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Australian Government
Department of Health and Ageing
NICNAS

Meeting Paper

Nanotechnology Advisory Group
4th Meeting – 29 May 2009

Agenda Item 4:

PROPOSED NICNAS REGULATORY STRATEGY FOR INDUSTRIAL NANOMATERIALS

PURPOSE
To seek members' views on an overarching regulatory strategy for the regulation of industrial nanomaterials.

BACKGROUND

- In response to the *Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Framework* (the Monash Report) NICNAS, along with other Australian Government regulators, is reviewing its legislative framework and administrative processes to ensure that it can adequately manage any risks posed by industrial nanomaterials.

- Additionally, the inquiry on 'Nanotechnology in New South Wales' (published 6 December 2008) made a number of recommendations, including that
    - nano-versions of existing chemicals are assessed as new chemicals (Recommendation 1); and
    - the NSW Government recommend that ingredient labelling requirements for sunscreens and cosmetics include the identification of nanoscale materials (Recommendation 6).

- The NSW Government's response to the recommendations is at **Attachment 1.** In relation to Recommendation 1, the NSW Government will raise with the Commonwealth the need for a coordinated response to human health, safety and environmental risk assessments of nanoscale materials by the TGA, APVMA, FSANZ and NICNAS.

- The overall objective of NICNAS's regulatory strategy is the safe and sustainable use of industrial nanomaterials through appropriate regulatory oversight, industry cooperation and community confidence. Following the draft workplan (**Attachment 2**) considered by NAG1 on 17 March 2008, NICNAS has developed its thinking on the various work items

1-4 (What is a manufactured nanomaterials?; How does NICNAS assess the potential risks associated with nanomaterials?; How does NICNAS manage the potential risks associated with nanomaterials?; and How can stakeholder engagement be improved and maintained?) in consultation with the NAG over the last few meetings, as well as through its own interactions with companies and researchers over the past 12 months.

- Managing the risks posed by new technologies (including nanotechnology) to health and safety of people and the environment can be achieved by:

    a. Reviewing the ability of the existing regulatory framework to deliver an efficient and effective response to the new technology. Where appropriate;
        i. Using the existing regulatory framework and implementing regulatory or procedural changes to maintain or enhance human health and environmental standards;
        ii. Considering whether a specific regulatory system may be required where a new technology poses unique challenges that cannot be regulated effectively under the existing regulatory framework;
        iii. Using inclusive and transparent processes for review activities.
    b. Making use of the best scientific evidence available for risk based assessment of the impacts of the new technology on human health and the environment, including the ability to review decisions as new scientific evidence becomes available;
    c. Adopting measures to protect public health and safety and the environment where best available scientific evidence is insufficient to support the safety of the product/chemical.

ISSUES

- In undertaking this review, NICNAS is working at agency, national and international levels to achieve the objective stated above. **Attachment 2** provides an overview of the NICNAS strategy for regulatory oversight of industrial nanomaterials. NICNAS has committed to developing this strategy by 30 June 2009.

- The strategy brings together the two streams of NICNAS activities, regulatory and technical. As indicated in Attachment 2, various national and international activities feed into these activity streams, while a range of NICNAS activities support the overall strategy.

- In relation to regulatory activities, NICNAS has developed a **working definition** that is entirely consistent with international definitions (within the OECD and regulatory authorities) as follows: "*industrial materials intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 nm and 100 nm*". This working definition has been applied to both NICNAS Calls for Information and other nanomaterials related activities.

- Strategies proposed for **new chemicals** (ie nanomaterials for which their conventional counterparts are not listed on the Australian Inventory) was discussed in part at the last NAG meeting and is continued at Agenda Item 5. Strategies proposed for **existing chemicals** (ie nanomaterials for which their conventional counterparts are listed on the Australian Inventory) is discussed at Agenda Item 6.

- NICNAS **technical activities** are progressing in parallel to the regulatory stream. NICNAS is:
    - developing the risk assessment and modelling capabilities of its staff;
    - considering data requirements for assessment of nanomaterials;
    - benchmarking risk assessment methodologies and practices to meet international best practice; and
    - developing technical capability in relation to nanomaterials of particular relevance to NICNAS. These are carbon nanotubes, fullerenes, silver, titanium dioxide, zinc oxide and cerium oxide.

- A range of NICNAS activities feed into and support the overall strategy. These include **communication** and outreach activities, **consultation** with a range of formal and advisory groups and NICNAS **compliance** activities.

- Stakeholder involvement and cooperation is seen as important in NICNAS's ability to deliver effective and efficient regulatory oversight of nanomaterials and thereby ensure their safe and sustainable use in Australia. The degree of stakeholder responses to date, such as response to the voluntary Calls for Information, is being taken into account when developing proposals under this strategy.

- Further stakeholder consultation and regulatory impact analysis are envisaged prior to finalising the regulatory components of this strategy.

RECOMMENDATION:

That members provide their views on the proposed Strategy for the Regulatory Oversight of Industrial Nanomaterials

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Attachment 1

NSW Government Response to the recommendations arising from the NSW Standing Committee on State Development Inquiry into nanotechnology in NSW

(Adobe PDF file)

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Attachment 2

Draft NICNAS Workplan on Industrial Nanomaterials
(NAG1, AI3, 17 March 2008

Australian Government
Department of Health and Ageing
NICNAS

This draft work-plan provides a possible framework for Nanotechnology Advisory Group discussion to develop advice for NICNAS on managing the potential risks associated with nanomaterials.

Work-plan

Below are the elements of a possible work-plan, for your consideration, in line with the draft Terms of Reference for the NICNAS Nanotechnology Advisory Group (NAG). Please also refer to the attached timeline for the draft work-plan, and possible interactions with other initiatives.

1 What is a manufactured nanomaterial?
- o Is a definition necessary?
- o If yes, should it focus on physico-chemical properties, and/or altered hazard profiles?
- o What types of information (data sets) does NICNAS need to characterise the chemical as a nanomaterial?
  - Physico-chemical (and the associated needs of advanced metrology)
  - Other?

2 How does NICNAS assess the potential risks associated with nanomaterials?
- o Should a nanoform of an existing (bulk) chemical be considered as "new" or not?
  - Are existing NICNAS processes[1] well suited to nanomaterials?
  - Is a specific nanomaterial programme necessary?
- o Are current risk assessment protocols, including chemical characterisation and toxicity testing, applicable to nanomaterials?
  - Review current literature
  - Assess what knowledge gaps exist and how these may be addressed
- o What risk related data is needed?
  - Impacts on health, safety and the environment (HSE)
  - Lifecycle, fate, end-uses

[1] Regulatory framework and notification protocols.

- Can nanomaterials be grouped in order to predict hazard profile (*vis a vis* modelling)?

3 How does NICNAS manage the potential risks associated with nanomaterials?
- Are existing management protocols applicable to nanomaterials?
  - For example, are specific user groups more exposed that others?
  - For example, are current engineering controls effective?

4 How can stakeholder engagement be improved and maintained?
- Community can nominate chemicals to NICNAS for assessment, therefore,
  - How can NICNAS involve them in education and information gathering?
- Industry will be a NICNAS source for data, therefore,
  - How can NICNAS progress and facilitate information gathering?
    - A voluntary or co-regulated programme?
    - What will be the objectives and features of such a programme?

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Attachment 3

Proposed NICNAS Strategy for the Regulatory Oversight of Industrial Nanomaterials

(Powerpoint slide)