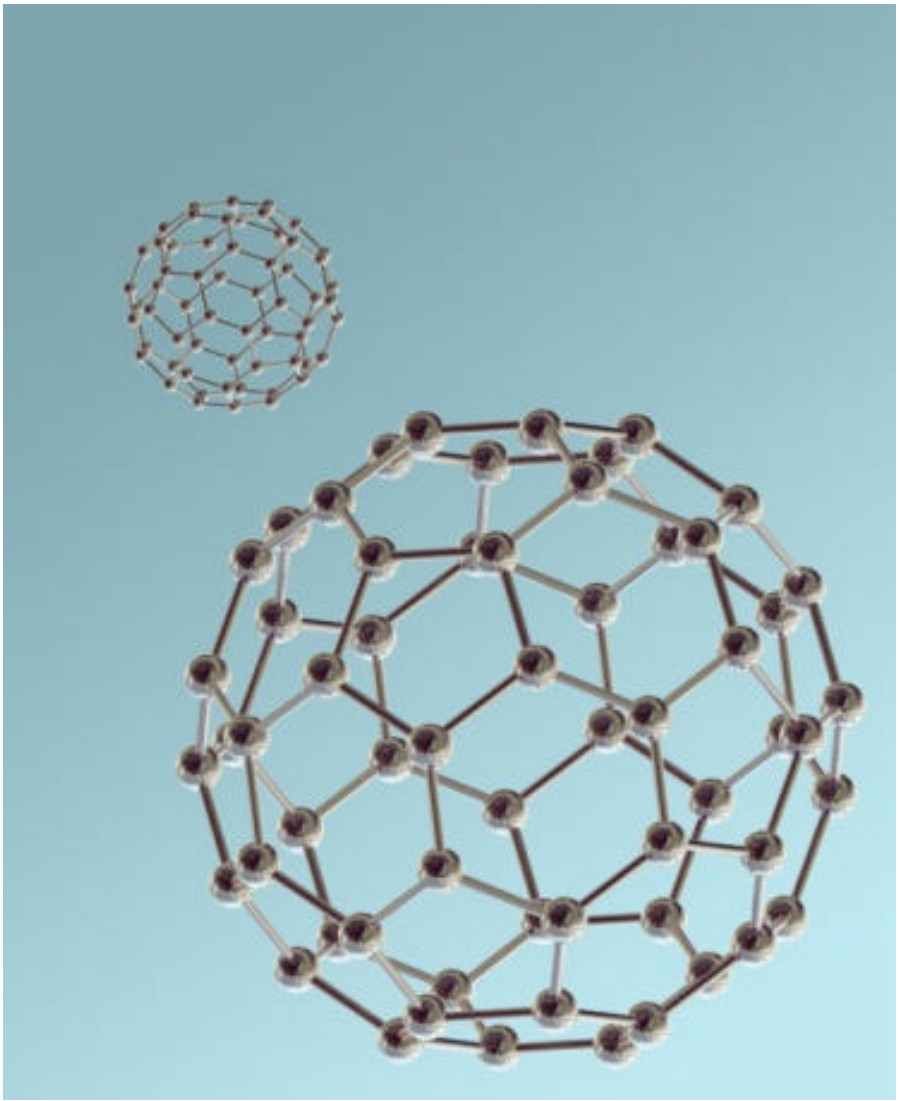
The Invisible Revolution

Nanotech commercialisation racing ahead of safety regulation



Fullerenes, *Getty Images*

June 2010

Sustainability Council

Executive Summary

- New Zealand women are being exposed to cosmetic products containing types of nanomaterials that have been stripped from the shelves in Europe and Australia. Face creams with nanoparticles called "**fullerenes**" remain on sale in New Zealand even though the European cosmetics industry has pledged not to use them until more is known about their safety.
- **Products containing nanosilver** also feature among the increasing number of products containing nanosized versions of existing chemicals and new substances that are effectively unregulated for their nanocontent. This includes washing machines that inject nanosilver into the wash for germ-killing action. Quantities of these nanosilver particles are expected to end up in wastewater.
- The lack of regulatory action on such products is surprising and of concern given that silver in its bulk form is known to be toxic in aquatic ecosystems. There is also considerable concern internationally about the environmental implications of nanosilver use. In New Zealand, Fisher and Paykel decided against using the technology in its laundry appliances because it did not believe it offered any benefits and the company was concerned about the effects of routine use of silver on the environment.
- The degree to which nanotech regulation has gone into snooze mode is underscored by the failure of one of the scant regulatory requirements for nanoproducts – a simple obligation for manufacturers and importers to report the use of some nanocosmetic ingredients to ERMA prior to market introduction.
- As of May 2010, no notifications have been filed yet the Sustainability Council has identified a number of cosmetic products that contain types of nanomaterials – including the face creams containing fullerenes - that would apparently require reporting to the regulator.
- While nanotech commercialisation is continuing apace, it is widely recognised that nanosafety research and risk assessment methodologies are immature and many regulators acknowledge that they are not able to risk assess nanomaterials. At present it is not possible to predict which products may cause harm and which may be benign.
- Allowing a growing stream of nanoproducts into commercial circulation under such conditions of ignorance, without any serious attempt to regulate or monitor, is not responsible governance. At present, developers can reap the benefits that come with an effectively unregulated technology, while the community and the environment bear the risks.
- Nanotechnologies are predicted to make a positive contribution across a range of areas, including healthcare and energy generation. However, waving nanotech products through with little or no effective regulation is

not the way to secure net benefits for society. Getting regulation in place will allow applications that are believed to have real benefits to be properly assessed and compared against other options to ensure the most sustainable options come forward.

- Lack of action to date means New Zealand must now play catch-up to regulate nanotechnologies. The products identified in this brief survey are simply the beginning of what is projected to be ubiquitous use of nanomaterials.
- The Government has commissioned a regulatory review to determine whether existing laws are triggered by nanoscale materials and products. This is welcome, but is a small step towards addressing the range of questions that arise with respect to nanotechnologies and how they should be governed.
- It is likely that regulatory change may take some time so interim measures are required to properly regulate products currently on the market and those likely to emerge while the Government review is underway. These include, but are not limited to, nanocosmetic products and products containing nanosilver.
- Of greater importance than narrow safety issues, however, is societal dialogue and critical thinking into what roles nanotechnologies might or might not play in achieving sustainability and in protecting and enhancing the health and well-being of New Zealanders. The challenge is then to devise the policy and good governance that will ensure these outcomes.

Contents

Researched by

Stephanie Howard

Sustainability Council, PO Box 24304, Wellington, www.sustainabilitynz.org
Tel: +64-4-9133-655, Email: council@sustainabilitynz.org

Disclaimer: While every effort has been made to ensure the accuracy of information in this report, no liability is accepted for errors of fact or opinion, or for any loss or damage resulting from reliance on, or the use of, the information it contains.

Growing Commercial Interest in Nanoscale Products

The nanoscale is of scientific and commercial interest due to the novel properties that matter displays when manufactured at that size. Wide-ranging use of nanotechnologies is being researched in medicine, industrial materials, energy and agriculture, among others. While the bulk of nanotech activity is still in the lab, hundreds of consumer products that incorporate nanoscale materials are already on the market internationally. The most widely-cited product inventory put the number of consumer products containing nanomaterials at over 1,000 last year.[1] That is acknowledged to be a very conservative tally, and the commercial use of nanomaterials is thought to be much higher.

