Sustainability Council Submission to the

Strategic Review of the Workplace Health and Safety System

November 2012

- Manufactured nanomaterials are rated as the top emerging workplace risk by the European Union's Agency for Health and Safety at Work.
- This review is described by government as "a once in 20 year chance to make substantive impacts". If is it is to address workplace risks of the 21st century, then it must establish safety requirements to protect New Zealand workers from nanomaterials.
- Nanotechnologies are predicted to become commonplace in manufacturing and other industries and are likely to be **a major source of occupational disease** for which New Zealand workplaces are at present ill-prepared.
- Due to inadequate regulation, the extent to which workers in New Zealand are already exposed is not known. However, it would be a mistake to categorise nanomaterials as a *future* workplace risk, and one that can be addressed at a later stage. In 2008, a Woodrow Wilson Centre project estimated that nanoproducts were reaching the market at a rate of 3-4 a week.
- An example of the urgent need to put nanotechnologies on the workplace safety map is carbon nanotubes. Types of these have been demonstrated to be similar in form to asbestos fibres and may cause similar damage and disease to the lungs. It is likely that products containing nanotubes are already making their way into manufacturing but government agencies have not instituted oversight of these.
- Carbon nanotubes are a clear example of the need for a precautionary response, given the research that links their form and effects to asbestos fibres. However, it would not be a sufficient regulatory response simply to focus on nanotubes and allow all other nanomaterials with less stark risk profiles to come onto the market without proper regulatory risk assessment. **It should be presumed that all nanomaterials carry risk until there is sufficient evidence to distinguish the harmful from the harmless.**
- It is also vital that the Taskforce advocates for proper regulatory coverage of nanomaterials. Government and regulatory agencies responsible for workplace safety have yet to take steps to manage the risks of nanomaterials

in the workplace and a government-commissioned study found numerous gaps in the HSNO and HSE legislation with respect to nanomaterials.

- There has been no official response to the study from the EPA, the Department of Labour or its successor ministry, to engage with the findings and identify ways in which the gaps are to be filled.

- On current course, Government will only act once there has been harm. In the meantime, developers and manufacturers will grow increasingly accustomed to working in an unregulated environment and more resistant to changes that would provide proper protection to New Zealand workers.

- The time for 'monitoring the situation' has expired, and it is time to introduce proper regulation and workplace protections.

- The Taskforce has a good foundation to work from: the report commissioned by MORST surveyed workplace safety laws, and identified a number of ways in which the HSNO and HSE Acts will currently fail to deliver sufficient workplace protections.

- We understand that the Taskforce is intending to keep recommendations high-level, rather than providing Government with a long list of issue-specific findings. Nevertheless, **we urge the Taskforce to highlight nanomaterials as a case study**, and to set out key steps required to make New Zealand workplaces 'nanosafe'. This is warranted because they are "platform technologies" and are expected to pervade manufacturing.

- This submission on two regulatory mechanisms that should be introduced, though other protections may also be required:

    - Regulatory risk assessment and approval before nanomaterials enter commercial use; and

    - Requirements that ensure transparency where nanomaterials are in use, and thus improve safe handling.

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Introduction

If anything is to distinguish "21st Century" workplace safety from the past, it is attention to early warnings signals and adopting precautionary action when faced with uncertainty or ignorance.

The story of asbestos is one of the major cautionary tales in workplace history – a how-not-to manual of early warning signals ignored and hopelessly retarded regulatory action. It was ultimately a failure of governance, rather than simply a story of a dangerous industrial material.

More than a century later, there are indications that among a new class of industrial materials, certain types behave like asbestos fibres. This presents a clear case for precautionary regulatory action in response to lessons from the past, given the physical closeness of a particular form of nanomaterial to asbestos fibres. Other nanomaterials may have less vivid characteristics, but could also become major new sources of occupational disease from prolonged exposure.

This submission focuses exclusively on the urgent need to protect New Zealand workers from the risks posed by manufactured nanomaterials. These have been rated by the European Union's Agency for Health and Safety at Work as the top emerging workplace risk in Europe.[1] They have also been ranked among the top emerging technology risks in six consecutive annual reports by the World Economic Forum's Global Risk Reports.[2]

Thus far, nanomaterials remain effectively unregulated in New Zealand and government agencies have little or no idea where nanomaterials are in use and have taken no steps to properly address this new source of workplace risk thus far.

The workplace safety review is described by government as "a once in 20 year chance to make substantive impacts"[3]. Addressing workplace risks of the 21st century will mean introducing safety requirements that protect New Zealand workers from nanomaterials.

