

# *De minimis curat lex* : New Zealand law and the challenge of the very small

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## Abstract

In 2010, the New Zealand Government commissioned a review on the ability of New Zealand's regulatory systems to manage the potential health, safety and environmental risks posed by manufactured nanomaterials. Whilst some of the gaps identified by this review are specific to New Zealand's regulatory arrangements, other potential gaps are common to regulators in different jurisdictions. Scientific uncertainties about hazard, human exposure, nano-toxicity and risk persist. Regulators charged with protecting public health face challenges due to these scientific gaps. Deciding what burden and standard of proof is most appropriate in the face of uncertain scientific evidence is a common challenge.

In light of this particular shared regulatory challenge, this article examines New Zealand's regulatory framework for hazardous substances. It will consider a range of potential regulatory challenges and 'gaps'. Specifically, it will explore the uncertainty surrounding standard of proof, for example, in the designation of 'hazardous' in New Zealand's *Hazardous Substances and New Organisms Act 1996*. It will also explore the question of how 'precautionary' approach should be adopted in relation to hazardous substances containing nanoparticles, using carbon nanotubes as a topical and paradigmatic case study. Regulatory enforcement and compliance issues are also examined. Like other jurisdictions, New Zealand is no stranger to the difficulties posed by regulatory notification requirements which are not adhered to and for which there are no mechanisms in place for monitoring compliance.

## 1. Introduction

It has become almost a trite observation that nanotechnologies possess certain novel properties that promise great benefits, but also pose particular challenges to regulatory systems (Royal Society, 2004b, p.vii; Renn and Roco, 2006, p.155) With this latter challenge in mind, government-initiated and independent reviews have been undertaken in the UK (Royal Society, 2004(a); Royal Society, 2004(b); Chaudhry, Q, Boxall, A, Aitken, R, Hull, M, 2005; Royal Commission, 2008; Chaudhry et al, 2006), EU (European Commission 2008(a) and (b)), Australia (Ludlow, Bowman and Hodge, 2007), and the US (EPA, 2007; FDA, 2007; Davies, 2006; Taylor, 2006) to determine the suitability of regulatory regimes to manage the potential health, safety and environment risks of nanotechnologies. These reviews identified regulatory gaps in the oversight of manufactured nanomaterials (Ludlow, 2008).

In New Zealand, a similar review was conducted in 2010, by the New Zealand Law Foundation Centre for Law and Policy in Emerging Technologies at the University of Otago's Law Faculty (Gavaghan and Moore 'The Otago Report', 2011). Drawing on the approach of the Australian Monash Report (Ludlow, Bowman and Hodge, 2007), this considered how regulatory oversight is triggered for manufactured nanomaterials (mNMs), and the adequacy of New Zealand's regulatory frameworks in dealing with mNMs. It also identified a number of potential regulatory gaps - a term which proved surprisingly controversial among some of the regulators, despite the frequency with which it (or near synonymous terms) is used in other reports of this nature (Ludlow, Bowman and Hodge, 2007; The Royal Society & The Royal Academy of Engineering, 2004a; Royal Commission on Environmental Pollution, 2008; International Risk Governance Council, 2007).

In this article, we explain some of our key findings in relation to New Zealand's regulatory framework for hazardous substances. While some of the gaps identified in our report are specific to New Zealand's regulatory arrangements - for example, terms such as 'substance' and 'hazardous', which have important roles in New Zealand law, present certain difficulties with regard to certain uses of nanotechnology - other potential gaps are common to regulators in different jurisdictions, particularly with regard to (a) uncertainties about hazard and risk, and (b) the challenge of monitoring and enforcing regulations. The options for New Zealand regulators to respond to those potential gaps are, of course, constrained by the specifics of New Zealand legislation, which may necessitate exploring different solutions to those employed in other jurisdictions.

## 2. The Otago Report on Manufactured Nanomaterials

In 2010, the Otago report authors undertook an analysis of ten legislative instruments and the eight regulatory agencies that administer those instruments. A summary of the sources of power (the legislative instruments) of the relevant regulatory agencies is shown in table 1 below.

