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 definition is reasonable as a working definition for the identification of materials NICNAS may want to look at more closely. However it is not suitable for other regulatory purposes as does not distinguish between the significant risk represented by a small particle sized raw material (eg as handled in a workplace), versus a small quantity of small particle material included in a formulated product intended for application to the skin. Application of such a rigid definition for purposes other than an internal tool to determine workflow streams could lead to Australian specific requirements as an international definition has not yet been agreed upon. Special consideration should be given to the impact of any proposed changes to the regulation of industrial chemicals on formulated products or cosmetics. Cosmetics typically contain many ingredients in very small quantities, such that the relevance of safety information relating to the raw material ingredient is very much diminished. In the Outcome of the International Workshop on Regulatory Issues regarding the Use of Nanotechnologies in Cosmetics, July 2009 including regulatory authority and industry representatives from Canada, EU, Japan and US it was considered that "ideally a nanomaterial in cosmetics should be characterized as it appears in the final formulation used by the consumer." Determination of regulation of ingredients in cosmetics should not be assessed against a definition based only on particle size of ingredients included in the formulation but in relation to the product as a whole. Manufacturers of cosmetics rigorously test the safety of their products in relation to their intended use and are concerned with the safety of their product in the hands of the consumer.

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?

   For new nano materials the proposal seems appropriate.

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

   Assessments by independent third parties is a good option provided the applicant can choose the independent assessor based on how quickly they can provide the requested assessment and cost.

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?

   No comment

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 proposed reform will increase the workload of NICNAS which unless arrangements are made to cope with this increase will result in delays to market for cosmetic products and will be a disincentive to introduce innovative products into Australia. The increased burden for industry will add to the costs of bringing such products to market. The risks of a product (bearing in mind its intended use) containing ingredients of small particle size need to be balanced against the overall cost of increased regulation.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
   Appropriate - however the data must be of significant robustness to warant a change. Consultation with introducers of such ingredients should be had before any amendments are made/introduced with appropriate transition periods.

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?

   Reporting small particle forms of well known existing chemicals that have been in use for decades and for which substantial information is available in the public domain and has been peer reviewed is not the best use of either NICNAS or industry resources. Such materials should not be required to be reported. Otherwise the proposal seems appropriate for less well known materials.

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?

   No comment

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

   No details have been given as to how the information is intended to be presented. If it was more than a list of materials this would be of concern. For those in the workplace to whom this information is necessary for OH&S reasons this information is already readily available from their suppliers. For persons in the lay community the

transferrance of information concerning a raw material from the internet to an ingredient in a formulated product could result in disemmintion of misinformation and scare mongering. Any information on materials should be given in the context of the form in which the material is provided; i.e. for cosmetics within the formulation.

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?

    Mandatory notification and assessment should be reserved for new nano materials handled in their ingredient form. Asessment of new ingredients in cosmetics should be done in context of the formulation.Nanomaterials already in use, such as titanium dioxide and zinc oxide should not require notification and assessment

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

    The current issues are cost versus benefit to the consumer/user. The program as described does not acknowlegde the characteristics of a cosmetic product.

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

    New nanomaterials should be treated as any other new chemical, however care should be taken to make it clear that the information used in the safety assessment concerns the raw material ingredient. The appropriate assessment for a formulated product relates to an assessment of the whole product relevant to its proposed use.

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?

    Multiple approaches increase complexity and cost for all concerned, therefore a single approach to a regulatory framework is desirable provided it takes into account the characteristics of the different types of goods it regulates.