In this submission, we use the term nanomaterial to refer to materials that are deliberately engineered to produce substances or devices at the nanoscale. Other terms used in the safety literature include manufactured or engineered nanoparticles. This is distinct from nanoparticles that are 'incidentally' created and not an intended product (such as by-products of welding or diesel exhaust). While particulate matter is a significant workplace risk, it is not the focus of this submission.

The Sustainability Council does not assume that all nanomaterials or products containing them will be harmful. However, given the pervasive uncertainty about the safety of nanomaterials, the early indications of harm from certain nanomaterials and the many challenges to overcome before regulators have sufficient data to properly assess their risk, a precautionary approach is required.

1. The Industrial Revolution on New Zealand's Doorstep

Nanotechnologies are widely seen to be the engine of a new industrial revolution and nanoprocesses and products are expected to enter all areas of industry.

Nanotechnologies are an emerging set of techniques that manipulate matter at the atomic level. At its most basic, this means manufacturing substances at the nanoscale – 1 micron is one thousand nanometres – to replace existing feedstock. More complex applications are in the pipeline, including nanomedicines, various nano devices that can change their state during operation and "nanosystems" that would, for example, build artificial organs and biological tissue.

The nanoscale is attracting major scientific and commercial interest because at that size range, known substances act differently. The novel properties found there – also referred to as quantum changes – include reactivity, strength, speed, durability and conductivity.

Nanomaterials are already incorporated in a wide and growing range of products and processes:

- **aerospace** (e.g. lightweight materials, resistant paints and coatings for aerodynamic surfaces)
- **automotive industry and transport** (e.g. scratch-resistant paints and coatings, plastics, lubricants, fluids, tyres)
- **construction** (e.g. insulation, stronger building materials, self-cleaning windows)
- **energy generation** (e.g. photovoltaics) **and storage** (e.g. fuel cells and batteries)
- **cosmetics** (e.g. sunscreens, tooth paste, face creams)
- **information and communication technologies, electronics and photonics** (e.g. semiconductor chips, new storage devices and displays)
- **security** (e.g. sensors to detect biological threats)
- **textiles** (e.g. protective clothing, stronger, self-cleaning or fire resistant fibres).[4]

Consumer products and intermediate products containing nanomaterials are already entering the market. Due to inadequate regulation, it is not known the extent to which workers in New Zealand are already exposed. In 2008 an online inventory estimated that nanoproducts were being reaching market at a rate of 3-4 a week and it is reasonable to assume that nanomaterials are already beginning to enter New Zealand workplaces.

2. Nature of the Workplace Risks Nanomaterials Pose

The nanoscale is also a new (bio)chemical frontier. It is the zone of 'quantum changes', where substances act and react differently at the nanoscale than in larger form. This is largely due to the different surface-to-volume ratio of particles in the nanoscale, which can make nanoforms of known substances more bioreactive.

The nanoscale is widely acknowledged to pose risks. The small size of the particles is reason to proceed carefully, as the EU's workplace safety agency describes:

> Because of their small size, nanoparticles can enter the body in three ways, via:
> - the digestive system (ingestion);
> - the respiratory tract (inhalation);
> - the skin (direct exposure).
>
> Once in the body, nanoparticles can move to other organs or tissues of the body. Such translocation is facilitated by the propensity of nanoparticles to enter cells, to cross cell membranes and to move along the nerves. Under certain conditions some nanoparticles can even cross the blood–brain barrier.[5]

The ability of nanoparticles to cross biological barriers is why they are of such great interest in medical and pharmaceutical R+D, but it is also why they pose considerable risks to public health beyond those applications.

Size is not, however, the only feature that determines risk at the nanoscale. Other properties (such as the coating) will also increase or decrease the potential for harm.

A distinction is often made between 'free' nanoparticles (those that workers handle in raw, particulate form) and nanomaterials that are "embedded in a matrix" and therefore less likely to expose workers to nanoparticulate matter. While useful, it is of limited value as even over the lifecycle of a product with 'embedded nanomaterials', certain phases may involve abrasion or handling that can expose workers to liberated nanoparticles.

2.1. State of ignorance and uncertainty prevails

The fundamental issue that the Taskforce must address in ensuring that New Zealand workplaces are 'nanosafe' is uncertainty.

This arises in two ways:

1. For most nanomaterials, there is not sufficient data to determine their safety, even for those that are already in commercial use
2. The nanoscale requires new instrumentation, characterization, detection and monitoring methods, as those used for larger scale particles are not suited for smaller particles.

