



NICNAS Information Sheet

Nanomaterials

September 2006

What is Nanotechnology?

Nanotechnology is engineering at the atomic or molecular (group of atoms) level. It is a group of enabling technologies that involve the manipulation of matter at the nanoscale (generally accepted as 100 nanometres or less) to create new materials, structures and devices. At this very small scale, the chemical and physical properties of materials can change, such as colour, magnetism and the ability to conduct electricity.

Nanotechnology research and its applications have been growing rapidly worldwide for the past decade, with an increasing number of nanotechnology products becoming commercially available. These include nanoscale materials, powders, solutions and suspensions of nanoscale materials as well as composite materials and devices having a nanostructure.

Nanotechnology, its products and applications have the potential to offer significant social and environmental benefits. For example, it is anticipated that nanotechnology will lead to new medical treatments and tools, more efficient energy production, more effective pollution reduction, and stronger, lighter materials. The potential benefits of nanotechnology to industry and the community in general have been highlighted in several reports (see list of information sources). However, there are concerns that some applications and products of nanotechnology may present health, safety and environmental hazards and risks.

Nanotechnology can be either a 'top-down' technique, such as etching and milling of larger material, or a 'bottom-up' technique that involves assembling smaller subunits to produce the nanoscale product.

What are Nanomaterials?

Engineered nanomaterials are materials designed at the molecular (nanometre) level to take advantage of their small size and novel properties which are generally not seen in their conventional, bulk counterparts. The two main reasons why materials at the nano scale can have different properties are increased relative surface area and new quantum effects. Nanomaterials have a much greater surface area to volume ratio than their conventional forms, which can lead to greater chemical reactivity and affect their strength. Also at the nano scale, quantum effects can become much more important in determining the materials properties and characteristics, leading to novel optical, electrical and magnetic behaviours.

Nanomaterials have extremely small size as their defining characteristic, although there is as yet no agreed national or international definition for nanomaterials. The current working definition of nanomaterials is a material having at least one dimension 100 nanometres or less. To put nanomaterials into perspective, up to 10,000 could fit across a human hair. Nanomaterials can be nanoscale in one dimension (eg. surface films), two dimensions (eg. strands or fibres), or three dimensions (eg. particles). They can exist in single, fused, aggregated or agglomerated forms with spherical, tubular, and irregular shapes. Common types of nanomaterials include nanotubes, dendrimers, quantum dots and fullerenes.

NICNAS Information Sheet

Products containing engineered nanomaterials are already in commercial use, with some having been available for several years or decades. The range of commercial products available today is very broad, including stain-resistant and wrinkle-free textiles, cosmetics, sunscreens, electronics, paints and varnishes. Nanocoatings and nanocomposites are finding uses in diverse consumer products, such as windows, sports equipment, bicycles and automobiles. There are novel UV-blocking coatings on glass bottles which protect beverages from damage by sunlight, and longer-lasting tennis balls using butyl-rubber/nano-clay composites. Nanoscale titanium dioxide, for instance, is finding applications in cosmetics, sun-block creams and self-cleaning windows, and nanoscale silica is being used as filler in a range of products, including cosmetics and dental fillings.

NICNAS and Nanomaterials

NICNAS is the Commonwealth regulatory authority responsible for industrial chemicals. It provides a national notification and assessment scheme for industrial chemicals introduced to Australia, and aims to protect the public and the environment from the harmful effects of these chemicals.

Under the *Industrial Chemicals (Notification and Assessment) Act*, 1989 (the Act), a 'chemical' includes chemical elements and compounds or complexes of chemical elements (including those contained in mixtures). An industrial chemical is any 'chemical' that has an industrial use. Therefore, nanomaterials which are considered to be chemicals and are used for industrial purposes will fall within the scope of NICNAS. Chemicals which are used solely as therapeutic agents, agricultural or veterinary chemicals, food or food additives are outside the scope of NICNAS.

NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used or released to the environment. NICNAS also assesses those chemicals that have been in use in Australia, known as existing chemicals, on a priority basis in response to specific concerns about their health and/or environmental effects.

Nanomaterials fall into both categories – new chemicals and existing chemicals. A chemical not listed on the Australian Inventory of Chemical Substances (AICS), which is based on the chemical formula and CAS number of chemicals (with no size definition), is generally regarded as new and must be notified and assessed for human health and environmental risks prior to their introduction and use. Nanoscale forms of chemicals already listed on AICS (ie. have identical chemical formula and CAS number) are currently considered to be existing chemicals. These nanoscale, existing chemicals can be selected for assessment if there is a potential risk of adverse health and/or environment effects. To date, NICNAS has not assessed any nanomaterials with novel properties.

NICNAS needs to ensure that the regulatory regime is appropriate for assessing and regulating nanomaterials in order to protect human health and the environment. To do so, it is necessary to understand both the hazards of the nanomaterials and the levels of exposure that are likely to occur.

What industrial Nanomaterials are in use in Australia?

There is very little publicly available information on what nanomaterials are used in Australia for industrial (including domestic and cosmetic) purposes. To date, research, development and commercialisation of nanomaterials has generally been for nanoscale forms of existing chemicals. That is, the nanomaterials have the same chemical formula and CAS number as existing, bulk materials. There are no regulatory requirements for companies to notify NICNAS of the introduction of these types of nanomaterials. Consequently, the extent of use of industrial nanomaterials in Australia is not readily available.

NICNAS Information Sheet

In February 2006, NICNAS issued a voluntary call to Australian industry to provide information on uses and quantities of nanomaterials imported or manufactured for industrial purposes, and use in cosmetics and personal care products. Approximately 20 companies responded, with about one third reporting that the material(s) was only used for research purposes. The largest group of nanomaterials reported was the metal oxides, utilized in surface coatings and toner, adsorbents, catalysts and cosmetics. Other nanomaterials included zeolite and clays for adsorption and structural purposes. This information is valuable as it allows NICNAS to understand the extent of use of nanomaterials in Australia and will assist in prioritising regulatory efforts to ensure safe introduction of nanomaterials.

Any chemical that is considered to be a new chemical, whether it is in nanoscale or bulk form, must be notified to NICNAS.

Do Nanomaterials pose health and/or environmental risks?

Concerns have been raised about potential health and environmental impacts of nanomaterials. This is principally because of their small size and novel properties and because research in experimental animals and in vitro systems on some nanomaterials has indicated potential environmental and health effects. Almost all concerns have related to free, rather than fixed nanomaterials.

There has been little research into the potential hazards (health, safety and environmental effects) of these materials, their exposure, fate or persistence or the risks to people or the environment exposed to them. Due to this lack of information, there are many uncertainties as to whether nanomaterials pose or are likely to pose health and environmental risks. However, the body of data is increasing, as more organisations research the health and environmental aspects of nanomaterials. For example, there is a great deal of ongoing research into nanoscale metal oxides, carbon nanotubes, fullerenes and quantum dots.

Hazards

The same properties that nanomaterials are designed to exhibit are also properties that may cause nanomaterials to present human health and environmental hazards. For example, with decreasing particle size, the surface area to mass ratio becomes greater. This means that there are potentially more atoms on the surface area to react with the environment and other substances. High reactivity is a desired property for many intended applications of nanomaterials, such as catalysts, however, this increased reactivity can lead to greater toxicity for cells and living organisms.

The physicochemical properties of nanomaterials are determined by the chemical composition, surface structure (including surface coatings), small size and associated increase in surface to volume ratio, solubility, shape and aggregation. The influences of physicochemical properties on the toxicological and eco-toxicological profile of nanomaterials are not yet fully understood. Changes in physicochemical properties can also increase the potential for some nanomaterials to exhibit fire and/or explosion hazards or catalytic activity.