**Table 1: NZ Regulatory Agencies' Legislative Sources of Power**

Regulatory Agency	Legislative Instruments
Department of Labour	<i>Health and Safety in Employment Act</i>
	Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work.
MedSafe, Ministry of Health	<i>Medicines Act 1981</i>
Ministry for the Environment & ERMA	<i>Waste Minimisation Act 2008 (MfE).</i>
	<i>Hazardous Substances and New Organisms Act 1996 (ERMA).</i>
Ministry of Consumer Affairs	<i>Consumer Guarantees Act 1993</i>
	<i>Fair Trading Act 1986</i>
New Zealand Customs Service	<i>Customs and Excise Act 1996</i>
New Zealand Food Safety Authority &	<i>Food Act 1981</i>
Food Standards Australia and New Zealand	Australia New Zealand Food Standards Code

As per the terms of reference (Ministry of Research, Science and Technology, 2010) under which the review was commissioned, the methodology employed in our research and the structure of the report closely followed that adopted in the report conducted by staff at Monash University in 2007 ('the Monash Report') regarding Australia's regulatory frameworks (Ludlow, Bowman and Hodge, 2007). Each regulatory framework and its adequacy to manage the possible impacts of mNMs was analysed. Following the Monash Report, the adequacy of each regulatory framework was analysed with reference to the five criteria adopted in that Report. [3]

Though similar, the approach of the Otago Report was not identical to that of its Australian predecessor. The Otago Report, for example, considered consumer protection legislation (specifically, the *Consumer Guarantees Act 1993* and the *Fair Trading Act 1986*); the Monash Report did not include the equivalent Australian consumer protection in its review. On the other hand, the Otago Report did not include the equivalent environmental legislation to that analysed by the Monash Report. Rather than analysing New Zealand's *Resource Management Act 1996* (analogous to the environmental legislation analysed in the Monash Report), the Otago Report examined the *Waste Minimisation Act 2008*. [4]

In many ways, the Otago Report's overall conclusions are similar to those of the Monash Report, and indeed to other reports in this area (Royal Society, 2004(a); Royal Society, 2004(b)). In particular, the Otago Report's conclusions in relation to food legislation were similar to those reached in the Monash Report because of the Trans-Tasman regulatory arrangements (the 'Food Standards Australia and New Zealand') which governs food regulation in both New Zealand and Australia. None of the areas of the New Zealand regulatory system that were considered were found to require wholesale changes in order to be applicable to mNMs, or to products containing and incorporating such products. In those areas where regulatory coverage is comprehensive for conventional products, it will usually be comprehensive for mNMs (Gavaghan and Moore, 2011, p.6). The corollary, of course, is that areas of weakness in the regulatory frameworks will provide areas of weak regulation for mNMs too.

However, the Otago Report identifies a number of possible regulatory gaps or weaknesses within those regulatory systems that are more specific to products containing mNMs. The potential regulatory gaps identified in the Otago Report can be placed into seven categories, which are broadly consistent with those identified by the Monash Report (Ludlow, Bowman, Hodge, 2007). Specifically, those gaps relate to:

1. Uncertainty as to the identification of mNMs as new or existing chemicals;
2. Regulatory scope and the remit of regulatory bodies;
3. The appropriateness of quantity-based triggers and conditions;
4. Nano-specific labelling;
5. Subsequent generations of nanotechnologies are likely to present a much more significant challenge to existing regulatory structures;
6. Obstacles arising from the limited state of current knowledge about the risks posed by some mNMs; and
7. The absence of effective mechanisms to monitor and enforce compliance with regulatory frameworks.

While some of the regulatory challenges and gaps that we identified are specific to New Zealand's regulatory arrangements, other potential gaps are common to regulators in different jurisdictions. Scientific uncertainties about hazard, human exposure, nano-toxicity and risk persist, and present significant challenges to regulators charged with protecting public health and the environment. Deciding what burden and standard of proof is most appropriate in the face of uncertain scientific evidence is a common challenge.