There is now a long line of reviews assessing the state of knowledge that underscore how little we understand nanoparticles.[6]

One of the most recent - the US National Research Council (2012) - identified the following, overarching challenges in the area of nanosafety:

- Great diversity of nanomaterial types and variants.
- Lack of capabilities to monitor rapid changes in current, emerging, and potential ENM [engineered nanomaterials] applications and to identify and address the potential consequences for EHS environmental health and safety] risks.
- Lack of standard test materials and adequate models for investigating EHS risks, leading to great uncertainty in describing and quantifying nanomaterial hazards and exposures.[7]

As a result:

> The types of ENMs in products, the sources of exposure, and the expected magnitudes of the exposures typically are not known. Therefore**, there is considerable uncertainty about potential exposures of populations—workers, consumers, and ecosystems.**[8] **(emphasis added)**

Lack of data

This year, the UK Nanosafety Partnership Group characterizes the state of toxicological data for most nanomaterials as **"within the *Minimal* to *Suggestive* range".** For only a few nanomaterials, "what could be considered *Adequate* information" is at hand.[9]

A review published in August assessing the safety literature on one particular nanoparticle that is already being used commercially – silica – illustrates this:

> After a decade of research, answers for the most basic questions are still lacking: the data is either not there, or inconsistent because experimental approaches vary from paper to paper making it impossible to compare results.[10]

The diversity of nanomaterials noted above widens the knowledge gap considerably. There could be up to 50,000 different types of single-walled carbon nanotubes, each version with potentially different chemical, physical and biological properties.[11] Meanwhile, just five of the 200 different types of nanoscale TiO_2 reportedly in circulation are being investigated in an OECD coordinated nanosafety programme, and the risk profile of anyone of those 200 could undergo further variation if functionalized with coatings.[12]

A member of the US National Research Council expert review panel cited above describes the variety of nanomaterials as "mind-boggling" and said "**There are not enough beakers to do all the experiments required.**[13] (emphasis added)

The "conditions of partial knowledge and significant ignorance" are likely to persist for years to come. The UK Royal Commission on Environmental Pollution concluded that the nanosafety research effort "will not necessarily deliver results **before irreparable harm is done to individuals or ecosystems"**.[14]

Lack of detection and monitoring capabilities

Equipment that would allow for comprehensive exposure assessment is either still in development or so prohibitively expensive and thus likely outside the resources of small and medium businesses, in particular.

Few workplace measurements of engineered nanoparticle exposure have been made, due to a lack of detection technologies that can distinguish engineered particles from background particulate matter.

Lack of known safe occupational exposure limits for nanomaterials

There are currently no known safe occupational exposure limits.[15] NIOSH has proposed provisional exposure limits for carbon nanotubes and nanoscale TiO2 but these have yet to be finalized and it is not known whether these are sufficient.

It is also uncertain how well existing control and risk management approaches will provide adequate protection for workers. According to Safe Work Australia, there are some indications that existing approaches may offer some level of protection but in the absence of toxicological data, these remain hypothetical**.**[16]

2.2 Early warning signals

It is not simply a case of uncertainty, however. There is a host of literature identifying the potential for a wide range of nanoparticles to cause harm to humans and other species.

Carbon nanotubes (CNTs) are one example. These hollow, cylindrical forms of carbon are lightweight, powerful conductors and extremely strong, and have already made their way into a range of electronic products, reinforced plastics, solar cells and sporting gear. In 2008, the first of a number of studies was published, indicating that certain types of CNTs are similar in form to asbestos fibres and may cause similar damage and disease to the lungs.[17] (Carbon nanotubes are presented as a case study below.)

This year, another nanoscale form of carbon - **graphene platelets** – were found to "pose an unusual risk to the lungs and the pleural space because of their aerodynamic properties".[18]

2.3 Early commercialization, lack of regulation increase risk

Early commercialisation without proper governance or regulation is compounding the risks to public health and the environment:

> innovation rates in nanotechnologies exceed our capacity to assess the human and environmental consequences of those innovations, especially when deployed at commercial scales.[19]

As characterised by the US National Research Council:

> There is insufficient connection and integration between generation of data and analyses on emergent risks and strategies for preventing and managing the risks.[20]

The NRC concludes that without proper governance, the potential for the technologies to make a positive contribution is uncertain:

> without strategic research into emergent risks associated with it—**and a clear understanding of how to manage and avoid potential risks**—the future of safe and sustainable nanotechnology-based materials, products, and processes is uncertain.[21] (emphasis added)

Put another way, the potential for unsafe or risky nanotechnology products is greater in absence of appropriate safety research and regulation.

