National Industrial Chemicals Notification and Assessment Scheme

Proposal for Regulatory Reform of Industrial Nanomaterials

Public Discussion Paper – November 2009

CONTENTS

This part outlines the purpose of this paper and what to do with it.

PART ONE What is the Public Discussion Paper for the Regulatory Reform of Industrial Nanomaterials?

1A Purpose of this public discussion paper

This 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.

NICNAS has a specific role in the overall regulatory framework for industrial chemicals in Australia, under legislation provided by the *Industrial Chemical (Notification and Assessment) Act 1989* (The Act).

Other government agencies are responsible for regulation of nanomaterials in medicines, food, pesticides and veterinary medicines.

We invite you to make comment on the overall proposal and in some cases on specific options/initiatives detailed in Part 3 of this Discussion Paper.

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.

In particular, noting the NICNAS's guiding principles for managing risks posed by new technologies (**Attachment 1**) we are seeking your input as to whether:

- this strategy provides for the sound management of industrial nanomaterials;
- the options meet the needs of all stakeholders to have confidence in the regulatory system through protecting human health and the environment and by providing a clear regulatory path for industry;
- there are other options which could be considered; and
- any imposts on industry are balanced against the objectives of government and the expectations of the community to ensure public health, worker safety and environmental standards are maintained.

At this stage we are specifically seeking your;

- input on the options contained in Part 3a and Part 3b of this paper, and;
- input on the principle of an integrated approach for industrial nanomaterials within the NICNAS framework as a longer term strategy.

Supporting information for comments should be provided. This will facilitate identification of potential impacts associated with these measures and enable NICNAS to properly weigh the advantages and disadvantages associated with such changes.

Further opportunities will occur for input into the regulatory impact assessment as well as consultation on the development and progression of regulatory reform options.

1B How to read this paper

With more facts…

This Discussion Paper has been compiled to present a proposal to a broad audience.

To increase the clarity and readability of this paper, details on specific aspects have been provided as Attachments. **To indicate when more information has been attached on a particular subject, a reference is made to the relevant attachment in the text.** You can choose to go directly to that document or read it later, depending on your preference.

A **Further Reading List** on relevant issues is hyperlinked in the text and the URLs are also included at the end of this Paper. Links may also be also found on the NICNAS website.

With a questionnaire - we want to know what you think!

Have your say. The purpose of this paper is to get feedback. What do you think of this proposal? How will it affect you?

The ***Have Your Say Questionnaire,*** supplied with this Paper, can be used to express comments and opinions on topics throughout the paper for NICNAS's attention. This questionnaire correlates to questions asked throughout this Discussion Paper at the appropriate sections and is intended for all stakeholders that want to provide a written submission.

A Business Impact Survey.

Will these changes affect your business? If so, we need to know. A ***Business Impact Survey*****,** supplied with this paper, is for those stakeholders whose business interests may potentially be impacted.

This may be submitted with the *Have Your Say Questionnaire*, or on its own. This has been designed according to the Office of Best Practice Regulation (OBPR) guidelines to assist us with a Preliminary Regulatory Impact Assessment.

Please note:

All submissions will be placed on the NICNAS 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.

1C What should you do?

By 23 December 2009:

Fill out and send back the *Have Your Say Questionnaire* referring to relevant sections/attachments for more information on each topic.

Fill out and send back the *Business Impact Survey* if applicable to you.

Options are supplied in Section 4 on how you can return written submissions to us.

Get in direct contact with NICNAS if you have any questions or wish to participate in public consultations that are occurring in major cities starting in the week of16 November 2009. Contact details are supplied at the end of the Paper. *If you can't attend one of these meetings, we may be able to arrange one on one consultation with you.*

This part provides objectives and context for the proposal

PART TWO Objectives of the Regulatory Reform Package for Industrial Nanomaterials.

2A Objectives of reform.

The proposed strategy addresses the uncertainty surrounding the risks posed by industrial nanomaterials, appropriateness of current risk assessment protocols and acknowledges NICNAS's links with national and international agencies that are actively considering similar issues. It aims to ensure appropriate regulatory oversight, industry cooperation and community confidence.

