

4-5 March 2010

Title: NICNAS Proposal for Regulatory Reform of Industrial Nanomaterials

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## Purpose

The purpose of the paper is to:

- To provide members with an overview of NICNAS's *Proposal for Regulatory Reform of Industrial Nanomaterials*.


## Background

Industrial 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. NICNAS developed a working definition for industrial nanomaterials that is consistent with international definitions as "... *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...*"

Currently, under NICNAS, all regulatory requirements applicable to conventional chemicals also apply to nanomaterials. The NICNAS new chemicals program (chemicals not listed on the national inventory) includes exemptions, permits and certificates, which represent increasing levels of pre-market scrutiny. Many industrial nanomaterials however are nano-forms of existing chemicals, (that is chemicals on the national inventory), that can legally be introduced and used without notification to NICNAS but have not been assessed for their novel nano-scale properties.

NICNAS has worked at agency, national and international levels to develop a comprehensive strategy for the regulation of industrial nanomaterials. This was developed in consultation with NICNAS's Nanotechnology Advisory Group (NAG), comprising of members from industry, community and research sectors. This strategy brings together the two streams of NICNAS activities, **technical** and **regulatory**, while compliance and outreach activities support this strategy.

NICNAS **technical** activities have been building the capability of the organisation to provide for the use of best available scientific evidence concerning the hazards and risks of industrial nanomaterials, and the ability to review regulatory decisions as new information becomes available. These activities include:

- Developing risk assessment and modelling capabilities for NICNAS staff that meet international best practice.
  - Compiling toxicity information from published literature on six nanomaterials of interest to NICNAS – titanium dioxide, zinc oxide, cerium oxide, nanosilver, carbon nanotubes and fullerenes.
  - Working with national and international agencies that are doing work in the same area to maximise efficiency of research.
  - Developing information products for use by industry and community.
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**Regulation of nano-forms of new chemicals:** The exclusion of nanomaterials from new chemicals low volume exemption and self assessment categories, given uncertainty in the risks they may present can not be adequately managed. Exemptions for R&D or transshipment should continue as potential exposure can be adequately controlled under these use situations.

**Principle of an *integrated approach* for industrial nanomaterials within the NICNAS framework:** Further exploration of this approach will be complemented as NICNAS gains experience through the implementation of (above) proposals and further national and international scientific activities builds on knowledge in this area.

The Public discussion paper for the *Proposal for Regulatory Reform of Industrial Nanomaterials* was published for comment in November 2009. Public consultations were held in Sydney and Melbourne in mid-November 2009, involving a total of 35 participants. Issues raised at the public meetings are summarised and published on the NICNAS website to facilitate written submissions. A "Have your Say Questionnaire" and "Business Impact Survey" accompanied the paper and were available to download or fill in and submit electronically. Written submissions in other formats were also accepted. The period for comment was extended until 12 February 2010 in response to several requests for more time. The discussion paper, questionnaire and survey are available from [http://www.nicnas.gov.au/Current\\_Issues/Nanotechnology/Stakeholder\\_Consultation.asp](http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Stakeholder_Consultation.asp).

#### Current Status

Approximately 40 submissions were received at the closing date. NICNAS is currently analysing these submissions which will be published on the NICNAS website for public access. NICNAS will also publish a summary of the issues raised in the submissions. The consultations to date indicate overall support for the proposed reforms, with specific suggestions that will be taken into consideration when further refining each proposal.

NICNAS will use feedback from the submissions to further refine the draft proposals and develop a final reform package in consultation with the NAG and the Office of Best Practice Regulation. The final proposal and regulatory impact assessment will be subject to a further round of public comment, beginning later in 2010, prior to implementation.

#### Budget implications

N/A

#### RECOMMENDATIONS

It is recommended that members:

1. Note this information.

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