



NICNAS Information Sheet

Adjustments to NICNAS new chemicals processes for industrial nanomaterials

December 2010

Frequently Asked Questions

What are industrial nanomaterials?

Industrial chemicals are defined by how they are used. For example, industrial chemicals are components used in such things as paints, dyes, inks and surface coatings, plastics, cosmetics and consumer goods.¹

Industrial nanomaterials are nano-forms of industrial chemicals.

Nanomaterials are chemicals engineered to take advantage of their small size and novel properties which are generally not seen in their conventional, bulk counterparts. Nanomaterials can exist as single, fused, or clustered forms, with spherical, tubular or irregular shapes.

At present, there is no internationally agreed definition for nanomaterials. Since consultation with stakeholders in late 2009-early 2010, NICNAS has developed a **working definition** that is consistent with other national and international working definitions for industrial nanomaterials for regulatory purposes. This is:

... industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (ie. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (ie. having an internal or surface structure at the nanoscale)"

Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (eg. increased strength, chemical reactivity or conductivity) that enable novel applications
- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.

¹ See "Who does What" at the end of these FAQs for a description of the types of chemicals that are regulated by NICNAS and how other regulatory schemes contribute to regulating chemicals in Australia.

Why is there a need for regulatory reform of industrial nanomaterials?

While many of the novel properties of nanomaterials may be beneficial, concerns have also been raised about the uncertainty that these novel properties present to human health, safety and the environment. Research into the potential hazards (the inherent property of an agent having the potential to cause adverse effects) of these materials is increasing, but is not yet comprehensive. A consequence of the current regulatory framework is that the extent of use of industrial nanomaterials in Australia is uncertain.

The objective of the adjustments to NICNAS's New Chemicals Program processes for industrial nanomaterials is to ensure appropriate regulation, industry cooperation and community confidence in this new technology. Adjustments to the existing NICNAS framework for New Chemicals will address some of the uncertainty surrounding the risks posed by industrial nanomaterials and the appropriateness of current risk assessment protocols.

NICNAS has links with national and international agencies that are actively considering similar issues.

How is NICNAS going to change the way industrial nanomaterials are regulated?

NICNAS has a specific role in the overall regulatory framework for industrial chemicals (including nanomaterials) in Australia, under legislation provided by the *Industrial Chemicals (Notification and Assessment) Act 1989*, (the ICNA Act). Other government agencies are responsible for regulation of nanomaterials in medicines, food, pesticides and veterinary medicines. (See *Who Does What?* section at the end of this FAQ sheet)

Regulatory requirements depend on whether a chemical is considered a "new" chemical or an "existing" chemical under NICNAS. The legal mechanism to distinguish between these is the Australian Inventory of Chemical Substances (AICS).

Nano-forms of chemicals not listed on the national inventory are considered to be "new chemicals". The NICNAS new chemicals program includes exemptions, permits and certificates, which represent increasing levels of pre-market scrutiny. In general, a new chemical must be notified to and assessed by NICNAS prior to its use in Australia. Chemicals introduced under exemptions must be reported annually to NICNAS. Introducers must hold data to meet "safeguards" for each specific exemption category and these are auditable by NICNAS.

The adjustments to these arrangements for nano-forms of *new chemicals* are administrative amendments. These are:

- exclusion of the introduction of nanomaterials through exemption categories where human or environmental exposure can reasonably be anticipated, thereby converting the current post-market compliance approach for exemptions to a pre-market assessment approach, and
- exclusion of self-assessments by industry, thereby ensuring that NICNAS undertakes pre-market assessment of all new nanomaterials.

Introducers reporting use under exemption categories, and those applying for certificates or permits will be required to declare that their chemicals are not nanomaterials. More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions. In addition, NICNAS may stipulate permit conditions for conventional chemicals where it can be reasonably assumed that a nano-form may be introduced in the future.

These new administrative arrangements take effect from 1 January 2011.

NICNAS has developed guidance for industry on these changes. The document, *New Chemicals Requirements for Notification of Industrial Nanomaterials*, is provided in the *NICNAS Notifiers Handbook*.

What about nanoforms of existing chemicals?

Nano-forms of chemicals on the national inventory are considered to be "existing chemicals". Currently, all legislative requirements applicable to conventional industrial existing chemicals also apply to their nano-forms. Many industrial nanomaterials in international commerce have conventional forms which are on the AICS and are therefore considered to be existing chemicals. At present these can legally be introduced and used in Australia without notification to NICNAS. NICNAS can, however initiate reviews of existing chemicals when health or environmental concerns are identified.

For nano-forms of *existing chemicals*, options for a mandatory notification and assessment program are under development in consultation with NICNAS's Nanotechnology Advisory Group. Stakeholder consultation on these options is expected to occur in 2011.

Further exploration of this approach will be complemented as:

- NICNAS gains experience through the implementation of proposals for new and existing nanomaterials outlined above.
- Further national and international scientific activities increase knowledge in this area.

How are international governments addressing this issue?

