazards involved.
4. Analysis of accident investigation details: section 7(2) of the HSE Act makes this method mandatory. Where harm or an accident occurs, the employer is required to take all practicable steps to investigate.

¹³⁰ HSE Act, ss 7-10.

¹³¹ HSE Act, subss 7(1)(a) and (b).

¹³² HSE Act, subs 7(1)(c).

¹³³ HSE Act, s 8.

¹³⁴ HSE Act, s 10.

¹³⁵ HSE Act, s 10.

¹³⁶ HSE Act, s 10(2)(e).

¹³⁷ HSE Act, subs 7(1)(a).

¹³⁸ HSE Act, subs 7(1)(b).

¹³⁹ HSE Act, s 2.

¹⁴⁰ OSH Guide at p.29.

¹⁴¹ Ibid at pp.29-30.

Information from manufacturers, designers, safety data sheets, product labelling should be reviewed as part of the hazard identification process.¹⁴² Employers should produce a list of hazards in the workplace.¹⁴³

Risk assessment, including hazard identification methods, may not be appropriate for NMs. It may be necessary to amend the SDS and labelling systems to recognise that NMs have unique properties. Current processes may not consider the high surface area and increased reactivity of NMs. Therefore, the current methods and procedures may be inadequate for the safety of workers. Hazard assessment for nanoparticles needs to consider shape, chemical properties, the role of particle size, functionality and dose.

There are further difficulties in protecting New Zealand workers from adverse health effects of nanoparticle exposure.¹⁴⁴ First, there is no national or international agreed definition to describe nanoparticles. Second, equipment and methods to enable routine measurements of nanoparticles are not yet available.

Assessment is concerned only with risks to people. Ecotoxicology does not have to be assessed. Risks to the environment are not directly addressed in the HSE Act. This deliberate gap is the result of the boundaries and scope of the regulatory regime. These aspects are covered by the HSNO Act, which dovetails with the HSE Act with respect to workplace management of hazardous substances.

Post-Market Monitoring

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 could be developed, if necessary.

The HSE Act requires monitoring of employees' exposure to hazards. Where elimination and isolation are not practicable, there is a requirement to minimise the hazard and to monitor the employee's exposure to the hazard.¹⁴⁵ Section 10 focuses on the requirement to monitor an individual employee's exposure to hazards. There may be monitoring of general workplace levels of exposure, but monitoring is targeted at the degree of exposure individual employees are likely to experience.¹⁴⁶

Section 10 does *not* require the monitoring of hazards, whether or not they are NMs, which have been isolated. However, the OSH Guide indicates that this kind of monitoring is "worth considering as part of a process of regular revision".¹⁴⁷

The HSE Act also requires monitoring of employees' health. The purpose of monitoring is to identify any health effects and to provide the necessary medical care. Under section 36(a) and (b), a departmental medical practitioner may require employees to submit to a medical examination where the practitioner is satisfied that the employee has or may have been exposed to a significant hazard while at work. Monitoring of employees' health is also a way to check the efficacy of measures taken to reduce exposure to hazards.

¹⁴² Ibid at p.30.

¹⁴³ Id.

¹⁴⁴ Ludlow, 'One Size Fits All?', loc. cit. at p.137.

¹⁴⁵ Section 10(2).

¹⁴⁶ OSH guide, at p.36.

¹⁴⁷ Id.

The HSE Act requires all employers, self-employed persons and principals to maintain a register of accidents and serious harm.¹⁴⁸ A hazard register must systematically identify and manage hazards in the workplace.¹⁴⁹ The register must contain details on every occurrence of serious harm to an employee while at work or as a result of a hazard to which the employee was exposed at work.¹⁵⁰ The particulars that must be recorded are set out in the regulations.¹⁵¹ An employer's register must record particulars about every accident that harmed, or might have harmed, any employee at work or any person in a workplace controlled by the employer.¹⁵²

Trained health and safety representatives may issue hazard notices that describe a hazard identified in workplaces.¹⁵³ Such notices must be in the prescribed form¹⁵⁴ and may set out suggested steps to deal with the hazard.¹⁵⁵

The HSE Act confers powers on inspectors who may monitor conditions in workplaces.¹⁵⁶ It is important that these monitoring and reporting procedures enable the timely and proper collection of information about exposure to nanoparticles which has caused harm, incidents and injuries.

Additional Notes Regarding Workplace Safety

Plant

The HSE Act contains duties for any person who sells or supplies plant that can be used in a place of work.¹⁵⁷ The section 2 definition of plant is broad and includes, but is not limited to, any: appliance, equipment, fitting, furniture, implement, machine, machinery, tool, or vehicle. The plant must be of a nature that can be used in a workplace. This definition will apply to plant, whether or not that plant contains NMs.

Section 18A(6) provides that the duty contained in section 18A does not limit the Consumer Guarantees Act 1993. See the analysis of this Act on page 70. The Consumer Guarantees Act provides consumer protection for the purchase of goods and services other than in trade.

Designers of plant have duties to take all practicable steps to design any plant in accordance with applicable ergonomic principles and design plant so that if the plant is manufactured and used appropriately there is no likelihood that the plant will be a cause or a source of harm to any person.¹⁵⁸ Manufacturers and suppliers of plant have similar duties to take all practicable steps to ensure that any plant if manufactured, used and installed correctly is unlikely to cause harm.¹⁵⁹

¹⁴⁸ HSE Act, ss 25(1), (1A), (1B).

¹⁴⁹ HSE Act, s 25(1).

¹⁵⁰ HSE Act, s 25(1)(b).

¹⁵¹ Health and Safety in Employment (Prescribed Matters) Regulations 2003.

¹⁵² HSE Act, s 25(1)(a).

¹⁵³ HSE Act, s 46A(1)(a).

¹⁵⁴ See the Health and Safety in Employment (Prescribed Matters) Regulations 2003 SR 90 for the prescribed form.

¹⁵⁵ HSE Act, subss 46A(1)(b) and (c).

¹⁵⁶ HSE Act, s 33(1).

¹⁵⁷ HSE Act, s 18A.

¹⁵⁸ Health and Safety in Employment Regulations 1995 R66(1).

¹⁵⁹ *Ibid*, at R 67.

These regulations apply to designers, manufacturers and suppliers of plant, including plant with NMs. The issue, however, is whether designers, manufacturers and suppliers would or should be aware of the presence of NMs and their risks.

3.1.2 The Code 1997

Scope and Triggers

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.¹⁶⁰

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.¹⁶¹ The criteria for classification as a hazardous substance are discussed under the Human and Environmental Safety Assessment heading below.

The Code applies to:¹⁶²

- Suppliers of substances hazardous to health for use at a place of work;
- An employer or self-employed person at a place of work where a substance hazardous to health is used; and
- An employee who may be exposed to a substance hazardous to health at a place of work.

The Code does not apply to the following situations or materials:¹⁶³

- Asbestos and materials containing asbestos;
- The carriage of hazardous substances;
- The discharge or disposal of substances hazardous to health as covered by the RMA, except where such discharge or disposal may involve exposure to employees;
- The use and handling of radioactive substances;
- Hazards posed by non-ionising radiation;
- The storage, transport and sale of motor fuel, aviation fuel, compressed natural gas, or liquefied petroleum gas; or
- Micro-organisms.

The Code does not apply to the following where the use of the product is not related to a work activity:¹⁶⁴

- Food or beverages;
- Cosmetics;
- Any product intended for use as a medicine for human use, or to any animal remedy intended for internal use; and

¹⁶⁰ Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work (The Code) 1997, at [8].

¹⁶¹ Id.

¹⁶² Id.

¹⁶³ Id. These situations or materials are excluded by The Code because they are covered by other regulatory instruments.

¹⁶⁴ Ibid, at p.9.

- Tobacco or products made of tobacco.

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.¹⁶⁵ This includes:

- 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.¹⁶⁶

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

¹⁶⁵ Ibid, at p.10.

¹⁶⁶ Workplace Exposure Standards published by OSH in 1994 and revised in 2002 www.osh.govt.nz
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Approval Prior to Regulated Activity

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.¹⁶⁷ Where a significant hazard has been identified, the HSE Act requires that the hazard be managed by considering the following hierarchy of action:

- Elimination;¹⁶⁸ then
- Isolation;¹⁶⁹ and finally
- Minimisation.¹⁷⁰

If NMs 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 NM from being identified as a significant hazard. However, significant hazard is defined in the HSE Act as an actual or *potential* cause or source of serious harm.¹⁷¹ If the NM is a potential cause of harm, it could be identified as a significant hazard and, therefore, trigger the hierarchy of action.

Minimisation of the risk of substances hazardous to health may be achieved by a variety of practices such as personal protective equipment (PPE).¹⁷² However, it is likely that nanoparticles will be able to penetrate more readily the material from which the protective clothing is made than macro particles.¹⁷³

Safety Data Sheets¹⁷⁴ and Labelling

Suppliers

Under The Code there is no legal requirement for the supplier of a substance hazardous to health to provide specific health and safety information due to the requirements for labelling and SDS under the HSNO Regulations. The Code states that suppliers¹⁷⁵ should¹⁷⁶ have Safety Data Sheets (SDS) available for all substances hazardous to health that they supply.¹⁷⁷ The purpose of SDS is to provide the information required to allow the safe handling of hazardous substances at work.¹⁷⁸

The SDS describes the identity of the substance, relevant health hazard information, precautions for use and safe handling, disposal and emergency response information.

¹⁶⁷ Ibid, at p.23.

¹⁶⁸ HSE Act 1992, s 8.

¹⁶⁹ HSE Act 1992, s 9.

¹⁷⁰ HSE Act 1992, s 10.

¹⁷¹ HSE Act, s 2 our emphasis.

¹⁷² The Code 1997, at pp.24 and 25.

¹⁷³ Ludlow, 'One Size Fits All?', loc. cit., at p.142.

¹⁷⁴ Safety Data Sheets were formerly known as Material Safety Data Sheets. The latter expression is the reference used in The Code 1997.

¹⁷⁵ 'Supplier' is defined as 'the importer, manufacturer, wholesaler or distributor, but excludes the person who transports the substances hazardous to health' (The Code, at p.10).

¹⁷⁶ 'Should' is defined as 'a way of indicating preference. It does not indicate a mandatory requirement...' (The Code, at p.10).

¹⁷⁷ The Code 1997, at p.34.

¹⁷⁸ Id.

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. Particle size is not necessarily specifically noted as a relevant property. The SDS may also describe other information (at the supplier's option). 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. However, there are deficiencies in the toxicological data for NMs, particularly for chronic exposure.

SDS could alert users to the presence of NMs and the risks posed by them, but there is no guarantee that this will occur. The Code, generally, and health hazard information, specifically, does not distinguish between nanoforms and conventional forms of chemicals. The SDS's requirements could generally apply to substances whether or not they contain NMs, but the SDS does not expressly require information relevant to NMs. For instance, the SDS does not expressly require the supplier to note whether a substance is, or originated as, a NM and may, thus, have special properties. There is no obligation on suppliers to disclose such information. Given the deficiencies in current knowledge regarding the safety of NMs, SDS requirement that health effects and health hazard information should be included is unlikely to trigger the provision of nanotoxicological information. These gaps mean that users may not receive adequate information on the possible hazards of substances to workers.

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. Labels should be legible and must comply with all New Zealand legal requirements.¹⁷⁹ The information on a label should contain the following minimum information:¹⁸⁰

- The product name and if necessary the product number or identifier;
- The name and address of the manufacturer or importer;
- A list of all substances hazardous to health contained in the product and their approximate concentrations;
- Warning of any particular handling requirement or incompatibility; and
- First aid procedures.

Employers

In order to comply with section 12 of the HSE Act, The Code specifies the information about hazardous substances that the employer must provide to employees. However, the HSNO Act requirements on this aspect are now applicable. SDS provided by the supplier may form the basis of the information, but this information may need to be configured for the particular workplace.¹⁸¹ Employers should ensure that all employees have access to SDS and have a clear understanding of safe handling requirements.¹⁸² Where a new substance is to be used in a place of work, the SDS should be obtained in advance to allow an assessment of the

¹⁷⁹ Id.

¹⁸⁰ Id.

¹⁸¹ The Code 1997, at p.14.

¹⁸² Id.

controls required.¹⁸³ This process will be triggered whether or not the new substance contains NMs.

Containers of hazardous substances in workplaces should be labelled to allow the substances to be used safely.¹⁸⁴ The HSNO Act requirements are now applicable and, therefore, this aspect is discussed in the section on the HSNO Act on page 51. Labelling requirements will apply to containers of hazardous substances whether or not they incorporate NMs. However, whether or not users are alerted of the presence of NMs depends on whether the product name, number or identifier used on the label references nano.

Human and Environmental Safety Assessment

As indicated under the scope and triggers heading above, 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. Some substances hazardous to health that are or could be NMs, or incorporate NMs, or are produced using nanotechnology could be caught by this definition provided they are known or suspected to cause harm to health. The current deficiencies in nanotoxicology may mean that hazardous substances containing NMs may not be “known”, but they may be “suspected”, to cause harm to health.

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.¹⁸⁵ The emphasis in conducting an assessment is on determining the extent of the risk to employees and others that arises from the use or presence of the hazardous substances.¹⁸⁶ 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;¹⁸⁷
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.¹⁸⁸ 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 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

¹⁸³ Id.

¹⁸⁴ The Code 1997, at p.15.

¹⁸⁵ The Code 1997, at p.16.

¹⁸⁶ Id.

¹⁸⁷ ‘Exposure’ is defined as the conditions that are likely to result in a person absorbing a substance hazardous to health by ingestion, inhalation, or through the skin or mucous membranes (The Code 1997, at p.10).

¹⁸⁸ Ludlow, ‘One Size Fits All?’, loc. cit. at p.145.

as monitoring (workplace exposure monitoring¹⁸⁹ and biological exposure monitoring¹⁹⁰) is required.

Assessments should be revised at least every two years, or if:¹⁹¹

- 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 NMs 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.

As indicated under the ‘approval prior to regulated activity’ heading above, hazards must be managed by elimination, isolation, or minimisation. The generality of this hierarchy of action process means that it will apply to NMs. Whether it does so adequately, however, depends on the knowledge of risks.

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.¹⁹² Therefore, monitoring is required but this depends on the assessment showing that monitoring and surveillance is required. The current deficiencies in scientific knowledge about NMs means it is unclear whether assessments will identify NMs. Further, these deficiencies in knowledge mean that health surveillance and monitoring processes under The Code may not be suitable or adequate for NMs.

Assessment is concerned only with risks to people in workplaces. Risks to the environment are not directly addressed. Environmental safety assessments are not required in The Code. This is an intentional ‘gap’ due to the scope of The Code and because such risks are covered by the HSNO Act assessments and controls. However, ecotoxicity¹⁹³ information is typically required in SDS.

Post-Market Monitoring

The Code describes monitoring processes in order to achieve compliance with sections 10(2)(c), (d) and (e) and section 11 of the HSE Act.¹⁹⁴ The employer is responsible for ensuring that an assessment of the risks to health be conducted for any work involving potential exposure to any hazardous substances. As part of the assessment process, it may be necessary to monitor the employee’s exposure to hazardous substances and, with her or his informed consent, to monitor the employee’s health in relation to exposure to the hazardous substance.¹⁹⁵

¹⁸⁹ Workplace exposure monitoring may be either personal monitoring (achieved by sampling the air in the breathing zone of the worker); or static monitoring (using equipment that samples the air at a fixed point in the workplace) (The Code 1997, at p.29).

¹⁹⁰ Biological exposure monitoring involves, for instance, measurement and assessment of hazardous substances and their metabolites in blood, urine, or expired air (The Code 1997, at p.28).

¹⁹¹ The Code 1997, at p.22.

¹⁹² The Code 1997, at pp.27 and 39.

¹⁹³ Ecotoxicity refers to toxic effects on the environment.

¹⁹⁴ The Code 1997, at 27.

¹⁹⁵ Id.

Monitoring includes the use of valid and suitable techniques to give a quantitative estimate of the exposure of employees to substances hazardous to health and their health in relation to exposure. For airborne substances, workplace exposure monitoring involves the periodic or continuous sampling of workplace atmospheres to derive a quantitative measure of exposure to hazardous substances. However, as outlined above, there are currently no effective methods available in the workplace to measure nanoparticles or exposure to nanoparticles. Therefore, monitoring will be difficult.

Monitoring also includes biological monitoring, workplace exposure monitoring and health surveillance, all of which were described above. Whether the health surveillance is suitable for NMs is unclear.

3.2 MEDSAFE

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is a business unit of the Ministry of Health (MOH). Medsafe is responsible for the regulation of therapeutic products in New Zealand. Medsafe administers the Medicines Act 1981 (Meds Act) and the regulations promulgated under this Act, most notably the Medicines Regulations 1984, the Medicines (database of Medical Devices) Regulations 2003 and the Medicines (Standing Order) Regulations 2002. The MOH has identified and consulted on several proposed amendments to these regulations.¹⁹⁶ However, changes to the Meds Act itself are not being consulted on at this stage.¹⁹⁷

The proposal to establish a joint Australia and New Zealand therapeutic products regulatory agency (ANZTPA) has been postponed.¹⁹⁸ The Therapeutic Products and Medicines Bill (the legislation that would implement the ANZTPA) has not progressed. The Medicines Act, therefore, remains in force.

Medsafe is responsible for applying a framework designed to ensure that therapeutic products, when used appropriately, have greater benefits than risks.¹⁹⁹ The main functions of Medsafe are exercised through two primary processes:

- pre-market approval of products
- post-market surveillance.

Scope and Triggers

The Meds Act is concerned with the law relating to the manufacture, sale, and supply of medicines, medical devices, and related products. The Act governs the distribution, supply and administration of medicines to humans for therapeutic purposes. The objective of the legislation is to manage the risk of avoidable harm associated with medicines.²⁰⁰ The Act is

¹⁹⁶ MOH Consultation on Proposed Amendments to Regulations under the Medicines Act (26 February 2010) www.moh.govt.nz

¹⁹⁷ Id.

¹⁹⁸ Australia New Zealand Therapeutic Products Authority <http://www.anztpa.org/> For information about the advantages of establishing a trans Tasman therapeutic products agency see <http://www.anztpa.org/about.htm#why>

¹⁹⁹ <http://www.medsafe.govt.nz/other/about.asp>

²⁰⁰ Id.

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designed to ensure the quality, safety and efficacy of medicines, medical devices and related products.

Medsafe regulates products used for a therapeutic purpose. Section 4 of the Meds Act defines therapeutic purpose to mean:

- treating or preventing disease; or
- diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition; or
- effecting contraception; or
- inducing anaesthesia; or
- altering the shape, structure, size or weight of the human body; or
- otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way; or
- cleaning, soaking, or lubricating contact lenses.

Products deemed as used for a therapeutic purpose will be caught by this definition by virtue of their use for a therapeutic purpose, and not on the basis of whether or not they contain NMs.

Medsafe regulates products used for a therapeutic purpose including:

- medicines;
- medical devices;
- related products;
- herbal remedies;
- controlled drugs used as medicines.

Pursuant to section 3(1)(a), medicine, new medicine, prescription medicine and restricted medicine (medicines) are defined as any substance or article, other than a medical device, that is manufactured, imported, sold, or supplied wholly or principally for administering to one or more human beings for a therapeutic purpose. Medicine is further defined in section 3(1)(b) and (c).

The definition of medicine does not include substances used for dental cavities, or bandages, surgical dressings or radioactive material.²⁰¹ Animal food and remedies are also excluded from the definition under the Act.²⁰² Substances declared by regulations made under the Meds Act not to be medicine are also excluded from the definition of medicine.²⁰³

New medicine, pharmacy-only medicine, prescription medicine and restricted medicine are further defined at length in section 3(3).

Nanomedicines such as Caelyx or Abraxane,²⁰⁴ and medicines which contain active nano-scale ingredients, will be defined as medicine whether or not they contain NMs. A product which falls within the definition will be a 'medicine' for the purposes of the Meds Act by

²⁰¹ Meds Act, subss 3(2)(a), (b) and (c).

²⁰² Meds Act, subss 3(2)(d) and (e).

²⁰³ Meds Act, subs 3(2)(f).

²⁰⁴ Timothy Vines and Thomas Faunce 'Assessing the Safety and Cost-Effectiveness of Early Nanodrugs' *JLM* (2009)16: 822.

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virtue of being a medicine and not on the basis of the particle size of the active ingredients of the product.

Under section 2 of the Meds Act medical device means any device, instrument, apparatus, or contrivance, including component parts and accessories thereof, that is manufactured, imported, sold, or supplied for use wholly or principally on or by one or more human beings for a therapeutic purpose; and includes bandages and other surgical dressings, except medicated dressings where the medication has a curative function that is not limited to sterilising the dressing. The definition of medical device does not include any ultrasonic therapy apparatus, any irradiating apparatus (except in section 38) or any article that is declared in the regulations as not being a medical device.

Where products are defined as medical devices under the Meds Act, the products will fall within the regulatory scope of Medsafe. A product which falls within the definition will be a medical device by virtue of being a medical device and not on the basis of whether or not the device contains NMs. As combination therapies, such as nanotherapeutics, confuse the boundaries between ‘medicine’ and ‘medical device’, it is unclear whether the Meds Act definitions can manage the challenges posed by these combinations.

The Meds Act definition is inconsistent with international definitions. For example, The Meds Act definition of medicine catches products such as pregnancy tests, which are regulated as devices in Europe, US, Canada and Australia.²⁰⁵ Redefinitions of medicine and medical devices were proposed in 1994,²⁰⁶ and again in the context of the proposed regulatory scheme to be administered by the ANTPA, but the change has not been adopted.

‘Related product’ is defined in section 94 of the Meds Act. Related product means any cosmetic or dentifrice²⁰⁷ or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose. The definition of related product does not include any medicine or any substance or article of a kind or belonging to a class that is declared by regulations made under this Act to be a kind or class of substance or article that is not a related product. Fluoride toothpastes and some anti-dandruff products fall within the definition of related product. The planned regulation change would declare these not to be related products, leaving them to be regulated under the HSNO Cosmetic Group Standard administered by ERMA.

Cosmetics that contain a hazardous substance are covered by a Cosmetic Products Group Standard under the HSNO Act.²⁰⁸

Under section 2 of the Meds Act, herbal remedies are a subcategory of medicine. A herbal remedy is a medicine that does not contain a prescription medicine, or a restricted medicine, or a pharmacy only medicine and consists of any substance produced by subjecting a plant to drying, crushing, or any other similar process.

Nanoparticles of silver, titanium dioxide, zinc and zinc oxide are used in nutritional supplements. These are most commonly regulated as Dietary Supplements under the Dietary Supplements Regulations 1985 (now administered by Medsafe). However, these regulations

²⁰⁵ Thank you to Dr Susan Martindale for this comment.

²⁰⁶ Ministry of Health *Medicines and Medical Devices: Discussion Paper on the Review of the Medicines Legislation* (Ministry of Health, Wellington, 1994) at [17].

²⁰⁷ Dentifrices are powders or pastes used for cleaning teeth.

²⁰⁸ MOH above n 10, 2.

will be revoked if the planned Natural Health Products Bill is passed. This Bill is currently at the policy development stage.

