NICNAS Information Sheet

Proposal for regulatory reform of industrial nanomaterials:

Frequently Asked Questions

What are industrial nanomaterials?

Industrial chemicals are defined by how they are used. See "Who does What" at the end of these FAQs for a description of the types of chemicals that are regulated by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). For example, industrial chemicals are components used in such things as paints, dyes, inks and surface coatings, plastics, cosmetics and consumer goods.

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. NICNAS has developed a working definition for industrial nanomaterials that is consistent with other national and international working definitions as follows:

... industrial materials intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 and 100 nanometres... (Measurement equal to one billionth of a metre)

How are industrial nanomaterials currently 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*. Other government agencies are responsible for regulation of nanomaterials in medicines, food, pesticides and veterinary medicines. (See Who Does What section)

Currently, all legislative requirements applicable to conventional industrial chemicals also apply to their nano-forms. 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 national inventory (Australian Inventory of

Chemical Substances).

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. Chemical 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. Attachment 5 to the Discussion paper provides an overview of the NICNAS New Chemical notification categories.

Nano-forms of chemicals on the national inventory are considered "existing chemicals". 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 .

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 this presents to health, safety and environmental impacts. Research into the potential hazards (the inherent property of an agent having the potential to cause adverse effects) of these materials has been limited to date, but is increasing. In some instances this research has started to identify possible health concerns relating to specific kinds of nanomaterials.

The Australian Government-commissioned *Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks* (Monash Report, September 2007) determined that while there is no immediate need for major changes to existing regulatory regimes, six areas ('triggers') should be addressed by Government to ensure that our regulatory frameworks can better manage the risks posed by nanotechnology in the future.

These 'triggers' are listed below, and are all relevant to industrial nanomaterials:

- *on the basis of name* – whether regulations consider nanomaterials to be 'new' or 'existing' substances
- *on the basis of weight or volume* – appropriateness of regulatory requirements that are triggered by weight or volume thresholds
- *requiring knowledge or presence* – risk assessments identifying the implications of the presence of nanomaterials
- *reliant on risk assessment protocols or conventional techniques* – appropriateness of risk assessment protocols
- *on the basis of research and development exemptions* – appropriateness of existing research and development exemption thresholds
- *risk assessment processes and protocols reliant on international documents* – where specifically applicable to Australian risk assessment processes.

A consequence of current existing chemical obligations and exemption categories for new chemicals is that the extent of use of industrial nanomaterials in Australia is uncertain.

How are international governments addressing this issue?

Similar to Australia, 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 inventories are subject to new chemicals requirements. The USA and Canada recognise the same issues as Australia, particularly for existing chemicals, and are taking steps to review their frameworks, impose nano specific risk management measures and reconsider appropriate data requirements.

Europe, and under Registration, Evaluation Authorisation and Restructure of Chemical Substances (REACH) legislation the overarching obligation is to ensure that there are no adverse human health or environmental effects. This applies to nanomaterials. Consideration is being given to the need to specifically address nanomaterials.

What are the proposals presented in this paper?

The objective of the reform proposal overall is to ensure appropriate regulatory oversight, industry cooperation and community confidence. The reforms utilise the existing NICNAS framework, and propose some adjustments to address the uncertainty surrounding the risks posed by industrial nanomaterials and the appropriateness of current risk assessment protocols. It acknowledges NICNAS's links with national and international agencies that are actively considering similar issues.

The proposal addresses three elements;

- Regulation of nano-forms of new chemicals;
- Regulation of nano-forms of existing chemicals;
- The principle of an integrated approach for industrial nanomaterials within the NICNAS framework as a longer term strategy.

The detailed proposals and their advantages and disadvantages are given in the Discussion Paper.

How and when will these proposals be implemented?

Following the conclusion of the Public Comment period, suitable reform options will be finalised and a Regulatory Impact Analysis (RIA) will be developed for each option. The final proposals will be subject to a further round of consultation prior to implementation. We anticipate that NICNAS will continue the development of this reform package through 2010.

