



**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 – November 2009*

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

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

### 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 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 of 16 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.*

**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<sup>1</sup> 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<sup>2</sup>...***

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**.*

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<sup>1</sup> Inherent property of an agent having the potential to cause adverse effects.

<sup>2</sup> 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

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*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, transshipment 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).

##### *Transshipment exemption*

NICNAS proposes to continue transshipment 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
- Transshipment 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 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.*

### 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**.*

## PART FOUR      Next steps

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### 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](mailto: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](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.***

## **FURTHER READING LIST**

### **Nanotechnology Advisory Group (NAG)**

[http://www.nicnas.gov.au/Current\\_Issues/Nanotechnology/Nanotechnology\\_Advisory\\_Group.asp](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](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](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](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](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](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 from 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

- Attachment 1** Overarching Principles of the NICNAS Regulatory Strategy.
- Attachment 2** List of potential forms of industrial nanomaterials.
- Attachment 3** Summary of findings from the Monash Report.
- Attachment 4** Overview of international activities addressing regulation of industrial nanomaterials.
- Attachment 5** Overview of new chemical notification and assessment categories.
- Attachment 6** Proposed strategy for nano-forms of new chemicals.
- Attachment 7** Proposed model for a mandatory notification and assessment program.

## **ATTACHMENT 1**

### **OVERARCHING PRINCIPLES OF THE NICNAS REGULATORY STRATEGY**

**(As agreed by the NICNAS Nanotechnology Advisory Group May 2009)**

Managing the risks posed by new technologies (including nanotechnology) to health and safety of people and the environment can be achieved by:

- a. Reviewing the ability of the existing regulatory framework to deliver an efficient and effective response to the new technology. Where appropriate;
  - i. Using the existing regulatory framework and implementing regulatory or procedural changes to maintain or enhance human health and environmental standards;
  - ii. Considering whether a specific regulatory system may be required where a new technology poses unique challenges that cannot be regulated effectively under the existing regulatory framework;
  - iii. Review undertaken using inclusive and transparent processes.
- b. Making use of the best scientific evidence available for risk based assessment of the impacts of the new technology on human health and the environment, including the ability to review decisions as new scientific evidence becomes available;
- c. Where best available scientific evidence is insufficient to support the safety of the product/chemical, measures to protect public health and safety and the environment can be adopted.

In reviewing the ability of existing frameworks in relation to (a) above, it is prudent to ensure that:

- Any risk from use of the nano-form of a chemical is no greater than that posed by the conventional form of the chemical or it is at or below the level of acceptable risk ie. humans and the environment are not exposed to unknown/unacceptable risks;
- Risk (including uncertainty) is addressed pre-market; and
- Industry innovation is supported through an appropriate level of regulatory oversight.

In relation to assessment of chemicals manufactured using new technologies:

- Risk assessment should be undertaken on a case-by-case basis; and
- Consistent with government policy on cost recovery arrangements for NICNAS, the cost of any assessment should be met by the beneficiary of the assessment.

Main Category	Sub Category		
<b>Nano Carbon</b>	single-walled carbon nanotubes (SWCNTs) *		
	multi-walled carbon nanotubes (MWCNTs) *		
	Carbon black (CAS 7440-44-0) *		
	fullerenes (C60) *		
	C70 fullerene		
	C76 fullerene		
	C84 fullerene		
<b>Polymers specifically synthesized to exploit nanoproperties</b>	C90 fullerene		
	C94 fullerene		
<b>Dendrimers *</b>	Polystyrene *		
	Polyamidoamine (PAMAM)		
	Polyethylene imine		
	Ferrocenyl		
<b>Components of Quantum Dots</b>	Polyglycerol		
	Aluminum Antimony	-	
	Barium Titanate	CAS	12047-27-7
	Cadmium selenide	CAS	1306-24-7
	Cadmium Selenium Telluride		
	Cadmium sulfide	CAS	1306-23-6
	Cadmium Telluride	CAS	1306-25-8
	Gallium Antimony	-	
	Gallium antimony/ Gallium arsenide	-	
	Gallium Arsenide	CAS	1303-00-0
	Gallium arsenide antimony		
	Gallium nitride	CAS	25617-97-4
	Germanium carbide	CAS	12334-26-8
	Indium Arsenide	CAS	1303-11-3
	Indium Arsenide Antimony	-	
	Indium Arsenide/ Gallium arsenide	-	
	Indium Gallium Arsenide	-	
	Indium Gallium Nitride	-	
	Indium phosphide	CAS	22398-80-7
	Indium tin oxide	-	
Lead selenide	CAS	12069-00-0	
Lead sulfide	-		
Mercury telluride	CAS	12068-90-5	
Silicon germanium	-		
Zinc oxide	CAS	1314-13-2	
Zinc selenide	CAS	1315-09-9	
Zinc sulfide	CAS	1314-98-3	
<b>Inorganic Nanomaterials (in Alphabetical Order)</b>	Aluminosilicates	-	
	Aluminum nitride	CAS	24304-00-5
	Aluminum borate	CAS	61279-70-7
	Aluminum hydroxide	CAS	20768-67-6
	Aluminum Magnesium	-	
	Aluminum oxide *	CAS	1344-28-1
	Aluminum oxides	-	
	Aluminum silicate	-	