Products will be defined as related products or herbal remedies by virtue of falling within the statutory definitions and not on the basis of whether or not the products contain nano-scale materials.

For medicines that are or contain new organisms, the requirements of the Meds Act are additional to the requirements in the HSNO Act.²⁰⁹ Medicines that are hazardous substances are excluded from the HSNO control.²¹⁰

Approval Prior to Regulated Activity

Product quality standards are agreed during the pre-marketing approval process and enforced through monitoring.²¹¹ The structure of the Act is to impose a broad prohibition on the sale or distribution of medicines unless the publicly notified consent of the Minister of Health has been obtained, or an exemption applies.²¹² The aim is to ensure that the products available are those that can be expected to have greater benefits than risks if used appropriately. A key mechanism to achieve this aim is a pre-marketing approval system which requires products to be assessed for safety, quality and efficacy before use.²¹³

In particular, no person may sell, distribute, or advertise new medicines before the Minister of Health's consent has been notified in the Gazette.²¹⁴ A person who contravenes this provision commits an offence.²¹⁵ An application for consent from the Minister of Health must be made in accordance with provisions of the Act.²¹⁶ On receiving an application for consent, the Minister must consider all the particulars and information on the medicine and weigh the medicine's likely therapeutic value against the risk of its use injuriously affecting a person's health.²¹⁷ If the Minister is not satisfied that consent for the medicine's distribution should be given, s/he must refer the matter to the appropriate committee.²¹⁸ After consideration, the committee must recommend what decision the Minister should make.²¹⁹ The Act lays down a procedure for conditions to be imposed. Once approval is granted, the medicine may be distributed and administered on those conditions. The pre-marketing approval process applies to medicines, whether or not they contain NMs and whether or not they are nanomedicines.

Every application for the Minister's consent under section 20 must state the particulars specified in section 21(2). One of the particulars required by 21(1)(d) is a full statement of the ingredients named by the descriptive or non-proprietary names of the medicine, including details of the quantities in which they are present.²²⁰ Particle size could be included in the statement under section 21(2)(d).

²⁰⁹ Meds Act, s 5A.

²¹⁰ HS (Minimum Degrees of Hazard) Regulations 2001, reg 5.

²¹¹ Meds and Med Devices at 10.

²¹² Nicola Peart, Fiona McKrimmon, John Dawson (2003) 'Clinical Trials', in *The Law of Research*. University of Otago Press, Dunedin, 175, 176.

²¹³ Meds and Med Devices discussion paper.

²¹⁴ Meds Act 1981 s20(2).

²¹⁵ Meds Act 1981 s20(4).

²¹⁶ Meds Act 1981 s21.

²¹⁷ Meds Act 1981 s22(1).

²¹⁸ Meds Act 1981 s22(2).

²¹⁹ Meds Act 1981 s22(2).

²²⁰ Meds Act 1981, s 21(2)(d).

Notwithstanding sections 20 to 22 of the Meds Act, the Minister may give provisional consent to the sale or supply or use of a new medicine where s/he is of the opinion that it is desirable that the medicine be sold, or used on a restricted basis for the treatment of a limited number of patients.²²¹ Provisional consent could be granted whether or not the new medicine contains NMs or is a nanomedicine.

The distribution of new medicines is prohibited unless the publicly notified consent of the Minister has been obtained, or an exemption applies. There are various exemptions covered in sections 25 to 34 of the Meds Act. For example, there are exemptions for practitioners²²² and in respect of herbal remedies.²²³ Under section 28, the sale of herbal remedies is permitted without written recommendations about their use. However, if the herbal remedy is to be sold or distributed with a recommendation that it be used for a therapeutic purpose, then it may not be distributed until ministerial consent is granted under section 20.

Under section 29, there is an exemption for a medicine required by a medical practitioner for the treatment of a particular patient. If the request for the section 29 exemption is successful, there will be no scrutiny of the medicine, whether or not it contains NMs. Accordingly, where an exemption applies to a medicine, that medicine (whether or not it contains NMs) will not be assessed by Medsafe prior to its supply in New Zealand.

An exemption is created for clinical trials of new medicines, even those not generally approved for use in New Zealand.²²⁴ According to this exemption, clinical trials will be permitted when the trial investigators and the trial itself have been approved by the Director-General, on the recommendation of the Health Research Council (HRC). The HRC has lawfully delegated its authority in this regard to the Standing Committee on Therapeutic Trials (SCOTT)²²⁵ or the Gene Technology Advisory Committee (GTAC) for biological products. Ethical approval for clinical trials is also required.²²⁶ The exemption for clinical trials will apply whether or not the trial involves medicines containing NMs or nanomedicines.

Although most medicines require pre-market approval, some products which claim therapeutic benefits and have risks, do not. For example, the approval process outlined above applies to medicines. Medical devices, however, are not subject to any pre-market assessment or approval. In contrast to New Zealand, most developed countries require pre-market approval for medical devices.²²⁷ Medical devices are excluded from the definition of medicine in the Meds Act. Their distribution is not regulated by other legislation.

SCOTT approval is not required for trials of new devices. However, medical devices are included in Medsafe's *Guidance Notes for Applicants for Consent to Distribute New and Changed Medicines and Related Products*.²²⁸

²²¹ Meds Act 1981 s23(1).

²²² Meds Act 1981 s25.

²²³ Meds Act 1981 s28.

²²⁴ Meds Act 1981 s30; Peart et al at p.176.

²²⁵ Peart, McKrimmon and Dawson (2003) 'Clinical Trials', loc. cit., at pp. 175-176.

²²⁶ Id.

²²⁷ Ministry of Health 2004 National Interest Analysis on the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products <http://www.anztpa.org/about/nznia.htm>

²²⁸ <http://www.medsafe.govt.nz/regulatory/Guideline/NZRGM%20Volume%201.asp>

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These omissions regarding medical devices are deficiencies in the Meds Act. The inconsistency in product regulation was one issue which prompted proposals to review the Medicines Act.²²⁹ The Meds Act will struggle with the challenges presented by emerging technologies such as nanomedicines without safety and approval processes for medical devices.²³⁰ For example, it is unclear how the Meds Act will manage a nanomedical device designed to replace human blood.²³¹ The Australian Therapeutic Goods Act provides the Agency with a range of regulatory controls in relation to the manufacturing of medical devices, which apply to these devices whether or not they contain NMs.²³²

In New Zealand, the manufacture and distribution of medicines is regulated through an activities licensing system. Everyone who manufactures a medicine, sells a medicine by wholesale, packs or labels a medicine, or operates any pharmacy must do so in accordance with a licence unless an exemption applies.²³³ Licences are issued under Part 3 of the Act.²³⁴ However, there are no product licences (approval for product) or activity licences required for medical devices.

Access to medicines is controlled through a classification system which allows some medicines to be obtained only on prescription, while others may be purchased only from a pharmacist or in a pharmacy. The Minister of Health is responsible for appointing the Medicines Classification Committee, which must make recommendations to the Minister on the classification of medicines as prescription medicines, restricted medicines, or pharmacy-only medicines.²³⁵ Medicines not restricted by the classification system may be purchased from any retail outlet. There is no comparable classification system for medical devices. Accordingly, unclassified medicines and medical devices, whether or not they contain NMs, will not be controlled through the classification system. For example, products such as nano colloidal silver dietary supplements and nano-silver hair straighteners are not subject to the classification system.²³⁶

Human and Environmental Safety Assessment

Risks assessments on products undertaken by Medsafe focus on the evaluation of the risks posed to human health. The human safety assessment must be favourable for the product to be approved.

The Common Technical Document is accepted by Medsafe. If another agency accepts a particular product, Medsafe reviews the technical report issued by the other agency and conducts a truncated review of the section 21 data.²³⁷

²²⁹ Meds and Medical Devices at 10.

²³⁰ For a discussion of the regulatory challenges (in Australia) posed by nanomedicines and nanomedical devices, see Vines and Faunce, 'Assessing the Safety and Cost-Effectiveness of Early Nanodrugs', loc. cit.

²³¹ Robert Freitas and Christopher Phoenix, 'A Personal Nanomedical Appliance to Replace Human Blood' (2002) 11 *Journal of Evolution and Technology* 26.

²³² Monash Report at p.89.

²³³ Meds Act 1981, s 17(1).

²³⁴ Meds Act, s 50-55.

²³⁵ Meds Act 1981, s 9(1).

²³⁶ Interview with Dr Susan Martindale. Skybright Natural Health (New Zealand is the country of origin) produces Colloidal Silver Cream and Colloidal Silver Liquid containing NMs.

²³⁷ We are grateful to Dr Susan Martindale for explaining this process.

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Section 22(1) of the Meds Act prescribes a procedure in respect of applications for the Minister's consent. On receipt of an application for his or her consent to the distribution of a medicine for the purposes of section 20(2) of the Act, the Minister shall:

- consider all the particulars and information relating to the medicine submitted under section 21 of this Act, and such other matters as appear to him or her to be relevant; and
- as far as practicable, weigh the likely therapeutic value of the medicine against the risk (if any) of the use of the medicine injuriously affecting the health of any person.

The human safety assessment under section 22 applies to medicines whether or not they contain NMs.

A change in the manufacturing process, for example, the reduction of the particle size of active ingredients to the nanoscale, will trigger reassessment of the product.

The human safety assessment process under the Meds Act is concerned with the principles of benefit/risk analysis, rather than solely the technology *per se*. This assessment method may not be appropriate for nanomedicines where there exists a deficiency of long-term exposure and nanotoxicology data. The potential adverse effects of nanoparticles may defy prediction from the known toxicity of the material of macroscopic size, and nanoparticles can accumulate in secondary organs. Therefore, some commentators argue that there may be long-term effects which present benefit/risk assessments fail to consider.²³⁸

If, after complying with the requirements in section 22(1), the Minister is not satisfied that s/he should give his/her consent to the distribution of the medicine, s/he will refer the matter to the appropriate committee. If the recommendation is to refuse consent, the applicant must be notified. The applicant can object.

Accordingly, there is a human safety assessment for products defined as medicine under the Act. However, there is no human safety assessment for medical devices under the Meds Act. Whether or not medical devices contain NMs, Medsafe is not required to undertake a case-by-case safety or hazard assessment of these devices.

Medsafe does not currently perform environmental risk assessments. Although environmental safety assessment is not a focus, Medsafe reviews labels submitted under section 21(2)(o). If Medsafe considers that a warning or caution is needed, theoretically, they could ask for such a warning when conducting the review. In practice, however, New Zealand typically gets the labels that are used in other, bigger markets as companies rarely label for the small New Zealand market.²³⁹

There are guidelines for DHBs on the disposal of unused, returned or expired medicines with adverse environmental effects.²⁴⁰ Medicines and devices should not be disposed of as part of normal household waste because of the potential for misuse and because municipal waste disposal in landfills is not the disposal method of choice for many pharmaceutical types.²⁴¹

The FDA requires that an environmental assessment accompany any New Drug Application (NDA) or Animal NDA for a drug with an expected environmental concentration greater than

²³⁸ SCENIHR The Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Nanotechnologies. European Commission, Brussels; Vines and Faunce, above n 14, 832.

²³⁹ Thank you to Dr Susan Martindale for alerting us to this important point.

²⁴⁰ Disposal of Unused, Returned or Expired Medicines in *Pharmacy Practice Handbook 2010* Pharmaceutical Society of New Zealand <www.psnz.org.nz>

²⁴¹ *Id.*

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one part per billion, as well as those known to cause adverse ecotoxicological effects at lower concentrations.²⁴² The TGA does not require environmental data, although Australia is considering introducing this requirement.²⁴³ The EU consider environmental data, but this examination does not necessarily translate into label cautions.²⁴⁴

Post-Market Monitoring

The Meds Act provides Medsafe with various post-market monitoring powers over products used for a therapeutic purpose in order to ensure that the safety and efficacy of products is maintained. According to the regulator, post-market surveillance is conducted through activities such as:

- monitoring adverse reactions to medicines used in New Zealand and monitoring the international literature and other information sources;
- testing marketed medicines against product quality standards;
- handling complaints and investigations; and
- auditing and licensing medicine manufacturers.²⁴⁵

Prescribers are advised about new safety information for products.²⁴⁶

Sections 35-42 of the Meds Act govern quality and standards. Under section 35, the Minister may at any time, by notice in the Gazette, revoke, or suspend for such period as s/he may determine, any consent given under section 20 or 23 of the Act if s/he is of the opinion that:

- the medicine can no longer be regarded as a medicine that can be administered or used safely for the purposes indicated in the application for consent; or
- the specifications and standards with respect to the manufacture of the medicine that were included in the terms of consent can no longer be regarded as satisfactory; or
- the efficacy of the medicine can no longer be regarded as satisfactory.

The ability to remove products shown to be unsafe gives Medsafe power over the supply of products within the New Zealand.

Section 36 provides the Director-General with powers to control established medicines. If the Director-General has reason to believe that any medicine (not being a new medicine) may be unsafe or ineffective for the therapeutic purpose for which it is sold, s/he may state the reasons for his/her belief and require the importer or manufacturer to satisfy him/her of the safety or efficacy of that medicine. The Minister may, by notice in writing to the importer or manufacturer, prohibit the importer or manufacturer from selling or supplying the medicine; or impose conditions on the sale or supply of the medicine by the importer or manufacturer.²⁴⁷ The broad powers in section 36 cover any medicine, whether or not the medicine contains NMs and whether or not the medicine is a nanomedicine.

The Minister has the power to prohibit the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines of any specified description or medical devices of any specified kind, either absolutely or subject to such conditions as s/he thinks fit, for any specified period not exceeding 1 year.²⁴⁸ But the Minister shall not exercise this power

²⁴² FDA www.fda.gov viewed 15 November 2010.

²⁴³ Email from Dr Susan Martindale to Dr Jennifer Moore regarding the *Medicines Act* (14 June 2010). Email from Dr Susan Martindale to Dr Jennifer Moore regarding the *Meds Act* (14 June 2010).

²⁴⁴ Id.

²⁴⁵ www.medsafe.govt.nz

²⁴⁶ Id.

²⁴⁷ *Meds Act* 1981, subss 36(3)(a), (b).

²⁴⁸ *Meds Act*, s 37.

more than once in respect of medicines or medical devices so specified.²⁴⁹ A person who contravenes this provision will commit an offence. Section 37 gives the Minister broad post-market monitoring powers for medicines and medical devices, whether or not they contain NMs. Section 37 could be used for an immediate ban of a medicine, but this power has never been used.²⁵⁰

Section 38 enables restrictions on the sale of medical devices, whether or not those devices contain NMs.

These post-market monitoring provisions are designed to ensure that the quality and standards of medicines are maintained. The post-market monitoring provisions outlined apply to products whether or not they contain NMs. The post-market monitoring provisions are sufficiently broad to cover products containing NMs.

Pursuant to sections 41, importers or manufacturers have a duty to report untoward effects of medicines. Failure to notify the Director-General of untoward effects of medicines, which may or may not contain NMs, will give rise to offences under the Act.

Under section 42, importers and manufacturers have a duty to have and produce specifications of medicines. No importer or manufacturer may sell, or distribute any medicine unless s/he is in possession of a certificate of results of testing. Section 42 may provide a mechanism whereby a product containing NMs may be identified through the specifications of the medicine.

3.3 MfE

New Zealand's primary agency for protecting the environment is the Ministry for the Environment. *The New Zealand Waste Strategy's* vision of "zero waste and a sustainable New Zealand"²⁵¹ is the background against which the Waste Minimisation Act 2008 (WMA) was passed.²⁵² The WMA was passed in September 2008. The WMA provides for waste management and minimisation. The collection and disposal of waste in urban areas is traditionally a function and service of territorial authorities.²⁵³ Territorial authorities are compelled to have regard to the *New Zealand Waste Strategy*.²⁵⁴ The *New Zealand Waste Strategy* is currently under review. A revised Strategy is expected to be released later in the year, subject to Cabinet approval. Waste management and minimisation plans are to have regard to the *New Zealand Waste Strategy*.²⁵⁵ Many of the OECD's recommendations in its *Environmental Performance Review of New Zealand* have been incorporated in WMA.²⁵⁶

²⁴⁹ Meds Act, s 37.

²⁵⁰ Interview with Dr Susan Martindale, Principal Advisor, Regulation, Medsafe (Dr Jennifer Moore, Law Faculty, University of Otago, 17 May 2010).

²⁵¹ *The New Zealand Waste Strategy: Towards Zero Waste and a Sustainable New Zealand* (March 2002 with reviews in 2003, 2006) at <http://www.mfe.govt.nz/publications/waste/waste-strategy-mar02/index.html> (accessed 1 June 2010).

²⁵² Helgard Wagener, 'The Waste Minimisation Act 2008 and the Ability of Territorial Authorities to Manage Solid Waste' (2009) *NZJEL* 295 at p.299.

²⁵³ Waste Management, Minimisation and Disposal, *The Laws of New Zealand*

²⁵⁴ WMA, s 42(c).

²⁵⁵ WMA, s 42(c).

²⁵⁶ Wagener, 'The Waste Minimisation Act 2008', loc. cit., at p.315, and OECD Environmental Performance Review of NZ (2007) www.oecd.org

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The Resource Management Act 1991 (RMA) and the Local Government Act 1974 (LGA) were the primary methods of dealing with solid waste management before the enactment of the WMA.²⁵⁷ The RMA deals with the environmental effects of activities such as solid waste disposal. The Health Act 1956 addresses the effects of solid waste where this creates a nuisance or any conditions likely to be injurious to health or offensive.²⁵⁸ The WMA is the first New Zealand statute that specifically regulates waste.²⁵⁹

The WMA brings territorial authorities' responsibilities for waste management into one statute. However, there are also provisions relating to waste in the RMA and the Hazardous Substances and New Organisms Act 1996 (HSNO). The RMA deals with the effects of activities such as waste disposal on the environment.

The Basel, Stockholm and Waigani Conventions are New Zealand's international obligations relating to the management of hazardous wastes. Each one is implemented through domestic legislation and policy that is not covered in this report and could be useful instruments to manage NMs, particularly if internationally, NM waste and products becomes a higher priority.

Scope and Triggers

The purpose of the WMA is to encourage waste minimisation and a decrease in waste disposal in order to protect the environment from harm and to provide environmental, social, economic, and cultural benefits.²⁶⁰ The WMA continues the sustainability objectives set out in the RMA and LGA. The objective to protect the environment from harm has a link to the purpose of the RMA.²⁶¹

The WMA is not underpinned by the precautionary principle to the same extent as the RMA. However, some of the tools in the RMA (such as the regulation making powers) could be applied in a precautionary manner.²⁶²

One of the main triggers of the WMA is the disposal of waste. Disposal means the final (or more than short-term) deposit of waste into or onto land set apart for that purpose; or the incineration of waste.²⁶³ Disposal facility means a facility, including a landfill, at which waste is disposed of; and at which the waste disposed of includes household waste; and that operates, at least in part, as a business to dispose of waste; and any other facility or class of facility at which waste is disposed of that is prescribed as a disposal facility. The disposal of waste will trigger the WMA, whether or not some of the constituents of the waste are NMs or produced using nanotechnology.

The Act is also triggered by the actions of territorial authorities. For example, under section 42 territorial authorities must promote effective and efficient waste management and minimisation within their districts.

The provisions of the WMA include:

²⁵⁷ Wagener, 'The Waste Minimisation Act 2008', loc. cit., at p.309.

²⁵⁸ Health Act 1956, ss 23, 29 & 63.

²⁵⁹ Wagener, 'The Waste Minimisation Act 2008', loc. cit., at p.339.

²⁶⁰ WMA, s 3.

²⁶¹ RMA, s 5. Wagener, 'The Waste Minimisation Act 2008', loc. cit., at p.327.

²⁶² Email MfE 14 July 2010.

²⁶³ WMA, s 6.

- introduction of product stewardship provisions²⁶⁴ to encourage (and in certain circumstances require) people and organisations involved in the life of a product to share responsibility for ensuring there is effective reduction, reuse, recycling or recovery of the product and managing any environmental harm arising from a product when it becomes waste;
- impose a waste disposal levy to promote and achieve waste minimisation and also increase the cost of waste disposal in order to recognise its costs on the environment, society and economy;²⁶⁵
- clarify the roles and responsibilities of territorial authorities with respect to waste minimisation;²⁶⁶
- allow regulations to be made making it mandatory for territorial authorities and others to report on waste to improve information on waste minimisation;²⁶⁷ and
- establish a Waste Advisory Board to give advice to the Minister for the Environment on waste minimisation issues.²⁶⁸

Section 5 defines ‘waste minimisation’ as the reduction of waste and the reuse, recycling, and recovery of waste and diverted material. ‘Waste’ is defined in section 5 as any thing disposed of or discarded and includes a type of waste that is defined by its composition or source (for example, organic waste, electronic waste, or construction and demolition waste and includes any component or element of diverted material, if the component or element is disposed of or discarded. What constitutes waste is a contentious issue.²⁶⁹ There are different types of waste such as solid waste, organic waste and hazardous waste. Hazardous wastes contain explosives, are flammable, or able to cause oxidisation or corrosion and are toxic or ecotoxic.²⁷⁰

Pursuant to this definition of ‘waste’, waste associated with NMs falls within the scope of the WMA. For example, the definition will include waste from the preparation and production of products containing NMs. Such waste will fall within the scope of ‘waste’ under the WMA by virtue of being ‘waste’, not as a consequence of incorporating NMs. The trigger for the application of the Act will not be whether or not the waste contains NMs. Rather ‘waste’ will be defined as such whether or not some of the constituents of the waste are NMs or produced using nanotechnology.

‘Diverted material’ is distinguished from ‘waste’ and has a separate definition in the WMA. Diverted material is anything that is no longer required for its original purpose and, but for commercial or other waste minimisation activities, would be disposed of or discarded.²⁷¹ Diverted material will be defined as such whether or not some of the constituents of the diverted material are NMs.

Approval Prior to Regulated Activity

²⁶⁴ WMA, Part 2 ss 8-24.

²⁶⁵ WMA, Part 3 ss 25-41.

²⁶⁶ WMA, Part 4, ss 42-64.

²⁶⁷ WMA, s 41.

²⁶⁸ WMA, Part 7, ss 89-99.

²⁶⁹ Wagener, ‘The Waste Minimisation Act 2008’, loc. cit. at p.300.

²⁷⁰ HSNO Act, s 2. See also the Hazardous Substances (Disposal) Regulations 2001 issued pursuant to s 76(1)(c) of the HSNO Act.

²⁷¹ WMA, s5(1).

The WMA does not provide the MfE with regulatory powers relating to the general approval of products prior to their importation, sale or use within NZ.

However, Part 2 of the WMA establishes a framework for product stewardship. Product stewardship enables the “best means of minimising the environmental risks of a product to be considered at the most appropriate stage of its lifecycle.”²⁷² Section 8 encourages (and, in certain circumstances, requires) people and organisations (including producers, brand owners, importers, retailers, consumers) to take responsibility for the environmental effects from the beginning to the end of the production process. ‘Producer’ is defined broadly to mean a person who –

- (a) manufactures a product and sells it in New Zealand under the person’s own brand; or
- (b) is the owner or licence holder of a trademark under which a product is sold in New Zealand; or
- (c) imports a product for sale in New Zealand; or
- (d) manufactures or imports a product for use in trade by the person or the person’s agent.

