



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.

GENERAL COMMENTS BY 3M AUSTRALIA

RECLASSIFICATION OF NANO-SCALE CHEMICALS AS "NEW CHEMICALS"

The definition of a chemical should be dependant on the molecular structure and identity. To treat a chemical as "new" only because it is of reduced particle size creates problems - where does that end? Since silica (or titanium dioxide, gold, cerium oxide, etc) may have different phys/chem properties in particle sizes of 1 mm, 1 micron, 100 nm, 50 nm, 5 nm, and 1 nm, should each particle size be regarded as new? While it may be necessary to require declarations that a substance manufactured or imported into the country meets the NICNAS nano-scale definition, and hence to structure the risk assessment differently, that is different than arbitrarily declaring it to be a different chemical substance.

CONFIDENTIALITY

If the chemical identity of a nano-scale substance must be revealed, either in a public aspect of a notice to NICNAS, or in mandated labeling of content in a product, trade secrets could be lost. It can be a valuable trade secret that Chemical X, when reduced to nanoscale, has commercial performance enhancing properties for Product Y. The intended use of Product Y would of course be public knowledge. That level of disclosure would be damaging to the commercial interests of the company that developed the technology.

Whether the issue is mandatory disclosures to NICNAS, or a third party evaluator, or the public, 3M Australia believes protection of intellectual property is an important issue that needs to be considered carefully, with a view to protecting commercial trade secrets.

REGULATION OF NANO-FORMS OF "NEW CHEMICALS"

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

It is important that the definition of nanomaterials is consistent with that of other key

trading partners to Australia such as the USA and EU.

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?

3M Australia does not oppose the concept of limiting exemptions for nano-forms of new chemicals. Use of the R&D exemption to introduce new nanomaterials should be a targeted compliance activity for ensuring that personnel involved in handling nano-materials are adequately trained. This may be outside of NICNAS legislative remit and could perhaps be monitored by state OHS regulators.

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

3M is not supportive of the introduction of a 3rd party evaluator. Issues concerning the protection of confidential business information and handling of such sensitive information would need to be addressed.

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 at this point in time.

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?

Disadvantages

Whilst the proposal does not immediately eliminate all certificate categories (only self-assessment certificate categories which 3M does not oppose). The statement that the certificate system is unsuitable for nano-materials is unjustified especially if certain nano-scale chemicals present data that indicates low hazard. Furthermore some certificate categories have more onerous data requirements that would be advantageous in completing a hazard and risk assessment of any new chemical.

The use of a permit system with a additional data requested as required for risk assessment makes estimating the cost of introducing a new nano-scale chemical impossible to determine especially when the reports are not public and there is no transparency in the risk methodology applied by the regulator. The issue of additional data requirements requires much closer examination with some general guidelines developed.

The time and cost of introducing a new nano-scale chemical to market may be outweighed by the lack of certainty for continued supply under the permit system. Certificate categories should remain as an option for new nano-scale materials. Otherwise NICNAS are effectively saying no new nano-scale chemicals will ever be added to the AICS.

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 aspect requires a much more in-depth and detailed review than what is presented in the discussion paper. The downstream consequences of action such as revoking a permit can have commercial impact not just on the introducer but on

downstream users. In some cases products from a specific company are written into the specifications for manufacturing further products. The risk of therefore using such new technology may be outweighed by the lack of certainty for continued supply. This will not aid in the introduction of innovative products to the Australian market.

REGULATION OF NANO-FORMS OF “EXISTING CHEMICALS”

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?

No details on what confidentiality provisions will be available to introducers required to respond to such reporting have been provided. Additionally the targeting of introducers only may not necessarily provide the best and most accurate use information. The ability to provide such information for introducers of formulated products is difficult. The basis of providing such data in many cases is reliable information from base raw material manufactures and relies on their ability to properly identify the material and supply correct data.

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?

N/A

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

Please see 3M's comments regarding confidentiality. If a company has no mechanism to protect CBI this will only harm Australia's ability to introduce products containing nano-scale chemicals and may result in the discontinuation of products in the Australian marketplace.

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?

No details on what confidentiality provisions will be available to introducers required to respond to such reporting have been provided. Additionally the targeting of introducers only may not necessarily provide the best and most accurate use information. The ability to provide such information for introducers of formulated products is difficult. The basis of providing such data in many cases is reliable information from base raw material manufactures and relies on their ability to properly identify the material and supply correct data.

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

Please see 3M's comments regarding confidentiality. A definition of information would be required. If a company has no mechanism to protect CBI this will only harm Australia's ability to introduce products containing nano-scale chemicals and may result in the discontinuation of products in the Australian marketplace