## Attachment 2 - Indicative list of nanomaterials.xls

Main Category	Sub Category		
	Aluminum Titanium Oxide		-
	Antimony tetraoxide	CAS	1332-81-6
	Antimony oxides		-
	Antimony Tin Oxide		-
	Apatite		-
	Arsenic composite		-
	Barium Ferrite		-
	Barium fluoride	CAS	7787-32-8
	Barium hexaaluminate		-
	Barium hexaferrite		-
	Barium hydroxyapatite		-
	Barium Strontium Titanate		-
	Barium Sulfate	CAS	7727-43-7
	Barium Titanate	CAS	12047-27-7
	Barium Zirconium Titanate		-
	Bismuth germinate		-
	Bismuth nanoparticle (elemental)		-
	Bismuth oxide	CAS	12048-50-9
	Bismuth oxides		-
	Bismuth tantalite		-
	Bismuth telluride	CAS	1304-82-1
	Bismuth titanate	CAS	11115-71-2
	Boron carbide	CAS	12069-32-8
	Boron nitride	CAS	10043-11-5
	Cadmium mercury telluride		-
	Cadmium nanoparticles (elemental)		-
	Cadmium phosphide		-
	Cadmium selenide	CAS	1306-24-7
	Cadmium selenide/Zinc sulfide		-
	Cadmium sulfide	CAS	1306-23-6
	Cadmium telluride	CAS	1306-25-8
	Cadmium telluride/Cadmium sulfide		-
	Calcium carbonate		-
	Calcium hydroxide	CAS	1305-62-0
	Calcium oxide	CAS	1305-78-8
	Calcium phosphate		-
	Calcium titanate		-
	Cerium Copper Oxide		-
	Cerium Gadolinium Oxide		-
	Cerium oxide *	CAS	1306-38-3
	Cerium- Terbium oxide		-
	Chromium hydroxide	CAS	1308-14-1
	Chromium nanoparticles (elemental)		-
	Chromium trioxide	CAS	1333-82-0
	Chromium oxides		-
	Cobalt nanoparticles (elemental)		-
	Cobalt monoxide	CAS	1307-96-6
	Cobalt oxides		-
	Cobalt-Iron Oxide		-
	Cobalt-Zinc Iron Oxide		-
	Copper nanoparticles (elemental)		-
	Copper Nickel Alloy		-
	Copper (II) oxide	CAS	1317-38-0
	Copper (I) oxide	CAS	1317-39-1

## Attachment 2 - Indicative list of nanomaterials.xls

Main Category	Sub Category		
	Copper (I) selenide	CAS	20405-64-5
	Copper (II) selenide	CAS	1317-41-5
	Copper telluride		-
	Copper Tin Alloy		-
	Erbium oxide	CAS	12061-16-4
	Europium iodide	CAS	22015-35-6
	Europium nanoparticles (elemental)		-
	Europium monoxide	CAS	12020-60-9
	Europium (III) trioxide	CAS	1308-96-9
	Ferric ferrocyanide (Prussian blue)		-
	Gadolinium biphthalocyanine		-
	Gadolinium Doped Ceria		-
	Gadolinium monoxide	CAS	62462-54-8
	Gadolinium (III) trioxide	CAS	12064-62-9
	Gallium Antimonide	CAS	12064-03-8
	Gallium arsenide	CAS	1303-00-0
	Gallium Nitride	CAS	25617-97-4
	Gallium oxide	CAS	12024-21-4
	Gallium phosphide	CAS	12063-98-8
	Germanium monoxide	CAS	20619-16-3
	Germanium oxides		-
	Gold nanoparticles(elemental)		-
	Gold oxide	CAS	1303-58-8
	Gold-iron-gold		-
	Hafnium Carbide	CAS	12069-85-1
	Hafnium Nitride	CAS	25817-87-2
	Hafnium Oxide	CAS	12055-23-1
	Indium arsenide	CAS	1303-11-3
	Indium gallium nitride		-
	Indium hydroxide	CAS	20661-21-6
	Indium nitride		-
	Indium oxide	CAS	1312-43-2
	Indium Oxide/Tin Oxide		-
	Indium Phosphite		-
	Indium sulphide		-
	Indium tin oxide		-
	Iron nanoparticle *		-
	Iron carbide	CAS	12011-67-5
	Iron Cobalt		-
	Iron Copper		-
	Iron Copper Tungsten		-
	Iron monoxide	CAS	1345-25-1
	Iron oxides		-
	Iron-boron		-
	Iron-nickel		-
	Laminin-apatite composite		-
	Lanthanum aluminum oxide		-
	Lanthanum chromite		-
	Lanthanum hydroxide		-
	Lanthanum oxide	CAS	1312-81-8
	Lanthanum oxyfluoride		-
	Lead monoxide	CAS	1317-36-8
	Lead oxides		-
	Lead selenide	CAS	12069-00-0