NICNAS, in conjunction with its Nanotechnology Advisory Group (NAG) - that comprises of representatives from industry, the community and research sectors - has developed a set of principles to manage the risks posed by new technologies (including nanotechnology) to health and safety of people and the environment (**Attachment 1**). NAG was involved in this proposal's development, and is supportive of the options presented in this Discussion Paper. See the **Further Reading List** for more information on NAG.

The options aim to maintain or enhance existing levels of public health, worker safety and environmental protection in relation to industrial nanomaterials, while facilitating the ability of the community to gain from the potentially beneficial aspects of this technology, and the ability of industry to innovate using the technology.

2B What are industrial nanomaterials?

Nanotechnology is engineering at the atomic or molecular (group of atoms) level. It is a group of so-called *enabling technologies* that involve the manipulation of matter at the nanoscale (generally accepted as 100 nanometres or less) to create new materials, structures and devices.

Industrial nanomaterials are chemicals engineered to take advantage of their small size and novel properties which are generally not seen in their conventional, bulk counterparts. Nanomaterials can exist as single, fused, or clustered forms, with spherical, tubular or irregular shapes.

While many of these novel properties may be beneficial, concerns have also been raised about the uncertainty that this presents to health, safety and environmental impacts. Research into the potential hazards[1] of these materials has been limited to date, but is increasing. In some instances this research has started to identify possible concerns relating to specific kinds of nanomaterials.

In relation to regulatory activities, NICNAS has developed a **working definition** that is consistent with international definitions (within the Organisation for Economic Co-operation and Development (OECD) as well as national and international regulatory authorities) as follows:

… industrial materials intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 and 100 nanometres[2]…

This working definition has been applied to both NICNAS Calls for Information and other nanomaterial related activities.

Attachment 2 is an indicative (but by no means exhaustive) list of substances that may be produced as nanomaterials.

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

To provide feedback on this question, please refer to the ***Have Your Say Questionnaire.***

[1] Inherent property of an agent having the potential to cause adverse effects.
[2] Measurement equal to one billionth of a metre

2C What is the current regulatory environment for industrial nanomaterials?

Currently, all legislative requirements applicable to conventional chemicals also apply to their nanoforms.

The *Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Frameworks* (also called the *Monash Report*, published in May 2008) determined that while there is no immediate need for major changes to existing regulatory regimes, six areas ('triggers' – presented below) should be addressed by Government to ensure that our regulatory frameworks can better manage the risks posed by nanotechnology in the future.

These 'triggers' are listed below, and elaborated on in **Attachment 3**. A URL for the entire report can be found in the **Further Reading List**.

Monash Report Triggers:

I. ***On the basis of name – 'new' or 'existing' substances or products.*** This recognises that uncertainty exists as to whether the nano-form of a chemical is considered a "new chemical" (and therefore different to its conventional counterpart) or an "existing chemical" (therefore the same as its conventional counterpart). The Monash Report recommended that this issue be clarified within each regulatory framework.

II. ***On the basis of weight or volume.*** The Monash Report recognised that within individual regulatory frameworks some regulatory requirements are triggered by threshold weights or volumes. The Report recommended that such thresholds be examined in the context of nanomaterials because scientific knowledge is such that it may not be known whether these thresholds are appropriate for nanomaterials and that low production volumes may mean that these thresholds may not be reached and therefore regulatory requirements not triggered.

III. **Requiring knowledge of presence – or implications of presence – of nanomaterials.** Regulations that are triggered by awareness of the presence of and/or risks posed by nanomaterials may not be effective because of the uncertainty surrounding the implications of nanomaterials on human health and the environment at present.

IV. ***Reliant on risk assessment protocols or conventional techniques*.** As nanomaterials can have unique physical and chemical properties, risk assessment protocols and/or analytical techniques designed for conventional chemicals may not be appropriate for accurate risk assessment of nanomaterials.

V. ***On the basis of research and development exemptions.*** The Monash Report recognises that some regulatory frameworks include exemptions from assessment for conventional chemicals in the research and development phase. It also recognises that weight thresholds may apply to these exemptions and highlights the need to review these thresholds in for nanomaterials. (Also see 'trigger' II).

