Australian Government
Department of Health and Ageing
NICNAS

National Industrial Chemicals Notification and Assessment Scheme

Proposal for Regulatory Reform of Industrial Nanomaterials

Public Discussion Paper – October 2009

Have Your Say Questionnaire

All submissions will be placed on the NICNAS's website. For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the NICNAS website. Confidential material contained within submissions should be clearly marked. Reasons for a claim to confidentiality must be included in the submission coversheet. Where possible confidential material will be redacted from information published on the NICNAS website.

1. What is the significance and/or consequence of this working definition for 'industrial nanomaterials'?

   (Working Definition: 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.)

   Significance: Recognition that the properitess of macro and nano forms of the same substance can be different. Novel properties will lead to more widespread use in the future

   Consequence: Nano forms will most likely receive increased scrutiny and regulation since the health and safety aspects are not well known

2. How do you think the proposal to limit access to exemptions for nano-forms of new chemicals will contribute to protecting health and the environment?

   Manufacturers and importers will be required to support toxicity testing that would otherwise not be required thereby providing more realistic data for assessments leading to increased protection of health and the information. Should the test results indicate issues with the test substance that substance would most likely not be approved for commercialization resulting in a benefit to health and the environmnet.

3. Describe any ways in which you think self-assessment by an independent third party could be used to effectively achieve the same results?

   A competent third party having received training from WorkSafe Australia or studied relevant guidance produced by WorkSafe Australia should be able to provide a self-

assessment to the required standards. NICNAS could have criteria or specific exemptions for nano-materials. Risk assessments could be performed, as they are now, to determine if a particular use of a nanomaterial meets the criteria for exemption.

4. If in R&D, what, if any, practical issues arise from the proposed administrative amendment for annual reporting of R&D exemptions? Would it require a significant increase in reporting? If so – how much?

   Increased recordkeeping and reporting is always a burden. However, the submission of chemical name information would be acceptable as long as the appropriate safeguards are in place to protect confidential business information.

   The increase in reporting is directly related to the number of R&D substances used and the levels they are used at. This would potentially have a larger impact on domestic manufacturers than importers. As a non-domestic importer of commercial products, annual reporting for R&D substances would have a minimal impact on our company.

5. What are your views on the impact of the proposal to regulate nano-forms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?

   Advantages- As nano-formsof new materials are anticipated to possess different and potentially more deleterious effects than their macro analogs, increased regulation is appropriate. Indeed, other jurisdictions are adopting this approach. Any new permit and certificate changes should take into account the cost-benefit of the work required to prepare the documentation. Disadvantages- Limiting access to exemptions for nano-forms of new materials could force excessive testing and evaluation of chemicals imported into Australia at volumes significantly below those that would reasonable be anticipated to cause harm to human health and the environent. A "guilty until proven innocent" classification of all volumes and uses of nanomaterials could hinder innovation.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
   This is a realisitc approach and is similar to TSCA Section 8(e) , Substantial Risk, and Sections 6, Regulation of Hazardous Chemical Substances and Mixtures and Section 7, Iminent Hazards, in the US.

7. What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nano-forms of ‘existing chemicals’? Can you identify additional advantages or disadvantages?

   This is also a good idea assuming the reporting requirements are realisitc, appropriate data may be maintained as confidential and sufficient time is allotted to submit the information. This is similar to the Inventory Update Rule under TSCA in the US.

8. Explain how you think the potential burden of once-off, use specific reporting could or could not balance community expectations in relation to health and environmental standards?

   Once-off reporting could satisfy community expectations in that it would show that government is addressing the concerns of their citiziens and more information would

be publicly available. A disadvantage would be public concern if much of the information that is made available is redacted.

9. What are your views on making the information gathered through streams 1A and 1B publicly available?

   Public availability is beneficial as long as the impact on on industry is not disruptive, i.e CBI is permitted.

10. What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for all nano-forms of existing chemicals? What are the reasons for this answer?

    Advantage: Required health and safety information would be made available to the regulators. Assessments would assist in mitigating health and safety effects for workers, the public.

    Disadvantage: Increased reporting and recordkeeping requriements could negatively impact smaller revenue manufactuers and importers thereby presenting a barrier to trade for Australia. Similarly, expensive testing and evaluation of all nano-materials, without consideration of volume, exposure, use, etc. could hinder innovation. Companies may be hesitant to take on full testing and evaluation for small volume nano-materials.

11. What are current issues that affect the feasibility of such a program?

    Resources for the regulators and the submitters. Preparation and/or review of the assessments by the regulators must be timely.

12. What are your views on making the information gathered from assessments of nano-forms of existing chemicals publicly available?

    No significant issues provided that reasonable confidentiality is permitted.

13. How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package of options proposed in sections 3a and 3b?

    An integrated approach has a better chance of capturing the information required by the regulators. It would also relieve industry of having to decide which notification and/or reporting option is appropriate.