Limited data from preliminary studies in experimental animals have shown that some nanomaterials can accumulate in the lungs and translocate to the blood, cross the blood-brain barrier, and produce inflammatory responses and are capable of direct interaction with DNA in vitro.

Parallels have also been drawn with the incidentally produced nanoparticles (such as ultrafine particles in diesel exhaust and other combustion products) and their associated adverse health effects. To date, there have been no confirmed reports of adverse effects to humans or the environment as a result of exposure to engineered nanomaterials.

NICNAS Information Sheet

In summary, little is known about the toxicology of nanomaterials, though early indications are that some nanoscale materials have greater reactivity than their bulk counterparts. Based on the limited data that are available, there are concerns that the adverse effects of nanomaterials cannot be reliably predicted or derived from the known toxicity of the bulk material.

Exposure

Factors determining human and environmental exposure include the extent and pattern of use, the exposure pathway and fate and behaviour of the nanomaterial. While reported applications of nanomaterials are diverse, there are very little data on actual uses and applications, thus increasing the difficulty of determining exposure in Australia. Some nanomaterials are designed for use in solution or suspension, others are immobilised in (or on the surface of) other materials, while some applications may require the nanomaterial to be used in an unconstrained form. There is potential for exposure to humans (workers and the public) and the environment during manufacture, use and disposal of nanomaterials, but it is difficult to identify and quantify at present.

Nanomaterials are orders of magnitude smaller than conventional bulk materials, and therefore may result in an increased dose, due to a greater capacity for absorption, and potential for translocation within the body and/or access to cells. Information on routes of exposure, movement or translocation of materials once they enter the body and interaction of materials with the body's biological systems are largely unknown.

Due to differences in physical and chemical properties, the fate, persistence and behaviour (such as agglomeration) of nanomaterials may differ from the bulk material and lead to a greater potential for increased exposure and dose.

Priority needs for Nanomaterials

There is insufficient knowledge concerning the characterisation, use and exposure, fate and persistence, toxicology and ecotoxicology of nanomaterials, to allow for adequate assessment of the risks of nanomaterials.

The difficulty in collecting this information is compounded by the current lack of uniform internationally accepted nomenclature for nanomaterials, and the absence of standard methods for their characterisation and measurement.

Several reviews have identified the following key areas that require further research to enable adequate risk assessment and regulation of nanomaterials:

Definitions, nomenclature and characterisation:

For toxicity testing and exposure measurement of nanomaterials, it is important to adequately characterise the materials. Chemical and physical properties that may be important for characterising nanomaterials include size, size distribution, surface area, shape, chemical composition and agglomeration state, though their importance will vary for different types of nanomaterials. It is probable that new methods will be required to characterise these properties.

There is also an overarching need for internationally agreed nomenclature for nanomaterials and nanoparticles, to facilitate harmonised descriptions of the materials and to eliminate ambiguities.

NICNAS Information Sheet

Hazards to human health and the environment:

There is a clear need for more data to understand the hazards that nanomaterials may present to human health and the environment.

The existing standard test methods may not be adequate to identify some of the hazards of nanomaterials. Methodologies for assessing toxicological endpoints may need to be developed or existing toxicity tests adapted.

There is also a need to review testing strategies and base datasets for human and environmental hazards and evaluate their adequacy to identify the potential hazards of different types of nanomaterials.

Exposure:

There is a need for data on use and potential sources of exposure to nanomaterials, their fate and behaviour. Methodologies to measure human and environmental exposure may need to be adapted or new ones developed to account for the different characteristics considered to be important for nanomaterials.

What is being done internationally and in Australia?

International activities

Risk assessment of nanomaterials has become the focus of increased international attention. International agencies and individual governments, research teams and industry are actively working to produce, gather and share information to assist in formulating appropriate approaches to the regulatory challenges posed by nanotechnology and nanomaterials.