The proposals for nano-forms of ***new chemicals*** are intended to be 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.

It is expected that these changes will be implemented in the short to medium term future.

For nano-forms of ***existing chemicals***, two distinct activities have been identified to run concurrently as short- to medium-term reform options. These are to:

- develop a once-off use specific reporting program for nanomaterials – commencing on a voluntary basis and progressing to mandatory once-off use specific reporting;
- assess the feasibility of a mandatory notification and assessment program for nano-forms of existing chemicals.

A voluntary reporting program for nano-forms of existing chemicals is an administrative measure that can be implemented in the short-to medium term future. Mandatory once-off use specific reporting and a mandatory notification and assessment

program will require legislative amendment and will therefore be medium to long term options. Additionally, legislative changes require full regulatory impact analysis and stakeholder consultation prior to being considered by Parliament.

Additionally and as a longer term proposal, NICNAS is seeking preliminary views on the principle of integrating the approach for industrial nanomaterials, within the NICNAS framework. 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 builds on knowledge in this area.

Why is the issue of labelling not covered in this proposal?

These reform proposals relate to the industrial chemicals regulatory framework under the *Industrial Chemical (Notification and Assessment) Act 1989.* No labeling provisions are specified under this Act and therefore, NICNAS does not administer a labeling code for industrial chemicals.

Labelling of industrial chemicals and products containing these chemicals must comply with requirements under relevant state/territory poisons and occupational health and safety statutes. Labelling of cosmetic products is governed by and enforced under the *Trade Practices Act 1974,* administered by the Australian Competition and Consumer Commission (ACCC).

Once finalised, how can we be confident that regulatory reforms are adopted?

When administrative changes are made to NICNAS operations, businesses are required to comply. Our expectation and experience is that these changes are usually respected and implemented by industry. Specific penalties apply to non-compliance with provisions under the Act (i.e. legislative requirements).

NICNAS activities include a compliance function that monitors compliance with legislative and administrative requirements through an annual audit program. Consistent with usual practice NICNAS will include compliance monitoring with any administrative and 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 training workshops for nanomaterial reforms once these have been finalised and prior to implementation. It is expected that these workshops will be held in the second half of 2010.

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

How can I contribute to the regulatory reform of industrial nanomaterials?

The Public Discussion Paper provides NICNAS's stakeholders (the community, industry and government) with the opportunity to comment on a reform initiative to introduce new approaches to the regulation of industrial nanomaterials in Australia.

In particular, we are seeking stakeholder input as to whether:

- this strategy provides for the sound management of industrial nanomaterials;
- the options meet the needs of all stakeholders to have confidence in the regulatory system through protecting human health and the environment and by providing a clear regulatory path for industry;
- there are other options which could be considered; and
- any imposts on industry are balanced against the objectives of government and the expectations of the community to ensure public health, worker safety and environmental standards are maintained.

NICNAS is running public consultations at venues around Australia depending on expressions of interest. Sessions have been planned in Sydney and in Melbourne, information on these consultations can be found at http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Public_Consult_PDF.pdf. For individuals or organisations that cannot make the public consultations, one on one consultation by teleconference could be arranged on request.

Written submissions are encouraged, a *Have Your Say* Questionnaire and Business Impact Survey accompany the Public Discussion Paper, available at http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Stakeholder_Consultation.asp. Individuals or organisations may fill out one or both of these documents and send them back to NICNAS. The period for public comment on this proposal will end at 5pm, 23 December 2009.

Who Does What?

What sort of chemicals come under NICNAS legislation?

Industrial chemicals that come under the *Industrial Chemicals (Notification and Assessment) 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.

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.

A fast guide to chemical schemes in Australia is available on the NICNAS website at:
http://www.nicnas.gov.au/Chemicals_In_Australia/Chemical_Schemes.asp

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

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

Environmental issues relating to the use, storage and disposal of chemicals that may result in pollution are dealt with by relevant environmental authorities. A list of State and Territory environmental authorities can be found here: http://www.environment.gov.au/about/library/govtdepts.html