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 proposed definition reflects the main elements of other definitions and specifications, adopted by international fora (e.g. ISO, OECD) and proposed by other jurisdictions (e.g. European Union). However, clarification is required on the terms 'intentionally produced, manufactured or engineered' and 'specific properties or specific composition'. Moreover, the definition should be practical and implementable in the regulatory context, within which it is being proposed, and it should be flexible to change, in order to specifically accommodate the developments of definitions in the aforementioned international fora.

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 nanomaterials which are new chemicals from low volume/low concentration exemptions and changes to administrative arrangements for annual reporting of chemicals introduced in under the R&D exemption category does not seem implementable; it will cause heavy, undue burden on both public and private research (and education) facilities and ultimately impact innovation. In turn, the proposed administrative exclusion from self-assessment (on the basis of the uncertainty concerning their hazard) and subsequent plans for the hazard status of the nanomaterials and the risk posed by the notified uses to be assessed by NICNAS may pose an enormous workload on the authorities. Moreover, the NICNAS assessment would require the publication of guidelines informing the notifier about the specific parameters, according to which the NICNAS assessment will be conducted, and – in particular – how this assessment differs from the (self-)assessment of chemical and polymers that are non-hazardous. It should furthermore be noted that in many market applications (for example the cosmetics industry) there are already regulations/protocols being put in place to regulate nanomaterials. It would therefore

seem advisable for NICNAS needs to harmonise its regulations with the TGA and other regulatory bodies to simplify the approval process for new nanomaterials.

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

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?

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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 declaration by the notifier on the permit or certificate application forms stating that the chemical is a nanomaterial essentially amounts to a notification/reporting scheme (see below). The need for provision of more specific information (such as particle size, shape and other specific information on properties) needs to be clarified before implementation: the specific necessary characteristics used to uniquely describe nanomaterials differ significantly between materials and with application, and over-generalised mandatory requirements for the measurement and notification of unnecessary physical-chemical endpoints can cause enormous economic burden. The exclusion of nanomaterials which are new chemicals from low volume/low concentration exemptions and changes to administrative arrangements for annual reporting of chemicals introduced in under the R&D exemption category does not seem implementable; it will cause heavy, undue burden on both public and private research (and education) facilities and ultimately impact innovation. In turn, the proposed administrative exclusion from self-assessment (on the basis of the uncertainty concerning their hazard) and subsequent plans for the hazard status of the nanomaterials and the risk posed by the notified uses to be assessed by NICNAS may pose an enormous workload on the authorities. Moreover, the NICNAS assessment would require the publication of guidelines informing the notifier about the specific parameters, according to which the NICNAS assessment will be conducted, and – in particular – how this assessment differs from the (self-)assessment of chemical and polymers that are non-hazardous. It should furthermore be noted that in many market applications (for example the cosmetics industry) there are already regulations/protocols being put in place to regulate nanomaterials. It would therefore seem advisable for NICNAS needs to harmonise its regulations with the TGA and other regulatory bodies to simplify the approval process for new nanomaterials.

6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicates a new risk profile?

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?

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?

   It is furthermore highly questionable, how a 'once-off' reporting programme could be implemented at a time, when the predominant (expert) opinion is that nanomaterials cannot be generalised and require case-by-case evaluation, until more is known about the potential intrinsic properties of materials on the 'nanoscale'.

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

   The publication of specific information on nanomaterials could have severe economic effects to the notifier and should be avoided under all circumstances.

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 feedback received on nanomaterials reporting/stewardship schemes conducted by various jurisdictions showed that the following elements are of utmost importance: (a) Clear definitions/specifications, (b) Clear indication of the anticipated use of the reported information, (c) Provision of measures to address CBI issues. Assessment of the ‘feasibility of a mandatory notification and assessment programme’, as proposed for Stream B, is highly recommended before either proposed streams (Stream 1 or Stream 2) are implemented; special consideration should be given to predict the number of reasonably expectable submissions to such programmes, as well as the resources required to generate the information (at the notifier) and process the information (at the authority).

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

    see above

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

    The publication of specific information on nanomaterials could have severe economic effects to the notifier and should be avoided under all circumstances.

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?

NIA Comment

on the
Australian Government, Department of Health and Ageing, National Industrial Chemicals Notification and Assessment Scheme
Proposal for Regulatory Reform of Nanomaterials

Background

The NIA, Nanotechnology Industries Association (NIA), is the market-independent, responsible voice for the industrial nanotechnologies supply chains; it supports the ongoing innovation and commercialisation of the next generation of technologies and promotes their safe and reliable advancement.

The NIA stands for science- and technology-based expertise in nanotechnologies, encompassing members companies that have successfully developed and commercialised nanotechnologies for over 25 years.

Through proactive collaborations with regulators on the national, European and international level, as well as engagement with other nanotechnology stakeholders, the NIA promotes a framework of shared principles for the safe, sustainable and socially supportive development and use of nanotechnologies, by securing a publically and regulatory supportive environment for the continuing advancement and establishment of nanotechnology innovation.