For example, the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology has started work in the area of risk assessment of nanomaterials. The OECD recognises that there should be a coordinated approach towards ensuring the safety of nanomaterials in order to help realise the benefits of nanotechnology. The OECD Chemicals Joint Meeting is considering establishing a Working Group to address issues such as international co-ordination in regulatory approaches; development of assessment methodologies and testing schemes; and information sharing and exchange in risk assessment and management.

There is also increasing activity within the international standards community to address standardisation and nomenclature issues arising from the development of nanotechnology. The International Standards Organisation ISO/TC 229, Nanotechnologies, held its inaugural meeting in November 2005.

A number of institutions have published reports discussing the potential environmental, safety and health risks associated with the manufacture, use and distribution of nanomaterials, including the UK Royal Society with the Royal Academy of Engineering, the UK Department for Environment Food and Rural Affairs, the US Environmental Protection Agency, the US National Institute for Occupational Safety and Health, the Woodrow Wilson International Center for Scholars. These reports are varied in approach and scope and are useful sources of information (see attached list).

Australian national activities

In March 2005, the *Prime Minister's Science, Engineering and Innovation Council* (PMSEIC) Working Group published a report on the opportunities that nanotechnology can provide Australian industry and the impediments to its uptake. Whilst acknowledging the potential benefits of nanotechnology, the report also

NICNAS Information Sheet

identified the need to address potential health, safety and environmental implications of nanotechnology and recommended development of a comprehensive impact and risk analysis framework.

In response to the PMSEIC report, the National Nanotechnology Strategy Taskforce was established within the Department of Industry, Tourism and Resources to consider options for a coordinated, national approach to nanotechnology across the Federal and State Governments.

NICNAS activities

While nanomaterials have the potential to provide significant benefits to society, it is important to ensure they are introduced safely. It is timely that NICNAS considers nanomaterials and their potential health and environmental impacts.

The challenge for NICNAS is to ensure the regulatory framework can adequately identify and assess any risks of nanomaterials, and that there are appropriate mechanisms for the management of the risks.

The current needs of regulators, in order to encourage the safe development of nanotechnology while ensuring the health and safety of the community at work, in the marketplace and in the environment, are many. Therefore, national and international collaboration is important to address issues of mutual benefit, such as nomenclature, measurement, standardisation, and common approaches to risk assessment.

Activities NICNAS is currently undertaking include:

- Issuing of a voluntary call for information for nanomaterials, seeking information on uses and quantities of nanomaterials imported or manufactured for industrial uses, including use in cosmetics and personal care products. This information will assist in understanding which nanomaterials are available on the market or close to commercialisation, and in focussing our efforts to ensure the adequacy of the regulatory scheme. NICNAS will analyse the information and prepare a report on the extent and scope of the use of nanomaterials in industrial, cosmetic and personal care products in Australia. This information will in turn assist in prioritising regulatory considerations to ensure these nanomaterials can be introduced safely.
- Monitoring relevant new chemical notifications will help NICNAS to identify research areas and to focus on ensuring it can adequately address safety issues for nanomaterials.
- Working with the Department of Health and Ageing and other government agencies and departments to ensure a nationally consistent approach to regulation of nanomaterials in keeping with COAG principles of good regulation. NICNAS is a member of interdepartmental committees providing advice to the National Nanotechnology Taskforce.
- Engaging the chemical industry and the community through the active participation in discussions on nanomaterials, such as with NICNAS's Industry Government Consultative Committee, and Community Engagement Forum.
- Participating in relevant national efforts, including the Standards Australia Nanotechnologies Committee (NT-001), to ensure a consistent approach in standards setting and to promote sharing of information.
- Taking an active role in international activities, such as the OECD Steering Committee on Safety of Manufactured Nanomaterials, to develop appropriate regulatory standards for nanomaterials and developing best practice testing protocols and risk assessment methodologies.
- Maintaining a watching brief on outcomes of research being undertaken on the health, safety and environmental aspects of nanomaterials.