VI. ***Reliant on international documents.*** This trigger relates to frameworks that either incorporate or allow applicants to rely on international documents or documents produced by bodies other than the regulator. The report recognises that this could be potential gap if those documents do not address health and environmental concerns raised by nanomaterials.

The NICNAS new chemicals program (chemicals not listed on the national inventory) currently applies to nanomaterials, and includes exemptions, permits and certificates, which represent increasing levels of pre-market scrutiny.

Many industrial nanomaterials however are nano-forms of existing chemicals, (that is chemicals on the national inventory), that can legally be introduced and used without notification to NICNAS but have not been assessed for their novel nano-scale properties.

Consequently these chemicals are not required to undergo a pre-market assessment and there is uncertainty in some cases about the health and environmental impacts. A consequence of current existing chemical obligations and exemption categories is that the extent of use of industrial nanomaterials in Australia is uncertain.

NICNAS proposes to use legislative and administrative changes detailed via options in this Paper to address this issue. These options address the 'gaps' identified by the Monash Report that are relevant to the industrial chemicals regulatory framework. The NICNAS website (see **Further Reading List**) supplies more information in regard to industrial nanomaterials.

*Please refer to the **Business Impact Survey** if you wish to provide further industry related feedback on this section.*

2D National and international activities in relation to regulation of nanomaterials.

NICNAS is actively addressing issues relating to the regulation of industrial nanomaterials in pace with widespread national and international activities.

The Australian Government specifically supports a whole of government approach to policy development, regulation, public engagement and coordinated involvement in international efforts to address health, safety and environmental concerns. The objectives of this overarching approach are to:

- Protect health and safety of humans and the environment;
- Foster informed community debate; and
- Achieve economic and social benefits from the responsible adoption of nanotechnology.

See the **Further Reading List** for more information on the Australian Government objectives for the responsible management and oversight of nanotechnology.

This approach is also in step with activities being broadly undertaken worldwide, including in countries with notification and assessment systems such as the US, Canada and EU, among others.

While current legislation in other countries/ regions does not specifically address nanomaterials, these substances are required to meet the same requirements as conventional chemicals.

In the USA and Canada nano-forms of chemicals on the respective national inventories are subject to existing chemical requirements and nano-forms of chemicals not on the inventories are subject to new chemicals requirements. The USA and Canada recognise similar issues to Australia, particularly for existing chemicals, and are taking steps to review their frameworks, impose nano specific risk management measures and reconsider appropriate data requirements.

In Europe, and under Registration, Evaluation Authorisation and Restructure of Chemical Substances (REACH) legislation the overarching obligation is to ensure that there are no adverse human health or environmental effects. This applies to nanomaterials. Consideration is being given to the need to specifically address nanomaterials.

In addition to scrutiny and adjustment of national and international frameworks that regulate nanomaterials, governments such as Australia, the US, UK and Canada are participating in activities being coordinated by international organizations such as the Organization for Economic Cooperation and Development and International Organization for Standardization. These organisations are actively working to provide the research, methodology and standards required for appropriate oversight of this area.

More information on this is also included in **Attachment 4**. Links and references to further information on national and international activities can also be found in the **Further Reading List**.

PART THREE Industrial Nanomaterial Reform Options

This part presents the proposed options for a regulatory strategy for nano-forms of new chemicals and nanoforms of existing chemicals

Please note: There are three sections in this part -

3A Regulation of nano-forms of 'new chemicals'

3B Regulatory 'package' for nano-forms of 'existing chemicals'

3C The principle of an integrated approach for industrial nanomaterials within the NICNAS framework as a longer term strategy.

3A Regulation of nano-forms of 'new chemicals'

Under NICNAS, new chemicals are those that are not listed on the Australian Inventory of Chemical Substances (AICS).

The new chemicals notification and assessment framework features a hierarchy of exemptions, permits and certificates that include self-assessment options, tailored to the level of risk of conventional chemicals.

Further details are supplied in Attachments 5 and 6.