## Attachment 2 - Indicative list of nanomaterials.xls

Main Category	Sub Category		
	Lead sulfide	CAS	1314-87-0
	Lead telluride	CAS	1314-91-6
	Lead zirconate titanate	-	-
	Lithium Cobalt Nickel Oxide	-	-
	Lithium ferrite	-	-
	Lithium manganate	-	-
	Lithium Manganese Oxide	-	-
	Lithium Titanate	CAS	12031-82-2
	Magnesium Aluminum Oxide	CAS	12068-51-8
	Magnesium ferrite	-	-
	Magnesium hydroxide	-	-
	Magnesium oxide	CAS	1309-48-4
	Magnesium phosphate	CAS	7757-87-1
	Magnesium silicate	-	-
	Magnesium Zinc	-	-
	Manganese dioxide	CAS	1313-13-9
	Manganese oxides	-	-
	Molybdenum carbide	CAS	12069-89-5
	Molybdenum disulfide	CAS	1317-33-5
	Molybdenum nitride	-	-
	Molybdenum (VI) oxide	CAS	1313-27-5
	Molybdenum oxides	-	-
	Molybdenum selenide	CAS	12058-18-3
	Molybdenum Silicide	-	-
	Molybdenum sulfide	-	-
	Molybdenum trioxide	CAS	1313-27-5
	Neodymium oxalate	-	-
	Neodymium oxide	CAS	1313-97-9
	Nickel Iron Oxide	-	-
	Nickel nanoparticles (elemental)	-	-
	Nickel monoxide	CAS	1313-99-1
	Nickel oxides	-	-
	Nickel zinc ferrite	-	-
	Nickel Zinc Iron Oxide	-	-
	Nickel-tungsten sulfide	-	-
	Niobium monoxide	CAS	12034-57-0
	Niobium oxides	-	-
	Palladium nanoparticles (elemental)	-	-
	Platinum nanoparticles (elemental)	-	-
	Platinum-ruthenium	-	-
	Platinum-ruthenium-nickel	-	-
	Potassium bismuth titanate	-	-
	Potassium chloride	-	-
	Potassium iodide	-	-
	Ruthenium oxide	CAS	12036-10-1
	Samarium carbide	-	-
	Samarium cobalt	-	-
	Samarium hydride	-	-
	Samarium oxide	CAS	12060-58-1
	Selenium nanoparticles (elemental)	-	-
	Selenium titanium dioxide	-	-
	Silicon carbide	-	-
	Silicon dioxide*	CAS	60676-86-0
	Silicon nanoparticles (elemental)	-	-

## Attachment 2 - Indicative list of nanomaterials.xls

Main Category	Sub Category		
	Silicon nitride		-
	Silicon oxide	CAS	14808-60-7
	Silver bromide	CAS	7785-23-1
	Silver-gold		-
	Silver nanoparticles (elemental) *		-
	Silver oxide	CAS	1301-96-8
	Silver Palladium		-
	Sodium silicates		-
	Strontium Carbonate	CAS	1633-05-2
	Strontium ferrite		-
	Strontium hexaferrite		-
	Strontium titanate	CAS	12060-59-2
	Strontium tungstate	CAS	13451-05-3
	Strontium-bismuth tantalate		-
	Tellurium dioxide	CAS	59863-17-1
	Terbium oxide	CAS	12036-41-8
	Terbium-europium		-
	Tin dioxide		-
	Tin nanoparticles		-
	Tin monoxide	CAS	21651-19-4
	Tin oxides		-
	Titanium Aluminum Vanadium		-
	Titanium Aluminum Vanadium Tin		-
	Titanium Boride		-
	Titanium Boride/Boron Carbide		-
	Titanium Boride/Boron Carbide/Tungsten Boride		-
	Titanium boride/boron carbide/tungsten boride		-
	Titanium carbide	CAS	12070-08-5
	Titanium Carbide/Nitrogen		-
	Titanium carbonitride		-
	Titanium dioxide *	CAS	13463-67-7
	Titanium fullerenoid		-
	Titanium nitride	CAS	25583-20-4
	Titanium oxide	CAS	1309-63-3
	Titanium oxides		-
	Titanium Tin		-
	Titanium Zirconium Niobium		-
	Titanium-silicon oxide		-
	Tungsten carbide	CAS	12070-12-1
	Tungsten Carbide/Cobalt		-
	Tungsten disulfide		-
	Tungsten nanoparticles		-
	Tungsten trioxide	CAS	1314-35-8
	Tungsten oxides		-
	Vanadium carbide	CAS	12070-10-9
	Vanadium dioxide	CAS	12036-21-4
	Vanadium nitride	CAS	24646-85-3
	Vanadium monoxide	CAS	12035-98-2
	Vanadium oxides		-
	Vanadium pentaoxide	CAS	1314-62-1
	Yttria Stabilized Zirconia		-
	Yttrium aluminum garnet		-
	Yttrium Iron Garnet		-
	Yttrium oxide	CAS	1314-36-9