A producer of products containing NMs would be considered a producer under the Act by virtue of falling within the definition in section 5(1) and not as a result of having products containing NMs.

‘Product’ is defined in section 5(1) include packaging and a class of products such as fridges and freezers. Manufactured products, whether or not they contain NMs, will be caught by this definition.

If that product is declared a priority product,²⁷³ a product stewardship scheme must be developed for a product as soon as practicable and that scheme must be accredited under the WMA.²⁷⁴ Under sections 5(1) and 9(1) a product is a priority product if it is so declared by the Minister for the Environment. The Minister can only declare a priority product when s/he is satisfied that:

- the product’s waste will or may cause significant environmental harm; or
- there are significant benefits from the reduction, reuse, recycling, recovery, or treatment of the product; and
- the product can be effectively managed under a product stewardship scheme.

The Minister for the Environment has not yet declared any priority products. Accordingly, no products containing NMs have been declared priority products. The MfE’s 2009 Discussion Document Waste Minimisation in New Zealand sought feedback on products that should be the initial focus for developing product stewardship schemes such as agricultural chemicals, used oil and refrigerant gases. Some of these products could contain NMs and may be declared priority products by virtue of their status as potential priority products, whether or not they contain NMs.

Current deficiencies in knowledge about NMs and their eco-toxicity mean that there may not yet be adequate information to assess against the thresholds in section 9(2). These deficiencies in knowledge mean that it is currently difficult to show that the waste from products containing NMs will cause significant environmental harm. Recent research on silver sulfide nanoparticles in sewer sludge suggests that there is sufficient use of products which incorporate silver NMs to generate silver sulfide nanoparticles in wastewater treatment

²⁷² www.mfe.govt.nz

²⁷³ WMA, ss 9 and 10.

²⁷⁴ WMA, s 15.

plants.²⁷⁵ However, despite the use of products containing silver NMs, there are scientific knowledge deficiencies; more evidence is required to establish how NMs move from products into the environment and how the environment will be impacted.

Before the Minister makes a declaration of priority products, s/he must provide the public with the opportunity to comment on the proposal.²⁷⁶ The Minister must obtain and consider advice from the Waste Advisory Board and also consider any public concerns about environmental harm associated with a product.²⁷⁷ There is no appeal process for the declaration of a priority product. However, the decision is open to judicial review.²⁷⁸

There is also provision for the development and accreditation of voluntary product stewardship schemes.²⁷⁹ A number of voluntary product stewardship schemes already exist: whiteware, refrigerants, cell phones and paint. NMs are used in some paints and whiteware such as refrigerators. The voluntary schemes can seek to be accredited for a non-priority product. These schemes could be accredited for non-priority products, whether or not the products contain NMs.

Also, the Act does provide the Governor-General with the power to make regulations to prohibit the sale of a priority product,²⁸⁰ and the power to control or prohibit the disposal or sale of products or waste whether or not priority products.²⁸¹ As already outlined, the thresholds in section 9(2) must be met before a priority product can be declared.

Human and Environmental Safety Assessment

Under WMA, the Ministry for the Environment does *not* undertake safety assessments. However, safety assessments for hazardous substances are conducted by ERMA under the HSNO Act.

Territorial authorities are required to undertake waste assessments for their districts before considering their waste management and minimisation plans.²⁸² Territorial authorities must indicate how their proposals will, *inter alia*, ensure that public health will be adequately protected.²⁸³ The enquiry into how public health will be protected will occur irrespective of NMs. “It is unlikely that issues to do with nanotechnology would be specifically addressed in [waste] assessments”.²⁸⁴ Territorial authorities are compelled to consult with the local Medical Officer of Health when doing their waste assessments.

Although the WMA does not have specific environmental safety assessment provisions, one of the objectives in the WMA is to protect the environment from harm.²⁸⁵ This objective is linked to the purpose of the RMA.²⁸⁶ Section 5 of the RMA integrates social, economic, cultural, health and safety considerations alongside the sustainable management of natural and

²⁷⁵ Bojeong Kim and others, ‘Discovery and Characterization of Silver Sulfide Nanoparticles in Final Sewage Sludge Products’ (2010) 44 *Environ Sci Technol* 7509.

²⁷⁶ WMA, s 9(3)(c).

²⁷⁷ WMA, s 9(3).

²⁷⁸ We are grateful to Ceri Warnock for raising this issue.

²⁷⁹ WMA, s 11.

²⁸⁰ WMA, s 22(1)(a).

²⁸¹ WMA, s 23(1)(a).

²⁸² WMA, s50.

²⁸³ WMA, s 51(1)(f)(i).

²⁸⁴ Email from MfE 1 June 2010.

²⁸⁵ WMA, s 3.

²⁸⁶ RMA, s 5.

physical resources. Assessments of environmental effects are required under the RMA.²⁸⁷ The definition of environment in the WMA has the same meaning as in section 2(1) of the RMA.²⁸⁸ The RMA's definition of environment includes people and communities.

Post-Market Monitoring

The WMA includes monitoring, compliance and enforcement provisions in relation to managing environmental harm. However, few of the enforcement and auditing powers are likely to be applicable to products containing NMs.²⁸⁹

The most relevant regulatory instrument which may cover products containing NMs is section 23(1). Pursuant to section 23, the Governor-General may make regulations for:

- controlling or prohibiting the disposal, or anything done for the purpose of disposing, of products or waste;²⁹⁰
- controlling or prohibiting the manufacture or sale of products that contain specified materials...;²⁹¹
- the labelling of products.²⁹²

Section 23(2) outlines when the Minister must not make regulations under section 23(1).

Section 23(1)(b) concerns controlling or prohibiting the manufacture or sale of products that contain specified materials. This section could potentially cover products with NMs.²⁹³

Regulations could be made for the labelling of products whether or not those products contain NMs.

Under section 20(a), for example, the Secretary for the Environment may monitor the performance of accredited product stewardship schemes and recover the costs of doing so from the scheme manager. However, as already outlined, products (whether or not they contain NMs), would have to be declared a priority product, therefore requiring a product stewardship scheme, or have an industry-led non-priority product stewardship scheme.

Pursuant to section 55 a Health Protection Officer²⁹⁴ may serve notice on a territorial authority if it provides a waste collection service to premises and s/he considers that:

- (i) the territorial authority has failed to collect waste from the premises promptly or efficiently; and
- (ii) the failure to do so is causing, or is likely to cause, a nuisance²⁹⁵.

The territorial authority must comply with such a notice.²⁹⁶

Section 18 gives the Minister the power to revoke the accreditation of any accredited scheme.

²⁸⁷ RMA, s 88 and sch 4.

²⁸⁸ Wma, s 5(1).

²⁸⁹ Email MfE 1 June 2010.

²⁹⁰ WMA, s 23(1)(a).

²⁹¹ WMA, s 23(1)(b).

²⁹² WMA, s 23(1)(f).

²⁹³ Email MfE 1 June 2010.

²⁹⁴ Health Protection Officer has the same meaning as in the Health Act 1956.

²⁹⁵ Nuisance has the same meaning as in section 29 of the Health Act 1956.

²⁹⁶ WMA, s 55(3).

The Secretary for the Environment may request the New Zealand Customs Service to provide any information that Customs holds about the importers and importation of priority products.²⁹⁷ This statutory request could be made for priority products whether or not they contain NMs.

Under section 48 the Governor-General may give directions to territorial authorities to include, omit, or amend 1 or more provisions in their waste management and minimisation plans. Such directions may be made whether or not the territorial authorities' plans contain specific provisions on the disposal of products containing NMs.

Section 86(1)(a), (b) and (c) give the Governor-General the power to make regulations to require:

- the operator of a disposal facility to keep, and provide to the Secretary, records and information;
- any class of persons to keep, and provide to the Secretary, records and information to assist the Secretary to compile statistics in order to measure progress in waste management and minimisation;
- a territorial authority to keep, and provide to the Secretary each year, records and information about the territorial authority's spending of levy money, performance in achieving waste minimisation and performance as measured against any performance standards set by the Minister under section 49.

Under section 90(1), the Waste Advisory Board's functions include providing advice to the Minister upon request about declaring a product to be a priority product, making guidelines about the contents and expected effects of product stewardship schemes for priority products, recommending the making of regulations prohibiting the sale of a priority product and recommending the making of regulations in relation to products (whether or not priority products), materials, and waste.

There are provisions for offences under and enforcement of the provisions of the WMA, including fines from \$20,000 to \$100,000 and the seizure and disposal of property.²⁹⁸ For example, under section 65(1)(a) a producer who contravenes regulations made under section 22(1)(a), relating to priority products, commits an offence and is liable on summary conviction to a fine not exceeding \$100,000. In any prosecution for an offence such as in sections 65(1)(a), (c), (e) or section 66, strict liability is imposed. Under section 76, enforcement officers may be appointed to ensure compliance with regulations.

3.4 MfE/ ERMA

The Hazardous Substances and New Organisms (HSNO) Act 1996 was enacted 'because of the need for a more integrated and consistent approach to managing hazardous substances and new organisms in New Zealand.'²⁹⁹ The Act's stated purpose is 'to protect the environment,

²⁹⁷ WMA, s 24.

²⁹⁸ WMA, Part 5 ss 65-85.

²⁹⁹ ERMA, 'A guide to the Hazardous Substances and New Organisms Act', April 2006

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and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms.³⁰⁰

Section 14 of the HSNO Act provides for the establishment of the Environmental Risk Management Authority (ERMA), ‘an independent, quasijudicial authority set up by the HSNO Act to decide on applications to introduce hazardous substances and new organisms.’³⁰¹ ERMA’s overall mission is to ‘achieve effective prevention or management of risks to the environment, public health and safety associated with importing or manufacturing hazardous substances and introducing new organisms, and their use.’³⁰²

More specifically, it exists to:

- assess and decide on applications to introduce hazardous substances and new organisms into New Zealand
- place controls, where appropriate, on hazardous substances and new organisms
- maintain a publicly available register of applications and approvals
- approve test certifiers and codes of practice.
- monitor compliance with and enforcement of the Act
- where appropriate, enquire into incidents or emergencies involving a new organism or hazardous substance
- report to Parliament annually on incidents caused by inadequate management of hazardous substances or new organisms, and the extent to which the Act has contributed to the health and safety of people and the environment.³⁰³

As of 1 July 2011, ERMA will be ‘disestablished’, and a new Environmental Protection Authority will assume its role in terms of the HSNO Act.³⁰⁴ For the purposes of this review, however, it is the function of ERMA, as presently constituted, that will be considered.

Scope and Triggers

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:

- (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.³⁰⁵

³⁰⁰ HSNO Act, Section 4

³⁰¹ ERMA, ‘A guide to the Hazardous Substances and New Organisms Act’, op. cit., at p.12

³⁰² <http://www.ermanz.govt.nz/about/whatwe-do.html>

³⁰³ ERMA, ‘A guide to the Hazardous Substances and New Organisms Act’, op. cit., at p.13

³⁰⁴ ERMA, *Statement of Intent for the Year 2010/11*

³⁰⁵ HSNO Act, Section 2

With the exception specified in (d), manufactured articles – even those containing or incorporating hazardous substances – are generally not considered to be ‘substances’ for purposes of the HSNO Act³⁰⁶ (subject to the partial exception in s.96B(2)(d)), discussed later). As discussed below, this has given rise to some controversy regarding ‘white goods’ that contain or produce nanoparticles.

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.³⁰⁷ These relate to

- (i) explosiveness;
- (ii) flammability;
- (iii) a capacity to oxidise;
- (iv) corrosiveness;
- (v) toxicity (including chronic toxicity);
- (vi) ecotoxicity, with or without bioaccumulation.³⁰⁸

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.

As ERMA explains, ‘If a substance does not trigger any of the 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 New Zealand other than in accordance with an approval from the Authority.’³⁰⁹ The manufacture or importation of a hazardous substance without an approval is an offence.³¹⁰

Certain substances which might otherwise meet the relevant criteria are exempt from the terms of the HSNO Act, and hence, from the need for ERMA approval. Excluded substances include: food in a ready-to-consume form,³¹¹ and finished dose-form medicines.³¹²

³⁰⁶ ERMA, ‘Interpretations and Explanations of Key Concepts’, paragraph 4.6; see also DSL Guide, p.20

³⁰⁷ DSL Guide at 2.2.2

³⁰⁸ HSNO Act, Section 2

³⁰⁹ ERMA, *Summary User Guide to HSNO Thresholds and Classifications* (March 2008), at 1.2.4

³¹⁰ HSNO Act, section 25(1)

³¹¹ Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, Section 6. Generally, food is managed under a separate regime; see Report, section 3.7. It should be noted, however, that ‘food additives that have not been mixed with, or added to, any other food or drink are *not* exempt from the Act.’ DSL, 2.4

³¹² Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, Section 5. It should be noted, however, that ‘[a]ny new ingredient used for formulating a medicine is not exempt and will require a HSNO approval.’ DSL, 2.4

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The relevant thresholds are set out in Hazardous Substances Regulations 2001.³¹³ A threshold, for these purposes, is described as ‘the amount or concentration of a substance that is likely to cause an adverse effect on people or the environment.’³¹⁴ The threshold level has been described as the ‘bottom rung on the classification ladder’,³¹⁵ the least hazardous level at which controls can be triggered. A substance will not be considered hazardous if it does not meet this minimum threshold, while substances located higher up the hazard ladder may merit tighter controls.

There are thirteen Hazardous Substances Regulations, covering, inter alia, minimum degrees of hazard, classification of hazards, packaging, identification and disposal. As noted above, the minimum *thresholds* for hazardous properties – which determine whether a substance is hazardous - are contained in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001,³¹⁶ while the *classification* criteria for hazardous properties - which determine hazard *levels* for hazardous substances - are contained in the Hazardous Substances (Classification) Regulations 2001.³¹⁷ As ERMA has pointed out, ‘The criteria in these regulations are based on those contained in the early version of the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). This system is currently being implemented on a widespread basis around the world. The HSNO regulations are currently being updated to reflect the 2009 version of the GHS.’³¹⁸

A substance with toxic properties will not be treated as ‘hazardous’ for the purposes of the HSNO Act unless data indicates that it meets the minimum degrees of hazard as stipulated in Schedule 4 of the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001. Data, for these purposes, ‘includes values that are directly measured, calculated, or estimated for any of the measures given’.³¹⁹ As ERMA has explained, ‘[t]his means it is not necessary to rely only on directly measured data to determine whether a substance exceeds any of the hazardous property threshold criteria’; rather, ‘a relevant parameter for a substance may be estimated based on the similarity of that substance to another substance for which the hazardous properties are known.’³²⁰

If a substance is deemed to have properties that exceed one or more of these hazardous property thresholds, then an approval from ERMA will be required. The initial responsibility for deciding whether such an approval will be required rests with the importer, manufacturer or user.³²¹

The Monash Report identified a number of potential regulatory gaps with regard to quantity-based assessment thresholds. For example, Australia’s industrial chemicals law allows for ‘low volume permits’, described as ‘a simple means of by-passing the assessment certificate system in respect of a new industrial chemical if the total of the quantities of the chemical that are to be introduced by the person in any 12 month period will not exceed 100 kilograms (or 1,000 kilograms in certain cases).’³²² The Monash Report expressed

³¹³ <http://www.ermanz.govt.nz/resources/hsno-regs.html>

³¹⁴ ERMA, *Summary User Guide to HSNO Thresholds and Classifications*, at 1.1.3.

³¹⁵ Id.

³¹⁶ Schedules 1 to 6.

³¹⁷ Schedules 1 to 6.

³¹⁸ Personal correspondence, For further information, see

<http://www.ermanz.govt.nz/hs/abouths/ghscriteria.html>

³¹⁹ Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001, section 3

³²⁰ ERMA, *Summary User Guide to HSNO Thresholds and Classifications*, at 1.1.4

³²¹ ERMA, *Summary User Guide to HSNO Thresholds and Classifications*, Preface

³²² Industrial Chemicals (Notification and Assessment) Act 1989, s.21Q

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concern that ‘under this permit system, there is the potential for many products containing new industrial chemicals, including those produced at the nanoscale, to be imported or manufactured in Australia, and subsequently sold’ without having to go through the assessment system.³²³ NICNAS, the Australian chemicals regulator, has responded by proposing to ‘exclude nanomaterials which are new chemicals from low volume/low concentration exemptions, thereby shifting a post-market audit activity to a pre-market assessment’.³²⁴

There is no analogous low volume exception under the HSNO Act. Hence, for the most part, this conclusion of the Monash Report – and this part of the NICNAS recommendations - has no relevance to New Zealand. The one permitted quantity-based exception under the HSNO Act relates to ‘small-scale use of hazardous substances in research and development or teaching’. Section 33 provides that the requirements of the HSNO Act do not apply to ‘any small-scale use of hazardous substances in research and development or teaching’, provided certain criteria are fulfilled, including

- that such ‘use occurs in a laboratory that meets the prescribed requirements’;
- the use does not create or involve a hazardous substance for which any application for approval has been declined under this Act; and
- the importation, storage, and transportation of the hazardous substances each meets the prescribed requirements.

R&D exemptions in Australia were identified by the Monash report as a potential gap. While acknowledging that ‘[t]hese gaps are not unique to NMs’, the Report’s authors nonetheless felt that ‘in light of the stage in development at which many NMs and products incorporating them currently are, this deliberate exception for research and development may be of greater significance for NMs and their products and therefore is included as a ‘gap’ for the purposes of this review.’³²⁵ NICNAS, however, have proposed that the R&D exemption be retained for mNMs, ‘due to their limited use (i.e. only in an R&D or analytical setting) and the assumption that they are handled only by trained personnel in a controlled environment.’³²⁶

Whether New Zealand laboratory personnel are adequately trained in handling mNMs is an empirical question that we have not been able to investigate. However, research conducted by Canterbury University’s Sally Gaw for the MacDiarmid Institute in 2009 suggested that complacency in this regard should be avoided. Gaw’s report identified a number of issues of potential concern, specifically:

- There is limited information on the effectiveness of engineering controls and personal protective clothing to minimise exposure to unbound nanomaterials.
- 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.

³²³ Monash Report, at p.83

³²⁴ NICNAS, *Proposal for Regulatory Reform of Industrial Nanomaterials: Public Discussion Paper* (November 2009)

³²⁵ Monash Report, at para. 5.1.5

³²⁶ NICNAS, *Proposal for Regulatory Reform of Industrial Nanomaterials*, op. cit.

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- The lack of readily available funding for upgrading research facilities to meet health and safety requirements.³²⁷

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” to or as the same as its’ [sic] conventional counterpart.’³²⁸

Similar uncertainty may be said to apply to applications for nanoforms of substances already present in New Zealand. As ERMA has said, ‘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.’³²⁹

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? The question of where the burden of proof should lie in questions of this nature – together with the appropriate standard of proof which should need to be satisfied - will be discussed later.

Regulatory scope: manufactured items

Some doubts surround the applicability of the HSNO Act to manufactured items that contain (or produce – as discussed later, the distinction may be of relevance) NMs. The recent Sustainability Council report,³³⁰ for example, expressed concern about Samsung’s SilverCare washing machines. As explained on Samsung’s website, the Silver Wash technology that these products employ ‘uses nano technology to electrolyze pure silver during wash and rinse cycles. Over 400 billion silver ions are released and penetrate deep into fabric for effective sanitization.’³³¹

Doubt may be said to exist as to whether nano-silver washing machines are ultra vires of ERMA’s regulatory remit. As explained earlier, the HSNO Act definition of ‘substance’ only extends to manufactured articles which they possess explosive properties.³³² The potential difficulty lies in the fact that manufactured articles which do not possess explosive properties – even those containing or incorporating other hazardous substances –

³²⁷ Gaw, S. ‘Identification of Potential Health and Safety Issues Associated with MacDiarmid Institute Funded Nanomaterial Research in University Laboratories’ (2009) MacDiarmid Institute

³²⁸ Monash Report, Para 5.5.1

³²⁹ Personal correspondence with ERMA Chief Executive, 9 July 2010

³³⁰ Sustainability Council, *The Invisible Revolution*, June 2010

³³¹

http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/wash_faq_popup.html

³³² HSNO Act, Section 2

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are not considered to be ‘substances’ for purposes of the HSNO Act.³³³ However, ‘manufactured products’ – ‘such as glues, paints, pesticides, etc’ – are regarded as substances rather than manufactured articles, and can (if other criteria are met) be subject to regulation under the HSNO Act ‘regardless of how they are packaged or presented’.

ERMA has issued detailed guidance on the criteria for determining whether an item will be considered a ‘substance’ or a ‘manufactured article’, with the latter being defined as ‘something for which its intended use is primarily to do with its physical shape, rather than its chemical composition’.³³⁴ Nonetheless, it has acknowledged that ‘there will continue to be “fuzziness” at the boundary when deciding what is a substance and what is an article. ... no matter how precise the boundary definition is, there will continue to be room for interpretation.’³³⁵

It may be that SilverCare washing machines could fall within this ‘fuzzy’ area around the boundary. On the one hand, it would seem strange to contend that a washing machine is a ‘substance’ rather than a ‘manufactured article’; the function of a washing machine may certainly be thought to owe more to its ‘physical shape’ than its ‘chemical composition.’ This is certainly the view taken by ERMA’s Chief Executive: ‘Common sense dictates that a washing machine is a manufactured article.’³³⁶ Indeed, the Sustainability Council has conceded that ‘regulating a laundry appliance might at least seem to fall outside the scope of HSNO, which broadly speaking does not cover “manufactured articles”’.³³⁷

On the other hand, it could be argued that the unique selling point of Samsung’s SilverCare range relates to claims about a chemical substance released during its operation. The Sustainability Council has argued that ‘the use of the nanosilver as a pesticide could be regulated independent of the appliance’.³³⁸ ERMA’s position, though, appears to be that the ‘nanosilver’ should be treated as a ‘component’ of the washing machine, rather than a substance meriting separate regulation, distinguishing this from the hypothetical scenario where ‘people needed to add “nanosilver” to the wash like they do powder or rinse aid.’³³⁹

Does a ‘common sense’ approach dictate that these particles should be treated as chemical substances, potentially requiring ERMA approval, or as integral parts of the manufactured article, i.e. the washing machine? The triggering of regulatory oversight seems largely dependent on this classification. In either event, it may be seen that there is a potential regulatory gap with regard to pre-market assessment of products of this nature. Either the Act, as properly understood, does not extend to nano-silver used in this way (as ERMA contends), in which case there is a potential gap at a legislative level; the somewhat anomalous outcome would be that NMs that required to be added to an item such as a washing machine would be subject to regulatory oversight (as ERMA concede), but identical NMs that happen to be contained or produced within the item would escape such oversight.

Alternatively (and we express no view either way on this point) it may be that ERMA’s understanding of its remit is overly restrictive, and that the HSNO Act does permit it jurisdiction over ‘substances’ such as nanosilver, even when contained or produced within a

³³³ ERMA, ‘Interpretations and Explanations of Key Concepts’, paragraph 4.6; see also DSL Guide, p.20

³³⁴ ERMA Information Sheet, ‘Manufactured Articles’, May 2001

³³⁵ Ibid, at p.2.

³³⁶ Personal correspondence with ERMA Chief Executive, 9 July 2010.