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

NICNAS proposes to administratively exclude nanomaterials from exemption categories where human and/or environmental exposure can reasonably be anticipated (see below).

The **rationale** for this proposal is as follow:

- The uncertainty surrounding the hazards, exposure and risk assessment methodologies for these novel materials means that the determination of 'no unreasonable risk' or 'non-hazardous', both of which are prerequisites to a range of exemptions, is not expected to be straightforward;
- The current lack of comprehensive information on the properties and health, safety and environmental effects of these novel materials;
- The need for a case by case approach through assessment by NICNAS to ensure consistency, for successful and responsible development of nanotechnology.

Low volume exemptions

NICNAS proposes to administratively exclude nanomaterials which are new chemicals from low volume/low concentration exemptions, thereby shifting a post-market audit activity to a pre-market assessment (ie. new nanomaterials to be assessed under permit or certificate categories prior to commercialisation).

Transhipment exemption

NICNAS proposes to continue transhipment exemptions of nanomaterials, on the basis that any hazard is adequately contained in terms of impacts on human health and the environment in Australia. These chemicals remain in containers under customs control until they leave Australia within 30 days, hence no human or environmental exposure can reasonably be anticipated.

R&D exemptions:

No restrictions are proposed for the introduction of new nanomaterials under the R&D exemption category due to their limited use (i.e. only in an R&D or analytical setting) and the assumption that they are handled only by trained personnel in a controlled environment. This approach is consistent with comparable overseas regulatory arrangements.

Slight changes to administrative arrangements for annual reporting of chemicals introduced under the R&D exemption category are proposed so that all nanomaterials introduced in volumes over 100g/year will be declared as nanomaterials and identified by their full chemical name. NICNAS will monitor the reporting threshold of 100g/yr to determine whether this needs to be revised in the future.

More detail of these administrative changes can be found in tables contained in **Attachment 6**.

In **summary**, the exemption categories for new nanomaterials will be:

- Low volume cosmetic and non-cosmetic exemptions – not available
- Low concentration (<1%) non hazardous cosmetic exemption – not available
- Transhipment exemption – available and current requirements unchanged
- R&D exemptions – available with minor administrative change to annual reporting requirements

Potential impacts:

The potential advantages and disadvantages of this proposal are:

Advantages:

- Restrictions will only be applied to circumstances where human and environmental exposure can reasonably be anticipated;
- Administrative arrangements enable reconsideration of decisions if new information regarding the safety of nanomaterials becomes available.
- Any potential risks to human health and the environment will be identified and addressed through pre-market assessment;
- Industry innovation will not be impacted because R&D exemptions will be retained;
- Knowledge of new nanomaterials being used in R&D will aid NICNAS in identifying trends and prioritising future regulatory efforts.

Disadvantages

- Low volume/low concentration exemptions will not be available to industry and notification fees will apply.

2. How do you think the proposal to limit access to exemptions for nanoforms of new chemicals will contribute to protecting health and the environment?
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?

*To provide feedback on this question, please refer to the **Have Your Say Questionnaire.***

*Please refer to the **Business Impact Survey** if you wish to provide further industry related feedback on this section.*

b Proposal concerning NICNAS notification categories (Permits and certificates)

How the permit and certificate system works:

The NICNAS **permit system** applies to new chemicals introduced in relatively low volumes, for specific purposes (eg commercialisation trials), in controlled circumstances or prior to completion of a full assessment. Specific application and assessment criteria (eg no unreasonable risk determinations) and maximum durations apply for all permits. While upfront data requirements are lower than for certificates, NICNAS can request additional data where it is required to determine no unreasonable risk. Use conditions can be stipulated for permits and these are auditable by NICNAS, enabling authorised post market compliance.

While certain permits may be renewed under specific conditions, these chemicals are not listed on the inventory and as such introducers are known to NICNAS through permit applications.

In contrast, the NICNAS **certificate system** has more extensive upfront data requirements. There are self-assessment options in this category for industry that are allowed under specific circumstances, such as polymers that meet low concern criteria for human health and the environment and chemicals that are non-hazardous, where this data can be supplied.