NICNAS Information Sheet

Any changes to the current regulatory framework to address nanomaterials need to be based on scientific evidence. It is important that NICNAS works collaboratively with industry and the community and other national and overseas agencies that regulate nanomaterials to ensure a consistent risk based regulatory approach.

NICNAS will continue to work openly and cooperatively with all interested parties within the framework of the *NICNAS Community Engagement Charter* available at:

http://www.nicnas.gov.au/Community/CEF_Charter_PDF.pdf

Abbreviations / Glossary

AICS	Australian Inventory of Chemical Substances
DNA	Deoxyribonucleic acid
Nano	1 part in 10 ⁹ or one thousand million
Nanometre	one thousand-millionth of a metre
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OECD	Organisation for Economic Cooperation and Development
PMSEIC	Prime Minister's Science, Engineering and Innovation Council
USEPA	United States Environmental Protection Agency
UV	Ultraviolet

Information sources

Further information on nanotechnology in Australia can be obtained by contacting the National Nanotechnology Strategy Taskforce at nano@industry.gov.au, or by visiting the Taskforce website at:

<http://www.industry.gov.au/nano>.

Invest Australia maintains information on Australian nanotechnology capacity at:

<http://www.investaustralia.gov.au/index.cfm?menuid=0DA5E4E7-B0D0-36D2-5C0BF55FC0AAA99D&setLanguage=AU>

There are many reports and reviews on nanotechnology. Some of the most useful are:

PMSEIC Report: Nanotechnology, Enabling Technologies for Australian Innovative Industries, March 2006
http://www.dest.gov.au/NR/rdonlyres/1E1B501A-727A-4153-85EF-134B2DAF0925/4112/nanotechnology_pms_eic110305.pdf

UK Royal Society and Royal Academy of Engineering: Nanoscience and nanotechnologies: opportunities and uncertainties, July 2004

<http://www.nanotec.org.uk/finalReport.htm>

UK Government Response to the Royal Society and Royal Academy of Engineering Report: Nanoscience and Nanotechnologies, Opportunities and Uncertainties, February 2005

http://www.ost.gov.uk/policy/issues/nanotech_final.pdf

UK Government Department for Environment Food and Rural Affairs: Characterising Potential Risks Posed by Engineered Nanoparticles, October 2005

<http://www.defra.gov.uk/environment/nanotech/nrcg/pdf/nanoparticles-riskreport.pdf>

US Environmental Protection Agency: Draft Nanotechnology White Paper, December 2005

<http://www.epa.gov/osa/nanotech.htm>

NICNAS Information Sheet

OECD and Allianz: Opportunities and Risks of Nanotechnologies

<http://www.oecd.org/dataoecd/4/38/35081968.pdf>

Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Coordination and Communication, April 2006

[http://appli1.oecd.org/olis/2006doc.nsf/linkto/env-jm-mono\(2006\)19](http://appli1.oecd.org/olis/2006doc.nsf/linkto/env-jm-mono(2006)19)

Other useful websites:

European Commission Nanotechnology information

<http://cordis.europa.eu/nanotechnology/>

UK Royal Society Nanotechnology information

<http://www.royalsoc.ac.uk/landing.asp?id=1210>

UK Government Department for Environment Food and Rural Affairs

<http://www.defra.gov.uk/environment/nanotech/>

US Environmental Protection Agency

<http://es.epa.gov/ncer/nano/>

US National Institute for Occupational Safety and Health

<http://www.cdc.gov/niosh/topics/nanotech/>

European Nanotechnology Gateway

<http://www.nanoforum.org/>

Asia Pacific Nanotechnology Forum

<http://www.apnf.org/content.php?content.1>

Lux Research

<http://cordis.europa.eu/nanotechnology/home.html>

The Innovation Society

http://www.innovationsgesellschaft.ch/nano_regulation.htm

Woodrow Wilson International Centre for Scholars and the Pew Charitable Trusts
'Project on Emerging Nanotechnologies'

<http://www.nanotechproject.org/7/mission>

International Council on Nanotechnology

<http://icon.rice.edu/>