³³⁷ Sustainability Council, *The Invisible Revolution*, op. cit.

³³⁸ Ibid, at p.15.

³³⁹ Personal correspondence with ERMA Chief Executive, 9 July 2010.

manufactured item. If this is the case, then it may be that there exists a potential gap at the level of interpretation and application of the legislation.

Whatever the better interpretation of the HSNO Act, it seems clear that items such as washing machines that contain or produce NMs are, in practice, being treated as ‘manufactured items’, and the NMs themselves as integral parts of those items, rather than as substances in themselves. Both the machines and the nano-particles, then, are treated as lying outwith the scope of the HSNO Act and of ERMA. If this interpretation of the Act, currently favoured by ERMA, is valid, then a regulatory gap may be identified with regard to such products.

Other nano-silver products could present similar problems of interpretation. Samsung’s Silver Nano Refrigerators have a ‘Silver Nano coating’ applied to their inner surfaces, ‘for an overall antibacterial and antifungal effect.’³⁴⁰ Though it is not entirely clear from the company’s various descriptions of the technology, it appears as though the NMs here are intended not to leave the refrigerator, or to adhere to any of the food contained within it.³⁴¹ If this is so, then the Silver Nano particles are likely to be regarded as intrinsic to the manufactured item (the refrigerator), and hence are unlikely to be regarded as falling within ERMA’s remit.³⁴² If nanosilver particles within refrigerators or other manufactured articles are considered to be an appropriate subject for regulatory oversight, this may be viewed as a potential regulatory gap.

By way of locating this issue within an international context, it may be of interest to note that the status of (certain) mNMs within electronic and electrical goods has been the subject of recent legislative debate within the EU. A recent Resolution from the European Parliament called for a ban on nanosilver, together with long multi-walled carbon nanotubes, in electrical and electronic products³⁴³ - though it should be noted that this proposed ban did not ultimately find its way into EU law.

Approval Prior to Regulated Activity

If a substance reaches one of the thresholds discussed above, an approval will be required before it can be imported, manufactured or used. ERMA will decide whether the substance’s likely benefits outweigh any risks and costs. With regard to mNMs, an example of this balancing exercise may be found in ERMA’s current position with regard to zinc oxide and titanium dioxide nanoparticles contained in sunscreens. As ERMA’s Chief Executive explained to us: ‘there are known and serious risks from UV radiation (including skin cancer) and the evidence against nano Zinc Oxide and Titanium Dioxide is scientifically unclear. Hence, given current knowledge, the known benefits of these products outweigh the potential risks.’³⁴⁴

³⁴⁰

<http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/refrigerator.html>

³⁴¹ ‘Can the silver stick to my food? No, silver ions will not stick to the food.’

http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/refig_faq_popup.html

³⁴² Particles which ‘remain in their container during normal use of the item, and ... serve an intrinsic part of the end purpose of the item,’ would be ‘considered to be an integral part of the article.’ ERMA, ‘Interpretations and Explanations of Key Concepts’

³⁴³ Draft European Parliament Legislative Resolution on the proposal for a directive of the European parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), at

<http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2010-0196&format=XML&language=EN#title2>

³⁴⁴ Personal correspondence with ERMA Chief Executive, 9 July 2010. Somewhat curiously, this statement was offered in response to a question regarding the exclusion of nano-form Zinc Oxide and *A Review of the Adequacy of New Zealand’s Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials*

If the benefits are considered to outweigh the risks, the application may be approved, subject to the imposition of certain controls. These may be the default controls applicable to the substance's hazard classification. Alternatively, ERMA may vary these default controls for the substance in question, making them either more or less stringent, as considered appropriate. In so doing, ERMA's objective will be 'to achieve the most cost-effective management of risks for the applicant and the community.'

Many of the controls are performance-based, specifying the outcomes that are desired, but not prescribing precisely how those outcomes are to be achieved. For example, controls may require that a substance be contained in a package that can withstand a drop from a certain height, or exposure to a certain temperature. This approach is intended to provide both certainty about what is required, and freedom to adopt new, potentially better and cheaper, methods of complying with these objectives. Other controls are more specific; for example, conditions relating to labelling may specify the precise wording to be printed on the labels.

Section 96A of the HSNO Act (as inserted by Hazardous Substances and New Organisms (Approvals and Enforcement) Amendment Act 2005) 'enable[s] the Authority to issue, amend, and revoke standards (known as Group Standards) for groups of hazardous substances ... that have a similar nature, are of a similar type, or have similar circumstances of use, so that the risks of the grouped hazardous substances can be effectively managed by 1 set of conditions.' According to ERMA, these 'provide for the efficient grouping of substances based on product type'.³⁴⁵

Section 96B(1) stipulates that ERMA may use group standards to (a) identify the group of hazardous substances or products ... concerned; and (b) impose as conditions under this section any obligations and restrictions that the Authority thinks fit on the identified group of hazardous substances or products. A list of group standards issued to date can be found at the ERMA website.³⁴⁶ The possibility that a Group Standard could be issued for products containing NMs will be considered later in this section.

As ERMA has explained, Group Standards apply to substances of a similar nature or type, or which have similar circumstances of use. The risks posed by all of the substances covered by the Group Standard must be capable of being managed by one set of conditions. Hence, a Group Standard may specifically exclude substances of a similar nature or type if those substances pose a significantly greater risk. A substance which is covered by the scope of an existing Group Standard will not require a separate application to ERMA for approval. Rather, its use will be subject to the conditions imposed by the relevant Standard.

In the previous section, we considered the possibility that the introduction of the nano-form of a substance already present in New Zealand would not require a separate approval, if the substance was not deemed to be 'new'. Our concern at that point was that a separate hazard

Titanium Dioxide from the notification requirements of the Cosmetic Products Group Standard, discussed below. Yet it is surely to be hoped that a similar statement could be made about the likely benefits and risks of any of the items that do require notification under that Standard. It has subsequently been explained to us by ERMA that another reason for the exclusion of these substances was that 'it was already known that such substances existed in some cosmetics so further notification was not necessary. The notification provision was included so that ERMA would be aware when new types of nano-substances were being included in cosmetics.'

³⁴⁵ ERMA, 'Features of a Group Standard', at

<http://www.ermanz.govt.nz/hs/groupstandards/features.html>

³⁴⁶ <http://www.ermanz.govt.nz/hs/groupstandards/index.html>

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profile would not be compiled for the nano-form of the substance. It is also worth considering, however, that the conditions applicable to the conventional form of the substance may not be appropriate for the nano-form. If the nano-form of a particular substance has no hazardous properties distinct from the conventional form of the substance, then this gap may be of little consequence. However, where uncertainty exists on this question, the application of the same quantity thresholds as per conventional forms may merit some further consideration.

Group Standards and nanomaterials

In 2006, ERMA issued the Cosmetic Products Group Standard (CPGS). ‘This group standard was created for products or preparations intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition.’³⁴⁷

The group standard is of particular interest as it is unique in making specific reference to nanoparticles. Clause 23 stipulates that:

Any person intending to import into, or manufacture in, New Zealand a cosmetic product containing nanoparticles other than zinc oxide or titanium dioxide, must at the time they first import or manufacture the substance, notify the Authority in writing of:

- (a) the name of the substance; and
- (b) the HSNO approval number and/or title of the Group Standard under which the substance has a deemed approval; and
- (c) the nature of the nanoparticles the substance contains.³⁴⁸

It should be noted that this requirement is simply one of notification; it does not trigger any additional assessment nor impose any additional conditions (beyond the need to notify ERMA). Nonetheless, it is noteworthy that there is now precedent for the use of this regulatory mechanism to make specific provision for NMs. Assuming that ERMA has not acted *ultra vires* of its statutory authority in laying down this requirement, it may well be open to the Authority to impose similar conditions for other products that contain mNMs. Furthermore, since a *prima facie* case has been recognised for according a separate status to mNMs, it may also be open to ERMA to impose more onerous conditions if considered appropriate. (The challenge of monitoring and enforcing compliance with such conditions will be discussed later in this section).

Group standards and manufactured articles

While the CPGS applies to substances that contain mNMs, the possibility exists that group standards may also provide a statutory route by which ERMA’s regulatory oversight could be extended to manufactured articles containing mNMs, such as nano-silver washing machines.

³⁴⁷ <http://www.ermanz.govt.nz/hs/groupstandards/standards/cosmetics/cosmetics.html>

³⁴⁸ ERMA, Cosmetic Products Group Standard 2006, as amended 24th July 2008, 28th July 2009 and 1st November 2010.

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Section 96B(2)(d) of the HSNO Act allows a group standard to be applied to ‘a product (including, but not limited to, a manufactured article ...) that is, contains, incorporates, or includes a hazardous substance.’

Whether or not ERMA is likely to use this statutory provision to extend its remit to manufactured articles containing mNMs will depend on various determinations by the Authority. First, it will require a determination that the included mNM qualifies as a ‘hazardous substance’, a qualifying criterion that raises the same issues of uncertainty of evidence that were discussed above.

Second, before issuing or amending any group standards, ERMA will require to be satisfied that:

- the benefits associated with a reduction of environmental and health risks outweigh the economic costs associated with complying with the group standard; and
- the issuing or amending (as the case may be) of group standards is the most efficient and effective way of managing the risks of all the products in the identified group, having considered matters including alternative methods of managing those risks; and
- the group standard is only applied to the extent that it is reasonably necessary to manage the risks of the products.³⁴⁹

Again, it is not the purpose of this Report to instruct ERMA on how it ought to interpret these determinations. It is noted only that, should ERMA form the opinion that imposing conditions on the manufacture or import of manufactured articles containing mNMs is justified, the amended Section 96 appears to provide a legislative mechanism allowing it to do so.

One possible further reservation relates to the requirement that the product ‘contains, incorporates, or includes a hazardous substance’.³⁵⁰ With regard to nanosilver washing machines, however, their precise function may be seen closer to *creating* the nanoparticles; the machines, as imported or sold, contain not NMs but silver plates that, when electrolysed, gradually release ‘Silver Nano ions or Ag+’.³⁵¹ While it may seem somewhat arbitrary for the law to distinguish between items designed to *produce* potentially hazardous substances, and items which already *contain* such substances, it may be that the wording of the legislation requires just such a regulatory distinction.³⁵²

Ministerial call-in provisions

The HSNO Act provides that the Minister for the Environment may ‘call in’ an application under the Act, to be decided by him/her, if s/he considers that the decision as to the application will have:

- significant cultural, economic, environmental, ethical, health, international, or spiritual effects; or
- significant effects in an area in which the Authority lacks sufficient knowledge or expertise.³⁵³

³⁴⁹ Section 96C(1)(d)

³⁵⁰ Section 96B(2)(d)

³⁵¹ <http://www.samsung.com/au/silvernano/site.html>

³⁵² Our thanks go to Peter Dawson of ERMA for drawing our attention to this potential gap.

³⁵³ Section 68(1)

It has been observed, though, that there is an expectation that the Minister's call-in power 'is a power that would be exceptionally used.'³⁵⁴ Nonetheless, it is at least legally possible that this power could be used with regard to applications concerning NMs, should the Minister deem it appropriate to use it in this way.

Labelling requirements and public register

The Cosmetic Products Group Standard, then, is the first GS to make specific provision for manufactured nanomaterials. While it requires that newly introduced mNMs be notified to ERMA, it does not impose any additional restrictions or regulations thereon. Unsurprisingly, some campaigning organisations have called for significantly tighter regulation of products containing mNMs. In particular, calls have been made for nano-ingredients to be labelled as such.³⁵⁵

The recently recast and consolidated European Union Cosmetic Products Regulation³⁵⁶ has introduced a requirement for labelling of NMs in cosmetics: 'All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets.'³⁵⁷ Additionally, in June 2010, the European Parliament's Committee on the Environment, Public Health and Food Safety proposed an amendment to the Restriction of Hazardous Substances Directive, stating that 'Producers should label electrical and electronic equipment that contains nanomaterials that can lead to exposure of consumers, in order to enable consumers to make an informed choice.'³⁵⁸

It should be noted that the version of the Directive finally accepted on 24 November 2010 contained no such requirement.³⁵⁹ While the principle of nano-specific labelling seems to have been accepted by some industry spokespersons, it may be that this particular recommendation was seen to cast its net too widely:

"Every transistor in a computer chip would then include a hazardous substance," explains Steffi Friedrichs, director general of the international Nanotechnology Industries Association. "Labelling is an understandable consumer demand, but it needs to be practical, and labelling every computer chip would be nonsensical."³⁶⁰

³⁵⁴ *Brookers Resource Management* (2008), Volume II, at C68.03

³⁵⁵ 'Given that the public faces very intimate daily exposure to nano-cosmetics and personal care products it doesn't seem unreasonable to demand rigour in their safety assessment and mandatory labelling to enable informed purchasing choices.' Georgia Miller, 'Science of the small may carry big risk', *The Age*, 28 March 2009. See also Sustainability Council, *The Invisible Revolution*, op. cit.

³⁵⁶ Regulation of the European Parliament and of the Council on cosmetic products (10 November 2009), at <http://register.consilium.europa.eu/pdf/en/09/st03/st03623.en09.pdf>

³⁵⁷ Regulation of the European Parliament and of the Council on cosmetic products (10 November 2009), Article 19(1)(g), <http://register.consilium.europa.eu/pdf/en/09/st03/st03623.en09.pdf>

³⁵⁸ 'MEPs flag potentially hazardous substances in electrical and electronic equipment', 2 June 2010, at <http://www.europarl.europa.eu/en/pressroom/content/20100531IPR75278/>

³⁵⁹ European Parliament legislative resolution of 24 November 2010 on the proposal for a directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast), at

<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P7-TA-2010-0431&format=XML&language=EN#BKMD-6>

³⁶⁰ 'EU Ministers Call For Nanomaterial Ban', 14 June 2010, at <http://www.rsc.org/chemistryworld/News/2010/June/14061001.asp>

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As discussed elsewhere in this Report, the issue of nano-specific labelling has become one of the most contentious in this area. It is beyond the remit of this report to consider in necessary detail the various considerations that should inform a decision as to the desirability of such labelling, or the form any such labels should take. However, it is worthy of note that there have been international moves in this direction with regard to cosmetics and electronic components, and that this is an issue that New Zealand will in all likelihood have to confront in the near future.

In addition, the EU Cosmetic Products Regulation requires the European Commission to produce, by 11 January 2014, a catalogue, regularly updated and publicly available, of 'all nanomaterials used in cosmetic products placed on the market, including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions.'³⁶¹ Although the CPGS requires notification to ERMA of nano-ingredients, this information is not at present made publicly available in the form of a register or catalogue.

As a letter to the editor of *Nature Nanotechnology* earlier this year suggested, 'with the EU now starting to regulate nanomaterials, other jurisdictions might also be encouraged to "ratchet up" their own regulatory frameworks in the short-to-medium term.'³⁶² Given that ERMA's CPGS is closely based on the EU Cosmetics regulations, and is regularly updated to reflect changes in the EU regulation, it may be expected that these recent EU moves with respect to NMs in cosmetics will be considered for incorporation in the HSNO CPGS when next it is updated.

Human and Environmental Safety Assessment

The form of safety assessment which ERMA must conduct in its pre-market assessment is set out in the Hazardous Substances and New Organisms (Methodology) Order 1998. When evaluating assessment of risks associated with the substance or organism in an application, the Authority must take account of the following risk characteristics:

- (a) exposure to the risk is involuntary:
- (b) the risk will persist over time:
- (c) the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence:
- (d) the potential adverse effects are irreversible:
- (e) the risk is not known or understood by the general public and there is little experience or understanding of possible measures for managing the potential adverse effects.³⁶³

A significant challenge to effective regulation of mNMs arises from the current uncertainty as to their likely effects. As the UK's House of Lords Science and Technology said a year ago: 'Our current understanding of how they behave in the human body is not yet advanced enough to predict with any certainty what kind of impact specific nanomaterials may have on

³⁶¹ Regulation (EC) No 1223/2009 (Cosmetics Regulation), Article 17(10)(a)

³⁶² Diana M Bowman, Geert van Calster and Steffi Friedrichs 'Nanomaterials and regulation of cosmetics' *Nature Nanotechnology* Vol. 5 | FEBRUARY 2010

³⁶³ Hazardous Substances and New Organisms (Methodology) Order 1998, Section 33

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human health.’³⁶⁴ An important question, then, relates to how New Zealand’s regulatory systems respond to uncertain risks. The HSNO Act provides for a ‘precautionary approach’, whereby ‘All persons exercising functions, powers, and duties under this Act ... shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.’³⁶⁵ As ERMA note, however, ‘the issue of “how cautious” is left open.’³⁶⁶

The Methodology Order offers some guidance on this:

29 Where the Authority encounters scientific and technical uncertainty relating to the potential adverse effects of a substance or organism, or where there is disputed scientific or technical information, the Authority—

(a) must determine the materiality and significance to the application of the uncertainty or dispute taking into account the extent of agreement on the scope and meaning of the scientific evidence; and

(b) may, where the uncertainty or dispute is material or significant, facilitate discussion between the parties concerned to clarify the uncertainty or dispute.

The Order goes on to stipulate that, where the uncertainty or dispute is not resolved to its satisfaction, ERMA ‘must take into account the need for caution in managing the adverse effects of the substance’³⁶⁷ (though again, this does not answer the question as to ‘how cautious’).

A current case study that may illustrate conflicting attitudes to precaution concerns CNTs. These are among the most controversial current uses of nanotechnology; indeed, as discussed earlier, the European Parliament passed a Resolution calling for them to be banned from electrical and electronic goods (though this did not find its way into EU law).

Precisely how ‘precautionary’ an approach should be adopted towards CNTs is, unsurprisingly, a matter of dispute. According to some of the people to whom we have spoken in researching this report, a sufficient body of evidence currently exists to justify a precautionary ban on use or manufacture of CNTs. ERMA, on the other hand, appear to be less persuaded of the hazardous nature of CNTs, stressing that the studies published to date are of a ‘preliminary/scoping nature’ which ‘must be interpreted with great care as they have tended to use routes which are not of direct relevance to occupational and consumer exposure situations.’³⁶⁸ As yet, ERMA has not formally assessed the hazards or risks of CNTs as no application involving them has been under HSNO.

³⁶⁴ House of Lords Science & Technology Committee, Nanotechnologies and Food report, December 2009. Q.v. ‘In spite of remarkable advances in the use of nanomaterials, there is a paucity of knowledge in understanding the toxicology of nanomaterials and a substantial gap between information obtained in the lab and how that information is applied to regulatory review. ... The production and use of nanoparticles result in unknown risks since the exposures of biological systems to materials of this size have not been adequately studied.’ Stratmeyer, Goering, Hitchins, Umbreit. ‘What we know and don’t know about the bioeffects of nanoparticles’ *Biomed Microdevices* (2010); 12: 569-573 (All four authors are employees of the US FDA)

³⁶⁵ HSNO Act, section 7

³⁶⁶ Annotated Methodology, at 8.3.5

³⁶⁷ Methodology Order, Section 30

³⁶⁸ Shown to us in personal correspondence from the Sustainability Council, 13 October 2010.

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With regard to free CNTs, it appears as though an adequate regulatory framework exists to allow ERMA to impose such safety requirements as it sees fit - though the situation of CNTs intrinsic to manufactured goods may, as noted above, constitute a regulatory gap. Determining whether the regulator is adequately discharging its precautionary remit with regard to free CNTs would seem to depend on an evaluation of contested toxicological evidence, a task which lies beyond the scope of this review. We note, however, that in January 2010, NICNAS (for Safe Work Australia) commenced a formal hazard assessment on carbon nanotubes,³⁶⁹ 'to clarify regulatory requirements.'³⁷⁰ ERMA has intimated that they are paying close attention to this review, and will respond to its findings if appropriate.

Post-Market Monitoring

Enforcement of the HSNO Act is the role of a number of enforcement agencies, 'at both local and central government level.'³⁷¹ The functions of these agencies include promoting and monitoring compliance with (i) the provisions of the Act itself, and (ii) controls set by ERMA. Although ERMA does not itself take a direct role in inspection and enforcement, it does have a supervisory role, which includes:

- ensuring that the provisions of the HSNO Act are enforced in all premises likely to contain a hazardous substance or new organism;
- advising the Minister for the Environment and relevant enforcement agencies if there is insufficient or unnecessary inspection;
- appointing or authorising others to appoint enforcement officers;
- enquiring into incidents and emergencies;
- reporting on incidents caused by inadequate management of hazardous substances and new organisms;
- advising the minister on levels of compliance with the HSNO Act; and
- leading prosecutions in landmark cases (where appropriate).³⁷²

The HSNO Act assigns enforcement roles to a number of agencies, some of which are discussed elsewhere in this report. ERMA has produced a chart showing how supervisory responsibility is allocated as between those agencies.³⁷³

Enforcement agency	Area of responsibility
Ministry of Health	In all places, to protect public health.
Department of Labour	In any place of work.
Maritime New Zealand	On any ship.
Police and Land Transport New Zealand	In and on roads, rail and vehicles.
Civil Aviation Authority	On any aircraft.
Energy Safety Service, Ministry of Economic Development	In, on or around any gas distribution system, installation or appliance.
Local government (regional councils and territorial authorities)	Responsibilities include: <ul style="list-style-type: none"> • premises not covered by the other agencies (e.g. private dwellings, public places)

³⁶⁹ NICNAS Annual report, 2009-10,

³⁷⁰

<http://www.safeworkaustralia.gov.au/AboutSafeWorkAustralia/WhatWeDo/Research/Nanotechnology/Pages/Nanotechnology.aspx>

³⁷¹ DSL Guide, at 8.3.1

³⁷² DSL Guide, at 8.3.1

³⁷³ <http://www.ermanz.govt.nz/resources/publications/pdfs/guide38-39.pdf>

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	<ul style="list-style-type: none"> • enforcement during inspection of land use controls for hazardous substances under the RMA • functions transferred by other enforcement agencies.
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It has been noted that ‘[b]oth overlaps and gaps exist in the areas of responsibility of those enforcement agencies’.³⁷⁴

As previously indicated, we have taken the view that ‘regulatory gaps’ can occur at three distinct levels. With regard to nanosilver washing machines or refrigerators, it appears that any potential gaps appear at the level of the legislation itself or at the level of its interpretation and application by the regulators. The Sustainability Council Report,³⁷⁵ however, identified a potential ‘third level’ (by our classification) regulatory gap with regard to cosmetic products containing mNMs. As discussed in the previous section, the Cosmetic Products Group Standard requires that any cosmetic products intended for use on human skin which contain NMs must be notified to ERMA. Nonetheless, despite the commercial availability of several products that should, in principle, have been notified under this standard, not a single notification had been received by ERMA prior to the publication of the SC’s report (though we understand that several have now been received).

This may well be an example of our third category of regulatory gap: a failure of enforcement or compliance. Rules applying to NMs are of limited utility if they are not adhered to, and even less so if there is no mechanism in place even to monitor whether they are being adhered to. This is to imply no criticism of ERMA, nor of any of the enforcement agencies, all of which operate with finite resources, and upon whom it is incumbent to make decisions about prioritisation. In those circumstances, it may well be that regulators had very good reasons to deploy those resources elsewhere than in pursuing non-notifying cosmetics manufacturers/importers.