3. New Zealand Regulatory Response Thus Far

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" and that "there is little room for complacency". The drive to commercialise nanotechnologies, it stated, should not overwhelm good governance.[22]

Two years later, the National Occupational Health and Safety Advisory Committee identified the need to monitor the risks to workers from nanotechnologies "as the health and safety implications of working with these technologies are still relatively unknown".[23]

Four years on, regulatory agencies and government departments have yet to introduce any measures to track, risk assess or regulate nanomaterials.

Agencies such as the EPA state that they are monitoring the situation and regularly attend the OECD Working Parties focused on nanosafety.[24] That approach has not translated into any meaningful workplace safety measures. Conversations with then Department of Labour officials confirmed that there was no plan of action and no intention to develop one in the foreseeable future.

A solitary exception is cosmetics regulation. There, the EPA has acknowledged that there is a reason to regulate nanocosmetic ingredients because "there is insufficient information available on the risks associated with nanomaterials".[25] This move is welcome. But while labeling is necessary, in isolation it is not sufficient to manage the risks that nanocosmetics pose. Further, the EPA has yet to extend this recognition of the need to actively manage the risks that nanomaterials pose to the much wider terrain it is responsible for.

Government-commissioned report identifies major gaps in regulatory protection

One positive step is the review commissioned by then Ministry of Research Science and Technology to establish the extent to which nanomaterials are covered by existing laws. The review was undertaken by the University of Otago Law Faculty's Centre for Law and Policy on Emerging Technologies.[26] That review (the "Otago Report") also examined the three instruments relevant to workplace safety:

- The Hazardous Substances and New Organisms Act (HSNO)
- The Health and Safety in Employment Act 1992 (HSE Act), and
- The Approved Code of Practice for the Management of Substances Hazardous to Health in the Place of Work 1997 (the Code)

The study identified numerous ways in which HSNO, HSE and the Code give no or little meaningful coverage of nanoparticles. In doing so, the report provided government agencies with a good framework for easily identifying where reforms are needed.

The following section summarises the gaps and then identifies some of the regulatory and other measures that the Taskforce should recommend in order to make New Zealand workplaces nanosafe.

Before turning to these, the Government and regulatory agency responses to this report are worth noting.

Government response to the report

There has been no meaningful response from the then Department of Labour (or its successor, the Ministry for Business Industry and Employment), the Ministry for the Environment, or the EPA. At the time of the report's release, the Minister for Science and Innovation's scripted statement was that "the report confirms issues that the government is already aware of/and does not identify of highlight any new concerns."[27]

In light of the evident lack of protection that current law provides, it is extraordinary that Government was either previously aware of these significant deficiencies and has done nothing to address them, or that their identification in the Otago Report has not prompted any response.

This underscores how vital it is that the Taskforce make clear that a safety regime to protect NZ workers from nanomaterials must be introduced.

We understand that the Department of Labour accepted the findings. We also understand that certain agencies – the Ministry for the Environment and then ERMA – found fault with aspects of the report. However, in the absence of any analysis by the relevant agencies that details where the authors erred in their assessment, the report stands and we recommend the Taskforce use it as a basis for introducing reforms that will protect New Zealand workers from nanomaterials.

THE NEXT ASBESTOS?

The Case of Carbon Nanotubes

Carbon nanotubes (CNT) provide a useful litmus test of regulator activity thus far. CNT are hollow, cylindrical forms of carbon at the nanoscale. There are many types, including single-walled nanotubes or multi-walled (with more than one concentric cylinder of carbon).

In 2008, the first of a number of studies was published indicating that certain types are similar in form to asbestos fibres and may cause similar damage and disease to the lungs.[28] The initial findings did not demonstrate the pathways to the lungs but the effects when CNT became lodged there.