Main Category	Sub Category		
	Yttrium oxysulfide		-
	Yttrium silicate		-
	Yttrium-Aluminum Oxide		-
	Zero-valent selenium (zero valent)		-
	Zinc ferrite		-
	Zinc oxide *	CAS	1314-13-2
	Zinc selenide	CAS	1315-09-9
	Zinc sulfide	CAS	1314-98-3
	Zinc telluride	CAS	1315-11-3
	Zinc-Iron Oxide		-
	Zirconium carbide	CAS	12070-14-3
	Zirconium dioxide	CAS	1314-23-4
	Zirconium hydroxide		-
	Zirconium oxide		-
<b>Nano clay *</b>			
	Allophane		Hydrated Aluminum Silicate
	Illite		Hydrated Potassium Aluminum Magnesium Iron Silicate Hydroxide
	Kaolinite		Aluminum Silicate Hydroxide
	Montmorillonite		Hydrated Sodium Calcium Aluminum Magnesium Silicate Hydroxide
	Palygorskite		Hydrated Magnesium Aluminum Silicate Hydroxide
	Sauconite		Hydrated Sodium Zinc Aluminum Silicate Hydroxide
	Talc		Magnesium Silicate Hydroxide
	Vermiculite		Hydrated Magnesium Iron Aluminum Silicate Hydroxide

## **Attachment 3**

# **SUMMARY OF FINDINGS FROM REVIEW OF THE POSSIBLE IMPACTS OF NANOTECHNOLOGY ON AUSTRALIA'S REGULATORY FRAMEWORK)**

## **Chapter 5 Regulatory Triggers, Gaps and Additional Comments**

### **5.1 Summary of Findings**

Australia's federal regulatory frameworks are generally well suited to allowing adequate management and control of risks posed by engineered NMs and products incorporating NMs, and their manufacture, use and handling. This conclusion uses as the baseline comparator the level of HSE protection provided by the regulatory frameworks in relation to conventional products. This review found that there was no case where a particular regulatory framework generally did not apply to a nanofamily as a result of the presence of NMs. Accordingly, whilst not all frameworks applied to all nanofamilies, this was not due to the involvement of nanotechnologies or presence of NMs.

Further, the application generally of the federal regulatory frameworks to NMs and products in the nanofamilies meant that regulation throughout the whole of the lifecycle of these materials is largely the same as for conventional products. Therefore, for example, those regulatory frameworks put in place to protect Australians and their environment from harm from imported products, such as the Customs and AQIS Regulatory Frameworks, and from imported and locally produced products, including the APVMA, FSANZ, GTR and NICNAS Regulatory Frameworks generally were relevant. The application of multiple regulatory frameworks at the one lifecycle stage means that, as for conventional products, there will be overlap between the regulators. For example, crops genetically modified for pest resistance are regulated under the APVMA, GTR and FSANZ Regulatory Frameworks. Functional foods whether incorporating NMs or not, will raise issues of the boundaries between FSANZ and the TGA Regulatory Frameworks.

The general repercussions of such applications were also the same as for conventional products – for example, some regulatory regimes involve regulatory approval prior to undertaking the particular regulated activity (such as the supply of a pesticide under APVMA or the use of a GMO under the GTR Regulatory Framework). But this also meant that steps not required to be taken under particular regulatory frameworks were also not taken for NMs. For example, food and therapeutic goods used by consumers are regulated without an environmental risk assessment having occurred. Whether this is appropriate for NMs depends upon whether the presence of NMs or involvement of nanotechnology in those products increases the potential environmental risks significantly when compared to the conventional products considered when determining the general operation of those frameworks. That assessment is outside the remit of this review. Nevertheless, as highlighted in the following Sections 5.1.1 to 5.1.6 (and in Table 5.1), some gaps were found where the regulatory frameworks either do not apply at all to NMs and products incorporating them or do not apply to NMs or nanoproducts as appropriately as they apply to conventional products in the same families. In summary, these gaps arose because of the following –

#### **5.1.1 Triggers on the Basis of Name – 'New' or 'Existing' Substances or Products?**

This is possibly the most significant potential gap because of its relevance, to varying degrees, to all regulatory frameworks with the exception of the GTR Regulatory Framework. For many NMs and products incorporating them, particularly chemicals, uncertainty exists as to whether the nanoentity would be considered as 'new' or 'different' to or the same as its' conventional counterpart. The ramification of this is that either the regulatory framework as a whole, or parts of the framework, may not properly apply to NMs or products incorporating NMs or produced using nanotechnology.

