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'?

   The term "intentionally produced" appears to exclude incidental production of nanomaterials such as may occur when welding. This is appropriate, as it would not be practicable to require all incidental generators of nanomaterials to comply with the same notification and assessment requirements as for intentionally produced nanomaterials. The issue of agglomeration of nanoparticles, the stability of agglomerates, and the affect this may have on particle dimensions should be considered. The proposed size range "typically between 1 and 100 nanometres" may need to be extended if slightly larger particles have similar toxicology (e.g. Safe Work Australia's 2009 publication "Engineered Nanoparticles: A review of the toxicology and health hazards" indicates some carbon nanotubes with dimensions above 100 nanometres may have similar toxicology to smaller carbon nanotubes).

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?

   The exclusion of low volume exemptions for nano-forms of new chemicals is reasonable given the uncertainty surrounding the hazard. While there is a lack of comprehensive information on the safety and environmental effects of nanomaterials this approach will contribute to protecting health and the environment.

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

   WorkSafe Western Australia has no comment on this.

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?

Not Applicable to WorkSafe WA

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?

   The proposal to regulate nano-forms of new chemicals appears to be an appropriate measure to minimise health and environmental risk without overly impacting R&D activities.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
   It is important to include flexibility into the permit conditions to allow conditions to be amended if necessary, as the risks are currently uncertain and new information on the properties and risks of nanomaterials is becoming available.

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?

   The advantages listed in the discussion paper for this item are substantial and would justify such reporting.

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 specific reporting in relation to nano forms of existing chemicals would likely assist in meeting community expectations; the counter position of not reporting such nanomaterials would be expected to be considered inadequate by the community. However in the longer term the community would expect assessment as well as reporting (see 10). In order to attain the advantage of increasing public confidence by facilitating regulatory oversight of nanomaterials in Australia, data obtained by NICNAS would need to be provided at least to state environmental, health, dangerous goods and occupational safety and health regulators (and any other relevant regulators). Without such data, information provided by nanomaterial manufacturers/importers may not adequately address the properties and hazards of the nano-form - they may provide information based on the conventional form. Without knowing a product is nano-form, regulators such as occupational safety and health regulators or environmental regulators would have difficulty identifying the information deficiency.

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

   This could discourage accurate reporting of the information (unless it is reported in a way that does not identify the manufacturer or products). An intermediate position is to make the information available to relevant regulators.

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?

This would be expected to allay community concerns about development of such nanomaterials. There is also information indicating that nano-forms of existing chemicals may have quite different hazards than the conventional forms, so mandatory notification and assessment could be justified on a risk management basis. However as NICNAS has limited resources, the priority of these assessments must be weighed against the value of conducting Priority Existing Chemical reviews of other existing chemicals known to present significant hazards.

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

    WorkSafe WA has no comment on this.

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

    This would be useful, and may assist people in assessing similar chemicals.

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?

    The package of options currently being proposed, to give nanomaterials specific priority, will serve to allay community fears that nanomaterials are not being managed adequately and is appropriate given the current uncertainties surrounding the risks associated with nanomaterials. It may be beneficial to consider an integrated approach at some point in the future as further information in regard to the specific risks and properties associated with nanomaterials becomes available. An integrated approach has the advantages of providing for regulatory simplicity and cost effectiveness.