Those on or nearing the market are characterised as first-generation nanomaterials, which are generally nanoscale versions of existing chemicals. Further along the evolution of the technologies envisaged are much more complex materials and applications, including hybrid chemical/biological materials, structures and machines; and applications such as so-called ubiquitous sensing, tissue engineering, through to human enhancement.

A corollary of the newness of manufactured nanomaterials is ignorance or uncertainty as to how they might affect human health, the health of other species and the wider environment. In terms of both methods and the data available on individual nanomaterials, nanosafety research is extremely immature, and a significant research effort is required to enable meaningful assessment of nanotech products. Furthermore, methods to identify nanomaterials in products or product residues in the environment are generally unavailable as yet. The conditions under which the commercialisation of nanotechnologies is taking place have been described as a state of "significant [2].

In New Zealand, nanotech products are generally unregulated, with exceptions including a scant reporting requirement for certain nanocosmetic ingredients and the potential for regulatory assessment of nano-food ingredients by the Food Standards Authority.[3] Nanofood ingredients and nano-food packaging – a significant area of activity in the food sector for which there are no nano-specific requirements in New Zealand law – are an issue that the Council intends to address in subsequent publications.

A preliminary scan of nanoproduct availability in New Zealand

The extent to which nanomaterials are now present in commercial products in New Zealand is unknown as there is no official, national register of nanotech products and officials tend to rely upon the above-mentioned product database when referring to products available locally.

The Sustainability Council has conducted a preliminary scan for consumer nanoproducts on the New Zealand market. Its purpose is not to provide a

[1] Project on Emerging Technologies Consumer Product Inventory, www.nanotechproject.org/inventories/consumer/
[2] UK Royal Commission on Environmental Pollution, *Novel Materials Report*, 4.1.
[3] Food Standards Australia New Zealand (2009) *Application Handbook.*

comprehensive picture of nanoproduct commercialisation. Instead, it is limited to two classes of products:

- Products containing nanoscale silver that could release nano-particles during use; and
- Cosmetic products containing nanomaterials.

These categories were selected as examples of products that tend to involve environmental and/or human exposure to nanomaterials during use. It should be noted, however, that product manufacture may expose workers to nanoparticles and that product use may not be the only point of environmental or human exposure to nanomaterials and, therefore, not the only phase in the life cycle that is relevant from the perspective of risk assessment and regulation.[4]

This research draws upon the above-mentioned US product inventory; similar work by an Australian public interest organisation[5]; as well as review of online product databases of New Zealand retailers and in-store research.

Even restricting our scan to just two categories, this proved a very challenging task. Identifying commercial products containing nanomaterials is challenging for several reasons. Chief among them is the lack of legal requirement to label for nanocontent, which leaves the Government and the wider community dependent on what manufacturers wish to divulge. Product labels, product descriptions and company websites offer little detail[6] and we found retailer awareness about the presence of nanomaterials in products in store to be low. It quickly became clear that it would be very difficult to come close to a comprehensive view, and the focus changed to identifying examples of products within those two categories.

[4] Consideration of the entire life cycle is required, from workplace exposure during manufacturing through to the end of product life, as even nanoparticles that are 'embedded' may eventually be released into the environment unless disposal or recycling are arranged accordingly

[5] Friends of the Earth Australia, "Beauty industry backs high-risk small particles: Controversial nano-ingredients found in big name brands", November 2009.

[6] This may be due in part to a reported retreat by product developers from associating their wares with nanomaterials, as has been noted in other countries as public interest in regulating the technology has grown. (See, for example, House of Lords Science and Technology Committee. *Nanotechnologies and Food*, January 2010 Volume 1: Report) A further cause of uncertainty arises because of reported instances where companies, to gain a perceived marketing advantage, have advertised their products as containing nanomaterials, without actually using the technology. It is therefore possible that some products identified below do not actually contain nanomaterials.

Cosmetics and Personal Care Products

The use of nanomaterials in cosmetics and so-called personal care items is apparently widespread. "All the major cosmetic manufacturers use nanomaterials in their products", says a European report issued last year.[7]

Properties of interest to the cosmetics and personal care industries include transparency at the nanoscale of UV protection ingredients such as zinc oxide and titanium dioxide; light diffusion to conceal signs of ageing (aluminium oxide); pigments (iron oxide); and delivery mechanisms for active cosmetic ingredients (nano encapsulation technologies).[8]

At present, use of nanomaterials in cosmetics and personal care products in New Zealand is not regulated per se. The sole requirement of manufacturers or importers of cosmetics containing these novel ingredients is that they report their use to ERMA. That meagre duty was introduced in 2006 and is set out in the "cosmetics group standard" under the Hazardous Substances and New Organisms Act (HSNO). However, not all nanoscale ingredients are included in the reporting scheme: the most common forms of nanoparticles used in cosmetics – titanium dioxide (TiO_2) and zinc oxide (ZnO) – are deemed safe and are thus exempt. For any other nanomaterial, manufacturers and importers must report to ERMA with:

- the name of the cosmetic substance; and the nanoparticles involved; and
- the existing approval the ingredient is deemed to come under, where the ingredient is a nanoscale version of an existing chemical already approved for use by ERMA.[9]

This reporting requirement was introduced by ERMA to "maintain a record of cosmetic products that contain nanomaterials"[10]. It was not intended to trigger further action by ERMA, unless evidence of hazard is available.[11] Thus novel products, or existing substances in nanoscale form that carry novel properties for which there is no

[7] Observatory Nano, *Cosmetics*, November 2008.
[8] Observatory Nano, *Cosmetics*, November 2008; Friends of the Earth Australia, "Beauty industry backs high-risk small particles: Controversial nano-ingredients found in big name brands", November 2009.
[9] Hazardous Substances and New Organisms Act 1996 Cosmetic Products Group Standard 2006, as last amended July 2009. Under the standard, a cosmetic includes "any product or preparation 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".
[10] ERMA, Response to Sustainability Council questions, December 8 2009. In a briefing to the then Minister for the Environment in 2006, officials explained that the purpose of the standard is "to provide information to inform technical review of such substances in the future, so that if necessary, the group standard can be amended to put in place controls relating to such substances" (Ministry for the Environment, "Nanotechnology and the HSNO Act". Briefing to the Minister for the Environment, February 24 2006.)
[11] Personal communication with ERMA, March 2 2010.

history of safe use and little safety data, will not necessarily be subject to risk assessment for those novel properties. As such, the use of novel, nanoscale ingredients in cosmetic products is not subject to risk assessment in New Zealand.