In November 2009, the Australian Government, Department of Health & Ageing – National Industrial Chemicals Notification Scheme (NICNAS), published a Public Discussion paper entitled *'Proposal for Regulatory Reform of Industrial Nanomaterials'* .[1]

According to the Discussion Paper's introduction, *'[the] paper provides NICNAS's stakeholders (the community, industry and government) with the opportunity to comment to NICNAS on a reform initiative to introduce new approaches to the regulation of industrial nanomaterials. The proposal utilises the existing NICNAS framework, and proposes some adjustments to address uncertainties in potential risks posed by these novel materials to health, safety and the environment.*

The proposal addresses three elements;

- *Regulation of nanoforms of new chemicals;*
- *Regulation of nanoforms of existing chemicals;*
- *The principle of an integrated approach for industrial nanomaterials within the NICNAS framework as a longer term strategy.'*

[1] Follow this link to find out more about the Australian Federal Government Proposal for Regulatory Reform of Industrial Nanomaterials: http://www.nanotechia.org/news/global/public-consultation-australian-government-propose

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The NIA and its member companies are grateful for the opportunity to provide the following comments.

Definition: What are 'industrial nanomaterials'?

The proposed definition reflects the main elements of other definitions and specifications, adopted by international fora (e.g. ISO, OECD) and proposed by other jurisdictions (e.g. European Union).

However, clarification is required on the terms 'intentionally produced, manufactured or engineered' and 'specific properties or specific composition'.

Moreover, the definition should be practical and implementable in the regulatory context, within which it is being proposed, and it should be flexible to change, in order to specifically accommodate the developments of definitions in the aforementioned international fora.

Regulation of nano-forms of 'new chemicals'

a. Proposal concerning NICNAS exemption categories (Low volume, transhipment and R&D)

Low volume exemption & R&D exemptions:

The exclusion of nanomaterials which are new chemicals from low volume/low concentration exemptions and changes to administrative arrangements for annual reporting of chemicals introduced in under the R&D exemption category does not seem implementable; it will cause heavy, undue burden on both public and private research (and education) facilities and ultimately impact innovation within Australia.

b. Proposal concerning NICNAS notification categories (Permits and certificates)

The proposed declaration by the notifier on the permit or certificate application forms stating that the chemical is a nanomaterial essentially amounts to a notification/reporting scheme (see below).

The need for provision of more specific information (such as particle size, shape and other specific information on properties) needs to be clarified before implementation: the specific necessary characteristics used to uniquely describe nanomaterials differ significantly between materials and with application, and over-generalised mandatory requirements for the measurement and notification of unnecessary physical-chemical endpoints can cause enormous economic burden.

In turn, the proposed administrative exclusion from self-assessment (on the basis of the uncertainty concerning their hazard) and subsequent plans for the hazard status of the nanomaterials and the risk posed by the notified uses to be assessed by NICNAS may pose an enormous workload on the authorities.

Moreover, the NICNAS assessment would require the publication of guidelines informing the notifier about the specific parameters, according to which the

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NICNAS assessment will be conducted, and – in particular – how this assessment differs from the (self-)assessment of chemical and polymers that are non-hazardous.

It should furthermore be noted that in many market applications (for example the cosmetics industry) there are already regulations/protocols being put in place to regulate nanomaterials. It would therefore seem advisable for NICNAS needs to harmonise its regulations with the TGA and other regulatory bodies to simplify the approval process for new nanomaterials.

Regulatory 'package' for nano-forms of 'existing chemicals'

The feedback received on nanomaterials reporting/stewardship schemes conducted by various jurisdictions showed that the following elements are of utmost importance:[2]

- Clear definitions/specifications
- Clear indication of the anticipated use of the reported information
- Provision of measures to address CBI issues

Assessment of the 'feasibility of a mandatory notification and assessment programme', as proposed for Stream B, is highly recommended before either proposed streams (Stream 1 or Stream 2) are implemented; special consideration should be given to predict the number of reasonably expectable submissions to such programmes, as well as the resources required to generate the information (at the notifier) and process the information (at the authority).

The publication of specific information on nanomaterials could have severe economic effects to the notifier and should be avoided under all circumstances.

It is furthermore highly questionable, how a 'once-off' reporting programme could be implemented at a time, when the predominant (expert) opinion is that nanomaterials cannot be generalised and require case-by-case evaluation, until more is known about the potential intrinsic properties of materials on the 'nanoscale'.

[2] Follow these links for more information on the discussion of voluntary and mandatory nanomaterials reporting schemes:

a) http://www.nanotechia.org/news/global/nanotech-2010-mandatory-reporting-nano-regulatio
b) http://www.nanotechia.org/news/nia/exclusive-documents-now-available-on-the-nia-websi-31
c) http://www.nanotechia.org/news/nia/exclusive-documents-now-available-on-the-nia-websi-22

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The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies.

The NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an ongoing advancement and commercialization of nanotechnologies.

For further information visit http://www.nanotechia.org or contact us on enquiries@nanotechia.org.

Brussels, 12th February 2010

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