Nonetheless, we believe it is important to consider – particularly if new legislation or regulations are being considered – what the prospects may be for monitoring, ensuring and if need be, enforcing compliance with those rules. A significant regulatory gap may be thought to exist if regulations were routinely to be ignored, with no means in place to address this.

3.5 MCA

The main role of the Ministry of Consumer Affairs (MCA) is to promote information flows between suppliers and consumers so that consumers can transact with confidence.³⁷⁶ The MCA has various functions such as investigating unsafe consumer products and developing consumer policy including consumer protection and product safety.

The MCA administers the Fair Trading Act 1986 (FTA) and the Consumer Guarantees Act 1993 (CGA). However, the MCA does not investigate breaches of the CGA.³⁷⁷ The MCA

³⁷⁴ DSL Guide, at 8.3.1

³⁷⁵ Sustainability Council, *The Invisible Revolution*, June 2010

³⁷⁶ MCA <http://www.consumeraffairs.govt.nz/about-mca/what-we-dont-do-and-who-can-help/about-the-ministry> accessed 27 May 2010

³⁷⁷ MCA <http://www.consumeraffairs.govt.nz/about-mca/what-we-dont-do-and-who-can-help/what-we-dont-do-and-who-can-help> accessed 27 May 2010

investigates product safety concerns where there are no product safety standards and the Minister can institute product safety bans, recalls and safety standards. The Commerce Commission investigates breaches of the FTA. The Commerce Commission enforces any breach involving misleading and deceptive conduct, false representations, product safety standards and product bans made under the FTA.

In the context of the role of MCA, 'product safety' means risks to consumers that arise from their design, construction or normal usage. This would include such things as choking hazards for young children in relation to toys, chemicals in the coatings of toys and the design and construction of pedal bicycles. The remit does not cover products not designed for consumer (for example, industrial goods) nor does it generally cover safety issues that arise if goods are misused.³⁷⁸

The MCA liaises and consults with other government agencies that may have an interest in government intervention.³⁷⁹ MCA investigates all product safety issues except those relating to food, medicines, or vehicles.³⁸⁰ NZFSA and Medsafe deal with product safety issues relating to food and medicine respectively. The New Zealand Customs Service can also enforce the safety provisions under the Customs and Excise Act 1996. Hazardous substances and organisms are dealt with by ERMA and hazardous products and products used in the workplace are dealt with by DoL.

New Zealand's consumer protection law is contained primarily in the FTA and CGA. New Zealand's consumer protection law overlaps with other areas of law such as contract and tort. For example, the misleading and deceptive conduct prohibited by the FTA is at the core of the torts of deceit, passing off and negligent misstatement.³⁸¹

3.5.1 FTA

Scope and Triggers

The FTA is designed to prohibit certain conduct and practices in trade, to provide for the disclosure of consumer information relating to the supply of goods and services, and to promote product safety.³⁸² The FTA prohibits misleading and deceptive conduct in trade and specifically prohibits particular types of misleading conduct and the making of false representations.³⁸³ The Act prescribes a broad standard of conduct by prohibiting any person in trade from engaging in conduct that is misleading or deceptive, or is likely to mislead or deceive.³⁸⁴ The FTA makes provision for the regulation and promotion of product safety.³⁸⁵

The FTA applies within New Zealand but also extends to the conduct outside New Zealand of any person who is resident or carrying on business in New Zealand to the extent that such conduct relates to the supply of goods and services within New Zealand.³⁸⁶

³⁷⁸ There is currently a proposal to amend the Fair Trading Act regarding the introduction of power to ban or recall products which could reasonably foreseeably cause injury in *Consumer Law Reform: A Discussion Paper* www.consumeraffairs.govt.nz

³⁷⁹ MCA www.consumeraffairs.govt.nz

³⁸⁰ Id.

³⁸¹ *Laws of New Zealand* (online ed) at [1].

³⁸² FTA, Long Title.

³⁸³ FTA, ss 9-26.

³⁸⁴ FTA, s 9.

³⁸⁵ FTA, Part 3.

³⁸⁶ FTA, s 3.

‘Goods’ means personal property of any kind (whether tangible or intangible) and includes ships, aircraft, vehicles, animals, including fish, minerals, trees, crops, gas, electricity, water and computer software. NMs and products incorporating NMs would be included in the statutory definition of goods. These goods will be ‘goods’ for the purposes of the FTA whether or not they contain NMs.

Trade means any trade, business, industry, profession, occupation, activity of commerce, or undertaking relating to the supply or acquisition of goods or services, or to the disposition or acquisition of any interest in land.³⁸⁷ The FTA provides that no person shall, in trade, engage in conduct that is misleading or deceptive, or is likely to mislead or deceive.³⁸⁸ Misleading conduct is the core of the Act and is particularly relevant to this nanotechnology analysis. For example, if a product states that it contains NMs, but it does not, then there may be a breach of the FTA. Also, if a product claims to contain ‘safe’ NMs, but it has not been tested, that would also be a breach of the FTA. With respect to products containing NMs, these breaches are likely to be more common than investigations into safety. Private transactions are not covered.

The trigger for the FTA will not be whether the goods contain NMs, or whether the undertaking relates to the supply or trade of goods containing NMs, but whether the goods and trade meet the statutory definition. The Act will be triggered if a person in trade engages in conduct that is misleading or deceptive, whether or not that conduct is misleading or deceptive in relation to goods containing NMs.

The FTA will also be triggered by ‘unsafe goods’³⁸⁹ whether or not those unsafe goods contain NMs.

Approval Prior to Regulated Activity

The MCA is not required to grant approval or authorisation prior to the regulated activity.

However, the FTA allows the MCA to recommend the introduction of product safety standards. Product safety standards may be prescribed by the Governor-General by regulation on the recommendation of the Minister of Consumer Affairs in respect of any goods which can or may cause harm to consumers. The key element in any situation is that there must be good evidence that a product presents a significant safety risk. MCA works on a ‘risk assessment’ basis with each issue assessed for the level and extent of risk presented. Some jurisdictions work on a hazard/precautionary basis in respect of consumer product safety. The Governor-General’s prescription is made for the purpose of *preventing* or reducing the risk of injury to any person.³⁹⁰ The product safety standard may cover:³⁹¹

- the nature of the product and its performance;
- *tests* the product should go through *during* or after *manufacture*;³⁹²
- the form and content of any markings, warnings or instructions on the product.

³⁸⁷ FTA, s 2.

³⁸⁸ FTA, s 9.

³⁸⁹ FTA, Part 3, s 31.

³⁹⁰ FTA, s 29(1).

³⁹¹ MCA www.consumeraffairs.govt.nz

³⁹² FTA, s 29(1)(b).

There are currently six mandatory product safety standards. There is currently no nano-specific product safety standard. Failure to comply with the requirements of product safety standards regulations is a breach of the FTA.

Human and Environmental Safety Assessment

The MCA has a lead responsibility for consumer product safety and is not directly responsible for harms to the environment or property. Environmental hazards are covered by other agencies and legislation and there was no intention for the FTA to cover these issues.

The MCA is not required to undertake a case-by-case safety or hazard assessment of goods prior to being placed on the New Zealand market. The onus for supplying safe goods lies squarely with manufacturers, importers, producers and suppliers.

However, as already outlined, product safety standards can cover testing of goods during or after manufacture or processing.³⁹³

Post-market Monitoring

The FTA does not include post-market monitoring requirements akin to the other legislation considered in this report. As well as the reactive work it undertakes, the MCA does carry out a limited amount of proactive work on specific products or issues such as test purchases and sampling. The MCA uses marketplace intelligence including overseas information to target resources.

The Commerce Commission plays an important role in gathering post-market intelligence and conducting the enforcement. Members of the public and businesses are encouraged to contact the Commerce Commission and provide information about behaviour that appears to breach the FTA.³⁹⁴ The Commission assesses information it receives in this way, along with information it gathers from its own market monitoring and surveillance activities, to determine the investigations that it carries out into unfair or misleading trading practices.³⁹⁵ Investigations are commenced according to a set of enforcement criteria.³⁹⁶ If the Commission considers that a breach of the Act may have occurred, it has a number of options open to it for resolving each investigation.³⁹⁷ The options include prosecuting the offending business where this is considered the most appropriate action. Only the courts can give an authoritative ruling as to whether behaviour breaches the Act and award appropriate penalties.

With regard to NMs, there are difficulties testing for NMs. A wide range of NMs are being used, and could be used, in a diverse range of applications. There are no agreed test methods established for NMs. This presents difficulties not only for regulators, but also for producers, who might be supplied products/components for incorporation into their products which may, unbeknown to them, contain NMs.

Section 9 concerns misleading conduct generally. Section 10 concerns misleading conduct in relation to goods. No person may, in trade, engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or

³⁹³ FTA, s 29(1)(b).

³⁹⁴ Commerce Commission <http://www.comcom.govt.nz/enforcement-of-the-fair-trading-act/>

³⁹⁵ Id.

³⁹⁶ Id.

³⁹⁷ Id.

quantity of goods.³⁹⁸ The conduct in question must mislead or deceive, or be likely to mislead or deceive, the class of person who is affected by the conduct. This class of person may be the general public.³⁹⁹ Misleading conduct in relation to goods will be caught by the Act by virtue of meeting the statutory standard of conduct and not as a consequence of the goods incorporating NMs.

False or misleading representations of various kinds are not permitted by any person in trade, in connection with the supply or possible supply of goods or with the promotion by any means of the supply or use of goods.⁴⁰⁰ For example, it must not be falsely or misleadingly represented that:

- goods are of a particular kind, standard, quality, grade, quantity, composition, style, or model, or have had a particular history or particular previous use;⁴⁰¹
- goods are new, reconditioned, or that they were manufactured, produced, processed, or reconditioned at a particular time;⁴⁰²
- goods have any sponsorship, approval, endorsement, performance, characteristics, accessories, uses, or benefits.⁴⁰³

Such false or misleading representations in connection with the supply of goods will be caught by the statutory regime whether or not the goods contain NMs.

Statements on labels and packaging are similarly subject to the prohibition against misleading or deceptive conduct by representations.⁴⁰⁴ Statements made about goods on packaging or labels are a factor in assessing whether goods supplied to a consumer are of acceptable quality.⁴⁰⁵ Products which contain hazardous or toxic substances, medicines and drugs have prescribed requirements as to the details and warnings required on their labels.⁴⁰⁶ Change of composition of a product over time so that it does not correspond with the representations as to composition on the label could result in the labelling being misleading and a breach of the FTA.⁴⁰⁷ These provisions concerning statements on labels and packaging apply whether or not the goods contain NMs.

In relation to product safety, the FTA allows the Minister of Consumer Affairs to:

- recommend the introduction of mandatory product safety standards;⁴⁰⁸
- declare goods to be unsafe (a product ban);⁴⁰⁹
- order a compulsory recall.⁴¹⁰

As outlined above under the heading ‘approval prior to regulated activity’, product safety standards may be prescribed under the FTA.⁴¹¹ If a product safety standard in respect of goods relates to a matter specified in section 29(1), a person must not supply, or offer to supply, or

³⁹⁸ FTA, s 10.

³⁹⁹ *Laws of New Zealand Consumer Protection* (online ed) at [51].

⁴⁰⁰ FTA, s 13.

⁴⁰¹ FTA, s 13(a).

⁴⁰² FTA, s 13(d).

⁴⁰³ FTA, s 13(d).

⁴⁰⁴ FTA 1908, s 9; *Laws of New Zealand Consumer Protection* (online ed) at [53].

⁴⁰⁵ CGA, s 7(1)(h).

⁴⁰⁶ HSNO Act, s 166; The Medicines Act 1981 and Medicines Regulations 1984; Toxic Substances Regulations 1993.

⁴⁰⁷ *Laws of New Zealand Consumer Protection* (online ed) at [53].

⁴⁰⁸ FTA, s 29.

⁴⁰⁹ FTA, s 31.

⁴¹⁰ FTA, s 32.

⁴¹¹ FTA, s 29(1).

advertise to supply those goods unless that person complies with that product safety standard.⁴¹² The performance, composition, contents, manufacture, processing, design, construction, finish, or packaging of the goods may be the subject of product safety standards. Also, the testing of the goods during or after manufacturing or processing, and the form and content of markings, warnings or instructions to accompany goods may be subject to product safety standards.⁴¹³

There are currently no nano-specific product safety standards. The deficiencies in the current knowledge mean that there is inconclusive evidence as to whether there is product safety risk to consumers from products that contain NMs. The Minister is prohibited from recommending any (including a nano-specific) product safety standard regulation unless the Minister has consulted with those affected, given them an opportunity to comment, and the Minister has considered any comments.⁴¹⁴

The Minister of Consumer Affairs may declare goods 'unsafe' if it appears to the Minister that the goods will or may cause injury to any person.⁴¹⁵ The declaration is made by notice published in the *Gazette*, and unless it is previously revoked by notice, the declaration will remain in force for 18 months from publication unless earlier revoked.⁴¹⁶ Where, after the notice has been in force for 18 months, and no product safety standard relating to the goods has been declared, the Minister may, by further notice, prohibit the supply of the goods for a specified period or indefinitely.⁴¹⁷ While a notice is in force, no one may supply, or offer or advertise to supply goods which are the subject of the notice.⁴¹⁸ Goods that will or may cause injury to any person may be declared unsafe, by virtue of being deemed unsafe for the purposes of the Act, and not on the basis of whether or not those goods contain NMs.

Where goods do not comply with a prescribed product safety standard, or are goods of a kind which may cause injury to any person, and the supplier has not recalled them, or taken satisfactory action to recall them, the Minister of Consumer Affairs may require the supplier, at its own expense, to provide one of several types of remedy.⁴¹⁹ These remedies include: recalling the goods; disclosing to the public information on the characteristics of the goods which make them unsafe or the circumstances in which use of the goods is unsafe or any other matters; or repairing or replacing the goods; or refunding an appropriate amount of money to purchasers.⁴²⁰ The Ministerial recall powers under the FTA apply to any goods (whether or not they contain NMs) which do not comply with product safety standards or may cause injury to any person.

It is prohibited to import into New Zealand, goods which do not comply with product safety standards or goods that are unsafe.⁴²¹ Any such goods which are imported are deemed prohibited imports under the Customs and Excise Act 1996 and may be forfeited under that Act.⁴²² The basis for the prohibition on importation of these goods will therefore be on the

⁴¹² FTA, s 30(1).

⁴¹³ FTA, s 29(1)(a) – (c).

⁴¹⁴ FTA, s 29(3)(a) and (b).

⁴¹⁵ FTA, s 31(1).

⁴¹⁶ FTA, s 31(1) and (2).

⁴¹⁷ FTA, s 31(3)(a) and (b).

⁴¹⁸ FTA, s 31(5).

⁴¹⁹ FTA, s 32(1).

⁴²⁰ FTA, s 32(3)(a)-(c).

⁴²¹ FTA, s 33; Customs and Excise Act 1996, s 54.

⁴²² Customs and Excise Act 1996, s 54.

basis of whether the goods do or do not comply with the statutory provisions, and not whether the goods do or do not contain NMs.

3.5.2 CGA

Scope and Triggers

The CGA implies mandatory guarantees as to title, quality, fitness, and performance in the supply in trade of goods and services normally acquired for household, domestic or personal use.⁴²³ Redress for breach of the guarantees is available against suppliers and manufacturers. The CGA amends the law relating to guarantees given, or deemed to be given, to consumers upon the supply of goods and services.⁴²⁴

The guarantees in the Act only apply to goods or services of a kind ordinarily acquired for personal, domestic, or household use or consumption, but not to those goods and services acquired for resupply, consumption in production, or repairing goods or fixtures in trade.⁴²⁵ The CGA only applies where the supplier of goods is in trade.⁴²⁶ 'Trade' includes any trade, business, industry, profession, occupation, activity of commerce, or undertaking relating to the supply or acquisition of goods or services.⁴²⁷ The CGA does not apply to goods supplied by auction or competitive tender.⁴²⁸ Accordingly, such goods are excluded by the Act, whether or not they contain NMs.

The guarantees implied into contracts for the supply of goods and services by the CGA apply only to acquisitions of goods by a person who is a 'consumer'. A 'consumer' is a person who acquires from a supplier, goods of a kind ordinarily acquired for personal, domestic, or household use or consumption.⁴²⁹

'Goods' means personal property of every kind (whether tangible or intangible), other than money and choses in action; and includes personal property of any kind, goods attached to, or incorporated in, any real or personal property; ships, aircraft, vehicles; and animals, including fish and minerals, trees and crops, whether or, under, or attached to land or not, electricity and gas and water and computer software.⁴³⁰ Pursuant to this definition, goods containing NMs will fall within the definition of 'goods' for the purposes of the CGA.

A 'supplier' is a person who, in trade, supplies goods or services to a consumer.⁴³¹ In the case of goods, supply is achieved either by transferring ownership or possession of goods pursuant to a contract of sale, exchange, lease, hire, or hire purchase to which that person is a party, or by transferring ownership or possession of the goods as directed by an insurer.⁴³²

A 'manufacturer' is a person who carries on the business of assembling, producing, or processing goods.⁴³³

⁴²³ CGA, ss 5-13.

⁴²⁴ CGA, Long Title.

⁴²⁵ CGA, s 2(1)(a) and (b).

⁴²⁶ CGA, s 41(1).

⁴²⁷ CGA s 2(1).

⁴²⁸ CGA, s 41(3).

⁴²⁹ CGA, s 2(1)(a).

⁴³⁰ CGA, s 2(1).

⁴³¹ CGA, s 2(1)(a)(i) and (ii).

⁴³² CGA, s 2(1) definitions of supplier and supply.

⁴³³ CGA, s 2(1).

Where goods are supplied to a consumer there is a guarantee that the goods will be of an acceptable quality.⁴³⁴ Goods are of acceptable quality if they are fit for all the purposes for which goods of the type in question are commonly supplied, and are acceptable in appearance and finish, free from minor defects, and safe and durable.⁴³⁵ Relevant to product safety is the guarantee that goods sold are of acceptable quality, including that goods are safe. This acceptable quality (safety) guarantee applies to all ‘goods’ that are supplied to a consumer, whether or not they contain NMs.

Using the CGA provision that a product must be safe, the MCA “adopts the philosophy that voluntary national standards (NZ, Australian and European etc) provide a reasonable minimum benchmark for safety requirements”,⁴³⁶ where there are standards, and where those standards address safety.

Goods supplied to a consumer are guaranteed to be reasonably fit for any particular purpose for which a consumer makes known to a supplier, expressly or by implication, as the purpose for which goods are being acquired, or for any purpose that the supplier represents that the goods will be fit for.⁴³⁷ This guarantee of fitness for a particular purpose applies whether or not the goods supplied to a consumer contain NMs.

The CGA provides remedies when these guarantees are not met. However, they are self-enforcing, meaning the consumer has to take action him/herself, such as returning the good to the retailer.

Approval Prior to Regulated Activity

The MCA is not required to grant approval or authorisation prior to the regulated activity. Given the nature of the legislation, approval prior to the regulated activity would be undesirable.

Human and Environmental Safety Assessment

The MCA is not required to undertake a case-by-case safety or hazard assessment of goods on the New Zealand market.

Post-market Monitoring

The MCA does not investigate breaches of the CGA. Consumers have rights of redress against suppliers and manufacturers in respect of the supply of goods,⁴³⁸ for example, where goods do not comply with guarantees.⁴³⁹

⁴³⁴ CGA, s 6.

⁴³⁵ CGA, s 7(1)(a)-(e).

⁴³⁶ MCA www.consumeraffairs.govt.nz

⁴³⁷ CGA, s 8(1)(a) and (b).

⁴³⁸ CGA, Part 2 and Part 3.

⁴³⁹ CGA, s 18.

The MCA can, and does, undertake monitoring mainly on a project type basis or in response to information received that indicates a potential consumer product safety issue might exist. If the an issue arose whereby there was prima facie evidence on a NM related product safety concern, then MCA could, if appropriate, instigate action in relation to the Minister's powers under FTA.

3.6 NZCS

Scope and Triggers

The New Zealand Customs Service (NZCS)⁴⁴⁰ is the government agency that facilitates the legitimate movement of goods and people across the border. The NZCS has various functions such as enforcing import and export prohibitions and restrictions.⁴⁴¹ The NZCS works closely with other agencies such as the New Zealand Food Safety Authority, Ministry of Economic Development and the ERMA.

The primary statute which regulates the movement of goods, craft and people crossing New Zealand border is the Customs and Excise Act 1996 (CEA). This Act is administered by the NZCS. The CEA seeks to create a modern customs regime by concentrating on essential matters, leaving administrative detail to regulations.⁴⁴²

The NZCS also enforces import and export prohibitions and restrictions under other statutes such as the HSNO Act and the FTA.⁴⁴³ Customs officers have powers to seize the goods under the CEA if they have reasonable cause to believe that a hazardous substance is being, or has been, imported in breach of the HSNO Act.⁴⁴⁴ Sections 26 and 33 of the FTA deem certain goods (such as goods bearing false trade descriptions) to be prohibited imports for the purposes of section 54 of the CEA. All of the provisions of the CEA apply to these goods.

New Zealand's CEA and other relevant legislation are designed to protect national borders by controlling the import and export of goods. Within this function, New Zealand's legislation prohibits the importation of certain harmful goods and substances, including weapons, explosives and narcotics, unless the importer has approval to import from the relevant authority. Products containing NMs (such as cosmetics) are being imported and exported across New Zealand's borders. The number of engineered nanoparticles and goods containing NMs entering New Zealand is likely to increase.

All goods imported into New Zealand are required by the CEA to be cleared through the NZCS. 'Goods' means all kinds of moveable personal property, including animals.⁴⁴⁵ Goods containing NMs will fall within this definition. For example, goods such as hair straighteners

⁴⁴⁰ Under s 5(1) of the Customs and Excise Act 1996, the previous Customs Department is reconstituted as the NZCS.

⁴⁴¹ New Zealand Customs Service <http://www.customs.govt.nz/about/What+We+Do.htm>

⁴⁴² *Laws of New Zealand* Customs and Excise (online ed) para 4. Relevant regulations include the Customs and Excise Regulations 1996 (SR 1996/232) and Customs and Excise (Fees) Regulations 2004 (SR 2004/367).

⁴⁴³ See *Laws of New Zealand* Customs and Excise para 5 for a list of other statutes under which NZCS operates. This report only identifies a number of statutes which are of relevance to the importation of goods containing NMs.

⁴⁴⁴ HSNO Act, s 122. See also *Laws of New Zealand* Customs and Excise para 5.

⁴⁴⁵ CEA, s 2.

containing nano silver, tennis rackets, or cosmetic products incorporating NMs will be caught by the statutory definition. These goods will be included in the CEA's definition by virtue of being goods imported into New Zealand, and not as a result of incorporating NMs. The good itself, not the fact that the good contains NMs, is the trigger.

Approval Prior to Regulated Activity

The NZCS's role in managing the border includes the responsibility of enforcing or assisting in the enforcement of the wide range of import prohibitions.⁴⁴⁶ The prohibitions are enforced on behalf of a number of government departments and agencies that administer, or have the policy responsibility for, the controls.