ERMA has recently proposed an amendment to the reporting requirement: a modified definition of nanomaterials, which, if introduced, would include nanomaterials that are insoluble and with at least one dimension between 1-100 nm.[12]

No notifications, but look what's on the shelves

As of the end of May 2010, ERMA had not received any notification from cosmetic manufacturers or importers that nanomaterials have been used in their cosmetic products.[13] Nevertheless, research by the Sustainability Council has identified a number of cosmetic and personal care products currently on the market in New Zealand containing nanoparticles, at least some of which would appear to require manufacturers or importers to notify ERMA, as set out under the group standard (see Table 1). In addition, the Council has confirmed that product containing nanomaterials identified through product testing in November 2009 by the Friends of the Earth Australia are also present on New Zealand shelves.[14]

Once again, these are presented *examples* of nanocosmetic products. The above-mentioned US product inventory listed 221 cosmetic and personal care products, but it is believed that many more beauty products contain nanomaterials.[15]

Of particular concern is the presence of **fullerenes** in some 'anti-ageing' cosmetic products retailing in New Zealand. Fullerenes are hollow, soccer-ball-like carbon nanostructures of around 1 nm in size.[16] While a form of carbon, fullerenes are considered sufficiently novel to be given their own Chemical Abstract Service (CAS) number.[17]

---

[12] New Zealand tends to follow European Union law in the field of cosmetics and the round of amendments to New Zealand's cosmetic standards proposed by ERMA arise from new European Union legislation adopted in November 2009 (European Union. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.) Although the new European Union provisions for nanocosmetics are a world first, these offer only partial regulatory coverage for nanocosmetics: EU lawmakers have persisted with an arbitrary definition of nanomaterials, restricting regulatory coverage to particles between 1-100 nm, leaving all nanoparticles outside that range unregulated. It also excludes from potential risk assessment soluble nanocosmetic ingredients and nanomaterials used as preservatives and UV filters.

[13] Response from ERMA to information request, first obtained on October 16 2009 and updated in March and at the end of May 2010.

[14] This presence was surveyed in February 2010 and the presence of fullerenes was rechecked in May 2010 along with that for a number of other nanomaterials. Friends of the Earth Australia, "Beauty industry backs high-risk small particles: Controversial nano-ingredients found in big name brands", November 2009. The organization commissioned the Australian Microscopy and Microanalysis Research Facility to test selected products for presence of nanoscale ingredients. The testing procedure identifies the presence of nanomaterials but not the proportions of nanoingredients. A different level (and cost) of testing is required to establish the latter. Irrespective of proportion, the presence of nanomaterials raises the question of how to respond from a regulatory perspective.

[15] http://www.nanotechproject.org/inventories/consumer/analysis_draft/. As of August 25 2009. Accessed June 2 2010. This tally includes 137 cosmetic products and 84 personal care products (such as shampoos, soaps and toothpaste).

[16] Royal Commission on Environment Pollution, *Novel Materials Report*, p. 11; The Royal Society & The Royal Academy of Engineering, *Nanoscience and nanotechnologies*, July 2004, p. 9.

[17] The CAS number for fullerenes is 99685-96-8.

Table 1: Examples of cosmetic products apparently containing nanomaterials

Brand	Type of cosmetic	Product	Nanoparticle content stated or found	Nanoparticle size**
Perricone MD	Skin Cream	Ceramic Eye Smoother	Fullerenes	Unknown. Typically around 1 nm
Perricone MD	Skin Cream	Ceramic Skin Smoother	Fullerenes	As above
Dr Brandt	Skin Cream	Lineless Cream	Fullerenes	As above
Clarins *	Foundation	Truly Matte Foundation Light Reflecting SPF 15	Alumino-silicate oxides	100nm rods (length), 100- 200nm plates (length)
Clinique *	Concealer	Line smoothing concealer	Titanium and aluminium oxides, some copper and silicon, Iron oxide	50-300nm spheroids 80-400nm rods (length
Lancôme Paris *	Concealer	Long lasting softening concealer SPF 12	Aluminium oxide	20-80nm spheroids
L'Oréal *	Foundation	Visible lift lifting anti- wrinkle foundation SPF 15	Titanium oxide Aluminium/ iron oxide	80nm spheroids 400nm to 1μm rods (length)
Max Factor *	Mineral Foundation	Natural Minerals Foundation	Aluminium oxide with high phosphor content Iron oxide rods	80nm spheroids 200nm-450nm rods (length)
Revlon *	Concealer	Revlon Age Defying Spa Concealer	Titanium oxides Aluminium/ iron oxide	50-80nm spheroids 300-500nm rods (length)
The Body Shop *	Mineral Foundation	Nature's Minerals Foundation SPF 25	Titanium Iron oxide	30-100nm spheroids 80-600nm rods (length)

** Nanoingredients identified by product testing commissioned by Friends of the Earth Australia.*

It should be noted that because HSNO defines "nanoscale" as at least one dimension below 100 nm, the use of some of the nanoingredients listed above may not require notification. Particle size is not known for all products. Product testing commission by Friends of the Earth Australia yielded a range of sizes, which suggests some ingredients are not captured by HSNO. These examples of products in New Zealand apparently containing nanoingredients is current as of June 2010.[18]

The use of such ingredients in cosmetic products available in New Zealand – albeit in just three high-end lines we have identified – occurs in spite of the following:

- The primary cosmetics industry lobby in **Europe** - the European Cosmetics Association (COLIPA) – has effectively instituted **a voluntary moratorium on the use of fullerenes** amongst its members in recognition that the case for their safety has yet to be made.[19]

[18] The standard defines nanoparticles as "a particle having three dimension in the nanoscale and a diameter of less than 100 nanometres" (Schedule 3: Interpretation)

[19] Colipa Nanotechnology, "Variety and diversity of nanotechnologies", http://www.colipa.eu/nanotechnology.html?sid=49&smid=115. Accessed May 18 2010.

- Fullerene-containing cosmetic products have also been **withdrawn from the market in Australia**. We understand that manufacturers/importers withdrew the products after the federal regulator – the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) - made known that as new chemicals, fullerenes would need to undergo regulatory risk assessment, and that manufacturers/importers.[20]

- The **UK Royal Commission on Environmental Pollution** has rated fullerenes as "potentially harmful **among four nanomaterials that give rise to "the greatest concerns"**. According to the Commission, very little is understood about their toxicological profile[21]; a statement that finds further support from a recently published, UK-funded nanosafety review which concludes that there is not sufficient information to even allow a risk assessment of fullerenes.[22]

- The scientists awarded the Nobel Prize for the discovery of fullerenes have warned against applying fullerenes to the skin and any exposure to new substances for trivial reasons.[23] As one stated, "I would take the conservative path of avoiding using such cosmetics while withholding judgment on the actual merits or demerits of their use".[24]

Regulators catching their beauty sleep

Responsibility for complying with the HSNO group standard lies first and foremost with manufacturers and/or importers of cosmetics. However, the public would expect government agencies to monitor and enforce compliance with the reporting requirements. In this case, ERMA and the Ministry of Health are jointly responsible: ERMA sets the standards and the Ministry is responsible for enforcement and compliance, although we understand that the Ministry relies on ERMA to interpret the

[20] Friends of the Earth Australia issued a press statement in November last year identifying several cosmetic products that contain fullerenes. ("High level British report flags toxic risks of tiny-tech ingredients now used in Australian cosmetics", November 2008). NICNAS subsequently issued a notice reminding operators that as fullerenes are novel cosmetic ingredients, they must undergo risk assessment. (NICNAS, "Presence of carbon fullerenes nanomaterials in cosmetics introduced into Australia", *NICNAS Matters*, December 2008). This notice apparently led manufacturers and retailers withdraw fullerene cosmetic products. (Personal communication, Georgia Miller, Friends of the Earth Australia, December 8 2009)

[21] Royal Commission on Environmental Pollution (2008) *Novel Materials Report,* paras 5.3; 3.55 and 3.25 respectively.

[22] Stone V, Hankin S, Aitken R, Aschberger K, Baun A, Christensen F, Fernandes T, Hansen S F, Bloch Hartmann N, Hutchison G, Johnston H, Micheletti C, Peters S, Ross B, Sokull-Kluettgen B, Stark D and L Tran, *Engineered Nanoparticles: Review of Health and Environmental Safety,* 2010. See for example, p. 76 and p. 353.