Particularly for regulation directed at protecting OH&S and public safety, where products are transported, and environment protection, regulation is often on the basis of the naming of particular substances or articles. In some cases these named products are prohibited (for example, particularly hazardous pesticides under the APVMA regulatory framework) and in other cases, permitted (for example, industrial chemicals under the NICNAS Regulatory Framework and therapeutic goods under the TGA Regulatory Framework). Uncertainty as to whether the nanoform of a conventional product is the equivalent to an existing entity means there is also uncertainty in the application of such regulations to NMs or products incorporating them. This is particularly the case in relation to industrial chemicals.

Addressing this issue will require not only a decision as to whether nanoforms should be considered as a 'new' substance or product or as an 'existing' substance or product when compared to their conventional counterparts, but would then require revision of most frameworks to ensure this is made clear.

### **5.1.2 Triggers on the Basis of Weight or Volume**

Some regulatory triggers depend upon thresholds determined by weight or volume being met or avoided. For example, the transport of small quantities of DG does not trigger the application of the *RTR Regulations* and *ADG Code*. This can cause gaps in the application of the regulatory frameworks to NMs and products incorporating NMs because of three reasons. First, current scientific knowledge is such that it may not be known whether these thresholds are appropriate for NMs and products incorporating them. Second, difficulties in measuring the presence of NMs may mean the thresholds are not meaningful. Finally and possibly the most significant at this time, the presently low production levels of NMs mean that thresholds that set a ceiling that must be met before the regulations apply are unlikely to be met, as highlighted in relation to industrial chemicals. This means regulatory frameworks requiring such satisfaction in order to be triggered will not apply.

### **5.1.3 Triggers Requiring Knowledge of Presence or Implications of Presence of NMs**

In some instances, appropriate regulation requires particular knowledge of either the presence of NMs and / or risks posed by the presence of NMs. Current public awareness and scientific knowledge is such that these triggers are unlikely to be met. For example, in the FSANZ Regulatory Framework, articles and materials are not to be in contact with food if such contact is 'likely to cause bodily harm'. It is probable that deficiencies in current knowledge regarding the effects of NMs on human health are such this trigger could not yet be satisfied, even if eventually it could be when science has improved our understanding of this branch of knowledge.

In some instances this may at first glance seem to mean that NMs and products incorporating NMs could be prevented from entering the market. An example of this is provided in the APVMA Regulatory Framework. Before APVMA registers or approves a chemical product, it is to be satisfied of certain things including that the use of the product would not be an undue hazard to the safety of people handling it and not likely to have unintended harmful effects on the environment. Theoretically, APVMA could use this provision to justify refusal to register or approve chemical products that are or incorporate NM or were produced using nanotechnology. However, APVMA must have grounds for reaching these conclusions and the matters relevant to those grounds are set out in the legislation. Whilst these grounds include matters important to the safety and environmental risks of NMs and nanotechnology, such as the form of the chemical constituents and the toxicity of the product, gaps nevertheless remain. Such gaps arise for the reasons discussed in 5.1.4 below – because of difficulties and uncertainty in applying risk assessment protocol and data collection techniques such as toxicity and ecotoxicity testing methodologies that were developed for conventional products.

### **5.1.4 Triggers Reliant on Risk Assessment Protocols or Conventional Techniques**

Risk assessment protocols are in some instances involved in the triggering process. If those protocols are not appropriate for NMs, the regulatory arrangements of which they are part will not be triggered. For example, in the APVMA Regulatory Framework analytical techniques may not necessarily be suitable for NM. Whilst in the instance of this regime, APVMA could refuse to be satisfied where inappropriate analytical techniques are used this does require APVMA to know that these techniques are not appropriate. Those regulatory frameworks which have human and environmental risk assessments as part of their regime, will also face difficulties given it is not known whether current toxicology testing techniques are suitable for NMs.

### 5.1.5 Research and Development Exemptions

There were some specific gaps relevant to research and development. These gaps are not unique to NMs and products, applying to any research and development. However, in light of the stage in development at which many NMs and products incorporating them currently are, this deliberate exception for research and development may be of greater significance for NMs and their products and therefore is included as a 'gap' for the purposes of this review. Examples of this arise in both the APVMA and ASCC – HS Regulatory Frameworks. In the case of APVMA, the research and development exemption is linked to a weight threshold, raising another possible gap as discussed in 5.1.2. The ASCC – HS exemption relates to bona fide research into certain listed carcinogenic substances.

### 5.1.6 Triggers Reliant on International Documents

A number of the regulatory frameworks incorporate or allow applicants to rely on international documents or documents produced by bodies other than the regulator. This is a potential gap if those documents themselves do not adequately address HSE concerns raised by NMs. For example, in the FSANZ Regulatory Framework, the *Plastics Standard* references international documents compliance with which satisfies the Standard. The DEW Regulatory Framework, the import and export of hazardous waste must be in compliance with the *Basel Convention*. In the APVMA Regulatory Framework, the *Agvet Regulations* allow the use of tests specified by bodies outside the control of the regulator such as the Association of Official Analytical Chemists.

