



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 working definition will provide clarity to producers, manufacturers and regulators as to what products are "in scope" as part of the proposed framework. It is however suggested that while the size of 1 to 100 nanometres is generally accepted, it should not be an exclusive size for the purposes of the definition as it is akin to the size of ultrafine particles. It is suggested that the definition could be reworded to something like...industrial material intentionally produced, manufactured or engineered to have specific properties or specific composition, and or more dimensions typically (but not exclusively) between 1 and 100 nanometres

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?

This proposal is supported and applauded. The Precautionary Principle should be invoked in this matter and any potential risks to human health and the environment will be identified and addressed through pre-market safety assessment.

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

In the interests of public confidence in the regulation of industrial nanomaterials, third party arrangements should not be supported at this time.

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?

It is not expected to have a significant impact.

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 permit and certificate categories appears to be sound. The potential advantages and disadvantages identified appear to address the major issues.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?
As research addresses the uncertainty surrounding the risks posed by industrial nanomaterials it is necessary to have in built flexibility in the permit system.

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?

It should be noted that very limited evidence based research on the public health risks of nanotechnology has been conducted. It is of concern that some nanomolecules have been added to consumer products based on toxicological data and efficacy of the parent molecule. It is considered more prudent to see all nanomaterials undergo the same rigorous testing as the parent molecule before being declared safe for addition to consumer products. This proposal will help to address the gap in existing information. The potential advantages and disadvantages identified appear to address the major issues.

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?

The potential burden of once-off reporting is balanced with community expectations in relation to health and environmental standards. Consumers have an expectation that industrial nanomaterials have been assessed against appropriate safety criteria.

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

This information being made publically available will enhance transparency of regulatory arrangements.

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?

The potential advantages and disadvantages identified appear to address the major issues.

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

Feasibility of the program will rely on timeliness of research concerning the health, safety and environmental effects of nanomaterials and the development of sound risk assessment criteria for nanotechnologies.

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

This information being made publically available will enhance transparency of regulatory arrangements.

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?

Further insight will be able to be offered as knowledge builds in this area and the experience gained in the short and medium term regulation of nanomaterials.