There are three ways in which prohibitions can be implemented:

1. Section 54 and/or the First Schedule of the CEA

Section 54(1) of the CEA may place a prohibition on the import of a certain good. At present, it places an absolute prohibition (that is, approval to import cannot be given) on the import of:

- All publications as defined in section 2 of the Films, Videos and Publications Classification Act 1993 that are objectionable within the meaning of that Act in the hands of all persons for all purposes.
- The following goods listed in the First Schedule of the CEA:
 - False or counterfeit money;
 - Goods made by prison labour;
 - Goods whose sale in New Zealand would be an offence under the Food Act 1981 or the Food (Safety) Regulations 2002; and
 - Cannabis and methamphetamine utensils.

Under section 54(1), a prohibition on the import of a certain good may be made, whether or not the good contains NMs.

2. Orders in Council under section 54(2) of the CEA

Section 54(2) of the CEA provides that the Governor-General may, by Order in Council, prohibit the importation of any specified goods, or goods of a specified class or classes, if it is necessary in the public interest to do so.

The import prohibition may:

- Be absolute (that is, approval to import cannot be given);
- Be conditional in that it may apply only under particular circumstances (production of a certificate); or
- Allow the import only with the approval of the Chief Executive of the NZCS or other person named in the Order.

The Orders in Council may only be in effect for up to three years. At the end of this period the Governor-General may extend them for another three years. Orders in Council under the CEA are in effect for the following import prohibitions:

Orders in Council	Goods	Expires on
Customs Import Prohibition (Trout) Order	Trout and trout products	11 November 2010

⁴⁴⁶ Our sincere thanks to David Ryan, Mike Wotherspoon and Kirsty Marshall (NZCS) for their extensive assistance with this section of the review.

2007		
Customs Import Prohibition Order 2008	Offensive weapons; Motor vehicles with incorrect odometer readings or no odometer	30 Sep 2011
Customs Import (Toothfish) Prohibition Order 2009	Toothfish	10 May 2012

There are currently no Orders in Council under the CEA for specific goods containing NMs. An Order in Council prohibiting the import of goods may be made if it is necessary in the public interest to do so, whether or not the goods contain NMs.

3. Import prohibitions in other legislation

Import prohibitions are also contained in other legislation, for example:

- *Import and Exports (Restrictions) Act 1988* for hazardous wastes tyres and certain dangerous chemicals - administered by the Ministry of Economic Development;
- *United Nations Act 1949* for United Nations import sanctions - administered by the Ministry of Foreign Affairs and Trade;
- *Trade in Endangered Species Act 1989* for controls on the import of endangered species, for example ivory, coral and New Zealand parrots (kakapo, kaka and kea) - administered by the Department of Conservation;
- *Dog Control Act 1996* for controls on the importation of dangerous dogs - administered by the Department of Internal Affairs.

Prohibitions and restrictions on the importation of many goods are mandated by statutes and regulations other than the CEA. The specific statutes place prohibitions and restrictions on the importation of certain goods.⁴⁴⁷ Many goods are controlled in this way and may only be imported with the consent of the relevant authority.⁴⁴⁸ For example, import prohibitions and restrictions are enforced at the border for goods such as the following:

- bulk importations of ozone depleting substances;⁴⁴⁹
- chemical weapons;⁴⁵⁰
- firearms;⁴⁵¹
- food whose sale in New Zealand would be an offence against the Food Act 1981;⁴⁵²
- goods bearing a label which contains false or misleading representation;⁴⁵³
- hazardous wastes;⁴⁵⁴

⁴⁴⁷ New Zealand Customs Service Import Prohibitions and Restrictions Schedule
<http://www.customs.govt.nz/library/Fact+Sheets/Fact+Sheet+5++Import+Prohibitions+and+Restrictions.htm?pageType=print>

⁴⁴⁸ Laws of New Zealand (online ed) at para 85.

⁴⁴⁹ Ozone Layer Protection Act 1996; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 1.

⁴⁵⁰ Chemical Weapons (Prohibition) Act 1996; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 2.

⁴⁵¹ Arms Act 1983; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 3.

⁴⁵² CEA, s 54 and First Schedule; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 3.

⁴⁵³ FTA; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 3.

⁴⁵⁴ Hazardous waste may be imported if the Minister of Commerce has consented to the importation. Imports and Exports (Restrictions) Prohibition Order (No. 2) 2004; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 4.

- prescription medicines;⁴⁵⁵
- hazardous substances including explosives and certain toxic substances.⁴⁵⁶

The importation of hazardous substances such as explosives and toxic substances will only be allowed with an approval issued under the HSNO Act.⁴⁵⁷ Approval for the importation will be based on the importer fulfilling the obligations for importation of the goods as required by the HSNO Act, and not whether the goods incorporate NMs.

Goods that do not comply with a relevant product safety standard or have been declared unsafe by the Minister of Consumer Affairs may not be imported.⁴⁵⁸

Various goods containing NMs such as medicines and hazardous substances may fall within these statutes outside the customs regime. However, the importation of such goods will be prohibited or restricted not on the basis of whether the goods contain NMs, but because the goods are caught by the relevant statute.

Human and Environmental Safety Assessment

The NZCS does not conduct case-by-case safety or hazard assessment of goods that are imported into New Zealand. However, import prohibitions can take human and environmental safety into account.

Post-Market Monitoring

The CEA does not grant the NZCS the power to undertake post-importation monitoring or safety testing in relation to imported goods in order to ensure the long term human and/or environmental safety of imported goods. The NZCS cannot monitor or test goods containing NMs after they have been imported.

3.7 NZFSA & FSANZ

It is perhaps not surprising that, at the time of writing, 'FSANZ has (still) not yet received a single application to amend the Code in relation to novel nanotechnologies.'⁴⁵⁹ Though it is difficult to be certain, it appears that, for the moment, applications of novel nanotechnology to food are fairly minimal. However, the UK House of Lords Science and Technology Committee Report has recently predicted that 'this may well change over the next five years or so as the technology develops'.⁴⁶⁰ The Select Committee identified a number of potential future applications of nanotechnology to food.

⁴⁵⁵ Medicines Act 1981; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 5.

⁴⁵⁶ HSNO Act; New Zealand Customs Service Import Prohibitions and Restrictions Schedule, at 4.

⁴⁵⁷ HSNO Act, ss25-73.

⁴⁵⁸ FTA, ss 33 and 29-31.

⁴⁵⁹ Personal correspondence with FSANZ, 11 August 2010.

⁴⁶⁰ UK House of Lords Science and Technology Committee Report, *Nanotechnologies and Food* (January 2010). See also Chaudhry, Q., et al. 'Applications and implications of nanotechnologies for the food sector.' *Food Additives and Contaminants* (2008); 25(3): 241-258 'The applications of A Review of the Adequacy of New Zealand's Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials' 81

- i. Food content: whereby NMs are incorporated directly into food; the Committee acknowledged that '[n]anotechnologies create the possibility of foods with new flavours and textures, and also healthier food products with reduced salt, fat or sugar content or increased vitamin and nutrient content'⁴⁶¹
- ii. Packaging: the Committee predicted that '[f]ood packaging involving the use of nanomaterials seems to be the most likely application to appear first in the mass market'. The Committee noted that a 'plastic beer bottle made using clay nanoparticles as a gas barrier to improve shelf-life is currently on the market in the EU ... and the US'.⁴⁶² Evidence to the Committee also pointed out the possibility of nano-scale sensors incorporated in food packaging to detect deterioration in food quality, resulting in more accurate sell-by dates for perishable foods which would, in turn, improve food safety and reduce wastage'.⁴⁶³
- iii. Preparation: 'Nano-coatings for food preparation surfaces and machinery are also predicted in the next five years'. Examples included 'chopping boards and food containers infused with nanosilver because of its anti-microbial properties'.⁴⁶⁴

FSANZ has also referred to the possibility that 'nanotechnology could be used to produce cheap and highly effective filters to eliminate contaminants and bacteria from water for drinking'.⁴⁶⁵ The Monash Report also noted that substances such as processing aids or agricultural and veterinary chemicals, which may incorporate nanoparticles, may also be added to or left in food.

It is widely recognised that the applications of nanotechnology to food and food preparation, packaging and storage promises a range of benefits to human health and to the environment. Most obviously, food that can maintain its flavour while having reduced salt, sugar and fat content promises a range of health benefits with regard to, inter alia, obesity, diabetes and hypertension. However, it has also been suggested that environmental benefits could also accrue through more effective packaging, by reducing:

- food waste through spoilage;
- energy expended in keeping food refrigerated;
- packaging waste, thanks to thinner and lighter packaging materials.

However, as the Committee recognised, '[n]anotechnologies may also present new risks, as a result of their novel properties. ... Persistent nanomaterials are of particular concern, since they do not break down in the stomach and may have the potential to leave the gut, travel throughout the body, and accumulate in cells with long-term effects that cannot yet be determined'.⁴⁶⁶

Concern has also been expressed as to the overall impact of the application of nanotechnology to food:

nanotechnology in the food sector are only now emergent, but they are predicted to grow rapidly in the coming years.'

⁴⁶¹ Ibid, at para 3.8

⁴⁶² Ibid, at para 3.16

⁴⁶³ Ibid, Q 158.

⁴⁶⁴ Id.

⁴⁶⁵ FSANZ, 'Small Particles, Nanotechnology and Food' (2008)

⁴⁶⁶ House of Lords Science and Technology Committee, *Nanotechnologies and Food*, op. cit.,

Summary

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‘I think we need to ask: will nanotechnology as a whole result, for example, in greater consumption of highly processed food and less consumption of fruit and vegetables? Will the addition of nano-additives to junk foods enable them to be marketed for health values, for example increased nano-encapsulated omega-3 or iron fortification? Will this perhaps further confuse people and lead to a further loss in terms of people's diet choices? If the answers to those things are “Yes” then it is possible that nano will actually result in poorer health outcomes.’⁴⁶⁷

It should, perhaps, be acknowledged that the presence of nano-sized particles in food is not, in any sense, new. It has been acknowledged that ‘Some traditional food manufacturing processes result in the creation of nano-sized particles—for example, production of ricotta cheese involves allowing whey proteins to aggregate into protein nanoparticles and production of chocolate and ice cream using natural ingredients involves changes to food structures at the nanoscale.’ This led the Select Committee to recommend that ‘for regulatory purposes, any definition of “nanomaterials” should exclude those created from natural food substances, except for nanomaterials that have been deliberately chosen or engineered to take advantage of their nanoscale properties.’⁴⁶⁸

Scope and Triggers

The examples considered should make it clear, then, that for a regulatory scheme in New Zealand to be adequate, it should apply to mNMs that are incorporated directly into processed food (as in example i. above), but also to those that are contained in food packaging or processes, from where they may migrate into food.

The FSANZ Act defines ‘food’ as:

- (a) any substance or thing of a kind used, capable of being used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared); and
- (b) any substance or thing of a kind used, capable of being used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a); and
- (c) any substance used in preparing a substance or thing referred to in paragraph (a); and
- (d) chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum; and
- (e) any substance or thing declared to be a food under a declaration in force under section 3B.⁴⁶⁹

The section makes clear that it does not matter whether the substance, thing or chewing gum is in a condition fit for human consumption. As the Monash Report explained, this definition of food also makes it clear that the FSANZ regulatory framework applies to food and food-related products incorporating NMs in the same way as it applies to ‘conventional’ food. There are no Standards in the Code that specifically regulate mNMs.

In addition to ‘food’, the Code also imposes standards for food additives, defined as ‘any substance not normally consumed as a food in itself and not normally used as an ingredient of food, but which is intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5.’⁴⁷⁰ Only additives expressly permitted under this section of

⁴⁶⁷ Georgia Miller, Friends of the Earth Australia, Oral evidence to HL Select Committee, Q286

⁴⁶⁸ *Nanotechnologies and Food*, at para 5.32

⁴⁶⁹ FSANZ Act, Section 3A(1)

⁴⁷⁰ FS Code, Standard 1.3.1

the Code may be added to food, and the use of these additives will be restricted to the purposes specified in the Code, e.g. as colourings, preservatives, or flavourings.⁴⁷¹

Some of the additives listed in Standard 1.3.1 are permitted subject to quantitative restrictions; specifically, some colourings are permitted subject to maximum levels of 290 mg/kg in foods and 70 mg/L in beverages. The Monash Report identified this as a potential regulatory gap, noting that this ‘may not be an appropriate trigger if that additive is added in a nano-form and therefore less material is included.’⁴⁷²

mNMs that may find their way into foodstuffs via packaging will be covered by Standard 1.4.3, while other contaminants that find their way into foodstuffs may be regulated by Standard 1.4.1.⁴⁷³ As with Standard 1.3.1, both contain Maximum Limits (MLs), ‘set at levels that are consistent with public health and safety’.⁴⁷⁴ Again, this was flagged by the Monash Report as a potential gap: ‘the trigger levels may need to be reviewed if nanoforms of the specifically referenced contaminants begin being used and the nanoform of the contaminant means the weight threshold is inappropriate.’⁴⁷⁵

FSANZ has responded to these concerns about the inappropriateness of quantitative triggers in the following terms:

‘FSANZ has the capacity to establish relevant restrictions in the Code should it become aware of a risk posed by a nanoscale material of an existing substance approved under existing Standards, and also for proposed new or novel nanoscale materials that may represent additional safety concerns. All relevant information will be rigorously assessed by FSANZ using the best available science. The risk assessment process will necessarily consider the most appropriate dose-metric for the material being assessed, and this could conceivably result in different maximum levels depending on product form.’⁴⁷⁶

With regard to *new* nanoscale additives, the most recent edition of FSANZ Application Handbook – while not referring specifically to NMs – does make it clear that ‘where particle size is important to achieving the technological function or may relate to a difference in toxicity, the applicant must provide information on particle size, size distribution, and morphology, as well as any size-dependent properties’⁴⁷⁷ (a requirement that applies also to processing aids, nutritive substances and novel foods). Some of the potential difficulties with classifying food additives as ‘new’ will be considered in the next section, but at least where

⁴⁷¹ ‘A food additive may only be added to food where expressly permitted in this standard.’ (Std. 1.3.1)

⁴⁷² Monash Report, at p.72. See also chart at p.98.

⁴⁷³ As has been drawn to our attention by one of the regulators, any nano-scale contaminants would have been unlikely to have been *intentionally* produced, and are thus arguably *ultra vires* of our report. However, we submit that a discussion of food standards and mNMs would seem incomplete without at least some reference to how potential nano-contaminants could be covered.

⁴⁷⁴ Standard 1.4.1, Purpose. Standard 1.4.3 uses the same maximum levels as are in Std 1.4.1.

⁴⁷⁵ Monash Report, at p.72; see also chart at p.98. We note that at least one regulator objected to this being designated as even a potential ‘gap’, but rather, as an example of the sort of periodic revision to which the Code is already subject. We would suggest that it does not require a great semantic leap in order to categorise a rule that is likely to require revision as a ‘potential gap’. However, we do not wish this report to become overly focused on disagreements about terminology; the main point we would emphasise is that the potential need for revision is paid due attention, regardless of precisely how this need is designated.

⁴⁷⁶ Personal correspondence with FSANZ, 11 August 2010

⁴⁷⁷ FSANZ Application Handbook (1 July 2020), at p.55.

additives are acknowledged to require an amendment to the Code, the insistence on providing information on particle size is welcome.

With regard to new information about risks posed by *existing* additives, it would appear that any such additional restrictions as are required could be implemented by the regulator, rather than necessitating change at the legislative level.

Regulating uncertainty

New food additives, then, will not be permitted without prior regulatory approval, in the form of an amendment to the FS Code (Std. 1.3.1). New packaging materials, on the other hand, need only comply with Standard 1.4.3, which specifies that:

‘Articles and materials may be placed in contact with food, provided such articles or materials, if taken into the mouth, are not -

- (a) capable of being swallowed or of obstructing any alimentary or respiratory passage; and
- (b) otherwise likely to cause bodily harm, distress or discomfort.’

The Monash Report expressed concern about this regulatory trigger, in that ‘[d]eficiencies in current knowledge regarding the effects of NMs means this provision is unlikely to prevent the use of NMs at this time because it could not be shown to be “likely” to harm.’ FSANZ’s view on this point is that ‘the current risk assessment framework and toxicological testing methodologies are generally sufficient for assessing new or novel nanoscale materials.’ However, it ‘accepts that modifications to current protocols may be warranted as the state of the science, and sophistication of the nanotechnologies, advance.’⁴⁷⁸

It seems to us that the interpretation of the adjective ‘likely’ is key to the applicability of this regulatory mechanism; indeed, determining applicable standards of proof is essential to the operation of many of the regulatory mechanisms considered in this report.

Rules specific to New Zealand

As we have explained, most food sold in New Zealand is regulated under the Australia New Zealand Food Standards Code. An exception relates to ‘supplemented foods’. Previously covered by the Dietary Supplement Regulations 1985, these are (as of 31 March 2010) now regulated under the Supplemented Food Standard, which is administered by the New Zealand Food Safety Authority (NZFSA). The Supplemented Food Standard (SFS) is seen as an intermediary measure by NZFSA, which will govern such products until agreement can be reached as to their inclusion in the FS Code.

The SFS defines ‘supplemented food’ as ‘a product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement’.⁴⁷⁹ Examples include ‘muesli bars, juices, sports foods and sports powders with levels of added vitamins, minerals, and other substances higher than those permitted by, or not permitted by, the Food Standards Code’.⁴⁸⁰ Dietary supplements, medicines, controlled drugs, formulated meal replacements and formulated caffeinated beverages are not covered by the SFS, but by other

⁴⁷⁸ Personal correspondence with FSANZ, 11 August 2010

⁴⁷⁹ Supplemented Food Standard, Clause 6(1)

⁴⁸⁰ NZFSA. *New Zealand Supplemented Food Standard: New Zealand user guide on implementing the requirements*. (30 March 2010), at p

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regulations and pieces of legislation. If a food fits the definition of ‘supplemented food’ but also meets the permissions in the Food Standards Code, then it will be governed by the Code and not the SFS.⁴⁸¹

The SFS requires supplemented foods to comply with the majority of the standards in the FSC.⁴⁸² For example, the food additives permitted in Standard 1.3.1 can all be used in supplemented foods, subject to any restrictions on their use imposed by Std 1.3.1.⁴⁸³ A number of exceptions from the FS Code do, however, apply; for example, ‘vitamins or minerals may be added at higher levels than in the Food Standards Code, or to foods to which they are not permitted to be added’.⁴⁸⁴ Unless specifically prohibited or restricted in the SFS, any vitamin, mineral, botanical or bioactive substance may be added to a supplemented food provided it is ‘safe and suitable for the purpose that it is being added.’⁴⁸⁵

In New Zealand, food substances are also required to comply with the Food Act 1981. Section 9(4) of the 1981 Act specifies that:

No person shall prepare or pack for sale, or sell,—

- (a) Any food that is unsound or unfit for human consumption or contaminated; or
- (b) Any food containing, or having attached to it or enclosed with it or in contact with it, any extraneous thing—
 - (i) That is injurious to health or harmful; or
 - (ii) That is offensive; or
 - (iii) The presence of which would be unexpected and unreasonable in food of that description prepared or packed for sale in accordance with good trade practice; or
- (c) Any food in any package, or any package intended to contain food, if that package is made wholly or partly of a material that may render the food injurious to health or that may taint the food; or
- (d) Any appliance that may render the food injurious to health or that may taint the food.

As with the Food Standards Code discussed above, doubts may be expressed about the likely efficacy of this section with regard to nano-risks. For example, Section 9(4)(b) of the Food Act does not qualify the phrase ‘injurious to health or harmful’, so it is unclear whether it would apply only where an extraneous material enclosed with or in contact with food is *known* to possess such qualities, or whether the offence could be committed by the presence of such extraneous materials that are *likely* to be harmful – and if so, how ‘likely’ would be

⁴⁸¹ NZFSA. *SFS User Guide*, at p.6

⁴⁸² *Ibid*, at p.9.

⁴⁸³ *Ibid*, at p.15.

⁴⁸⁴ *Ibid*, at p.12.

⁴⁸⁵ *Ibid*, at p.12.

interpreted. While this ambiguity is not in any way unique to mNMs, the current uncertainty about risks posed by mNMs may render further clarity in this area desirable.

Approval Prior to Regulated Activity

New food additives, then, will not be permitted without prior regulatory approval, in the form of an amendment to the FS Code (Std. 1.3.1). New packaging materials, on the other hand, do not need pre-market approval, but must comply with Standard 1.4.3. Food itself will require a pre-market safety assessment if it is classified as ‘novel’ (Standard 1.5.1).

The determination of whether a food qualifies as ‘novel’ is made by FSANZ. Following a review of the Novel Food Standard in 2007, FSANZ’s decisions will be informed by the Advisory Committee on Novel Foods (the ACNF), which will provide recommendations in response to enquiries about whether particular foods meet the definitions of ‘non-traditional food’ and whether or not an assessment of public health and safety is required.⁴⁸⁶ It is not mandatory for potential applicants to seek the view of the ACNF; instead, they may proceed directly to submitting an application seeking to amend Standard 1.5.1 of the Code to permit a particular food that they believe meets the definition of novel food in Standard 1.5.1.⁴⁸⁷

Under the revised Standard, a two-stage assessment must be undertaken, according to which it is decided whether a food is (a) a non-traditional food, and (b) whether a public health and safety assessment is required. A ‘non-traditional food’ is defined as:

- (a) a food that does not have a history of human consumption in Australia or New Zealand; or
- (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
- (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

Key areas influencing the interpretation of the term ‘history of human consumption’ are: length of use; extent of use; quantity (level of intake) of use; and purpose or context of use.⁴⁸⁸

If a food is deemed to be ‘non-traditional’, it will only be classified as a ‘novel food’ if it ‘requires an assessment of the public health and safety considerations having regard to -

- (a) the potential for adverse effects in humans; or
- (b) the composition or structure of the food; or
- (c) the process by which the food has been prepared; or
- (d) the source from which it is derived; or
- (e) patterns and levels of consumption of the food; or
- (f) any other relevant matters.⁴⁸⁹

FSANZ has made it clear that the order of these considerations corresponds to their perceived importance; therefore, the potential for adverse effects in humans is the primary consideration in any recommendation from the ACNF. Information relevant to a determination of the potential for adverse effects might include:

⁴⁸⁶ <http://www.foodstandards.gov.au/consumerinformation/novelfoods/advisorycommitteeonn3927.cfm>

⁴⁸⁷ FSANZ, ‘Guidance Tool for Determining Whether a Food is Novel or Not’

⁴⁸⁸ Id.

⁴⁸⁹ Standard 1.5.1(1). N.B. this definition therefore differs from that discussed in the Monash Report.

