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11 February 2010

Dr Marion Healy
Director
National Industrial Chemicals Notification and Assessment Scheme
Department of Health and Aging
GPO Box 58
SYDNEY NSW 2001

Attention: Ms Nicola Hall
Senior Regulatory Scientist - Reform

Dear Dr Healy

PROPOSAL FOR REGULATORY REFORM OF INDUSTRIAL NANOCHEMICALS – PUBLIC DISCUSSION PAPER

I refer to the public discussion paper *Proposal for Regulatory Reform of Industrial Nanomaterials* (November 2009).

Attached is this agency's submission to the public consultation, in the form of a completed questionnaire. A completed consultation submission form is also attached.

Please contact the officer nominated at the head of this correspondence if you have any queries regarding the attached submission.

Yours sincerely

John Mollison
DEPUTY GENERAL MANAGER

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'?

   Adoption of a nationally consistent defintion of 'industrial nanomaterials' is highly desirable. Nonetheless, the basis for the proposed 1-100 nm range is not explained in the discussion paper. There may be a need for special regulatory consideration of materials in the 100-1,000 nm range also. For example air quality research has demonstrated particular human health concerns about particles in the <1 micron range.

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?

   As research to date has raised concerns about the human health and environmental impacts of nanomaterials, limiting access to exemptions is a necessary precaution for protection of health and the environment for the current situation. The proposed continuation of the transhipment exemption (page 8 of the discussion paper) only mentions shipments out of Australia. What is proposed in regard to incoming shipments of nanomaterials? In any case the exemption presumably only relates to international shipments. Environmental and dangerous goods legislation controls domestic (interstate and intrastate) movements of 'controlled' wastes - does NICNAS have any proposals about domestic movements?

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

   Self-assessment should only be an option where the independence and capacity of the third party can be ensured, and should also be accompanied by NICNAS providing comprehensive guidelines on conducting assessments. Assesment reports provided to NICNAS would need to be checked by NICNAS staff, and supplementary

reports demanded where the initial report is unsatisfactory. There should also be penalties for provision of false or misleading information. The self-assessment option should not be available where a high level of human health or environmental risk is likely in regard to a particular nanomaterial.

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?

   The basis for the 100 g/year reporting threshold is not explained in the discussion paper. As very small quantities may be used in R&D, further information would be required to consider if this is appropriate or not. It may be preferable to have no threhold at all, i.e. to require reporting of any R&D use of nanomaterials, in order to ensure NICNAS and government awareness of emerging uses.

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?

   Given the current level of uncertainty about the health and environmental impacts of nanomaterials, NICNAS and other agencies should adopt a precautionary approach and closely regulate nanomaterial use until the effects and impacts of such materials becomes clearer. For this reason we strongly support the exclusion of nanomaterials which are new chemicals from low volume or concentration exemptions, and these should be assessed (permit or certification) prior to commercialisation.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
   The proposals in the discussion paper seem satisfactory except for two matters. First, how will users of nanomaterials obtain ongoing approvals (approvals with no fixed period) if certificates will not be available? Ongoing approval should be available where a nanomaterial is conclusively demonstrated to be safe. Second, chemicals approved by permit are not listed in the Inventory, and this has transparency and public access implications. These considerations suggest that certificates should be available, perhaps after an initial period of permit approval in each case.

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?

   A once-off mandatory call for reporting on nanomaterials (Stream 1B) is supported - it appears to be an essential precutionary measure at this time given the lack of knowledge of nanomaterial use. No thresholds should apply - *all* use should be reported given that the exercise will be seminal and once-off. The NICNAS legislation should be amended if necessary to enable this to be undertaken. It is essential that the results of the reporting exercise are analysed by NICNAS and that further investigations are conducted where health or environmental risks are evident, followed by any necessary regulatory action. While the use of a voluntary reporting phase may be useful in the short term while legislative change is made to support the wider system, it should not be relied on as a comprehensive means of managing nanomaterials. The use of such voluntary systems should be undertaken with industry support to demonstrate industry responsibility, and as a precursor to legislative reform to ensure industry-wide compliance.

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?

   As noted above, a once-off reporting exercise is an essential precaution with the current low levels of available information.

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

   All significant information should be made publicly available, to assist public awareness and confidence, and to assist further scientific investigation.

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?

    A mandatory reporting system is fully supported given that nanomaterials have health and environmental risks inherent to their nano-size. The advantage of a reporting system is reduction of health and environmental risk. There will be economic disadvantages, but they should be of a lesser order to existing chemical reporting requirements as many of the issues will already have been identified in the analysis of the non-nano form. Thresholds and reporting requirements would of course have to be determined.

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

    A matter for discussion with affected industries. The main internal issues for NICNAS would, presumably, be budgetary and the availability of suitable expertise. This then leads to the issue of other regulatory agencies being able to have confidence in the NICNAS regulatory process when considering related matters in their own jurisdictions.

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

    All significant information should be made publicly available, to assist public awareness and confidence, and to assist further scientific investigation.

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?

    A matter for internal consideration by NICNAS and discussion with affected industries.