## **Attachment 4:**

### **Overview of international activities addressing regulation of industrial nanomaterials.**

*US government (Environmental Protection Authority) approach to regulation of industrial nanomaterials:*

#### **Chemical Nanoscale Materials**

Many nanomaterials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). This law provides EPA with a strong framework for ensuring that new and existing chemical substances are manufactured and used in a manner that protects against unreasonable risks to human health and the environment.

For example, TSCA requires manufacturers of new chemical substances (i.e., those not on the [TSCA Chemical Substances Inventory](#)) to provide specific information to the Agency for review prior to manufacturing chemicals or introducing them into commerce. EPA can require reporting or development of information to assess existing chemicals already in the marketplace. Additionally, EPA can take action to ensure that those chemicals that pose an unreasonable risk to human health or the environment are effectively controlled.

One of the key questions for manufacturers and importers is determining whether a given nanoscale material is already listed on the TSCA Inventory or if it is a new chemical requiring premanufacture notification to the Agency. On January 28, 2008, EPA released the [TSCA Inventory Status of Nanoscale Substances – General Approach \(2008\) \(PDF\)](#), (7 pp, 37K), describing EPA's current thinking regarding whether a nanoscale material is a "new" or "existing" chemical substance under TSCA.

EPA has received and reviewed numerous new chemical notices under TSCA for nanoscale materials including carbon nanotubes. The Agency has taken steps to control or limit exposures to these chemicals, including: limiting the uses of the nanoscale materials, requiring the use of personal protective equipment, such as impervious gloves and NIOSH approved respirators, and limiting environmental releases.

The Agency has also required testing to generate health and environmental effects data where appropriate. EPA has permitted limited manufacture of new chemical nanoscale materials through the use of administrative orders or Significant New Use Rules under TSCA. The Agency has also allowed the manufacture of new chemical nanoscale materials under the terms of certain regulatory exemptions, but only in circumstances where exposures were tightly controlled to protect against unreasonable risks (using, for example, the protective equipment and environmental release limitations discussed above).

To complement and support EPA's new and existing chemical programs under TSCA, the Agency developed a [Nanoscale Materials Stewardship Program \(NMSP\)](#). The NMSP will help provide a firmer scientific foundation for regulatory decisions by encouraging the development of key scientific information and contribute to an improved understanding of risk management practices for nanoscale chemical substances (nanoscale materials).

Taken from: <http://www.epa.gov/oppt/nano/>

*Canadian government (Environment Canada) approach to regulation of industrial nanomaterials:*

#### **PROPOSED APPROACH FOR A REGULATORY FRAMEWORK FOR NANOMATERIALS**

A regulatory framework for nanomaterials needs to be developed in a way that is scientifically robust and harmonizes with the outcomes of international efforts. Environment Canada and Health Canada are proposing the development of a regulatory framework for nanomaterials consisting of two phases of implementation based on shorter and longer term objectives.

- Phase 1 (started fall 2006)
  - a. Continue work with international partners to develop scientific and research capacities (OECD, ISO).
  - b. Inform potential notifiers of their regulatory responsibilities under the current framework.
  - c. Develop initiatives to gather information from industry on the uses, properties, and effects of nanomaterials.

d. Consider whether amendments to CEPA 1999 or the NSNR would be needed to facilitate the risk assessment and management of nanomaterials.

• Phase 2 (starting 2008)

- a. Resolution of terminology and nomenclature by ISO TC229.
- b. Consider establishing data requirements under the NSNR specific to nanomaterials.
- c. Consider the use of the Significant New Activity (SNAc) provision of CEPA 1999 to require notification of nanoscale forms of substances already on the DSL.

Taken from: [http://www.ec.gc.ca/substances/nsb/pdf/nanoproposition\\_e.pdf](http://www.ec.gc.ca/substances/nsb/pdf/nanoproposition_e.pdf)

*UK government (Environmental Protection Authority) approach to regulation of industrial nanomaterials:*

The UK Government and the European Commission have commissioned several [studies of current legislation](#) affecting the development and marketing of nanomaterials. These have found that the existing regulatory framework is broadly adequate but that some changes are needed and there may be some regulatory gaps. Although progress is being made in improving our understanding of potential risks from nanomaterials, our knowledge in many areas is not yet sufficient to enable us to determine if there are real regulatory gaps or how they should be remedied. In addition, our understanding has still to reach the stage at which we can be confident that methods of identifying hazards and evaluating risks are adequate, and thus that businesses are able to carry out reliable risk assessments of new products.

The Government is committed to ensuring that legislation is proportionate and evidence- and risk-based and focused on the specific properties and functionalities of nanomaterials as well as their size. The regulatory issues are not unique to the UK and the Government is working with –

- The [OECD](#) to share information and agree priorities for regulation; and
- The [EU](#) to ensure that EU legislation is amended in a timely and appropriate manner, where necessary following advice from the relevant EU scientific advisory committees.