Regulator responses overseas

In response to these findings, the US National Institute of Occupational Safety and Health (NIOSH) has confirmed that precaution is required:

> these findings of adverse respiratory effects in animals indicate **the need for precautionary measures** to limit the risk of occupational lung diseases in workers with potential exposure to CNT and CNF.[29]

Three years ago, a Safe Work Australia report stated:

> Evidence leads to a conclusion that as **a precautionary default**: all biopersistent CNTs, or aggregates of CNTs, of pathogenic fibre dimensions could be considered as presenting a potential fibrogenic and mesothelioma hazard unless demonstrated otherwise by appropriate tests…"[30]

In a more significant development, Safe Work Australia announced last month that CNT should be classed as hazardous substances.[31]

That assessment was made against the *Approved criteria for classifying hazardous substances* (Approved Criteria) and the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Safe Work Australia recommended that CNT be provisionally classed as hazardous with respect to **repeated or prolonged inhalation exposure** and **carcinogenicity (see box)**

While more research has been done on multiwalled CNT than single-walled types, Safe Work Australia recommends that there is sufficient evidence of harm to treat both as hazardous:

> Although the toxicity of SWCNTs has not been as extensively studied as MWCNTs, they both produce pulmonary inflammation, oxidative stress, interstitial fibrosis and granulomas[32]

Safe Work Australia's Hazard Classification for CNT

Repeated or prolonged inhalation exposure

Approved Criteria:
Xn; R48/20 Harmful:
Danger of serious damage to health by prolonged exposure through inhalation;

GHS:
Specific target organ toxicity following repeated exposure Category 2
Warning: May cause damage to lungs/respiratory system through prolonged or repeated inhalation exp

Carcinogenicity

Approved Criteria: Xn; R40
Harmful: Limited evidence of a carcinogenic effect;

GHS
Carcinogen Category 2 Warning: Suspected of causing cancer

Contrast this with **Government agency response in New Zealand.**

In 2010, the Sustainability Council contacted the EPA to test the regulator's preparedness to act on early warning signals. We provided a list of peer-reviewed literature that indicated the potential for harm from CNT and asked the regulator to confirm:

- Whether the evidence met HSNO standards of 'hazard', or
- Whether there was sufficient indication of potential harm for the regulator to invoke its discretionary powers to act with (pre)caution

The EPA simply stated that the studies were "preliminary" and that it was waiting on reports from other countries.[33] When approached for further clarification, the CEO noted that

> while the HSNO Act provides for decisions to be precautionary where there is scientific or technical uncertainty … it does not empower ERMA to act when there are suspicions but little or no evidence.[34]

This response not only shows an improper characterization of the available evidence; it also suggests that the regulator is not moved to act on early warnings.

Meanwhile, carbon nanotubes may enter New Zealand workplaces and products without explicit requirements for importers and manufacturers to account for them and provide suitable workplace safety measures.

Products containing carbon nanotubes are already available in New Zealand. Among them, sports equipment such as CNT-reinforced badminton and tennis rackets and archery items will not present risks in the workplace. There is, however, reason to believe that CNT products that could well pose health and safety risks are already making their way into New Zealand workplaces. Officials have intimated that they may be present in vehicle parts (such as timing chain covers). They may also be incorporated in high-performance resins being used in the marine industry, and which may be coming into the country via online retail. In both of these instances, grinding and sanding during boat building and repair as well as during vehicle servicing/repair could expose workers to airborne CNT.

In November, we approached the EPA to ascertain:

- what progress, if any, the regulator has done in the intervening two years and
- what steps it might take in the light of Safe Work Australia's recommendation that CNT be classed as hazardous substances.

At the time of filing this submission, the EPA has given a preliminary response, noting that CNT will need to be notified if theses are not present on the New Zealand Inventory of Chemicals (NZIoC), and that no applications have been received for CNT import or manufacture. This approach, however, provides no guarantee that CNT will be come to the regulator's attention as it depends on what Chemical Abstract Number (CAS) number manufacturers or importers assign CNT. While some CNT manufacturers market CNT under CAS number 308068-56-6 (not present on the inventory), others assign CNT products the same CAS number as carbon black (1333-86-4) or carbon (7440-44-0) or graphite (7782-42-5)[35], although CNT have a very different risk profile to carbon black, carbon or graphite. CNT imported under these CAS numbers would not need to be notified to the EPA as they are already present on the NZIoC and would not trigger any risk assessment process.

This demonstrates the need for the regulator to be proactive by determining the correct CAS number for carbon nanotubes and by classing CNT as hazardous substances.

Carbon nanotubes are a stark example and the case for regulation is clear given the research that links their form and effects to asbestos fibres. However, it would not be a sufficient regulatory response simply to focus on nanotubes while leaving unregulated other nanomaterials, some of which may turn out to be harmful long after they have been allowed into commercial circulation.

Instead it should be presumed that all nanomaterials carry risk until there is sufficient evidence to distinguish the harmful from the harmless.

4. How NZ Workplace Safety Laws Fail at the Nanoscale

The key finding of the Otago Report is that the HSNO and HSE Acts currently provide no or uncertain coverage of nanomaterials.