Proposal

Four concurrent strategies are proposed to apply to certificates and permits:

- Addition of a declaration by the notifier on the permit or certificate application forms stating that the chemical is a nanomaterial.
- More specific information (such as particle size, shape and other specific information on properties) will be required under specified conditions, refer to flow chart in **Attachment 6**).
- Nanomaterials will be administratively excluded from self-assessments on the basis of the uncertainty concerning their hazard. Self-assessments are intended for chemicals or polymers that are non-hazardous. This change will ensure that the hazard status of the nanomaterials and the risk posed by the notified uses will be assessed by NICNAS.
- Permit conditions or specific secondary notification conditions will to apply to conventional chemicals assessed by NICNAS, where it can be reasonably assumed that a nano-form may be introduced in the future (see flow chart **Attachment 6**).

Features that make a permit system suitable for nanomaterials:

Assessing new nanomaterials under a **permit** category has the advantage that NICNAS can determine if the criterion for no unreasonable risk is met consistently across nanomaterials being considered on a case by case basis. In addition NICNAS can stipulate enforceable use conditions, amend these conditions, or revoke the permit. This may be important in the current environment, where new information on these nanomaterials is being generated.

Consistent with current practice for conventional chemicals, a **permit** will only be issued when the applicant has demonstrated “no unreasonable risk” or “low hazard” as required under the Act. The Director can refuse to approve an application for renewal, or revoke a permit under specific conditions outlined in the legislation.

Features that make a certificate system unsuitable for nanomaterials:

NICNAS, however, only has a limited ability to impose conditions of use for **certificates** (annotation of the inventory). NICNAS can make recommendations to standard setting bodies when national standards are

warranted. These national standards must be embodied in state/territory legislation to be enforceable. Chemicals under certificates are placed on the Inventory (existing chemical) five years after the certificate is issued (unless immediate listing is specifically requested by the applicant) enabling legal introduction by any number of companies without further prior notification to NICNAS.

Potential impacts:

The advantages and disadvantages of the above proposal are:

Advantages:

- The proposal will enable NICNAS to identify and assess new nanomaterials introduced into Australia.
- Introducers will be aware of circumstances under which particle size data likely to be required.
- Additional data concerning specific health/environmental effects of the chemicals will only be requested where these data are required for risk assessment.
- Nano-forms of assessed conventional chemicals introduced in the future will be re-notified to NICNAS as appropriate

Disadvantages:

- There will be an increased burden on introducers when additional data are sought, however it is anticipated that the large majority of introducers should have access to this information.
- One certificate category, ie self-assessments, will not be available, therefore nanomaterials will need to be notified under non-self assessed categories. This change is required to ensure that human health and environmental standards are maintained in relatively uncertain circumstances.

5. What are your views on the impact of the proposal to regulate nanoforms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?
6. What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicate a new risk profile?

*To provide feedback on this question, please refer to the **Have Your Say Questionnaire.***

*Please refer to the **Business Impact Survey** if you wish to provide further industry related feedback on this section.*

3B Regulatory 'package' for nano-forms of 'existing chemicals'.

How the system for existing chemicals currently works:

Many industrial nanomaterials in international commerce have conventional forms which are on the AICS and are therefore considered to be existing chemicals. All regulatory requirements applicable to conventional existing chemicals also apply to their nanoforms.

A current issue with this system:

To date, voluntary calls for information on nanomaterials that may give us insight into use of nanoforms of existing chemicals have had limited success both nationally and internationally (eg in UK, USA). This has been attributed to a range of potential reasons including the nature of the voluntary calls, the lack of incentives for industry to respond and possibly a lack of awareness or certainty about when a particular chemical falls within the definition of a nanomaterial. The response to NICNAS's most recent Call for Information elicited limited information.