Hilary Benn, the Secretary of State for Environment, Food and Rural Affairs wrote to the European Commission in 2008 to encourage it to expedite actions to update its legislation. Since then –

- Agreement has been reached on updating and amending the [EU Cosmetics Directive](#) to take account of nanomaterials. It will require prior notification and labelling of products containing nanomaterials;
- Negotiations have begun on a proposal to update the [Novel Foods Regulation](#) and make it clear that nanomaterials fall within its scope; and

A working group has been established that is considering the applicability of the new EU Chemicals regime, the [REACH Regulation](#), to nanomaterials. For example, it will consider the need for different weight thresholds for nanotechnologies. In addition, methods for identifying hazards and evaluating risks of substances at the nano-scale need to be further refined over the next few years.

Taken from: <http://interactive.bis.gov.uk/nano/cross-cutting-issues/managing-risks-and-uncertainties/>

*EU government (REACH) approach to regulation of industrial nanomaterials:*

The first registration deadline under REACH (30 November 2010) applies to substances manufactured or imported at 1000 tonnes or more per year. The registrations of nanomaterials in this tonnage band will help to generate more information useful for the assessment of risks. [The European Chemicals Agency \(ECHA\)](#) receives the registrations and the Agency plays a central role in the collection, evaluation and dissemination of information on substances and preparations, including nanomaterials.

Moreover, nanomaterials that fulfil the criteria for classification as hazardous under [Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures](#) must be classified and labelled. Many of the related provisions, including safety data sheets and classification and labelling apply already today, independently of the tonnage in which the nanomaterials are manufactured or imported. Substances, including nanomaterials, meeting the classification criteria as hazardous must be notified to ECHA by 1 January 2011.

In close co-operation with the [CARACAL](#) subgroup on nanomaterials ("CASG Nano", composed of Member States and stakeholder experts) the Commission is elaborating advice on how nanomaterials should be managed in accordance with REACH. The first paper [Nanomaterials in REACH](#) [236 KB] provides an overview of how the provisions of REACH apply to nanomaterials. Additional papers are planned on registration and classification and labelling. These papers will be handed over to ECHA for integration into the relevant guidance documents.

Taken from: [http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm)

## **Attachment 5:**

### **Overview of NICNAS New Chemical Notification Categories**

#### **Permit Categories**

Permit notification categories are suitable for chemicals which meet certain criteria. These notification categories result in the issue of a permit allowing the introduction of fixed quantities of the chemical for the duration of the permit. This permit has enforceable conditions imposed by NICNAS which may be related to use, disposal and handling. They also result in the publication of a notice of the permit in the *Chemical Gazette*. The chemical is not added to the AICS. The assessment timeframes for permit categories are shorter and the fees lower than certificate notification categories (see below). An application to renew an existing permit can be made in certain circumstances.

**Commercial Evaluation Chemical (CEC)** permit notifications are for limited volume chemicals to be introduced solely for the purpose of market evaluation where the maximum quantity to be introduced is four tonnes in a maximum period of two years.

**Low Volume Chemical (LVC)** permit notifications are for small volume chemicals to be introduced at a rate of up to 100 kg per year or 1000 kg per year (where the chemical meets low-hazardous criteria) for a maximum of three years.

**Controlled Use Permit (CUP)** notifications are for the introduction of low risk new chemicals used in highly controlled circumstances for a maximum of three years. There is no volume restriction provided certain hazard and exposure criteria are met.

**Export Only Permit (EOP)** notifications are for controlled introduction of a new chemical for export purposes or for its use in controlled formulation of products in Australia for export of the entire quantity for a maximum of three years.

**Early Introduction Permit (EIP)** applications may be made under certain circumstances, in conjunction with a certificate notification. An EIP allows introduction of a chemical into Australia before its certificate assessment is complete. Chemicals/polymers which may be eligible for an EIP are:

- polymers of low concern (PLC);
- non-hazardous chemicals/polymers;
- chemicals/polymers meeting low-hazardous criteria; or
- low risk highly controlled chemicals/polymers.

#### **Certificate Categories**

The certificate notification categories are for chemicals which do not meet the permit criteria or where the introducer prefers a certificate notification to a permit notification. Certificate categories result in an assessment report, the issue of an assessment certificate, publication of a summary report in the *Chemical Gazette* and a full public report on the NICNAS website and the eventual addition of the assessed chemical to the AICS. There are different fees and data requirements for each category.

**Polymers of Low Concern (PLC)** notifications are for polymers for which meet certain criteria.

Limited Notifications are for chemicals that fit into the following categories:

- a. small volume chemicals, biopolymers and low molecular weight synthetic polymers (NAMW < 1000), i.e. those which are to be imported or manufactured at a rate of up to one tonne per 12 month period; or
- b. site-limited chemicals, biopolymers and low molecular weight synthetic polymers (NAMW < 1000), i.e. those restricted to their manufacturing site and manufactured at a rate of not more than 10 tonnes per 12 month period; or
- c. synthetic polymers with NAMW greater than 1000 and which do not meet the PLC criteria (no volume restriction).