### **3. New Zealand's Regulatory Framework for Hazardous Substances**

In New Zealand, hazardous substances are dealt with under the *Hazardous Substances and New Organisms (HSNO) Act 1996*. The statute was enacted 'because of the need for a more integrated and consistent approach to managing hazardous substances and new organisms in New Zealand.' (ERMA, 2006). 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.' (HSNO Act, s.4.).

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' (ERMA, 2006, p.12). ERMA's overall mission was 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' (Environmental Risk Management Authority).

More specifically, ERMA was created 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. (ERMA, 2006, p.13).

As of 1 July 2011, ERMA was 'disestablished', and a new Environmental Protection Authority (EPA) assumed its role in terms of the HSNO Act. (*Environmental Protection Authority Act 2011*). Although it is, at the time of writing, too early to tell whether the new agency will adopt a significantly different approach to this role, it seems likely that at least some of the issues we have identified will present as much of a challenge for the EPA as for its predecessor. Before any particular form of mNM, or object containing mNMs, will require EPA approval, it must satisfy three separate criteria, each of which poses certain challenges with regard to mNMs.

#### **3.1. It must be a 'substance'**

A 'substance' is defined as:

- any element, defined mixture of elements, compounds, or defined mixture of compounds, either naturally occurring or produced synthetically, or any mixtures thereof;
- 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;
- any mixtures or combinations of any of the above;

- any manufactured article containing, incorporating, or including any hazardous substance with explosive properties. (HSNO Act, s.2).

With the exception specified in section 2(d), manufactured articles - even those containing or incorporating hazardous substances - are generally not considered to be 'substances' for the purposes of the HSNO Act (ERMA, 2009, para 4.6.) - though this is subject to the partial exception in section 96B(2)(d)), discussed later. [5] As we also discuss later, this has given rise to some controversy regarding domestic appliances (for example, fridges, washing machines) that contain or produce nanoparticles. [6]

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) mNMs. A recent Sustainability Council report (Sustainability Council, 2010), 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 electrolyse pure silver during wash and rinse cycles. Over 400 billion silver ions are released and penetrate deep into fabric for effective sanitization.' [7] The possibility exists that nano-silver washing machines are *ultra vires* of the HSNO Act, and therefore outside ERMA's regulatory remit. As explained above, the HSNO Act definition of 'substance' only extends to manufactured articles which possess explosive properties (HSNO Act, Section 2). The potential difficulty lies in the fact that manufactured articles which do not possess explosive properties - even those containing or incorporating other hazardous substances - are not considered to be 'substances' for the purposes of the HSNO Act (ERMA, 2009). 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' (ERMA, 2001). 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.' (ERMA, 2001) 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 was certainly the view taken by ERMA's Chief Executive: 'Common sense dictates that a washing machine is a manufactured article' (Personal correspondence, 9 July 2010). 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"' (Sustainability Council, 2010).

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' (Sustainability Council, 2010, at 15). ERMA's position, though, appears to have been 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.' (Personal correspondence, 9 July 2010).

Does a 'common sense' approach dictate that these particles should be treated as chemical substances, potentially requiring EPA 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. The Act, as properly understood, may not extend to nano-silver used in this way (as ERMA contended). The somewhat anomalous outcome of this interpretation would be that mNMs that required to be added to an item such as a washing machine would be subject to regulatory oversight (as ERMA acknowledged), but identical mNMs that happen to be contained or produced within the item would escape such oversight. Alternatively, it may be that ERMA's understanding of its remit was overly restrictive, and that the HSNO Act does permit it jurisdiction over 'substances' such as nanosilver, even when contained or produced within a manufactured item.