Limitations of the system for existing chemicals in relation to nanomaterials:

The following limitations have been identified in the current NICNAS Existing Chemicals Program in relation to assessing and managing the risks of nanomaterials:

- inability to reliably identify introducers of nanoforms, given that under the legislation Calls for Information can only be mandated when NICNAS is considering declaration of chemicals for priority review;
- most conventional chemicals on the Inventory have not been assessed, therefore the nano-form can be legally introduced without notification to, and, assessment by NICNAS;
- any existing risk management measures have been assigned on the basis of the characteristics of the conventional form of the chemical;
- it may not be apparent to introducers of nanomaterials that secondary notification provisions (which operate for assessed chemicals) apply to their nano-forms. Therefore any uncertainty in relation to unique hazards posed by nanoforms may not be addressed.

Proposal

Two distinct short- to medium-term activities have been identified to run concurrently to address the limitations outlined above. These are:

Stream 1A – A voluntary once off, use specific reporting program

leading to…..

Stream 1B – A mandatory once off, use specific reporting program,

AND

Stream 2 – examine the feasibility of a mandatory notification and assessment program.

Stream 1A

Voluntary pre-introduction once-off, use specific, reporting of all nanomaterials is proposed as the first step. NICNAS will compile an internal database of the information collected to inform further consideration of its strategy for nanoforms of existing chemicals.

Stream 1B

Stream 1B will be a sequential progression of Stream 1A, to a mandatory pre-introduction once-off, use specific, reporting program when legislative change is enacted to implement outcomes from the NICNAS Existing Chemicals Program Review, a separate activity currently underway. (See **Further Reading List**)

The outcome of the review is a proposal to de-link mandatory information gathering powers from NICNAS assessment products and this change will facilitate implementation of a mandatory reporting program for nanomaterials.

Potential impacts

The advantages and disadvantages of a reporting program are:

Advantages

- Builds a database of information on nanoforms of existing chemicals in use in Australia,
- Assists in identifying nanomaterials of potential concern for further NICNAS review,
- Increases public confidence by facilitating regulatory oversight of nanomaterials in Australia and focussing NICNAS efforts,
- The voluntary reporting proposal (stream 1A) provides an opportunity for industry to develop appropriate processes to respond to a mandatory reporting program as a next stage (stream 1B).

Disadvantages

- The program would incur an extra, once-off use specific, reporting burden on industry.

In addition

NICNAS will have to set up mechanisms to appropriately manage and use the information reported to us.

7. What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nanoforms 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?
9. What are your views on making the information gathered through streams 1A and 1B publicly available?

*To provide feedback on this question, please refer to the **Have Your Say Questionnaire.***

*Please refer to the **Business Impact Survey** if you wish to provide further industry related feedback on this section.*

Stream 2

Concurrent with activities identified in stream 1, NICNAS is exploring the feasibility of implementing a more comprehensive regulatory proposal for nano-forms of existing chemicals that addresses triggers identified in the Monash Report and acknowledges:

- the lack of comprehensive information on properties and health, safety and environmental effects of nanomaterials and
- the uncertainty surrounding the applicability of conventional hazard, exposure and risk assessment methodologies

and is consistent with ongoing national and international efforts to address these challenges.

Please note that this proposal is contingent on regulatory impact analysis.

It is desirable that such a program include:

- the ability to reliably identify introducers of nanoforms of existing chemicals,
- knowledge of specific nanoforms of existing chemicals being introduced, volume information and use scenarios,
- the ability to ensure human health and safety and environmental protection is maintained through enforceable conditions of use, where such measures are warranted,
- health and environmental risk assessments to be based on the best available scientific information,
- the ability of the regulator to obtain "non-standard" information relevant to the risk assessment on a case by case basis,
- adopting measures to protect human health and/or the environment where the best available scientific information is insufficient to support safety of the material,
- the ability to review risk assessment decisions as new scientific information becomes available,
- the regulatory impost on industry is commensurate with the risk posed by these materials (to the extent this can be determined up front).

Please read the following section in conjunction with the flowchart supplied in Attachment 7.

Proposal:

The NICNAS new chemicals permit framework could be used as a potential model (modified as required). The features of the permit framework that are suitable for this purpose include:

- nanomaterials will be assessed on a case by case, using best available scientific information
- NICNAS can request "non-standard" information relevant to the risk assessment as required
- assessed nanoforms of existing chemicals will not be included on the inventory and each introducer will need to seek "permission to introduce" (for example through a "permit" application) therefore NICNAS will have knowledge of introducers of specific nanomaterials at all times.
- the ability to impose mandatory, auditable conditions of introduction when granting "permission to introduce"
- the ability to amend permit conditions or revoke permits (hence introduction) should significant adverse health and environmental effects be identified.
- provisions for recognising commercially confidential information.