[23] Harry Kroto and Robert Curl, cited in "Possible risks: No small matter". *Consumer Reports*, July 2007.http://www.consumerreports.org/health/conditions-and-treatments/nanotechnology-7-07/possible-risks/0707_nano_risks_1.htm

[24] Halford B, "Fullerene For The Face: Cosmetics containing C60 nanoparticles are entering the market, even if their safety is unclear". Chemical & Engineering News. 2006: Vol 84 (13):47

standard and identify where enforcement is needed.[25]

Last year, ERMA indicated its intent to contact the cosmetics industry "to remind them of the requirements of the cosmetics group standard"[26] and ERMA undertook further 'awareness raising' moves in April this year. [27] These, however, appear to have had little effect as no notifications for the use of nanomaterials were filed as of late May 2010.

The task of monitoring for compliance is not made easy by the lack of labelling requirements for nano ingredients, as short of random testing products (for which ingredients?), the regulator must rely on manufacturers' and importers' willingness to comply. These difficulties are demonstrated in the case of the products identified by Friends of the Earth Australia, where the ingredients are not advertised as being nanoscale.

With respect to the cosmetic products we have identified, there is surely little excuse for the apparent absence of monitoring and enforcement of even the wafer-thin regulatory standard. These products were rather easily discovered, as the manufacturers have chosen to advertise the nanocontent.

However, even if regulators decide to take action in response to an apparent breach of the reporting requirement, we understand that manufacturers or importers have little more to fear than a reminder of their obligations.[28] The docility of this response arises because the HSNO Act effectively places the burden of proof for harm occurring on the regulator and it is ill-equipped for situations where little or no safety research has been done.

Whatever the reasons for the lack of action, it would appear that a duty to simply report nanoingredients is being ignored by the relevant manufacturers, importers or retailers. The extent of the regulatory failure is unknown because the scale of commercial use of nanoscale ingredients in cosmetics is unclear.

In addition to retail outlets, we found a great number of beauty products containing nanomaterials were available online – at sites located both internationally and in New Zealand – and being sold on New Zealand auction sites.

Testing required before commercialisation

Of greater concern than a failed reporting requirement is the absence of regulatory risk assessment, labelling and monitoring of nanocosmetic ingredients. New Zealand women are being exposed to a number of other nanocosmetic ingredients (in a far greater number of products) whose safety cannot, as yet, be easily demonstrated, if at

[25] ERMA, Response to enquiries, December 8 2009.
[26] ERMA informed the cross-governmental Nanotechnology Regulatory Subgroup of this intention. Nanotechnology Regulatory Subgroup, Minutes of the Meeting, July 30 2009.
[27] ERMA, Personal communication, ERMA, March 3 2010.
[28] Discussions with ERMA highlighted that as the nanomaterials might not qualify as a hazardous substance as defined under HSNO, response options would accordingly be limited.

all. While there is some experience with certain ingredients (such as titanium dioxide), questions still remain.[29]

In their now seminal report, the UK Royal Society and the Royal Academy of Engineers recommended that "[cosmetic] ingredients in the form of nanoparticles undergo a full safety assessment by the relevant scientific advisory body *before they are permitted for use in products.*[30] (Our emphasis.) In New Zealand there is no scuh requirement, even though it has been recognized since 2006 that nanocosmetic ingredients are "lightly regulated"[31]. Nor can regulators be unaware of the considerable debate internationally about the safety of nanocosmetic ingredients. Foremost among the questions that remain to be resolved are whether nanocosmetic ingredients, due to their extremely small size, can penetrate into the body through the layers of the skin to then reach and potentially accumulate in other organs; and what skin conditions and scenarios might increase uptake.

Transparency an important ingredient

Last year, the Minister for Consumer Affairs told cosmetics industry representatives that questions arising from nanotech cosmetic ingredients include "whether nano-particles can be absorbed into the body and what effect that may have." She also stated that given her ministry's responsibility for product safety, she needed "to be assured that industry is actively managing these risks." [32] These are welcome words, but in practice the cosmetics industry is being given a regulatory holiday and there is no means as yet for government and the wider community to independently verify whether claims to safety that companies might make meet an adequate standard.

The Minister also underscored the importance of informed choice, namely that consumers "have ingredient information that enables them to make informed personal choices about products."[33] At present, however, it is very difficult to establish which cosmetic products contain nanoscale ingredients and New Zealanders cannot consciously and willingly assume the associated risks. There is no requirement for nanocosmetic ingredients to be labelled (a measure that could serve to alert consumers to an issue they need to inform themselves about) and the primary cosmetics industry association in New Zealand (the Cosmetic Toiletry, Fragrance Association (CTFA)) does not support the labelling of cosmetic products containing nanomaterials:

---

[29] Scientific Committee on Consumer Products (SCCP) *Preliminary Opinion on Safety of Nanomaterials in Cosmetic Products.* European Commission, 2007.

[30] The Royal Society & The Royal Academy of Engineering, *Nanoscience and nanotechnologies,* July 2004, p. 73. The call was repeated two years later in a follow-up document. The Royal Society and The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties Two-year review of progress on Government actions: Joint academies' response to the Council for Science and Technology's call for evidence.* RS Policy Document, 2006.

[31] Ministry for Research, Science and Technology, *Nanosciences + nanotechnologies.* Roadmaps for Science, 2006, p. 21.

[32] Roy H, "Effective Market And Consumer Choice". Opening address to the Cosmetic, Toiletry and Fragrance Association of New Zealand's Annual Industry Conference; Sky City, Auckland; Friday, March 13 2009. http://www.beehive.govt.nz/speech/effective+market+and+consumer+choice

[33] The Minister highlighted "the need to ensure that not only are product ingredients generally safe but also consumers have ingredient information that enables them to make informed personal choices about products." Ibid.

> The requirement to add the word (nano) alongside any nano ingredients we believe would be counterproductive and damages consumer perceptions on the safety of products without scientific justification. […] Such requirement is based on emotive reasoning and not on scientific concerns[34]

Further adding to the obscurity of nanocosmetic ingredients, their use has a very low profile in the public domain; and understanding about the novelty of the technologies and the nascent state of nanospecific methodologies and nanosafety research would appear to be low. As such, these novel cosmetic ingredients have gained a regulatory invisibility that matches their physical invisibility.

Actions required on nanocosmetics

We believe there is sufficient concern regarding potential harm from **fullerenes** for **products containing these to be withdrawn from the market** until sufficient nano-safety research has been undertaken to assess them. If ERMA determines that the HSNO Act requires there is insufficient information to justify a product withdrawal, we urge **manufacturers, importers or retailers to remove these products from their shelves until sufficient evidence as to their safety is presented.**

Removing products containing fullerenes until proper safety assessment has been conducted are not in themselves sufficient responses, however. New Zealanders are not being afforded any specific protection from the use of novel ingredients in high-exposure products and **wider regulatory action should occur with some urgency**. This includes bringing into place nanospecific risk assessment methodologies for determining the safety of such ingredients; requiring all nanocosmetic ingredients to undergo pre-market regulatory assessment, and introducing mandatory product labelling.