The Otago Report details various instances. The underlying reasons for this may be summarized as follows:

- **Hazard triggers:** HSNO and HSE coverage is activated by the presence of 'hazards'. However nanosafety is in such early stages that hazard or evidentiary burdens such as toxicity in HSNO or the HSE - may not be triggered. This means that the Act may not cover the vast majority of nanomaterials for some time.

- **Newness:** Nanomaterials are at present primarily nanoscale forms of existing, previously approved substances. The law is silent on whether nanomaterials are new in themselves and this makes it unclear for all parties within workplace safety as to whether the nanoform of existing substances must be specifically. The EPA predecessor ERMA has stated that the nanoform of a substance will be treated differently if the hazards are different from the 'larger' forms of the substance.[36] However, in practice, we have yet to see any activity by the EPA that would suggest it is actively monitoring this or that a new evaluation for a nanoversion of an existing substance would be reliably and routinely triggered when evidence suggests the hazards are different.

- **Without specific reference to materials in the nanoscale**, HSE tools that should create transparency and set out safety procedures – such as the Code, safety data sheets – will not tend to be silent.
- **Regulators interpretation of the precautionary mandate:** Where discretionary powers are available to regulators to act in cases where evidentiary requirements are not met but there are indications of potential harm, these have not been exercised. A case in point is the precautionary mandate that would allow the EPA to take a precautionary approach, even where the evidentiary-based hazard thresholds are not met.

Gaps in the Health and Safety in Employment Act

Excerpts from the Otago Report

- "There is a potential regulatory gap in that the "current state of knowledge" [s2A] regarding harm attributed to many NMs [nanomaterials] is deficient." (p. 30)

Hazard identification

- "Nanoparticles and NMs may be covered by the hazard identification process. However, the identification of hazards may require the employer to know or suspect nanoparticles are a potential risk to human health. Deficiencies in current knowledge may preclude the identification of nanoparticles as a hazard." (p. 32)

- A potential regulatory gap may exist if the deficiencies in nanotoxicology prevent a potentially harmful NM from being identified as a significant hazard. (p. 37)

Risk assessment:

- "Risk assessment, including hazard identification methods, may not be appropriate for NMs. It may be necessary to amend the SDS and labelling systems to recognise that NMs have unique properties. Current processes may not consider the high surface area and increased reactivity of NMs. Therefore, the current methods and procedures may be inadequate for the safety of workers." (p. 33)

Lack of definition or capability to monitor for exposure:

- "There are further difficulties in protecting New Zealand workers from adverse health effects of nanoparticle exposure. First there is no national or international agreed definition to describe nanoparticles. Second equipment and methods to enable routine measurements of nanoparticles are not yet available." (p. 33)

Safety Data Sheets:

- "Given the deficiencies in current knowledge regarding the safety of NMs, SDS requirement that health effects and health hazard information should be included is unlikely to trigger the provision of nanotoxicological information." (p. 38)

- the SDS does not expressly require information relevant to NMs (p. 38)

Monitoring:

- "There are currently no effective methods available in the workplace to measure nanoparticles or exposure to nanoparticles, nor are there currently effective methods for assessing particle surface area. Therefore, the assessment process described in The Code will be difficult for hazardous substances that contain NMs or for nanoparticles." (p. 39)

5. Considerations

There are several considerations in making New Zealand workplaces 'nanosafe':

Can the risks of nanomaterials be effectively managed at present?

The fundamental question is whether it is currently possible to ensure proper health and safety protections. This question has been raised by a US federal agency inspectorate, in assessing whether the US Environmental Protection Agency is currently able to manage the risks of nanomaterials. The Federal Office of the Inspector General (OIG) concluded that:

> Even if mandatory reporting rules are approved, **the effectiveness of EPA's management of nanomaterials remains in question"**

This, because:

> EPA does not have sufficient information to determine the risks nanomaterials pose to human health and the environment.[37]

The OIG also questioned whether, in the event of a contamination incident, remediation would be possible:

> the Agency may not be able to monitor, identify, and remediate nanomaterial contamination if it were to occur in the natural environment.

For such reasons, the US federal workplace safety agency has recommended minimizing exposure:

> Minimizing occupational exposure to the lowest possible level is the most prudent approach for controlling materials of unknown toxicity, such as nanomaterials.[38]

Some companies suggest that the lack of data and nano-specific methods for characterization and detection are reason not to regulate for the time being. This would be viable only if commercialization were also to be delayed until such issues have been resolved.