However, some features of the current permit framework for conventional new chemicals may not be suitable for this purpose. These are:

- the current data requirements for conventional chemicals may be inadequate for risk assessment of nanoforms of existing chemicals,
- maximum durations (currently up to 4 years depending on permit type) and therefore the need to seek further permissions to introduce may be an unjustified burden on industry, particularly in the absence of adverse effects being identified,
- risk assessment reports are not published in full therefore the transparency of the assessment process is limited.

At this stage we are only seeking stakeholder views on the **feasibility** of implementing a mandatory notification and assessment program for nanoforms of existing chemicals. Further stakeholder consultations including regulatory impact analysis will be undertaken prior to a finalising the reform proposal.

Potential impacts:

The advantages and disadvantages of a mandatory notification and assessment program for nanoforms of existing chemicals (on preliminary consideration only) are identified below:

Advantages

- Provide significant public assurance that potential risks presented by industrial nanomaterials that are nanoforms of existing chemicals are adequately identified and managed,
- Potential health and safety issues will be addressed systematically before the chemical enters the marketplace,
- Decisions can be revisited and revised (as required) when new information becomes available.

Disadvantages

- The proposal will require legislative amendment and will therefore take time to implement.
- This proposal will have cost implications for business and possibly downstream users.

10. What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for nano-forms of existing chemicals? What are the reasons for this answer?
11. What are current issues that affect the feasibility of such a program?
12. What are your views on making information gathered from assessments of nano-forms of existing chemicals publicly available?

*To provide feedback on this question, please refer to the **Have Your Say Questionnaire.***

*Please refer to the **Business Impact Survey** if you wish to provide further industry related feedback on this section.*

This part presents the principle for an integrated approach to nano-forms of NEW AND EXISTING CHEMICALS

3C The principle of an integrated approach for industrial nanomaterials within the NICNAS framework as a longer term strategy.

Sections 3a and 3b collectively provide a proposed approach for regulating nano-forms of new and existing chemicals. After consultation, suitable reform options will be progressed in the short to medium term future.

As a longer term proposal, NICNAS is seeking preliminary views on the principle of integrating the approach for industrial nanomaterials, within the NICNAS framework, as a longer term strategy.

Further exploration of this approach will be complemented as:

1. NICNAS gains experience through the implementation of proposals in sections 3a and 3b.
2. Further national and international scientific activities builds on knowledge in this area.

Please note that we are seeking preliminary views only on this approach at this stage.

13. How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package proposed (for nano-forms of new and existing chemicals) in sections 3a and 3b?

*To provide feedback on this question, please refer to the **Have Your Say Questionnaire.***

This part provides information on how to respond to this paper and what will happen next ion the consultation/reform process

PART FOUR Next steps

4A Making your response count

Make sure you fill out the ***Have Your Say Questionnaire***, and if you have a business interest in these reforms, please also fill out the ***Business Impact Survey***. ***The period for public comment on these proposals will finish at close of business on the 23 December 2009.***

Submit these forms electronically or to ATT: Nicola Hall by:

Fax: (02) 8577 8888;

Email: nicola.hall@nicnas.gov.au, or;

Post (no stamp required):
Nicola Hall, NICNAS
Reply Paid 58
Sydney, NSW 2001

In addition, if you wish to participate in face to face public consultation, please register your interest with NICNAS via electronic Expression of Interest form at:

http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Expression_Nanomaterials_PDF.pdf

Or by contacting NICNAS directly.

Consultations are expected to occur in major cities around Australia from 16 November, 2009. Dates and locations for these consultations will be confirmed shortly, the number and location for these consultations is subject to expressions of interest.

4B What lies ahead?