[34] Cosmetic Toiletry, Fragrance Association. Letter to ERMA: Requests for the Cosmetic Group Standard at next review 2010, February 22 2010. (Obtained under the Official Information Act)

Nanosilver Products

Nanoscale silver is believed to be one of the more commonly used nanomaterials in consumer products.[35] An overseas product inventory lists 259 nanosilver products on the market as of August 2009, these accounting for around a quarter of all consumer products listed. In the main, nanosilver is used as a biocide for its anti-bacterial or anti-microbial properties but consumer products containing nanosilver are wide-ranging.

The Sustainability Council has identified a number of nanosilver products available in New Zealand, including:

- Clothing (including socks, shirts, sportswear, shoe liners);
- Medical products (such as plasters and wound dressings);
- Home appliances (such as fridges, air conditioners and washing machines); and
- Home cleaning products and personal care products.

Other nanosilver products known to be on the market in other countries and which may be available here include children's toys, teethers and cutlery; food contact materials and kitchen implements; vacuum cleaners; and paints.[36]

The items detailed in the following table by no means represent the full number or range of products on the market: they are a selection of those that could be expected to result in a release of silver nanoparticles during use – albeit in small amounts for some product lines.[37]

[35] The most recent update of the US-based Project on Emerging Nanotechnologies consumer product database indicates nanosilver is used in around a quarter (259) of known commercial products containing nanomaterials. See: http://www.nanotechproject.org/inventories/consumer/

[36] See http://www.nanotechproject.org/inventories/consumer/ and Friends of the Earth, *Nano and Biocidal Silver*, June 2009.

[37] It should be noted that the regulatory context with respect to the products identified below is different to that of nanocosmetics. While silver is classified as a hazardous substance under the HSNO Act, there is, to our knowledge, no legislation requiring manufacturers or importers to comply with specific reporting or other regulatory obligations.

Table 2: Examples of nanosilver products available in New Zealand that might release nanosilver during use

Sector	Product Name	Brand	Description/Claims
Home appliances	Silver Wash washing machine (6.5kg; SW65USP SKU 41004)	Samsung	"Silver Wash - Kills germs in a cold wash"
Home appliance	Top Load Washing Machine (8kg; SW80USP SKU 32785)	Samsung	"Silver Wash - Kills germs in a cold wash"
Home appliance	Front loading washing machine (7.5kg; J1455AV)	Samsung	"Silver Nano Health System"
Home appliance	Front loading washing machine (7 kg; J1045AV)	Samsung	"Silver Nano Health System"
Home appliance	Top loading washing machine (SW55USP)	Samsung	"Silver Nano Health System"
Clothing	MR1036a Comp Short Sleeve Top MR1043a Elite Run Top MR1629a Elite Run Top MZ1358a Performance Polo	2XU	"with silver nano technology to provide permanent anti-bacterial and thermal regulation properties."[38]

A product line that has attracted particular concern overseas is the range of **Samsung SilverCare washing machines** available in New Zealand.[39] Release of nanoscale silver particles appears to be an intentional and routine feature of these products. According to the company, the silver particles are generated by "electrolysation" of silver plates inside the washing machine, such that "400 billion nano-sized silver ions are emitted, directly penetrating into fabrics during the wash and final rinse cycles"[40]. The company also claims that some of these particles remain on items for as long as a month following washing and continue to sanitise clothing.[41] The other silver nanoparticles generated during washing are then flushed away in wastewater, although estimates vary as to how much nanosilver enters the wastewater system.[42]

[38] http://nzstore.2xu.com/products.asp?Search=True&ResetActionTracker=True&Group=2351&SubGroup = 2370&NoSub=True&GroupName=Men's+Run+Tops

[39] As this report was being finalized, we became aware that two washing machine models manufactured by Daewoo also described as using silver nanotechnology are available in New Zealand. (See, for example, http://www.psp.co.nz/Products/Appliances/Daewoo/Washing-Machines/default.aspx.) No details of the mechanism for using nanosilver are described of this site but on the company's European site, the company describes the nanosilver washing machines as follows: "Nano Silver Washing Machine is made by use of Nano Poly Technology. "Nano" means 1 over billion, that is 1/10E+09. Nano Poly Technology is that particle of silver can be divided into 1 billion pieces. As a rule, the size of silver particle is 10 to 50 ppm. This particles of silver are mixed in plastic resin. Using Nano Poly Technology in "Pulsator" & "Tub U" in Washing Machine many hurtful bacteria in clothes shall be sterilized perfectly." http://www.daewoo-electronics.com/eu/products/living_washing_glos.asp

[40] http://www.samsung.com/nz/consumer/detail/detail.do?group=homeappliances&type=washingmachine&subtype=frontload&model_cd=J1455AVIW1/XSA

[41] According to Samsung, "the silver colloid will stick to the fabric, the positively loaded ions will break away and act with other negatively loaded cells. The whole process will last up to 30 days until all ions are emitted from the colloid" http://www.samsung.com/au/silvernano/site.html. Accessed March 2 2010.

[42] A report for the German Ministry for the Environment calculates that 2.75 mg of nanosilver are introduced into each 55 l wash. (Hund-Rinke K, Marscheider-Weidemann F and M Kemper (2008). "Beurteilung der Gesamtumweltexposition von Silberionen aus Biozid-Produkten". Forschungsbericht

From there, the ultimate environmental fate of the nanosilver generated by Samsung's washing machines will depend on the nature of wastewater treatment and disposal systems.[43]

Fabrics incorporating nanosilver may also lead to release of silver particles during washing. Preliminary research conducted in Switzerland and the US suggests that nanosilver fibres will likely be released during washing although how significant the loss will be appears to be depend on a range of factors including the way in which the silver is incorporated into the fibre.[44] Those experiments did not necessarily test the types of fibres used in the garments available in New Zealand, but do point to a risk that should be considered in assessing them.

Concern about the use of nanosilver

The growing, unchecked availability of nanosilver products in New Zealand is surprising given the significant concern expressed internationally around the use of nanosilver:

- The German Federal Ministry for the Environment has recommended that **commercial use of nanosilver be avoided** until more is known about the fate of nanoscale metal.[45] Subsequently, the German Federal Institute for Risk Assessment supported that call, urging the use of nanosilver in consumer products (including washing machines) to be avoided until safety research has been conducted.[46]

- The UK Royal Commission on Environmental Pollution considers **nanosilver to be among four nanomaterials that raise the greatest concern** in terms of environmental and biological exposure.[47]

- A UK-funded, global review of nanosafety research recommends "any industry/institute using silver nanoparticles should consider taking the necessary

des Umweltbundesamtes, Texte 43/08)

[43] According to a US federal advisory panel, " 'down-the-drain' disposal will result in introduction to sewage treatment plants, where much of the material is likely to be retained in sludge. Land application of these solids or releases of effluents containing particles will then lead to introduction into the environment." Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held November 3-5, 2009 on the Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products, January 26 2010.

[44] Geranio L, Heuberger M and B Nowack, "The Behaviour of Silver Nanotex *Environmental Science & Technology,* 2009, Online version; Benn TM and P Westerhoff, "Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics. *Environmental Science & Technology,* 2008, 42(11): 4133–413

[45] Umweltbundesamt, *Nanotechnik für Mensch and Umwelt. Chancen fördern und Risiken mindern*, October 2009, p. 8.

[46] German Federal Institute for Risk Assessment (BfR), "BfR recommends that nano-silver is not used in foods and everyday products." BfR Opinion Nr. 024/2010, 28 December 2009.