As many developers and manufacturers are intent on using nanomaterials, regulation using the best available options must be introduced, and subject to ongoing review as new information and risk management methods come to hand. The most important step is to make the use of nanomaterials subject to regulatory risk assessment and approval as a condition for commercialization (as outlined below). If sufficient data is available and there are effective methods for eliminating or minimizing risk to workers, then there is a case for approving the commercial use of a particular nanoscale substance or product. Those information and management standards should form minimum expectations for regulators asked to approve a nanomaterial on to the market.

Such conditions will incentivise targeted nanosafety research. In the absence of these, the risks of nanomaterials will be socialized – on workers, their families and communities and the public health purse.

Regulation is not a show-stopper

Regulating nanotechnologies is not a barrier to commercialization. On the contrary, industry surveys overseas suggest that lack of regulation is a barrier to commercialization:

> The emerging nanomaterial manufacturing community has repeatedly stated that it cannot operate effectively in an environment of uncertainty created by a lack of authoritative recommendations from government agencies.[39]

The insurance industry is also strongly urging good regulation of nanomaterials and is loathe to provide cover until this is in place.[40]

Indeed, recent workplace tragedies and the history of occupational disease burdens underscore that unregulated or poorly regulated technologies can come at a great cost to groups within society, regulatory credibility, the public health purse and New Zealand's reputation.

Good workplace safety laws will ensure that manufacturers chose the best overall option. This may, in some cases, mean that nanomaterials are not selected for manufacturing until sufficient safety research has been done to support their safe use.

Nanomaterials are not the only option

Nanomaterials will rarely be the only option available for manufacturers. (They may provide some performance advantages for the commercial properties sought, but this must be set against what is not known about them and the potential harm to public health.) As such, there is no in principle reason for giving nanomaterials a regulatory discount over alternative options, which may pose fewer risks.

Voluntary mechanisms not sufficient

In canvassing options the Taskforce may consider voluntary approaches. Experience in other jurisdictions indicates that this would bear little fruit and likely generate significant frustration.

Australian, UK and US schemes intended to inform regulators of where nanomaterials are in use in manufacturing were dismal failures, with manufacturer responses accounting for just a tiny portion of nanomaterial use.[41] A survey of workplace safety practices in nanomaterial companies in 14 countries revealed very low awareness and adherence to guidance documents. The results led the researchers to conclude that "**a more top-down approach from regulators is needed** to protect workers and the environment" (our emphasis). Further:

> our research suggests that current ''soft'' regulatory approaches are likely insufficient and, given the current inconsistencies between government-recommended and company-reported practices, regulators should be cautious about the efficacy of further guidance and information alone to protect the environment and the nanotechnology workplace from harm.[42]

In the light of overseas experience, we urge the Taskforce to recommend mandatory measures wherever possible. These are outlined in the section following.

Regulation slow in other countries; still New Zealand lagging

Progress to provide proper protection for workers is slow in most countries. However even then, New Zealand lags behind other countries. In any case, employer and government responsibility to protect workers from risks such as those nanomaterials pose are *absolute*, not relative to the level of protection offered in other countries. Finally, New Zealand is likely to be a net importer of nanotechnology products and processes and should not be paying twice for the technologies, first in technology rents and products and secondly, from the public health purse, for the costs of any harm to workers.

6. Necessary Protections: What the Taskforce Can Propose

We understand that the Taskforce is intending to keep recommendations high-level, rather than providing Government with a long list of issue-specific findings.

Nevertheless, we urge the Taskforce to highlight nanomaterials as a case study, and to indicate some of the key steps that can be taken to make New Zealand workplaces nanosafe. This is warranted because they are platform technologies that are expected to become pervasive.

6.1 Regulatory risk assessment as a condition for commercialisation

The most important step is **to require regulatory risk assessment prior to commercial use** under the HSNO Act.

This can be achieved in two ways:

- A **new group standard** requiring that all nanomaterials be notified and risk assessed prior to commercial use should be introduced to HSNO.
- A **new section in the HSNO statute** that would be exclusively dedicated to regulatory risk assessment and approval of nanomaterials. This would sit alongside sections of the Act dealing with new organisms, and hazardous substances.

Issues

- A group standard is probably the easiest way of securing routine risk assessment as this can be achieved without statutory change. The drawback of this approach is that nanomaterials would still be classed as hazardous substances and subject to the evidentiary thresholds that are not appropriate given the lack of safety research that would either meet the definition of hazard or demonstrate that any given nanomaterial is not hazardous as currently defined. This could be addressed by additions to the regulations setting out the regulatory definition of hazard.
- Whichever route is taken, it should be explicit that the specific requirements cover nanoscale versions of substances already in use to remove any confusion as to whether new approvals are required.
- Group approvals of classes of nanomaterials can be made to streamline the approval process, provided that their risk profile allows for this.
- Either route would require further detail to address questions such as characterization and hazard identification. This is a task for the relevant regulators and not issues that the Taskforce needs to resolve.