Following the conclusion of the Public Comment period, suitable reform options will be finalised and a final Regulatory Impact Analysis (RIA) will be developed for each option. **The final proposals will be subject to a further round of consultation prior to implementation.**

We anticipate that NICNAS will continue the development of this reform package through 2010.

Optional readings related to this Discussion Paper

FURTHER READING LIST

Nanotechnology Advisory Group (NAG)
http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Nanotechnology_Advisory_Group.asp

Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Framework **(The Monash Report)**
http://www.innovation.gov.au/Industry/Nanotechnology/Documents/MonashReport2008.pdf

National Industrial Chemical Notification and Assessment Scheme (NICNAS)
http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp

National Emerging Technology Strategy (NETS)
http://www.innovation.gov.au/Industry/Nanotechnology/Pages/NationalEnablingTechnologiesStrategyConsultations.aspx

Australian Government objectives for the responsible management and oversight of nanotechnology
http://www.industry.gov.au/Industry/Nanotechnology/Documents/ObjectivesPaper.pdf

Organisation for Economic Cooperation and Development (OECD) WPMN
http://www.oecd.org/about/0,3347,en_2649_37015404_1_1_1_1_37465,00.html

International Organization for Standardization TC229
http://www.iso.org/iso/hot_topics/hot_topics_nanotechnology.html

US Government (Environmental Protection Authority) approach to regulating nanomaterials
http://www.epa.gov/oppt/nano/

Canadian Government (Environment Canada) approach to regulating nanomaterials
http://www.ec.gc.ca/substances/nsb/eng/nano_e.shtml

UK Government approach to regulating nanomaterials
http://interactive.bis.gov.uk/nano/

European Union (REACH) approach to regulating nanomaterials
http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials_en.pdf

GLOSSARY

Australian Inventory of Chemical Substances (AICS) is the list of chemical identity data maintained by NICNAS; legal device that distinguishes new form existing chemicals and lists all industrial chemicals in use in Australia between 1 January 1977 and 28 February 1990; includes new assessed chemicals since 1990 and corrections as required.

Director Director of NICNAS

Enabling technology a technology in the form of material, equipment or methodology that, alone or in combination with associated technologies, provides the means to generate significant advances in particular applications, in a given field.

Existing chemical an industrial chemical listed on the Australian Inventory of Chemical Substances.

Industrial chemical a chemical that has an industrial use (whether or not it also has another non-industrial use).

International Organization for Standardization *(ISO) is the world's largest developer and publisher of International Standards. ISO is a network of the national standards institutes of 162 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system. ISO is a non-governmental organization that forms a bridge between the public and private sectors.*

Nanotechnology Advisory Group (NAG) has the objective to advise the Director on strategic approaches to address regulatory and safety impacts of industrial nanomaterials. The NAG has members drawn from industry, community, academia and NICNAS. The NAG was convened following consultation with the Community Engagement Forum (CEF) and Industry Government Consultative Committee (IGCC).

Nanomaterial by working definition are industrial materials that are intentionally produced, manufactured or engineered to have specific properties or specific composition, and one or more dimensions typically between 1 and 100 nanometres.

Nanotechnology is engineering at the atomic or molecular (group of atoms) level. It is a group of so-called enabling technologies that involve the manipulation of matter at the nano-scale (generally accepted as 100 nanometres or less) to create new materials, structures and devices.

National Notification and Assessment Scheme (NICNAS) established in 1990, NICNAS regulates industrial chemicals for the protection of people at work, the public and the environment. It operates under the Industrial Chemicals (Notification and Assessment) Act 1989. NICNAS is accountable to the people and Parliament of Australia for implementing this Charter.

New chemical an industrial chemical NOT listed on the Australian Inventory of Chemical Substances.

Office of Best Practice Regulation (OBPR) assists Australian Government departments and agencies to meet the Australian Government's requirements for best practice regulatory impact analysis and in monitoring and reporting on their performance.

Organisation for Economic Cooperation and Development (OECD) groups 30 member countries sharing a commitment to democratic government and the market economy; plays a prominent role in fostering good governance in the public service and corporate activity; work covers economic and social issues from macroeconomics to trade, education, development and science and innovation.

LIST OF ATTACHMENTS