[47] Royal Commission on Environmental Pollution, *Novel Materials Report,* para 3.55.

steps **to reduce or eliminate the potential exposure of the environment to these nanoparticles**." [48]

- The European Parliament Environment Committee has proposed **a ban on the use of nanosilver in electrical and electronic equipment** on the basis that it presents "a major hazard to people and the environment in the phases of production and/or use and recovery."[49]

- The seminal report issued by the UK Royal Society and the Royal Academy of Engineers called for **a prohibition on the release of free, engineered nanoparticles** (such as would occur with the Samsung washing machines) until appropriate nanosafety research has been conducted.[50]

- Authorities for **publicly-owned wastewater treatment plants** in the state of California are extremely concerned about the growing use of nanosilver in products and the burden this could place on water treatment and the environment, and is recommending that all nanosilver products be regulated. The technical advisory group to these facilities has called on the EPA to regulate all nanosilver products as "to allow the unrestricted usage of products that intentionally release silver in to the environment would be an irresponsible neglect of the principles of environmental sustainability."[51]

Silver clouds and their linings: ignorance and early warnings

Such concerns arise in part because so little is yet known about nanosilver. A **US Environmental Protection Agency panel** recently concluded that traditional risk assessment may not be possible for nanosilver products because of a paucity of data to date and that a significant research effort is required.[52] That however, is not grounds for regulatory inaction. Indeed, early warnings from research conducted to

---

[48] Royal Commission on Environmental Pollution, *Novel Materials Report*, 2008, p. 39; Aitken R J, Hankin S M, Ross B, Tran C L, Stone V, Fernandes T F, Donaldson K, Duffin R, Chaudhry Q, Wilkins T A, Wilkins S A, Levy L A, Rocks S A and A Maynard, *EMERGNANO: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology*, 2009, p. iv.

[49] European Parliament Committee on the Environment, Public Health and Food Safety, 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). Draft report, Jill Evans Amendments 197 – 339. (PE439.897v01-00), March 13 2010, p 93. The full European Parliament is to vote on the proposed amendments in early July.

[50] The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties*, 2004, p. 47. The two science institutions reiterated this call in 2006, mentioning the example of the Samsung washing machines in addition to bioremediation strategies that might involve the release of free, engineered nanoparticles. The Royal Society and The Royal Academy of Engineering, *Nanoscience and nanotechnologies: opportunities and uncertainties Two-year review of progress on Government actions: Joint academies' response to the Council for Science and Technology's call for evidence*. RS Policy Document, 2006.

[51] Tri-TAC, Letter to the US Environmental Protection Agency regarding the Silver and Compounds Registration Review, September 22 2009.

[52] Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel, Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting held November 3-5, 2009 on the Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products, January 26 2010, p. 37.

date points to greater toxicity of nanosilver particles than the bulk form[53]; and an widely used database of nanosafety research offers over 110 peer-reviewed papers reporting research thus far on aspects of nanosilver safety, many of which point to potential or actual toxicity.[54]

As a leading US research center explains, "there is enough evidence from laboratory tests with both silver metal and nanosilver to be certain that potential adverse effects from silver nanotechnologies must be investigated."[55] Similarly, the above-mentioned UK study concluded there is already sufficient evidence to indicate that nanosilver is "detrimental" to the environment and that use of the precautionary approach should be considered**.**[56]

Regulatory status of nanosilver products

Silver's toxicity at the 'bulk-scale' is known to New Zealand regulators: it is classed as a hazardous substance under HSNO and is described by ERMA as "very ecotoxic in the aquatic environment" in relation to ecological indicators such as fish, crustacean and algae.[57]

The environmental effects and exposure scenarios from different nanosilver formulations used in different products will vary.[58] For some products, the amount of nanosilver released may be relatively small. However nanosilver products are a fast-growing category and it is the total and cumulative release of nanosilver from all products that is an issue. There are predictions that, on current course, the environmental release/loading from nanosilver products could be greater than that released by the photographic industry in the 1980s, before the industry shift to digital technologies.[59] Further, the synergistic impacts of allowing unfettered a new waste stream to join existing contaminant flows are also as yet unknown, and it would

---

[53] The above mentioned EMERGNANO review reports on research conducted in the UK which would suggest that even at low levels, nanosilver can cause harm to aquatic inverterbrates, p. 97. Also see Aegis Laboratory International, "Understanding Silver Based Antimicrobials: Mode of Action, Testing Methods, Environmental Fate, and Performance Expectations", September 2008.

[54] International Council on Nanotechnology, *Virtual Journal*: http://icon.rice.edu/virtualjournal.cfm. Search conducted June 4 2010. These are research papers dedicated exclusively to silver. There is, additionally, a number of papers reporting on research on the safety metal nanoparticles, including nanosilver.

[55] Davies J C, *EPA and Nanotechnology: Oversight for the 21st Century*. 2007, Washington, DC: Woodrow Wilson International Center for Scholars, Project for Emerging Nanotechnologies.

[56] Aitken R J, Hankin S M, Ross B, Tran C L, Stone V, Fernandes T F, Donaldson K, Duffin R, Chaudhry Q, Wilkins T A, Wilkins S A, Levy L A, Rocks S A and A Maynard, *EMERGNANO: A review of completed and near completed environment, health and safety research on nanomaterials and nanotechnology*, 2009, p. iv.

[57] ERMA, HSNO Chemical Classification Information Database.

[58] Luoma S N, *Silver nanotechnologies and the environment: Old problems or new challenges?* 2008, Project on Emerging Technologies 15, p. 6.

[59] "[I]t is in the wide-spread use of products employing the new silver technologies, each of which itself seems intuitively innocuous, that the greatest environmental implications of the new silver technologies lie. No individual product releases silver at rates equal to those released by photographic development in the 1980s. But the sum of silver releases from a proliferation of different products could release much more silver than did photographic development." Luoma S N, *Silver Nanotechnologies and the Environment: Old Problems or New Challenges*, 2008, Project on Emerging Technologies 15, p. 41.

appear, unexplored - certainly in New Zealand. Overall, we are not aware of any work by New Zealand regulators to determine which products might be more harmful than others, in which quantities, and whether certain environments might be more sensitive to exposure to nanosilver particles.

A further consideration that arises from the increasing use of nanosilver in consumer products is the potential for **bacterial resistance** to develop. This is of significance because nanosilver is said to have important medical uses, such as coatings on medical implants that prevent the buildup of bacterial biofilms that can cause life-threatening infections.[60] For this reason, members of the medical community have expressed concern at frivolous or unnecessary use of nanosilver in consumer products.[61]

Inaction on washing machines using nanosilver is of particular concern. Arguably, regulating a laundry appliance might at least seem to fall outside the scope of HSNO, which broadly speaking does not cover "manufactured articles". However, ERMA has acknowledged that the boundary between manufactured items and substances may in some cases be blurred and has pledged to use common sense in working through such instances.[62] The SilverCare washing machine is one such case where the use of the nanosilver as a pesticide could be regulated independent of the appliance, as ERMA has already foreshadowed:

> Manufactured products such as glues, paints, pesticides, etc (or granules or liquid formulations produced as a feedstock for some further manufacturing operation) however are not manufactured articles for the purpose of the HSNO Act regardless of how they are packaged or presented (i.e. they are substances). If they exceed the hazard thresholds, they will be considered to be hazardous substances within the jurisdiction of the Act.[63]

There is an international precedent for classing nanosilver as a pesticide. Following considerable efforts by non-governmental organisations in the US, the Federal Environmental Protection Agency agreed to regulate the SilverCare washing machine as a pesticide under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[64] That decision was formalised two years ago: sufficient time for New Zealand regulators to consider this approach. While the EPA ruling is not sufficient in that it does little more than require use of the machine to be registered, it does point to how the use of nanosilver as a biocide in consumer products might be classed so as to come under existing New Zealand law rather than remain the orphan it is today.

