



INFO/ ADVICE BRIEF

ADVISER: Ruth Kearon/Phuong Pham via Josh Shaughan

Issue	USE OF NANOPARTICLES: EMERGING AND TOPICAL ISSUES
Key Advice	That you NOTE the information provided by the regulatory agencies in the health portfolio on nanoparticles and any emerging and topical issues
Comment	<ul style="list-style-type: none">• The Government has robust regulations to ensure the safety of food, medicines and chemicals and has put in place a program of work to examine the potential environmental, health and safety impacts of nanotechnologies.• The current regulatory framework involves a number of regulatory agencies, including the Therapeutic Goods Administration (TGA), the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and Food Standards Australia New Zealand (FSANZ). All regulatory agencies have been aware of the possible future uses of nanotechnology and the health and safety aspects of the technology for some time.• This work includes understanding potential health and safety effects of materials in the nano-size range, looking at the adequacy of current regulatory frameworks, and investigating the effectiveness for nanomaterials of current workplace control measures.• The Monash report ('A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework') was commissioned by the Australian Government to assess the adequacy of nanotechnology regulation. Australia was amongst the first governments in the world to do this.• It found that while Australia's regulatory regime is well placed to respond to the impact of nanotechnology, there are certain aspects of the regulatory system that will potentially need amending in the future, which will require a long-term effort across multiple government agencies.• A key conclusion of the report was that "All regulatory frameworks applying to conventional products also were found to apply to nanomaterials and nanotechnology-based products."• NICNAS, TGA and FSANZ are continually assessing the risks of these products and have been working with their overseas counterparts and international organisations to address emerging issues.• NICNAS, TGA and FSANZ have not identified any emerging issues relating to nanotechnology. Below are examples of topical issues that these agencies are monitoring. <p>NICNAS:</p> <ul style="list-style-type: none">• advises that since April 2009 concerns have been expressed in the media and by interest groups on the ability of the regulatory framework to manage the risks posed by nanomaterials and thereby protect human health and the Australian environment;• advises that since April 2009 there have been issues raised in the media of potential health concerns from exposure to carbon nanotubes particularly for those working with

- nanomaterials. Concerns stem from their structural similarity to asbestos fibres and animal experiments indicating the potential for mesothelioma formation;
- is aware of recent issues that have been raised by CSIRO in relation to zinc nanoparticles in sunscreens entering the body (which is primarily an issue for TGA);
 - has worked at agency, national and international levels to develop a comprehensive *Proposal for Regulatory Reform of Industrial Nanomaterials* to bring together the regulatory and technical activity streams. Stakeholder outreach activities, such as developing information products for use by industry and community, and compliance monitoring to detect any potentially illegal introduction of nanomaterials, support the overall strategy; and
 - has access to several national and international toxicological reviews and has specifically commissioned a literature review on six nanomaterials of interest to NICNAS – titanium dioxide, zinc oxide, cerium oxide, nanosilver, carbon nanotubes and fullerenes – all of which are taken into account when making regulatory decisions. NICNAS' Nanotechnology Advisory Group gives it access to unpublished developments in the application of nanotechnology by industry and in research.

TGA:

- advises that the use of silver nanoparticles is one of the fastest growing product categories using nanotechnology;
- advises that from time to time there are concerns raised in the media and in correspondence by members of the public in relation to nanosilver and possible human health or environmental health impacts;
- advises that nanosilver poses questions common across nanomaterials such as its unique characteristics may alter its toxicity. Combined with unknown levels of exposure, this equates to an uncertain risk.

FSANZ:

- has not, to date, received any applications to approve any new type of engineered nanoscale particles for use in food;
- advises there is a potential for nanotechnology to be used in food and food packaging. The Australian Government has in place robust regulatory arrangements to ensure the safety of food through the *Australia New Zealand Food Standards Code* (the Code) administered by FSANZ. Since 2006, FSANZ has been proactive in considering the implications of the use of nanotechnology in food and food packaging and has undertaken a comprehensive review of the current food regulations to ensure that all foods involving nanotechnology are safe.
- Food regulators in many countries have been watching the development of nanotechnology and considering the potential risks and benefits. Within Australia, the emergence of the commercial application of nanotechnology is being monitored by several Australian Government agencies including Food Standards Australia New Zealand (FSANZ). FSANZ continues to work within the whole of government framework to consider the implications of nanotechnology.

Background

NICNAS

Under the *Industrial Chemical (Notification and Assessment) Act 1989* all regulatory requirements that apply to conventional forms of chemicals also apply to their nanoforms. Industrial chemicals, including nano-forms, introduced into Australia through import or manufacture must either be listed on the *Australian Inventory of Chemical Substances* (AICS), or be notified and assessed as a new chemical prior to its introduction. NICNAS

assesses existing chemicals (i.e. chemicals listed on the inventory) on a priority basis in response to concerns about their health and/or environmental effects.

Known commercial applications of organic (eg polymers) and inorganic (eg metal oxides) nanomaterials are in surface coatings, cosmetics (including secondary sunscreens), printing inks, water treatment products and fuel catalysts.

Carbon nanotubes are a group of chemicals, not listed on the AICS and therefore require notification to, and assessment by, NICNAS prior to commercialisation, unless they meet specific exemption criteria. Chemicals introduced under exemption categories must pose "no unreasonable risk" to human health and/or the environment. Importers and manufacturers who make use of NICNAS exemption categories have a legal obligation to notify NICNAS annually and to hold data to support the claim that these chemicals pose no unreasonable risk. This data is audited by NICNAS.