HSNO is **a first port of call**. The Act covers substances and not goods in which hazardous substances are used. As such, it will not cover all nano products to which workers may be exposed. Regulating nanomaterials under the Act will nevertheless be a cornerstone of managing the risks of nanomaterials pose New Zealand workers. The Otago Report can be used to identify the full suite of laws that will need to be amended to ensure nanosafety in the workplace, and the Taskforce can recommend that a plan of regulatory action be developed to achieve this.

6.2 Transparency and traceability: SDS

Requirements for Safety Data Sheets and other HSE labeling and information tools should be amended to specify that nanoscale substances must be notified and safe handling procedures (where these are known) set out.

Requiring the presence of namomaterials in raw or processed form to be notified through the manufacturing and supply chain is fundamental to risk management. This provides information to employers, workers and regulators that can be used to ensure that proper protections and safety processes are used when handling such materials.

At present, there is no requirement for nanoscale substances to be identified on Safety Data Sheets. This means that even though the risks of a substance may be very different in the nanoform, employers do not need to make known that the nanomaterials are present.

6.3 Nano-specific Code and Guidance Materials

> Guidance, while not sufficient on its own to ensure safety, can be an effective means of creating awareness and indicating best practice because it has "powerful persuasive" authority.

Currently, the Code is silent on nanomaterials and a nano-specific Code and making other guidance is relevant to nano would provide help employers in particular identify the risks/hazards that nanomaterials might pose in their workplaces and how best to address these.

6.4 Risk-relevant definition of nanomaterials

The idea that the nanoscale is 1-100nm is still used in many policy discussions, but is increasingly seen as scientifically arbitrary and an inappropriate framing for the purposes of risk management.

This is because the quantum effects that are of interest, and potentially of concern from a risk management perspective, also occur above 100 nm.[43] As discussed in a recent, joint report of the WHO/FAO:

> The current state of knowledge about the unique properties of engineered nanomaterials **does not permit identifying exact criteria that present "bright lines" for inclusion, or exclusion, for nanospecific risk evaluation.** For example, the use of 100 nm as a cutoff point for particle size does not have a biological basis, **so one cannot simply assign this as an inclusion or exclusion criterion, such as "if the mean particle size exceeds 100 nm, then no nanospecific testing is necessary.[44] (emphasis added)**

This view has recently been endorsed by the UK Nanosafety Partnership Group:

> the size cut-off for nanoparticles **has no basis in toxicology,** meaning that there is no step-change in toxicity when a particle becomes below 100 nm in any dimension.[45]

Clearly persisting with a definition that is not relevant to risk will undermine efforts to ensure proper workplace safety. It will also create perverse incentives for manufacturers to use nanomaterials that hover above the 100nm mark in order to duck regulation. Anecdotally, we are already aware of instances where companies are redirecting R+D programmes to focus on nanoparticles above 100nm for that very reason.

The detail of such considerations is beyond what the Taskforce will wish to address but it can recommend this task be undertaken by government agencies within a reasonable timeframe.

6.5 Priority nanomaterials

In order to determine where to place resources for providing guidance, assessment and the like, it may be necessary for the relevant agencies to identify "priority nanomaterials". That is, those that are:

- most likely to be already in use in New Zealand workplaces, and/or
- used most commonly, and/or
- involve greater exposure due to handling or processing, and/or
- of heightened risk due to their properties.

As recommended by Safe Work Australia, this analysis should include:

> a complete life-cycle analysis of the nanomaterial […] to identify potential 'hotspots' of worker exposure, including construction, packaging, manufacturing, handling, maintenance or cleaning work, and end-of-life and safe disposal issues.[46]

6.6 Medical surveillance

It is generally held that at present, qualitative - not quantitative - risk assessment is possible. It is also not yet known how well existing means of protecting workers from particulate matter will be for nanomaterials. Further, in many cases there is likely to be a long latency period before any health effects become evident.

To assure that such approaches are working and in keeping with good occupational health practice, medical screening and surveillance should be considered for all workers using nanomaterial.[47]

NIOSH has stated that medical surveillance is prudent to protect workers' health where risk is felt to be present, or at least cannot be ruled out.[48]

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