The latter interpretation would be more in keeping with the approach adopted in the EU, under the REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) rules. Although REACH adopts a similar distinction to that set out in the HSNO Act (though it refers to 'articles' rather than 'items'), it specifically requires that 'substances in articles have to be registered if they are intended to be released from the article under normal or foreseeable conditions of use.' (European Commission, 2008c, p.6). Deciding when this requirement comes into play is not always straightforward - though the European Chemicals Agency provides fairly detailed guidance on the question (European Chemicals Agency, 2011) - but it seems hard to dispute that the release of nanosilver from the SilverCare washing machine is both intentional, and something that will occur under normal conditions of use.

Whatever the better interpretation of the HSNO Act, it seems clear that items such as washing machines that contain or produce mNMs are, in practice, being treated as 'manufactured items', and the mNMs 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/EPA. If this interpretation of the Act, which was favoured by ERMA, is valid, then a regulatory gap may be identified with regard to such products. [8] 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.' [9] 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. [10] 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. [11] If nanosilver particles within refrigerators or other manufactured articles are considered to be an appropriate subject for regulatory scrutiny, this may be viewed as a potential regulatory gap.

However, it may be that a statutory mechanism exists whereby EPA's remit can be extended to cover even manufactured items. Section 96B(2)(d) of the HSNO Act allows EPA to apply a group standard - conditions applied to a category of products deemed to have a similar nature - to 'a product (including, but not limited to, a manufactured article ...) that is, contains, incorporates, or includes a hazardous substance.' Whether or not EPA 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 we discuss in the following section. Second, before issuing or amending any group standards, EPA 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. (Section 96C(1)(c))

It appears, then, that if EPA were to form the opinion that imposing conditions on the manufacture or import of manufactured articles containing mNMs is justified, Section 96 appears to provide a legislative mechanism allowing it to do so. However, one possible further reservation relates to the requirement that the product 'contains, incorporates, or includes a hazardous substance' (Section 96B(2)(d)). With regard to nanosilver washing machines, however, their precise function may be seen as closer to creating the nanoparticles; the machines, as imported or sold, contain not mNMs but silver plates that, when electrolysed, gradually release 'Silver Nano ions or Ag+'. [12] 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.

### **3.2 It must be 'hazardous'**

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

1. explosiveness;
2. flammability;
3. a capacity to oxidise;
4. corrosiveness;
5. toxicity (including chronic toxicity);
6. ecotoxicity, with or without bioaccumulation. (HSNO Act, s.2.).

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 explained, '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.' (ERMA, 2008, para 1.2.4). The manufacture or importation of a hazardous substance without an approval is an offence. (HSNO Act, section 25(1)).

### **3.3 It must present new hazards**

A third 'threshold' criterion that must be satisfied before particular mNMs fall within the remit of ERMA/EPA relates to novelty. 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 (para 5.5.1) 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 conventional counterpart'.

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.' [13] A question inevitably arises, then, 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?

## 4. Regulating in the face of uncertainty

For a substance to fall within the remit of EPA, then, it must be determined that (a) it is a substance, (b) it is minimally hazardous, and (c) that it is hazardous in a novel way. If these criteria are satisfied, it will fall to EPA to decide whether (d) an approval should be approved for import, manufacture or use, and (e) whether any controls should be imposed on the substance's import, manufacture or use. In reaching decisions about (d) and (e), EPA will decide whether the substance's likely benefits outweigh any risks and costs. With the possible exception of decisions about (a), it seems clear that all of these other decisions are made considerably more difficult when the evidence as to a substance's hazard profile is minimal or ambiguous. As the UK's House of Lords Science and Technology Committee said in 2009: '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 human health.' [14] An important question, then, relates to how New Zealand's regulatory systems respond to uncertain hazards and risks.

With regard to the classification of a substance as new - our criterion (c) - uncertainties about the unique properties, and potential long-term effects of mNMs have led some reports to conclude that, for example, chemicals (Royal Society and the Royal Academy of Engineering, 2004a, para 22 or foods (House of Lords Science and Technology Committee, 2010, para 8.1) containing mNMs should be treated as new, and accordingly subject to new risk assessments. Indeed, 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. [15]

More generally, in making any of these determinations, 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.' (HSNO Act, s.10.) As ERMA noted, however, 'the issue of 'how cautious' is left open.' (Annotated Methodology, para 8.3.5). Some guidance about how EPA must conduct 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:

- exposure to the risk is involuntary;
- the risk will persist over time;
- the risk is subject to uncontrollable spread and is likely to extend its effects beyond the immediate location of incidence;
- the potential adverse effects are irreversible;
- 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 (*Hazardous Substances and New Organisms (Methodology) Order 1998, Section 33*).