---

[60] Luoma S N, *Silver nanotechnologies and the environment: Old problems or new challenges?* 2008, Project on Emerging Technologies 15, p. 5.
[61] Professor Peter Collignon of Canberra Hospital, cited in Salleh A, "Call for control of nano-silver use", *ABC Science*, June 14 2009.
[62] ERMA, *Interpretations and Explanations of Key Concepts*, August 2009, 4.6 Manufactured articles as hazardous substances.
[63] Ibid.
[64] Environmental Protection Agency, *Federal Register: September 21, 2007* (Volume 72, Number 183): Pesticide Registration; Clarification for Ion-Generating Equipment.

Due diligence by a New Zealand company

New Zealand company, Fisher and Paykel has gone to considerable effort to assess the benefits and potential harm from adopting nanosilver technology in its refrigeration and laundry appliances. The company conducted tests to measure the antimicrobial efficacy of nanosilver in refrigeration and laundry appliances. It concluded that washing clothes at 20 C with detergent could achieve 99.79% elimination of fungus and bacteria (compared with Samsung's claims of 99.99% elimination rate).[65]

The finding that the use of nanosilver offers no exceptional advantage is also borne out by comparative research carried out in 2005 by the Korean Consumer Protection Board. That research found that the washing machines using nanosilver were not necessarily more effective at removing bacteria – the value-add claimed for the product - than four other brands of washing machines tested.[66]

At the time the technology first came onto the market around 2006, Fisher and Paykel felt under quite some pressure to incorporate nanosilver coatings because of the novelty and surrounding hype. According to the company, the decision not to use nanosilver was made not simply because the technology offered no benefit over existing approaches to hygiene; the company also cites concern at the potential contaminant burden on New Zealand waterways from the unnecessary use of nanosilver. For Fisher and Paykel, the technology was not in its view, consistent with the pursuit of sustainability:

> when most clothing manufacturers are making great inroads into making their industry more sustainable its hard not to see the use of this heavy metal as anything but a backward step.[67]

Fisher and Paykel's approach is exemplary. Most adopters of nanosilver appear to have little awareness that the technologies cannot as yet be risk assessed and that there is good reason to believe that nanosilver particles could be harmful. The regulatory holidays currently enjoyed by nanosilver and other nanomaterials incorporated in commercial products provide inadequate incentives for companies to do such due diligence; and unclear rewards for those which do.

[65] Personal communication, Anna Duncan, Fisher and Paykel, May 2010.

[66] Korea Consumer Protection Board, "Comparative Test of Drum-Type Washing Machines", November 18 2005. Also reported in "'Normal' drum washers can kill bacteria in clothes: consumer orea, November 18 2005.

[67] Fisher and Paykel, "Silver Nano Technology- Our perspective", 2007. Briefing for sales people.

Actions required on nanosilver products

Until such time as a risk assessment is conducted, we recommend that **no further nanosilver washing machines be imported and that they in this way be withdrawn from the market** until sufficient nanosafety research has been undertaken to assess them**.** There are different opinions about how much nanosilver is released during a single wash. However, the intentional release of silver particles and the potential cumulative burden overtime justify such regulatory action.

The potential cumulative effect of a range of nanosilver products on the market and the uncertainty about their fate means that even items as apparently innocuous as socks raise concern when they become a mass market vehicle for dissemination of nanosilver. **It would be a welcome move if retailers of products containing nanosilver particles removed these from the shelves until nanospecific risk assessment methodologies and regulatory provisions are in place, should ERMA not require such a step.**

Concurrently, the Minister for the Environment should give ERMA a clear mandate and the necessary resources to develop **a strategy for assessing and regulating nanosilver products over the lifetime of products incorporating the nanomaterial**. This should include:

- Identifying what nanosafety data is currently available to inform risk assessment;
- Identifying what nanosilver products are on the market, what types of nanosilver they contain, and the environmental fate of those substances during use and at end of product life;
- Developing a regulatory approach on the overall use of nanosilver in products, rather than simply assessing individual products in isolation;
- Addressing wider questions such as the desirability of using nanosilver in particular products and ensuring the ongoing viability of nanosilver as an option in medical applications.

With the number of nanosilver products on the rise, the Government should swiftly introduce interim measures to regulate nanosilver products. This could be done by way of regulation under HSNO – a regulatory pathway that allows rapid introduction of interim provisions while more in-depth consideration is given by Parliament. The longer the delay, the greater the potential for adverse environmental impacts and the greater the political resistance from manufacturers or operators who have invested in bringing nanosilver products to market.

The Way Ahead

"Little room for complacency"

Nanotechnologies are often billed as the next industrial revolution, and there are predictions that manufactured nanomaterials will become ubiquitous. On current course, it is an invisible revolution in New Zealand, with nanomaterials often entering into a diverse range of products unlabelled and apparently unnoticed by regulators and the public alike.

Government has known for some time about the presence of nanoproducts on the New Zealand market. Already in 2006, the Ministry of Research, Science and Technology (MORST) reported that "a range of products currently in New Zealand are likely to contain manufactured nanomaterials", but that no complete list was available because nanoproducts do not require labeling.[68] At that time, MORST warned that "there is little room for complacency" and that the drive to commercialise nanotechnologies should not overwhelm good governance.[69]

That advice did not find a receptive audience. New Zealand's approach to nanoproducts allows all-comers onto the market largely unregulated and unmonitored with the hope that nothing goes wrong. This provides products containing nanomaterials a regulatory discount over comparable substitutes that may use less risky technologies.

New Zealand is not alone in taking a complacent approach to regulating nanotechnologies. Indeed, a Ministry for the Environment official described New Zealand's approach as "following international best practice".[70] However, the 'safety in numbers' argument surely does not hold merit from an environmental stewardship perspective, particularly when 'best practice' amounts to doing nothing (or at best very little) in the face of a growing stream of products whose safety cannot be properly assessed, and whose environmental fate can in many cases scarcely be tracked - let alone predicted.

Advice from officials to Government has not helped stimulate the necessary political momentum for a change of approach. Briefings to Ministers have repeatedly stated that the regulatory regime – in particular HSNO – is well equipped to deal with nanotechnologies and their products. In 2008, the Minister for the Environment was advised that HSNO "is capable of preventing or managing any adverse effects to human health or the environment that may be attributable to manufactured nanomaterials".[71] To the extent that this statement is true, it relies upon a degree of

---

[68] Ministry for Research, Science and Technology, *Nanoscience and Nanotechnologies.* Roadmaps for Science, 2006, p. 51.
[69] Ibid., p. 20.
[70] Personal communication, Ministry for the Environment representative, Nanotechnologies: Here and Now seminar, April 23-24 2009.
[71] Ministry for the Environment, "Overview of Ministry's Involvement in Nanotechnology". Briefing for the Minister for the Environment. April 23 2008. In previous Ministerial briefings, officials stated that "[i]f a nanomaterial has hazardous properties, it would be regulated by the Environmental Risk Management Authority (ERMA) as a hazardous substance under the Hazardous Substances and New Organisms Act 1996 (HSNO). Officials have reviewed the HSNO Act and do not consider there are

knowledge about nanomaterials that is simply not at hand, and is unlikely to be for some time. Indeed, 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. Further, the harm that use of nanomaterials might cause may not arise from a so-called "gray goo apocalypse" but from chronic, widespread environmental exposure to nanomaterials that are not in the category of those attracting concern now but are used in small quantities in a range of products.[72]

Whatever the political justification for inaction thus far, New Zealand is already in catch-up position when it comes to regulating nanotech products. Internationally, the rate of product commercialisation has been estimated to be around 3-4 products per week[73] and the types of nanomaterials identified in this report are the first trickle of what is predicted to be a wide range of increasingly complex nanostructures and products.