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- reports of adverse reactions from food use in other countries;
- demonstration of safe use in other countries;
- reports of adverse reactions from medicinal use;
- animal toxicity studies;
- observations in humans participating in clinical trials;
- or the presence of a particular component known to cause adverse reaction or illness.⁴⁹⁰

With regard to composition and structure – which the Monash Report identified as a factor that could lead to food incorporating NMs being treated as ‘novel’ - relevant information could include:

- the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen);
- analyses of the amount of any such substances known to cause adverse reaction or illness;
- structural similarity of any of the components to substances for which there are known safety concerns;
- special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.⁴⁹¹

It appears, then, that FSANZ has made considerable efforts to render this area more transparent. FSANZ has, however, acknowledged that ‘some degree of subjectivity is unavoidable due to the broad nature of novel foods’,⁴⁹² and it may be that the question of whether such an application will be required for food may inevitably remain an area of some ‘fuzziness’ for producers or sellers. A similar concern has been expressed about the European novel foods framework:

‘If a company responsible for placing a nanofood product on the market did not recognise it to be novel (e.g. because the ingredients already have a history of use at the macro-scale) and/or did not consider the properties of the nanofood to be substantially different from its macro-scale counterpart (e.g. because of a lack of information to the contrary or the lack of a precise definition of the term “substantially altered”), then it is possible that a safety evaluation under (EC) 258/97 will not be carried out.’⁴⁹³

Sue Davies, of the consumer organization Which?, expressed similar concerns to the House of Lords Select Committee: ‘we are concerned, about how you can be sure that people who are potentially looking at producing these types of products actually understand what applies to them and what route they need to go through’⁴⁹⁴

⁴⁹⁰ FSANZ, ‘Guidance Tool for Determining Whether a Food is Novel or Not’

⁴⁹¹ Id.

⁴⁹² FSANZ, Final Assessment Report, Proposal P291, Review of Novel Food Standard, October 2007

⁴⁹³ Chaudhry, Q; Scotter, M; Blackburn, J; Ross, B; Alistair, A; Castle, L; Aitken, R; Watkins, R. ‘Applications and implications of nanotechnologies for the food sector’ *Food Additives & Contaminants: Part A*, (2008) 25(3): 241 - 258

⁴⁹⁴ Sue Davies, Oral evidence to House of Lords Select Committee, Q291

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The option of seeking a recommendation from the ACNF on whether a food should be regarded as ‘novel’ may be a considerable step towards clarifying manufacturers’ responsibilities in this regard. Nonetheless, it is worthy of note that the novel foods regulatory process will only be triggered when a manufacturer recognizes the need to apply to FSANZ. Although FSANZ has confirmed that the presence of ‘any nano-sized particle’ must be included in an application,⁴⁹⁵ whether an application will even be made will depend on the manufacturer recognising that the food is prospectively novel.

Any residual uncertainty as to whether manufactured nano-forms of existing foods, or indeed new processing techniques that actually or potentially produce nanomaterials, should be regarded as ‘novel’ should therefore be clarified. FSANZ’s most recent factsheet on the subject⁴⁹⁶ clearly spells out that:

Applications for food additives, processing aids, novel foods and nutritive substances must include particle size, size distribution and morphology, where the substance(s) is particulate in nature and will remain so in the final food.

The question of when a nanoform of an existing food will be regarded as ‘novel’, however – and hence, whether such an application will be required – is not made entirely clear to prospective manufacturers or importers. Furthermore, the Authority’s reference to ‘an application for *a new type of* engineered nanometre scale particle in food’ (our emphasis) may be taken to imply that the particle’s nanometre size alone would not be sufficient to lead to a finding of novelty, an impression confirmed to us by FSANZ.

If manufacturers are unclear about the necessity to apply to FSANZ, then the relevant regulatory mechanisms – however thorough – will not be triggered, and a regulatory gap may be identified. To avoid this possibility, FSANZ could stipulate more precisely in what circumstances nanoscale food ingredients should be regarded as prospectively ‘novel’ (for example, when the nanoform has no history of presence in the human food chain), or alternatively, that all manufacturers of such foods should contact the ACNF for an opinion on the status of such foods. A third option would involve a change to the Code analogous with that recently implemented in the European Union with regard to food additives, whereby:

When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.⁴⁹⁷

It should be noted that even this may not be regarded as satisfactory. The European Parliament recently called for further clarification as to when food should be regarded as novel; in particular, ‘novel food’ should ‘include foods derived from *plants and* animals, produced by non-traditional breeding techniques, and foods *modified* by new production

⁴⁹⁵ <http://www.foodstandards.gov.au/consumerinformation/newfoodsandtechnolog4358.cfm>

⁴⁹⁶ FSANZ, *Nanotechnology and Food*, December 2010, at

<http://www.foodstandards.gov.au/consumerinformation/nanotechnologyandfoo4542.cfm>

⁴⁹⁷ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, Article 12

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processes, *such as nanotechnology and nanoscience*, which might have an impact on food.⁴⁹⁸

As noted above, recent amendments to the FSANZ Application Handbook have stressed the importance of providing information about, e.g., particle size when applying to amend the Code.⁴⁹⁹ The possible concern here, though, is about the perception among manufacturers, etc, as to whether such an amendment to the Code is required.

⁴⁹⁸<http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2010-0152&language=EN&mode=XML> Original emphasis.

⁴⁹⁹ FSANZ Application Handbook (1 July 2020), at p.55.

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Labelling requirements

Standard 1.2 sets out manufacturers' obligations with regard to labelling of food. Standard 1.2.2 requires that the label on a package of food must include either the prescribed name of the food, where listed in the Code, or in any other case, a name or a description of the food sufficient to indicate the true nature of the food. Standard 1.2.4 requires that, subject to some exceptions of minor relevance for present purposes, the label on a package of food must include a statement of ingredients, listing every ingredient in the food. Ingredients generally should be declared using their common name or a name that describes their true nature, while additives should be declared by the specific name or number provided in the Schedule to Standard 1.2.4.

The Monash Report pointed to 'uncertainty as to whether the name (for example, titanium oxide as listed in the Schedule) would include that additive in a nano form,' identifying this as 'a possible gap here if this regulation is relied on as a means to alert consumers to the presence of NMs for the purposes of protecting their health and safety'.⁵⁰⁰

The mandatory labelling of 'nanofoods' has been called for by, among others, Friends of the Earth, whose 2008 report claimed that 'Mandatory labelling of all nanofoods is required to enable people to make an informed choice about whether or not to eat them.'⁵⁰¹ Furthermore, it is currently the subject of ongoing debate in the European Union. The European Parliament, Commission and Council of Ministers are, at the time of writing, engaged in conciliation talks about amendments to EU novel food regulations.⁵⁰² The European Parliament has voted for nano-specific labelling,⁵⁰³ and in March 2010, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) approved a series of recommendations pertaining to regulation of novel foods, which included the following:

'All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word 'nano' in brackets.'⁵⁰⁴

The EU Council, in contrast, has rejected the argument for nano-specific labelling: 'systematic specific labelling of ingredients in the form of nanomaterials is excessive; there is a requirement to consider specific labelling requirements on a case-by-case basis.'⁵⁰⁵

⁵⁰⁰ Monash Report, at p.74. q.v. K. Ludlow, 'The Readiness of Australian Food Regulation for the use of Nanotechnology in Food and Food Packaging', *The University of Tasmania Law Review* (2007); 26(2): 177, at p.198.

⁵⁰¹ Friends of the Earth, *Out of the Laboratory and Onto Our Plates: Nanotechnology in Food & Agriculture*, March 2008, at p.45, at http://www.foe.org/pdf/nano_food.pdf

⁵⁰² 'MEPs reiterate opposition to food from cloned animals,' 1 October 2010, at <http://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20101019IPR88128&format=XML&language=EN>

⁵⁰³ 'The European Parliament adopted by 362 votes to 4, with 5 abstentions, a resolution on regulatory aspects of nanomaterials ... The Parliament also reiterates its call for the provision of information to **consumers** on the use of nanomaterials in consumer products: all ingredients present in the form of nanomaterials in substances, mixtures or articles should be **clearly indicated in the labelling** of the product (e.g. in the list of ingredients, the name of such ingredients should be followed by the word 'nano' in brackets).' 'Regulatory aspects of nanomaterials', INI/2008/2208, at <http://www.europarl.europa.eu/oeil/file.jsp?id=5680552>.

⁵⁰⁴ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-428.273+03+DOC+PDF+V0//EN&language=EN>, Amendment 81

⁵⁰⁵ Position (EU) No 6/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No *A Review of the Adequacy of New Zealand's Regulatory Systems to Manage the Possible Impacts of Manufactured Nanomaterials*

FSANZ has acknowledged that '[a]t present, there are no specific labelling requirements in the Code for food products which contain nanoscale material.'⁵⁰⁶ With regard to the possibility of implementing such a requirement, it has said the following:

'Labelling requirements in the Code can be amended either through an application to FSANZ or through a proposal raised by FSANZ. In amending food regulatory measures, such as mandatory labelling, FSANZ must consider the matter based on a rigorous assessment process, including a thorough risk analysis and cost-benefit analysis, and following public consultation. Such analyses and consultation processes apply to any application or proposal to change the Code.'⁵⁰⁷

Whether foods containing mNMs should be labelled as such is, of course, a multi-faceted question, which extends beyond the risk-based remit of this report, encompassing questions of consumer choice and fairness to producers. It could, for example, be argued that requiring producers to draw attention to mNMs risks prejudicing potential consumers against their produce, without any justification in terms of health and safety. Following the passing of the new EU Cosmetics Regulation, the German government asked to be minuted a statement of concern that 'using the term "nano" might be misunderstood by consumers as a warning'⁵⁰⁸

It could also be noted, of course, that similar arguments have been advanced against the compulsory labelling of genetically modified produce. Yet the FS Code requires that the presence of genetically modified (GM) foods, ingredients, additives, etc requires to be notified on a label.⁵⁰⁹ FSANZ has referred to this requirement as 'represent[ing] a balance between the needs of consumers and what governments can realistically enforce.'⁵¹⁰ This might reasonably invite speculation as to whether an analogous rationale could be advanced for an analogous requirement for foods, ingredients, additives, etc containing manufactured NMs.

We note that a 'comprehensive review of food labelling law and policy', commissioned by the Australia and New Zealand Food Regulation Ministerial Council, is currently approaching completion (the final report is due to be provided to Government through the Ministerial Council in December 2010 and to the Council of Australian Governments in early 2011).⁵¹¹ The Terms of Reference for the review do not make explicit reference to nano-food, but the general questions it has set out to confront are likely to be indicative of the sort of balancing of interests that will inform the approach taken to that area:

'There are tensions between the varying objectives sought to be achieved from food labelling laws by the different stakeholders in the food regulatory system. Calls are regularly being made for new labelling requirements to address a range of issues of

1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (15 March 2010), <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:122:0038:01:EN:HTML>

⁵⁰⁶ Personal correspondence with FSANZ, 11 August 2010

⁵⁰⁷ Personal correspondence with FSANZ, 12 October 2010

⁵⁰⁸ Statement for the minutes by the Federal Republic of Germany on the proposal for a Regulation of the European Parliament and of the Council on cosmetic products, Brussels, 17 November 2009. At <http://register.consilium.europa.eu/pdf/en/09/st12/st12682-ad01re01.en09.pdf>

⁵⁰⁹ FS Code, Standard 1.5.2

⁵¹⁰ FSANZ, *GM Foods: Safety Assessment of Genetically Modified Foods* (2005)

⁵¹¹ <http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/home>

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concern to diverse groups within the community. Increasingly these do not relate to the characteristics of the food itself, but are about food production systems or attributes.

However, all food labelling requirements impose costs. Therefore it is important that all food labelling laws –

- i. are evidence based and effective at achieving their policy purpose;
- ii. do not impose unjustifiable regulatory burdens on business; and
- iii. are capable of being enforced in an effective, proportionate and consistent manner.⁵¹²

An evaluation of the arguments around, and the options for, nano-specific labelling may well justify another report. For present purposes, we note only that:

- there is a body of opinion to the effect that failure to inform prospective consumers as to the presence of mNMs constitutes a significant regulatory gap. We note, however, the existence of a contrary argument, expressed to us on several occasions by FSANZ regulators, that this is not properly considered a ‘gap’ at all, but rather a ‘position, or preferred policy’. As stated earlier in the report, we are less concerned about the terminology used in this area than about trying to ensure that it receives due attention;
- ‘the provision of adequate information relating to food to enable consumers to make informed choices’ is a statutory objective of FSANZ;⁵¹³
- as FSANZ has noted, ‘Food labelling, whether it is for consumer information related to health matters, food safety and/or to enable consumers to make informed food choices, requires that consumers will understand the information on the label and that it assists them in choosing appropriate food.’⁵¹⁴ Were it to be decided that mandatory labelling of nano-ingredients, additives, etc were desirable, attention would require to be paid to the form of such labelling, especially given the widely presumed low level of public awareness of nanotechnology.

In considering these options for developing and amending food standards, it should be borne in mind that FSANZ also has obligations under the Inter-Governmental Agreement (IGA) established by the Council of Australian Governments (COAG) in 2008. This requires minimum effective regulation be used in the provision of a safe food supply; that regulatory decision-making be based on science; and that a cost-benefit approach be employed where there may be impost on industry.⁵¹⁵

Human and Environmental Safety Assessment

If a food is not specifically regulated by the Code, no human or environmental safety assessment is required prior to sale, though it must, as explained above, comply with the provisions of the Food Act 1981. Where the food is specifically listed in the Code, a human safety assessment will either have occurred, or must occur. Where an unlisted food is regarded as novel, a safety assessment will be required in terms of Standard 1.5.1. In conducting such an assessment, FSANZ must pursue the following objectives (in descending priority order):

- (a) the protection of public health and safety; and

⁵¹² <http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/Content/terms>

⁵¹³ FSANZ Act 1991, Section 18(1)(b)

⁵¹⁴ FSANZ, *The Analysis of Food-Related Health Risks* (2008), at p.42

⁵¹⁵ *Ibid*, at p.65

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(b) the provision of adequate information relating to food to enable consumers to make informed choices; and

(c) the prevention of misleading or deceptive conduct.⁵¹⁶

As the Monash Report noted, '[t]here is no objective directly relevant to protecting the environment.' – move to main text

FSANZ must ensure that standards are 'based on a risk analysis using the best available scientific evidence'.⁵¹⁷ If FSANZ considers that the best available scientific evidence is insufficient, it may provisionally adopt 'sanitary or phytosanitary measures on the basis of available pertinent scientific information.'⁵¹⁸ FSANZ is therefore empowered to take measures to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs; (10(4)(b)). Such measures may apply to, inter alia, 'any relevant law, decree, regulation, requirement or procedure';⁵¹⁹ testing, inspection, certification and approval procedures;⁵²⁰ and packaging and labelling requirements directly related to food safety.⁵²¹ If FSANZ takes action on this basis, it 'must take all reasonable steps to obtain the information necessary for a more objective risk analysis and a review of the sanitary and phytosanitary measures, to be undertaken within a reasonable period of time.'⁵²²

The process of risk analysis undertaken by FSANZ will involve consideration of:

- the context of the problem (e.g. whether it is urgent or likely to be wide-spread in nature and involve a range of foods);
- the nature of the risk (e.g. low versus high and the toxicological endpoint);
- the likelihood and severity of the risk (e.g. low risk and low severity vs. high risk and high severity);
- uncertainty associated with the risk assessment; and
- the most appropriate options (e.g. regulatory or non-regulatory).⁵²³

A Regulatory Impact Statement (RIS) addressing the issue of cost effectiveness of various options (regulatory and non-regulatory) will also be prepared.

Post-Market Monitoring

FSANZ may undertake monitoring to examine the current state of the food supply in order:

- to assess the impact of the change to the Code on consumers over time;
- to determine changes in the status of particular foods in the market; or
- to verify the conclusions from pre-market risk assessment regarding the estimated dietary exposure levels or absence of unexpected health effects.⁵²⁴

⁵¹⁶ FSANZ Act 1991 section 10(1).

⁵¹⁷ FSANZ Act 1991, Section 10(2)(a)

⁵¹⁸ FSANZ Act 1991, Section 10(4)

⁵¹⁹ Section 10(5)(e)

⁵²⁰ Section 10(5)(g)

⁵²¹ Section 10(5)(j)

⁵²² Section 10(4)

⁵²³ FSANZ, *The Analysis of Food-Related Health Risks*, 2008, at p.40

⁵²⁴ *Ibid*, at p.53

As Ludlow has noted, however, ‘because any Standard amendment is so resource intensive, it is likely only to occur if evidence of new public health and safety considerations arises.’⁵²⁵

⁵²⁵ K. Ludlow, ‘The Readiness of Australian Food Regulation ...’, loc. cit., at p.199
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4 REGULATORY TRIGGERS, GAPS AND ADDITIONAL COMMENTS

The Monash Report concluded that, in Australia, ‘there was no case where a particular regulatory framework generally did not apply to a nanofamily as a result of the presence of NMs.’⁵²⁶ In general, our report has reached the same conclusion with regard to New Zealand. The regulatory mechanisms applicable to conventional products will, in broad terms, apply to mNMs, and to products containing and incorporating mNMs (though a possible gap was identified where the product actually *creates* nanoparticles, subsequent to sale.)

It follows, then, that in those areas where regulatory coverage is comprehensive for conventional products, it will often be comprehensive for mNMs too. The corollary, of course, is that areas of weakness in the regulatory frameworks will also provide weak regulation for mNMs. For example, perceived deficiencies identified in the Medicines Act, while not always specific to nano-products, will apply as much to them as to any other products (see Section 3.2).

We have, however, identified a number of possible regulatory gaps that are more specific to products containing mNMs. As explained at the outset of our report, we have distinguished between gaps that occur at different levels: respectively, at the level of legislation, at the level of regulatory policy, and at the level of compliance and enforcement. The options for addressing those gaps will often depend upon which of these categories they are considered to fall within.

We have also followed the methodology of the Monash Report in grouping the gaps under headings, though our headings do not map precisely onto those utilised in the earlier report.

4.1 Is a nanoform ‘new’?

Identified by the Monash Report as ‘the most significant potential gap’,⁵²⁷ we have also found points within New Zealand’s regulatory framework where the identification of nanoforms of existing products as new or ‘novel’ is potentially uncertain. A safety assessment under the HSNO Act, for example, will only be triggered if ‘the hazards differ between the “conventional” substance and the nano substance’.

Similar uncertainty may be seen to exist with regard to the regulation of food; in many circumstances, an item will be subject to a pre-market safety assessment only if it satisfies the criteria for a ‘novel food’ set out in Standard 1.5.1 of the FS Code. Although particle size and form will be relevant considerations for FSANZ in making a determination as to novelty, there is no specific provision to the effect that nanoforms of existing foodstuffs must be regarded as novel foods.

Uncertainties about the unique properties, and potential long-term effects of mNMs have led to a growing consensus that, for example, chemicals⁵²⁸ or foods⁵²⁹ containing mNMs should

⁵²⁶ Monash Report, at para. 5.1.

⁵²⁷ Monash Report, at p.5.

⁵²⁸ ‘We believe that chemicals in the form of nanoparticles and nanotubes should be treated separately to those produced in a larger form.’ The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties* (July 2004), at paragraph 22

⁵²⁹ ‘Given the uncertainty about the potential risks of nanomaterials, it is essential that any nanomaterial used in a food product ... should to be subject to a formal risk assessment process’ House of Lords Select Committee, *Nanotechnologies and Food* (January 2010), at 8.11.

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be treated as new, and accordingly subject to their own risk assessment. Indeed, as noted above, the new EC regulation on food additives requires that a food additive that has undergone a significant change in particle size will be regarded, for regulatory purposes, as a new additive.⁵³⁰

Although the establishment of the Advisory Committee on Novel Foods to offer guidance on whether a food is novel is a commendable step, that process of recommendation and decision will only be triggered where a manufacturer *understands the need* to make an application or seek advice. Although FSANZ appears to have made considerable efforts to provide detailed advice to prospective food manufacturers, that guidance may be seen as somewhat lacking in clarity and precision with regard to the status of ‘nanofood.’

We have suggested that, with regard both to the HSNO and FSANZ Acts, these gaps could potentially be addressed by the regulators, without need to amend the legislation. ERMA could, for example, modify its Group Standards to require that nano-forms of existing substances could be subject to new assessments, or at least that they must be notified to ERMA. A partial precedent already exists in the form of the Cosmetic Products Group Standard, which requires notification of any cosmetic product containing nanomaterials. It seems possible to us that Group Standards could be used to require not only notification, but a separate risk assessment for nanoforms of existing substances.

With regard to food, we have suggested that the least burdensome step for the regulator would be to stipulate unambiguously that all foods (additives, contact materials, etc) containing manufactured NMs should be submitted either to the ACNF for a recommendation as to novelty, or to FSANZ for an approval.

4.2 Regulatory scope

Some questions have also arisen with regard to the remit of some of the regulatory bodies. As discussed at 3.4, the applicability of the HSNO Act to nano-silver washing machines, and – in future – other items such as nano-silver fridges is an area of uncertainty, in view of the likely designation of such items as ‘manufactured articles’. The potential difficulty lies in the fact that manufactured articles – even those containing or incorporating hazardous substances – are not considered to be ‘substances’ for purposes of the HSNO Act, and are therefore (for the most part) ultra vires of ERMA.

It has been suggested by the Sustainability Council that a ‘common sense’ approach to the definition of ‘hazardous substances’ would encompass manufactured articles that contain nano-silver. It is unclear to us whether the wording of the HSNO Act is flexible enough to admit of such an interpretation. Certainly, ERMA’s own view appears to be that such items lie outwith its regulatory remit.

A more promising mechanism to extend ERMA’s reach to such items (assuming that to be desirable) may lie with section 96B(2)(d) of the HSNO Act, which allows a Group Standard to be applied to ‘a product (including, but not limited to, a manufactured article ...) that is, contains, incorporates, or includes a hazardous substance.’ Before doing so, the Authority would need to be satisfied that such a Group Standard was justified; the environmental and health benefits, for example, would need to outweigh the economic costs associated with complying with the group standard. It lies beyond the remit of this report to advise ERMA on whether it *should* use this power to regulate a particular manufactured item, but its availability

⁵³⁰ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, Article 12, discussed above at 3.7.

suggests that – once again – this is a regulatory gap that could be addressed without the necessity of amending the relevant legislation.

A more intractable problem may be thought to exist with regard to products – such as Samsung’s nano-silver washing machine – that do not, at the time of pre-market assessment, contain any mNMs whatever, but which nonetheless possesses the capacity to create nanoparticles. As we noted above, while it may seem somewhat arbitrary for the law to distinguish between items designed to *produce* potentially hazardous substances, and items which already *contain* such substances, it may be that the wording of the legislation requires just such a regulatory distinction. If so, this would be one of the few examples of a regulatory gap that can only be addressed at the statutory level.

4.3 Appropriateness of quantity-based triggers and conditions

The existence of quantity-based regulatory *triggers* was identified in the Monash Report as a significant regulatory gap. Indeed, its conclusions have led NICNAS, 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).’⁵³¹ This relates to an exemption from the requirement for assessment certification for persons importing or manufacturing less than 100 kilograms of the substance per calendar year. As no analogous exemptions exist in New Zealand, this particular proposal is not applicable to the New Zealand regulatory framework.

The one quantity-based exception that does exist under the HSNO Act relates to ‘small-scale use of hazardous substances in research and development or teaching’ (HSNO Act, Section 33). Whether training and practice within laboratory environments is adequate to ensure safe handling of mNMs is not a question we have been able independently to explore, but we note that a number of issues of concern were raised in Sally Gaw’s review of the current state of practice for handling nanomaterials in NZ university laboratories (discussed at 3.4).