The Methodology Order also offers some guidance on dealing with uncertain evidence:

'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-

- 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
- 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 (or from now on, EPA) 'must take into account the need for caution in managing the adverse effects of the substance' (Methodology Order, Section 30) - though, again, this does not answer the question as to 'how cautious'.

Carbon nanotubes (CNTs) provide an example to illustrate the conflicting attitudes to precaution. These are among the most controversial current uses of nanotechnology, largely because of concerns about certain asbestos-like characteristics they possess. In 2009, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks reviewed the scientific literature on the effects of CNTs, concluding that the risk of mesothelioma 'cannot be excluded' - though such a risk would require 'inhalation exposure to such structures.' [16] Such concerns led

the European Parliament to pass a Resolution calling for CNTs to be banned from electrical and electronic goods<sup>[17]</sup> - though it should be noted that no such ban has actually found its way into EC law. <sup>[18]</sup>

Precisely how 'precautionary' an approach should be adopted towards CNTs is, unsurprisingly, a matter of dispute. At one end of the opinion spectrum, some of the parties to whom we spoke expressed support for a policy of 'putting commercial use of CNT on hold ... at least with regard 'to products where manufacturing and consumption will lead to human exposure'. <sup>[19]</sup> ERMA appeared 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.' <sup>[20]</sup> Indeed, our research revealed no certainty as to whether they even passed the 'hazardous' threshold, which would be required for them to be within EPA's remit at all. This would depend upon whether 'they have hazardous properties per HSNO and what test methodologies are used to determine those hazardous properties.' <sup>[21]</sup> Since, at the time of writing, neither ERMA nor the EPA had received any applications for CNTs, the question as to whether they will be deemed 'hazardous' for purposes of the Act remains moot.

## 5. Regulatory Enforcement and Compliance

The Otago Report distinguishes 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.

The first level of potential regulatory gap is at the statutory level (or level of legislation). If some of the legislation that is evaluated 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 (or level of regulatory policy); thus, some gaps may be thought to exist because regulators have interpreted a piece of legislation 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 situation with regard to nanosilver washing machines or refrigerators may either illustrate a potential gap at the level of the legislation itself, or alternatively, at the level of its interpretation and application by 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.

A possible example of such a 'third level' gap may be found in the attempts to regulate cosmetic products containing mNMs. 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.' <sup>[22]</sup>

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:

- the name of the substance; and
- the HSNO approval number and/or title of the Group Standard under which the substance has a deemed approval; and
- the nature of the nanoparticles the substance contains.' (ERMA, 2006b)

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, or now, EPA). Nonetheless, it is noteworthy that there is now precedent for the use of this regulatory mechanism to make specific provision for mNMs.

The Cosmetic Products Group Standard requires that any cosmetic products intended for use on human skin which contain mNMs must be notified to ERMA. However, an investigation by the Sustainability Council (2010) identified several products which were commercially available in New Zealand which should have, but had not, been notified to ERMA. [23] Indeed, not a single notification had been received by ERMA prior to the publication of the Sustainability Council'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 mNMs 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.