The objective of the *Proposal for Regulatory Reform of Industrial Nanomaterials* is to ensure the safe and sustainable use of industrial nanomaterials through appropriate regulation, industry cooperation and community confidence. It addresses the uncertainty surrounding the risks posed by industrial nanomaterials, appropriateness of current risk assessment protocols and acknowledges NICNAS' linkages with national and international agencies that are actively considering similar issues;

The overarching principles governing NICNAS' strategy include using the best available scientific evidence in regulatory decisions and systematic review of decisions as new scientific information becomes available. Where available scientific information is insufficient to support safety, measures to protect public health and the environment will be recommended.

Given the known hazards of carbon nanotubes, it is unlikely that they will meet the 'no-unreasonable risk' criterion and be eligible for a NICNAS exemption. NICNAS is currently reviewing the human health effects of carbon nanotubes with a view to developing appropriate hazard classification and labelling statements for these chemicals for occupational health and safety. The review is expected to be completed by late 2010.

Media articles reported in early 2009 and 2010 on a possible causal link between exposure of workers in China to nanoparticles and lung damage and death. Information in the articles indicated that workers were also exposed to conventional chemicals that are subject to greater regulatory controls in Australia (than those in China). These controls include stringent requirements to minimise worker exposure that may have minimised any adverse health outcomes in that situation. NICNAS is working collaboratively with relevant occupational health and safety and research agencies to identify issues of potential concern arising from these media reports.

NICNAS and TGA are aware of further research and analysis, which in some cases is supported by the Australian Government, to provide a robust evidence base from which to make further decisions on the use and management of nanomaterials, such as nanosilver. A program of work is underway to examine the potential environmental, health and safety impacts of nanotechnology, including:

1. Australia is participating in the OECD program plans to test nanomaterials for their physical-chemical properties; environmental degradation and accumulation; environmental toxicology; and mammalian toxicology. Australia has agreed to participate in testing nanosilver as part of this program.
2. Following up from the report on environmental fate of nanoparticles, the Department

of the Environment, Heritage and the Arts has now commissioned a research study to determine the partitioning of both metallic and carbon-based nanoparticulates, namely nanosilver, cerium oxide, fullerene and carbon nanotubes in a representative number of Australian soils and in soils exposed to urban waste streams.

3. Safe Work Australia, within the Department of Education, Employment, and Workplace Relations, conducted a review of organisations using nanomaterials from data available in the public domain. They identified eight universities working with nanosilver and five companies.
4. The National Industrial Chemical Assessment and Notification Scheme (NICNAS) located within the Department of Health and Ageing, conducted a voluntary call for information on the use of nanoparticles in the commercial sector during 2005-06. No usage of nanosilver was recorded.
5. Agencies are conducting further workplace and company surveys currently to update data in this area.

TGA

Following exposure to relatively high oral or dermal doses of silver colloids, silver can be deposited under the skin and turn it to a blue-grey colour (called 'argyria'), and this is considered the main human toxicity associated with silver. However, the main concern with nanosilver is the environmental risk, particularly if significant amounts are dispersed into the environment.

Silver is known to be effective in killing a wide range of bacteria and this behaviour is attributed to the silver ions (positively charged silver atoms). Nanotechnology allows silver to be incorporated into fabrics, plastics and as coatings on medical devices to reduce infection rates, coatings on artificial joints and pacemakers to prevent deadly microbial growths, and coating of ceramic filters for water purification. However, most products that use nanosilver are household items where the nanosilver provides an antibacterial function to keep surfaces clean or to reduce odours.

Some products, such as washing machines that feature silver as a cleaning agent, are designed to release silver into the wash and hence the environment; other products, such as self-deodorising socks, contain nanosilver impregnated into the fabric. In this case, the nanosilver is not designed to leach out, but some studies show that nanosilver can indeed be washed out of these articles.

Nanosilver poses questions common across nanomaterials such as how its size, shape, charge state, and other characteristics alter its toxicity. Combined with unknown levels of exposure, this equates to an uncertain risk.

There is an increased risk of environmental impacts from nanosilver if substantial releases occur as the use of these types of products becomes more widespread. Internationally, levels of conventional silver emissions have peaked in the past, and the characteristic was for a halo of silver contamination to surround domestic waste treatment plants. This is not a current problem, but total silver emissions will need to be monitored as the nanosilver applications grow.

*****CONFIDENTIAL*****

In 2009, the Department of the Environment, Water, Heritage and the Arts published a

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report on the fate of nanomaterials in the environment with a focus on interactions with water and soil. (the report is currently awaiting clearance). It notes that although laboratory results show toxicity to algae and fish species from metal oxide nanoparticles, there is limited data on the impact of nanoparticles in the natural environment. The interaction with the soil and water will greatly influence the threat to the environment of metal oxides and this will have to be established on a case-by-case basis.

FSANZ

- continues to monitor its regulatory measures and supporting material to ensure they capture the use of nanotechnology in food;
- continues to assess new scientific data or information as it becomes available and in 2009, FSANZ undertook a review of the scientific literature relevant to oral bioavailability, as a determinant of potential toxicological novelty, of nanomaterials. This review consolidates all available current scientific and technical information on the assessment of nanotechnology in this area as it relates to food safety;
- has actively participated in and contributed resources to the FAO/WHO Expert Consultation on Nanotechnology. This international workshop considered the food safety implications of the application of nanotechnology to food and was driven by FSANZ, FAO and WHO;
- continues to review assessments undertaken by international agencies and maintain an open dialogue with other regulatory agencies including those who may be considering the use of nanotechnology in food applications;
- continues to respond to issues raised by groups such as Friends of the Earth (FOE), who currently maintain the stance of banning the use of nanotechnology in food applications. FSANZ maintains that the available scientific evidence does not show any cause for concern in relation to public health and safety; and
- will continue to monitor and ensure the food regulatory system is suitably adapted to regulate nanotechnology.

Clearance

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Outcome: Outcome 1: Population Health

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Attachments:

Not applicable