In general, however, we have found quantity-based triggers to be less a cause for concern in New Zealand than the Monash report found to be the case in Australia. Quantity-based *conditions*, however, are present in the New Zealand regulatory scheme. For example, in terms of food regulation, some additives and contaminants are permitted only subject to quantitative restrictions. Doubts have been raised regarding the suitability of such limits to nanoforms. Again, it appears to us as though the regulator – in this case, FSANZ – has the capacity to vary these limits, either with regard to nanoforms of existing materials or new/novel nanoscale materials (see Section 3.7).

As this report is a regulatory scoping exercise, rather than detailed review of, for example, toxicological data, we make no particular finding or recommendation about any particular quantitative condition. More generally, we note that the suitability of each of these conditions to mNMs is something that requires further and ongoing evaluation, especially as more detailed evidence becomes available regarding the unique or distinctive properties of particles at the nano-scale.

⁵³¹ NICNAS, Proposal for Regulatory Reform of Industrial Nanomaterials. Public Discussion Paper – November 2009

4.4 Nano-specific labelling

The European Union has recently legislated for compulsory labelling of cosmetics containing NMs, 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. At present, there are no nano-specific labelling requirements in New Zealand, either for cosmetics, foodstuffs, or for any other products containing manufactured NMs.

This could be argued, in some contexts, to be a regulatory gap. In relation to food regulation, for example, we have noted that one of FSANZ's objectives, as laid down in the FSANZ Act, is 'the provision of adequate information relating to food to enable consumers to make informed choices'.

Insofar as this is properly seen as a regulatory gap, it may be one that could be addressed at a regulatory, as opposed to statutory level. FSANZ could, for example, vary the FS Code to require nano-specific labelling, while it would seem to be open to ERMA to use Group Standards to impose a similar condition on manufacturers of, e.g., cosmetics containing NMs. As we noted above, however, due consideration would have to be paid to the appropriate wording of such labels, so as to impart useful information to prospective consumers without causing unjustified alarm.

4.5 Regulating uncertainty

The limited state of current knowledge about the risks posed by some nanoscale particles presents a number of obstacles to any attempt to regulate in this area. In some cases, regulatory triggers require the identification of a product as being likely to present a risk. Under the Waste Minimisation Act, for example, the absence of documented cases of adverse environmental effects directly attributable to NMs may mean that products containing NMs may not be singled out as products likely to harm the environment when disposed of as waste. Likewise, in relation to food regulation, the wording of Standard 1.4.3 of the FS Code uses the concept of 'likely to cause bodily harm, distress or discomfort.' Again, the relative absence of reliable nanotoxicological data may mean that it will be difficult to designate such a risk as 'likely', meaning that the power to prohibit the food which has been in contact with an NM may not be useable.

It is therefore obviously important that regulators remain apprised of the most recent reliable information with regard to the possible hazards presented by NMs; indeed, we are reassured that many of the regulators had already acknowledged this obligation. More challenging, however, is the question of how to proceed in situations of uncertainty. As lawyers, we are inclined to view this problem as relating to burdens and standards of proof. With regard to burden of proof, should regulators, for example, assume that a nanoform of an existing product is safe until reliable evidence shows otherwise? Or should they operate the contrary assumption: that a new product is unsafe until the contrary can be demonstrated?

Some of the regulatory frameworks we have examined offer some guidance in this regard. Section 7 of 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'.⁵³² In similar terms, the Hazardous Substances and New Organisms (Methodology) Order 1998 provides that, where there is technical uncertainty or dispute as to the risks posed by a substance, which is not resolved to ERMA's satisfaction,

⁵³² HSNO Act, section 7

ERMA ‘must take into account the need for caution in managing the adverse effects of the substance’.⁵³³

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 (section 7), it does not empower ERMA to act when there are suspicions but little or no evidence.’⁵³⁴ This understanding of s.7 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’.

Unsurprisingly, some commentators have advocated a more risk-averse understanding of this obligation. The Sustainability Council, for example, has called for the withdrawal of cosmetics containing NMs ‘until sufficient nanosafety research has been undertaken to assess them’. The Council’s report argued that ‘the test of HSNO’s relevance to nanotech is not whether it can finger the known, worst offenders (given adequate information), but how it caters for the vast number of nanomaterials about which very little is known, some of which may turn out to be harmful long after they have been allowed into commercial circulation.’⁵³⁵ ERMA has rejected this approach:

‘In effect the Sustainability Council arguments are of the “guilty until proven innocent” nature. Our interpretation of the HSNO Act and broader regulatory principles is that while novel products are not “innocent until proven guilty” restricting a product through regulation requires evidence of risk to be above a minimum threshold (The hard part is determining where that threshold is in practice)’⁵³⁶

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.’⁵³⁷ However, we would submit that regulators will require to adopt one or other of these presumptions when dealing with NMs about which the evidence of hazard is still uncertain. That is, in the absence of compelling evidence either way, NMs must either be presumed to be safe or unsafe. It is unclear what an approach avoiding either of those presumptions might look like, even in theory.

Having said that, more nuanced options may exist within those broad presumptions. For example, an approach could perhaps be adapted from criminal law, whereby anyone objecting to an NM would bear an *evidentiary burden* of demonstrating *some* risk of harm – of ‘putting the issue into play’, as it has been described – but having passed that threshold, the burden of proof would then transfer to the manufacturer to prove that the risk was unfounded or adequately managed. This could potentially avoid the possibility of an NM being banned because of a mere *suggestion* of hazard, but would perhaps avoid the danger of regulatory paralysis until some harm has actually occurred.

The question of *standard* of proof has also been identified as an area of possible uncertainty, for example, the ‘likelihood’ trigger in Standard 1.4.3 of the FS Code, or the designation as ‘hazardous’ in terms of the HSE or HSNO Acts. How compelling must the evidence be before

⁵³³ Methodology Order, Section 30

⁵³⁴ Personal correspondence, 9 July 2010

⁵³⁵ Sustainability Council, *The Invisible Revolution*, op. cit.

⁵³⁶ Personal correspondence, 9 July 2010

⁵³⁷ Roger Brownsword, *Rights, Regulation, and the Technological Revolution*. Oxford: Oxford University Press, 2008, at p.106

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such triggers are activated? Whether carbon nanotubes would fall within the terms of the HSNO Act, for example – and thus, within ERMA’s regulatory remit – would depend upon whether ‘they have hazardous properties per HSNO and what test methodologies are used to determine those hazardous properties.’⁵³⁸ Since at the time of writing, no applications have been received by ERMA for approval of CNTs, this must remain a hypothetical question.

It seems likely, however, that CNTs will be a manifestation of mNMs that will generate most controversy, at least in the near future. The view has several times been expressed to us, for example, that existing evidence about the risks they pose should be sufficient to justify a moratorium on their use, or at least on certain uses to which they could be put. ERMA’s view, on the other hand, is that the studies published to date are preliminary and inconclusive.

Insofar as existing regulations are not specific about the level of proof that would be required to trigger regulatory action, we must agree with the Monash Report that these may be seen as potential regulatory gaps.

4.6 Compliance and enforcement

Finally, it should be borne in mind that even the most comprehensive regulatory framework will be an ineffective safeguard of public health if no effective mechanism exists to monitor and enforce compliance with it. This is what we identified as a third level regulatory gap. For example, the notification requirement of the presence of NMs in cosmetics relies upon the voluntary compliance of manufacturers. It appears, however, that this requirement has been widely ignored. As stressed earlier in the report, we wish to imply no criticism of ERMA when we note that such a requirement serves negligible purpose if there is no mechanism in place even to ascertain whether it is being complied with.

We therefore make the general recommendation that, before implementing any rule or measure to address nano-safety concerns, consideration should be given to the practical necessity of monitoring, and where need be, enforcing compliance with that rule or measure. This may involve a range of measures, from merely reminding manufacturers in clear terms of their obligations, to invoking such legal sanctions as are considered appropriate – though it should be noted that, to date, voluntary notification approaches ‘have had limited success both nationally and internationally’.⁵³⁹

Where regulators are not empowered to conduct such monitoring and enforcement roles, amendment of their foundation statutes may be required. More often, we suspect, the gaps will be the result of policy decisions by the regulators themselves, and the resource realities within which they operate.

⁵³⁸ Personal correspondence with ERMA, 21 December 2010.

⁵³⁹ NICNAS, Proposal for Regulatory Reform of Industrial Nanomaterials: Public Discussion Paper – November 2009, at p.12

Agency	Triggers	Potential Gaps	Additional comments
DoL	<ul style="list-style-type: none"> 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 process for hazards, whether or not the hazards involve NMs. The Code applies to all workplaces in which hazardous substances are being used or produced, whether or not they contain NMs. 	<ul style="list-style-type: none"> There is a potential regulatory gap in that the “current state of knowledge” regarding harm attributed to many NMs is deficient. Although many of the OSH implications of NMs and nanoparticles are unknown, scientific studies indicate that adverse health consequences are possible from NM and nanoparticle use and exposure. For some nanoparticles, such as carbon nanotubes, the small size and fibre shape has led to speculation that carbon nanotubes may have similar adverse health effects to asbestos fibres. Workers in workplaces are potentially being exposed to nanoparticles, hazardous substances and dangerous goods containing NMs. The main exposure routes are inhalation and dermal absorption. A potential regulatory gap may exist if the deficiencies in nanotoxicology prevent a potentially harmful NM from being identified as a significant hazard. However, significant hazard is defined in the HSE Act as an actual or <i>potential</i> cause or source of serious harm... (section 2, our emphasis). If the NM is a potential cause of harm, it could be identified as a significant hazard and, therefore, trigger the 	<p>Although there is no environmental safety assessment under the HSE Act, this is intentional and a result of the scope of the Act and because of coverage under the HSNO Act.</p> <p>The HSE Act drafters wanted to separate regulating safety at work from general regulation of product liability issues. Therefore, the regulation of product liability issues (including products containing NMs) falls outside the scope of the HSE Act. However, the HSE Act applies to places of work in which hazards (which means <i>inter alia</i>, substances) and/or significant hazards are identified, whether or not those hazards and/or significant hazards involve NMs.</p>

Agency	Triggers	Potential Gaps	Additional comments
		<p>hierarchy of action. In addition, the HSNO Act is the primary legislative instrument for dealing with hazardous substances.</p> <ul style="list-style-type: none"> • There is no approval prior to the regulated activity. However, the HSNO Act is the primary legislative instrument for dealing with hazardous substances. • There is no environmental safety assessment under the HSE Act. However, the HSNO Act is the primary legislative instrument for dealing with hazardous substances. • Current processes may not consider the high surface area and increased reactivity of NMs. Therefore, the current methods and procedures may be inadequate for the safety of workers. Hazard assessment for nanoparticles needs to consider shape, chemical properties, the role of particle size, functionality and dose. • There is no national or international agreed definition to describe nanoparticles. Second, equipment and methods to enable routine measurements of nanoparticles are not yet available. • It is unclear whether designers, manufacturers and suppliers of plant, not specifically concerned with NMs, would or should be aware of the presence 	

Agency	Triggers	Potential Gaps	Additional comments
		<p>of NMs and their risks.</p> <ul style="list-style-type: none"> • 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 physical and chemical properties of the substance are to be included in SDS. Particle size is not specifically noted as a relevant property. The SDS may also describe other properties and additional information (at the supplier's option). 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. However, SDS are required under the HSNO Act. • Health hazard information is required. However, there are deficiencies in the toxicological data for NMs, particularly for chronic exposure. • SDS could alert users to the presence of NMs and the risks posed by them, but there is no guarantee that this will occur. • The Code, generally, and health hazard information specifically, does not expressly distinguish between nano and conventional forms of chemicals. 	

Agency	Triggers	Potential Gaps	Additional comments
ERMA	<ul style="list-style-type: none"> • HSNO Act applies only to ‘substances’ that are ‘hazardous’. Substance is ‘hazardous’ if it meets or exceeds one of the thresholds set down in the Hazardous Substances (Minimum Degrees of Hazard) Regulations 2001 • If a substance reaches one of these, ERMA 	<ul style="list-style-type: none"> • SDS do not impose obligations on suppliers to disclose whether a substance is, or originated as, a NM and may, thus, have special properties. Given deficiencies in current knowledge regarding the safety of NMs, SDS requirement that health hazard information should be included is unlikely to trigger the provision of nanotoxicological information. These gaps mean that users may not receive adequate information on the possible hazards of substances to workers. However, these aspects are more applicable to HSNO Act requirements. • 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 nanoparticles will be able to penetrate the material from which the protective clothing is made more readily than macro particles. • Ecotoxicity assessment is not required but this is covered by the HSNO Act. 	<ul style="list-style-type: none"> • Gap re low volume permits, identified in Monash Report, not applicable to New Zealand. R&D exemptions, however, do apply, and perhaps merit closer examination.

Agency	Triggers	Potential Gaps	Additional comments
	<p>approval will be required before it can be imported, manufactured or used. ERMA will decide whether the substance's likely benefits outweigh any risks and costs.</p>	<p>containing carbon nanotubes) may be ultra vires of ERMA's regulatory remit.</p> <ul style="list-style-type: none"> • No requirement for nano-specific labelling, or public register of products containing mNMs. • ERMA's interpretation of precautionary approach – as required by HSNO Act – subject to some criticism. How much and how clear must evidence be before a substance can be treated as 'hazardous' (e.g. in the contentious example of carbon nanotubes)? • Some doubts have been raised about the exemption for 'small-scale use of hazardous substances in research and development or teaching' 	<ul style="list-style-type: none"> • Appears to be open to ERMA to use Group Standards to extend regulatory remit to manufactured articles containing, incorporating or including hazardous substances. (HSNO Act, s. 96B(2)(d)). Doubts, however, concern certain manufactured items that appear to create mNMs subsequent to sale; do they 'contain, incorporate or include' a hazardous substance at the point of pre-market assessment?
FSANZ	<ul style="list-style-type: none"> • Food will require a pre-market safety assessment if it is classified as 'novel' (FS Code, Standard 1.5.1). New food additives will not be permitted without prior regulatory approval, in the form of an amendment to the FS Code (Std. 1.3.1) 	<ul style="list-style-type: none"> • Some potential room for uncertainty around whether food, food additives or contact materials should be classified as 'new'/'novel'. • Absence of nano-specific labelling requirement regarded by some as unsatisfactory. • Some additives, etc permitted subject to quantitative restrictions (e.g. some colourings permitted subject to maximum levels of 290 mg/kg in foods and 70 mg/L in beverages.) Doubts have been raised regarding suitability of such limits to nanoforms. • As with other regulatory areas, doubts have 	<ul style="list-style-type: none"> • 'comprehensive review of food labelling law and policy', commissioned by the Australia and New Zealand Food Regulation Ministerial Council, is currently approaching completion.

Agency	Triggers	Potential Gaps	Additional comments
		<p>been expressed regarding adequacy of current risk assessment methodologies in view of limited available nanotoxicological data.</p>	
Medsafe	<ul style="list-style-type: none"> If products (including medicines, medical devices, related products, herbal remedies) are used for a therapeutic purpose, whether or not they contain NMs. 	<ul style="list-style-type: none"> Exemptions Definitions such as medicine and medical devices are inconsistent with international norms. There is no approval process for medical devices. There is no human safety assessment for medical devices. As combination therapies, such as nanotherapeutics, confuse the boundaries between ‘medicine’ and ‘medical device’, it is doubtful whether the Meds Act definitions can manage the challenges posed by these combinations. Risk assessment is only concerned with human health and safety. Medsafe is not required to consider broader environmental risks associated with therapeutic products (e.g. those with NMs). The human safety assessment process under the Meds Act is concerned with the principles of benefit/risk analysis, rather than solely the technology per se. This assessment method may not 	<ul style="list-style-type: none"> Exemptions and exempt products Potential for increase in products which blur the boundary between ‘medicine’ and ‘medical device’. Potential for increase in number of products which sit at the NZFSA, ERMA/MfE and Medsafe interface.

Agency	Triggers	Potential Gaps	Additional comments
MfE	<ul style="list-style-type: none"> The disposal & minimisation of waste, whether or not some of the constituents of waste contain NMs. If products are considered waste, whether or not they contain NMs or are produced using nanotechnology. The actions of territorial authorities (e.g. s42). 	<p>be appropriate for nanomedicines where there exists a deficiency of long-term exposure and nanotoxicology data. There may be long-term effects which present benefit/risk assessments fail to consider.</p> <ul style="list-style-type: none"> While some products containing NMs will be considered ‘waste’, it is unclear whether this control will be adequate for classifying risks associated with products containing NMs. The WMA encourages waste minimisation. Therefore, the Act deals with some events before they occur. There are powers in the Act to prohibit the disposal of certain types of waste. However, there will be challenges in applying the Act to NMs. Although there are potential health and environmental risks associated with NMs, to date there have been no documented cases of adverse environmental effects directly attributable to NMs. The current lack of data on exposure and ecotoxicological properties of some NMs means that products containing NMs may not be singled out as products likely to harm the environment when disposed of as waste. Under WMA, the Ministry for the Environment does <i>not</i> undertake safety assessments. But ERMA does conduct safety assessments. The WMA includes monitoring, compliance 	<ul style="list-style-type: none"> It is unlikely that the monitoring techniques under the WMA are adequate for detecting NMs that are released into the environment. This issue is not limited to NZ. Section 23(1)(b) concerns controlling or prohibiting the manufacture or sale of products that contain specified materials. This section could potentially cover products with NMs. There is currently no national policy statement or national environment standard covering NM disposal management.⁵⁴⁰

⁵⁴⁰ We are grateful to Ceri Warnock for asking whether a RMA NPS or NES is required for NM disposal management, or whether the WMA (with revision) could provide appropriate national consistency.

Agency	Triggers	Potential Gaps	Additional comments
Ministry of Consumer Affairs	<ul style="list-style-type: none"> • FTA: <ul style="list-style-type: none"> ○ ‘Goods’ and ‘unsafe goods’ whether or not they contain NMs. ○ The FTA will be triggered if a person in trade engages in conduct that is misleading or deceptive, whether or not that conduct is misleading or deceptive in relation to goods containing NMs. • CGA <ul style="list-style-type: none"> ○ ‘Goods’ whether or not they contain NMs. ○ The statutory guarantees in the supply of goods apply to goods whether or not they contain NMs. ○ Specifically, the statutory acceptable quality (safety) guarantee applies to all ‘goods’ that are supplied to a consumer, whether or not they contain NMs. ○ Specifically, the guarantee of fitness for a particular purpose applies whether or not the goods supplied to a consumer contain NMs. 	<p>and enforcement provisions in relation to managing environmental harm. However, few of the enforcement and auditing powers are likely to be applicable to products containing NMs.</p> <ul style="list-style-type: none"> • FTA: <ul style="list-style-type: none"> ○ There is no approval prior to the regulated activity, therefore the statutory regime is primarily reactive rather than proactive. ○ There are no human and environmental safety assessments. ○ However, these comments apply to all goods, including those containing NMs, due to the deliberate scope, and reactive nature of, the legislation. <ul style="list-style-type: none"> • CGA: <ul style="list-style-type: none"> ○ There is no approval prior to the regulated activity. ○ There are no human and environmental safety assessments. ○ There is no post-market monitoring. ○ However, these comments apply to all goods, including those containing NMs, due to the deliberate scope of the legislation. 	<ul style="list-style-type: none"> • There are no nano-specific product safety standards.

Agency	Triggers	Potential Gaps	Additional comments
NZCS	<ul style="list-style-type: none"> Applies to the importation of goods, whether or not they contain NMs. 	<ul style="list-style-type: none"> The NZ government may place prohibitions and restrictions on the importation of goods. At present, the goods will be prohibited or restricted by virtue of falling within one of the three general sources of prohibitions and controls on imports, and not as a consequence of the goods containing NMs. 	

5 CONCLUSION

It may be seen, then, that some of the potential gaps we have identified are quite specific to a particular regulatory area. Others – such as the challenge of deciding what burden and standard of proof, or attitude towards precaution, is most appropriate in the face of uncertain evidence – are likely to be common to all regulators, and probably in all jurisdictions. Insofar as specific gaps have been identified, we have tried where possible to consider some possible strategies whereby they could be closed, or at least narrowed. Where we have done so, these should be seen merely as options for further consideration, rather than explicit recommendations on our part.

As the Monash Report concluded, it is now for each of the regulatory agencies to consider in detail the potential gaps we have identified, and to consider whether these potential gaps require some action on their part. If some action is regarded as appropriate, detailed consideration should then be given to what form of action would be most appropriate to the gap in question, giving consideration to the scale and urgency of the possible problem, and to issues of proportionality.

This report, then, in no way purports to be the last word on the subject of regulation of nanoproducts in New Zealand. It is hoped, however, that it will make a worthwhile contribution to clarifying the terms of the discussions that must follow.

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APPENDIX ONE: CONSULTATIONS

Date Consultation	of	Agency Organisation	or	Name
12 May 2010		FSANZ & NZFSA		<p>Dennis Thomas Principal Food Technologist FSANZ</p> <p>Dr Leigh Henderson Section Manager Products Safety Standards FSANZ</p> <p>Trish Ranstead Programme Manager NZFSA</p> <p>Dr Paul Danstead Principal Advisor (Chemicals) NZFSA</p> <p>Matthew Green Solicitor</p>
12 May 2010		ERMA		<p>Dr Peter Dawson Principal Scientist, Hazardous Substances</p> <p>Dr Donald Hannah General Manager Strategy & Analysis</p> <p>Dr Lynne Waterson Toxicologist</p>
13 May 2010		Canterbury University		<p>Associate Professor Simon Brown Academic, Professor, Physicist</p> <p>Dr Sally Gaw Academic, Lecturer, Chemist</p>
17 May 2010		MedSafe, MOH		Dr Susan Martindale Principal Advisor Regulation
17 May 2010		Department Labour	of	<p>Colin du Plessis Technical Leader</p> <p>Richard Steel</p>

			Manager Technical Support Services
24 May 2010	Ministry of Consumer Affairs	of	Alison Cossar Senior Policy Analyst
			Martin Rushton Principal Advisor Measurement & Product Safety Service
25 May 2010	Ministry for the Environment	the	Sue Ruston Manager – Risk and Adaptation
			Natasha Tod Manager of Business & Communications
26 May 2010	Otago University		Professor Nicola Peart Academi Lawyer Medical law and Medicines Act expert
26 May 2010	Canterbury University		John Hughes Academic Lawyer Senior Lecturer HSE Act expert
26 May 2010	Otago University		Nicola Wheen & Ceri Warnock Academic Lawyers Environmental law experts
15 June 2010	NZ Customs Service		David Ryan Chief Legal Counsel
			Mike Wotherspoon Senior Policy Analyst
			Kirsty Marshall Senior Policy Analyst

APPENDIX TWO: ABBREVIATIONS USED FOR LEGISLATION

Abbreviation	Statute
CEA	Customs and Excise Act 1996
CGA	Consumer Guarantees Act 1993
Food Act	Food Act 1981
FS Code	Australia New Zealand Food Standards Code
FTA	Fair Trading Act 1986
HRC Act	Health Research Council Act
HSNO Act	Hazardous Substances and New Organisms Act 1996
HSE Act	Health and Safety in Employment Act 1992
Meds Act	Medicines Act 1981
RMA	Resource Management Act 1991
WMA	Waste Minimisation Act 2008