## 6. Conclusion

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.' In general, the Otago Report has reached the same conclusion with regard to New Zealand. The regulatory mechanisms applicable to conventional products will, in broad terms, apply to manufactured NMs, and - at least potentially - to products containing and incorporating such products. As with its Australian counterpart, though, the Otago Report does identify a number of possible gaps in the regulatory framework that are more specific to products containing NMs. Doubts were identified as to whether domestic appliances containing mNMs fall within the statutory definition of 'hazardous substances' for the purposes of the HSNO Act. As things stand, items such as Samsung's SilverCare washing machines are being treated as 'manufactured items', and the mNMs themselves as integral parts of those items, placing both the machines and the nano-particles beyond the scrutiny of EPA. (This, of course, presupposes that EPA will adopt a similar approach to that of its predecessor organisation, ERMA). While section 96B(2)(d) of the HSNO Act does allow EPA to apply group standards to a manufactured article that 'contains, incorporates, or includes a hazardous substance', a further gap may exist with regard to washing machines which may more properly be described as creating nanoparticles.

Potential technical obstacles to regulating objects such as refrigerators and washing machines appear, then, to be answerable by exercises in discretion by the regulatory body, with one exception that may require to be addressed at the level of the legislation. Other obstacles to effective regulation, though, may arise from the current state of uncertainty about the effects of NMs, and less amenable to an obvious resolution. How should a regulator proceed in the face of uncertain evidence as to hazard? This is potentially relevant both to decisions as to whether a substance falls within the Act's remit, to decisions as to whether it should be approved for manufacture, use or import, and to decisions about conditions to be attached.

The HSNO Act stipulates that a 'precautionary approach' to such matters must be taken, which emphasises 'the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects'. Precisely how this should be interpreted in practice, though, 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.' (Brownsword, 2008, at 106) 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 a mNM being banned because of a mere suggestion of hazard, but would perhaps avoid the danger of regulatory paralysis until some harm has actually occurred.

Finally, the Otago Report identified a degree of concern regarding compliance with the reporting requirement for cosmetics containing mNMs. Our decision to include possible concerns at the level of enforcement and compliance proved somewhat controversial with some regulators. Our view, however, was that a review of regulatory adequacy would be incomplete without consideration of such concerns. Lee and Stokes (2009, pp.472-473) point 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.' Although the Otago Report does not address all of the areas to which Lee and Stokes refer, we hope that our approach has at least prevented such practical concerns from being altogether overlooked.

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[3] The five criteria are: trigger and scope; requirement for regulatory approval; human safety assessment; environmental safety assessment; post-market monitoring.

[4] The authors' suggestion that the Resource Management Act be included in the review was rejected by some of the regulators.

[5] This section is discussed on in a later section.

[6] The controversy surrounding domestic appliances is discussed in a later section.

[7] [http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/wash\\_faq\\_popup.html](http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/wash_faq_popup.html)

[8] The question of what can properly be described as a 'gap' actually became one of the most contested in our dealings with the regulators. In particular, doubts were raised at whether a 'gap' can be identified when a policy decision was made not to extend regulatory coverage to a particular area. It is our contention that gaps can come to exist by design as much as by accident; it is neither etymologically nor logically problematic to speak of choosing to leave a gap. Hence, in identifying the existence of a possible regulatory gap, we imply nothing about whether that gap arose as a result of regulatory oversight, or after considered deliberation. Neither do we imply anything about the appropriate response to such gaps; a regulatory gap, in our sense of the term, 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. (Otago Report, p.6)

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

[10] '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](http://www.samsung.com/sg/consumer/learningresources/silvernano/silvernano/refig_faq_popup.html)

[11] 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'

[12] <http://www.samsung.com/au/silvernano/site.html>

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[14] 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

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

[16] SCENIHR, 'Risk Assessment of Products of Nanotechnologies', at [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihhr/docs/scenihhr\\_o\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_023.pdf), at p.30.

[17] 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), Amendment 88, at <http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2010-0196&format=XML&language=EN#title2>

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[19] Personal correspondence with Sustainability Council, 6 December 2010.

[20] Shown to us in personal correspondence from the Sustainability Council, 13 October 2010.

[21] Personal correspondence with ERMA, 21 December 2010.

[22] <http://www.ermanz.govt.nz/hs/groupstandards/standards/cosmetics/cosmetics.html>

[23] There seems to have been no dispute between the regulators and the Sustainability Council that at least some of the products listed in the report were of the sort that should have been reported under the Group Standard.