The challenge of the nanoscale

A recurring theme of this report has been the level of ignorance and uncertainty around how nanomaterials and products incorporating them might act and react in biological and ecological systems. The scale of the effort required should not be underestimated. It is not simply about being 'a few steps' behind. The challenge of governing nanotechnologies has been likened by a UK government official to "shouting a warning to the driver of an express train as it thunders past".[74]

The nanoscale is indeed a new frontier, with the quantum effects that occur at that invisible level requiring new equipment, methodologies and information. Some estimates suggest it will be several decades before accurate prediction of the environmental behaviour of nanomaterials are available. After a considerable investigation, the UK Royal Commission on Environmental Pollution reached the pessimistic conclusion that the international research effort currently underway might not deliver results "before irreparable harm is done to individuals or ecosystems".[75] Nor should it be assumed the ecological/public health questions that nanomaterials pose will all be readily amenable to scientific enquiry.

Nanotechnologies are predicted to make a positive contribution across a range of areas, including healthcare and energy generation. While there is considerable hype around the economic and technological possibilities and many of the benefits identified relate to applications that are some time away from realisation, some of these may come to fruition.

---

any immediate gaps in legislative coverage for hazardous substances that are nanomaterials" (Briefing to the Minister for the Environment, "Nanotechnolo

[72] Anon., "Nano-Risks: A Big Need for a Little Testing". Editorial, *Scientific American Magazine*, January 2010.

[73] Project on Emerging Nanotechnologies, "New Nanotech Products Hitting the Market at the Rate of 3-4 Per Week", April 24 2008.

[74] UK Royal Commission on Environmental Pollution, *Novel Materials Report*, para 4.55.

[75] Ibid., para 4.9.

However, the desire to reap benefits from the technologies is not aided by ignoring or downplaying the scale of ignorance nor the effort required to establish their safety, let alone their contribution towards sustainability compared to other approaches and technologies.

New Zealand's environment – the ecosystems, waterways, soil and biodiversity that sustain us – is already under considerable pressure from existing industrial activities, consumption patterns and waste streams. Adding new, unknown waste streams to the environmental burden before there is adequate understanding of their effects is not responsible and an approach that has not served New Zealand well in the past.[76] As described with respect to nanosilver, the science thus far provides early warnings that affirm a precautionary approach must be adopted for nanomaterials.

Next steps

Government has commissioned a regulatory review of nanotechnologies that is due to be completed in the coming weeks. That is welcome, but due to scarcity of funds the scope of that report is restricted to whether relevant laws are triggered by nanotech activity and the presence of nanomaterials in products. This falls short of what is needed. Nanotechnologies pose considerable governance challenges and new, innovative approaches may be required. There is an opportunity for New Zealand to lead the way in developing such approaches to the governance of new technologies.

Until such work is properly completed and the necessary policy and legislation in place, Government will need to introduce **interim measures** that protect the community and the New Zealand environment from potential harm from nanotech products. Failing to adequately respond to the presence of nanoproducts, with their potential for harm to public health and the environment during manufacture, use and disposal is not acceptable. Some of these measures are set out above, in relation to nanocosmetics and nanosilver products.

Regulatory review alone insufficient

Review of the adequacy of regulation is important, but this just one step of many required for good governance of nanotechnologies. **In parallel,** Government should address the following:

- **Regulatory capacity** to properly manage the potential stream of new nanomaterials and products. Agencies such as ERMA and local authorities, to whom many administrative functions of hazardous substances management have been delegated, are significantly under-resourced, and are in serious catch-up mode with existing chemicals. The additional regulatory burden posed by nanomaterials will be significant because their regulation will be information intensive and require high levels of expertise to assess what will be a broad array of nanoparticles with wide variation of risk profiles for one nanosubstance, depending on surface chemistry, size and use, among others. A large backlog of

[76] Parliamentary Commissioner for the Environment, *Key Lessons from the History of Science and Technology: Knowns and Unknowns, Breakthroughs and Cautions.* March 2001; Harremoës P, Gee D, MacGarvin M, Stirling A, Keys J, Wynne B and S Guedes Vaz (eds) *The Precautionary Principle in the 20th Century. Late Lessons from Early Warnings.* European Environment Agency. Earthscan, 2002.

products and substances to assess as a result of ongoing political neglect will place added pressure on regulators and create conditions for suboptimal decision-making to cope with the workload.

- **Nanosafety capacity:** Thus far, New Zealand does not have a nanosafety strategy. Clearly, New Zealand will rely heavily on research being conducted in other countries with deeper public science investment pockets and on research collaborations run by institutions such as the OECD. However, this does not obviate the need for independent, domestic nanosafety capacity that is specific to New Zealand's ecology. (This was recognised by MORST in 2006, but there is as yet a strategy has yet to emerge.[77]) Developing such a strategy will require prioritisation of resources. Independence of nanosafety capacity from nanotechnology developers will be critical to public confidence in its authority.

- **Life-cycle governance:** Policy and legislation over the lifecycle of nanotech products is required. This will need to encompass manufacturing or processing, in particular worker safety and environmental discharges, through to product use and disposal, and should be employed as a tool for strategic decision-making as to the desirability of nano solutions compared to other means of achieving similar results.

Public engagement

Proper governance of nanotechnologies is not restricted to these relatively narrow issues of avoiding harm. There are more substantive issues that Government needs to **engage with the community** on to build critical capacity and a democratic mandate on the role the technologies might play in society.

Traditional, expert-dominated legislative processes will not be sufficient alone to determine whether and how best to move forward with nanotechnologies. Internationally, it is accepted that governments must engage with communities in an open-ended and iterative manner about nanotechnologies and their prospective role. The Ministry of Research, Science and Technology affirmed this in 2006, in the roadmap developed for nanotechnologies. In the Roadmap, the then Government and MORST identified the need for "inclusive forms of public engagement" that recognised that engagement should extend beyond questions of safety and "avoid simply paying lip service to the issues".[78]

Little has materialised from this commendable vision, and New Zealand is one of the few OECD countries yet to seriously engage its communities on nanotechnology. Fortunately, there is considerable expertise within New Zealand to draw upon to develop more participatory processes.

The importance of moving down the path of public engagement does not arise from the first generation of nanotechnologies alone. More startling, complex and troubling areas of technology – for example, in nanobiotechnology and synthetic biology – are looming and a commitment now to building an inclusive, critical culture on new technologies in society will reap rewards.

---

[77] MORST, *Nanoscience and Nanotechnologies.* Roadmaps for Science, 2006, p. 52.
[78] Ibid., pp. 49 and 19 respectively.