In the USA and Canada nano-forms of chemicals on the respective national inventories are subject to existing chemical requirements and nano-forms of chemicals not on the national inventories are subject to new chemicals requirements. The USA and Canada are taking steps to review their frameworks, impose nano specific risk management measures and reconsider appropriate data requirements.

In Europe, and under the Registration, Evaluation, Authorisation and Restriction of Chemicals Substances (REACH) legislation, the overarching obligation is to ensure that there are no adverse human health or environmental effects. This applies to both conventional chemicals and nanomaterials. Consideration is being given by the European Commission to the need to specifically address nanomaterials.

What are NICNAS's next steps?

When administrative changes are made to NICNAS operations, businesses are expected to comply. Our expectation and experience is that these changes are usually respected and implemented by industry. Legislative requirements are enforceable by law. Specific penalties apply to non-compliance with provisions under the Act.

NICNAS activities include a compliance function that monitors compliance with legislative and administrative requirements through an annual audit program. NICNAS will include compliance monitoring with these administrative changes and any subsequent legislative requirements relating to industrial nanomaterials on its annual compliance audit programs.

As part of its core business NICNAS undertakes a significant stakeholder engagement and outreach program. This includes specific workshops to inform and assist industry to comply with changed requirements. It is envisaged that NICNAS will conduct awareness and training workshops to accompany these changes to the New Chemicals Program. Training sessions commenced at the end of 2010 and are expected to be held in 2011, subject to interest.

NICNAS also works with individual companies that approach us for assistance, to resolve compliance problems quickly and in a cooperative manner.

NICNAS Information Sheet

Who does what?

What sort of chemicals come under NICNAS legislation?

Industrial chemicals that come under the *ICNA Act 1989* (administered by NICNAS) are varied and covers components of substances such as dyes, solvents, adhesives, plastics, laboratory chemicals, paints, as well as chemicals used in cleaning products and cosmetics and toiletries.

A fast guide to chemical schemes in Australia is available on the NICNAS website at: [www.nicnas.gov.au/Chemicals In Australia/Chemical Schemes.asp](http://www.nicnas.gov.au/Chemicals%20In%20Australia/Chemical%20Schemes.asp)

Who regulates how chemicals are used, transported, stored and disposed of?

While the ICNA Act concerns the introduction (that is manufacture or import) of industrial chemicals, State and Territory Government agencies control use, release and disposal.

A number of different agencies are involved in the regulation of industrial chemicals in the workplace. Safe Work Australia is an independent statutory agency with primary responsibility to improve occupational health and safety and workers' compensation arrangements across Australia. States and Territories each have OHS authorities that have compliance and enforcement capabilities, under the national OHS legislative framework.

The States and Territories have legislative responsibility for the road and rail transport of Dangerous Goods and the National Transport Commission (NTC) has a role in maintaining and updating the *Australian Dangerous Goods Code (Road and Rail)* (ADG Code) and its associated model legislation. The Department of Infrastructure, Transport, Regional Development and Local Government (the department) works with the States and Territories, and the National Transport Commission, to promote best practice and internationally harmonised legislation for the land transport of dangerous goods in Australia.

Environmental issues relating to hazardous waste that may result in pollution are dealt with by relevant environmental authorities under the *Hazardous Waste (Regulation of Exports and Imports) Act 1989* ('the Act'). A list of State and Territory environmental authorities can be found at: www.environment.gov.au/about/library/govtdepts.html

Which agencies cover chemicals that are not industrial chemicals?

Food Standards Australia New Zealand (FSANZ) regulates food and food additives. If ingredients in food wrapping are to be manufactured or imported, please check with FSANZ first; if not within their scope, the chemical may require notification and assessment through NICNAS. Also see: [The FSANZ website](#).

Agricultural products include chemicals which generally destroy/repel pests or plants. This encompasses most herbicides, insecticides and fungicides used in agriculture. Veterinary products are used to prevent, diagnose or treat diseases in animals. These chemicals are regulated by the Australian Pesticides and Veterinary Medicines Authority (APVMA). Their web site is www.apvma.gov.au

A 'therapeutic good' is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use and includes products from medicines to sunscreens. The *Therapeutic Goods Act 1989* is administered by the *Therapeutic Goods Administration* (TGA), provides a national framework for the regulation of therapeutic goods in Australia to ensure the quality, safety and efficacy of medicines and ensure the quality, safety and performance of medical devices. Their web site is www.tga.gov.au/.

Who is responsible for labelling of products that may contain industrial nanomaterials?

Labelling of industrial chemicals and products containing these chemicals must comply with requirements under relevant state/territory poisons, occupational health and safety and transport statutes. These include:

Labelling of hazardous workplace products is set out in the *National Code of Practice for the Labelling of Workplace Substances*. Safe Work Australia is the responsible agency.

Labelling of poisonous substances is addressed in the *Standard for the Uniform Scheduling of Drugs and Medicines*.

Labelling requirements for goods classified as dangerous are outlined in the *Australian Dangerous Goods Code (7th Edition)* that is maintained by the Australian Transport Commission.

Labelling of cosmetic products is governed by and enforced under the *Trade Practices Act 1974*, administered by the Australian Competition and Consumer Commission (ACCC).