Standard Notifications are for chemicals, biopolymers and low molecular weight synthetic polymers imported or manufactured at greater than one tonne per year and which do not fulfil the requirements of any other category.

### **Self-Assessment**

It is possible to submit a self assessment application for the following categories of chemicals:

1. Polymer of Low Concern (SAPLC)
2. Non-hazardous chemicals and non-hazardous polymers other than PLC (SANHC and SANHP).

Self-Assessments have a shorter assessment timeframe and lower assessment fees than other certificate categories.

### **Secondary Notifications**

Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* a chemical that has been formally assessed by NICNAS, either as a new or existing chemical, may necessitate a reassessment due to changed circumstances, a secondary notification assessment.

Standard circumstances of which the Director must be advised are stated in section 64(2) of the Act, and include if the use or volume significantly change, or if any additional information becomes available as to the adverse effects of the chemical. Specific circumstances can be included in the assessment report, and may include changes in the form in which the chemical is introduced, and changes in the concentration of the imported products. These obligations apply *even* after the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

NICNAS will appraise the information provided, and determine whether the change in circumstances impacts significantly on the findings of the original report. If this is the case, NICNAS will call for secondary notification of the notified chemical through the Chemical Gazette.

## **Attachment 6:**

### **Proposed strategy for nano-forms of new-chemicals.**

#### **6.1 Proposal for regulation of industrial nanomaterials under NICNAS exemption categories**

*The Industrial Chemicals Notification and Assessment Act 1989* (the Act) has provisions for two categories of exemption from notification for new chemicals used in research and development. The details of these categories, as well as the proposed amendments for nanomaterials, are set out in the table below.

<b>Exemption</b>	<b>Volume restriction</b>	<b>Other criteria</b>	<b>Advice required prior to introduction</b>	<b>Annual reporting requirements</b>	<b>Proposal for nanomaterials</b>
Research and Development	Not more than 100 kg in any 12 month period	No Unlike other exemptions these do not have restrictions related to the hazard of the chemical or a requirement for the introducer to demonstrate no unreasonable risk.	No	< 100g no reporting requirements (legislative requirement)  100g - < 10 kg: administrative requirements: option available to report only numbers of chemicals without chemical names  10-100 kg: chemical names and quantity must be reported	No change proposed to volume threshold  Reporting of chemical name and declaration of nanomaterial  Declaration of nanomaterial
Research and Development (manufactured)	No volume restriction	Site limited. Apparatus cannot operate effectively to produce smaller quantities.	Yes (Form 6)*  Chemical name required.	No	Declaration of nanomaterial on Form 6

\*Form 6 requires the notifier to state the chemical name and CAS number (if known) and details of manufacture and disposal.

### 6.2 Proposal for regulation of industrial nanomaterials under NICNAS permit categories

A summary of the permit categories, including the current data requirements for particle size, and the proposed changes for nanomaterials are set out in the table below,

Category	Chemical amount introduced	Duration of permit	Particle size distribution scheduled data requirement	Proposal for nanomaterials
CEC	< 4 tonnes	2 years	No	Declaration of nanomaterial on Form 1
LVC	< 100 kg/yr	3 years		Under certain circumstances*, request for particle size distribution data
EOP	No volume restriction	3 years		If fraction < 100 nm, further information on the physical characteristics of the nanoparticle may be required
CUP	No volume restriction	3 years		
LVC (1000) <i>low hazard</i>	< 1000 kg/yr	3 years	No	Permits will be issued only if no/low hazard can be demonstrated
EIP	No volume restriction	Permit terminates when certificate issued	Yes ( <i>for solids only</i> ) Notifiers are required to specify percentage of particles < 10 µm and < 100 µm	

\*Particle size information will be requested in the following cases:

- where it can reasonably be anticipated that the chemical could be a nanomaterial; or
- in cases where there is uncertainty regarding whether the chemical could be a nanomaterial for high risk scenarios i.e. uncontrolled exposure; and
- the particulates are insoluble or biopersistent.

### 6.3 Proposal for regulation of industrial nanomaterials under NICNAS certificate categories

#### *Summary of the certificates available and proposed changes*

Category	Chemical amount introduced	Particle size distribution scheduled data requirement	Proposal for nanomaterials*
STD	No volume restriction	Yes ( <i>for solids only</i> )  Notifiers are required to specify percentage of particles < 10 µm and < 100 µm	Declaration of nanomaterial on Form 1
LTD <sup>1</sup>	< 1 tonne/yr <sup>2</sup> < 10 tonne/yr <sup>2</sup> for site limited chemicals		Under certain circumstances <sup>3</sup> , request for particle size distribution data (including percentage < 100 nm) for dispersions
PLC	No volume restriction		If fraction < 100 nm, further information on the physical characteristics of the nanoparticle may be required
SAPLC, SANHC, SANHP	No volume restriction		Nanomaterials to be excluded from these categories

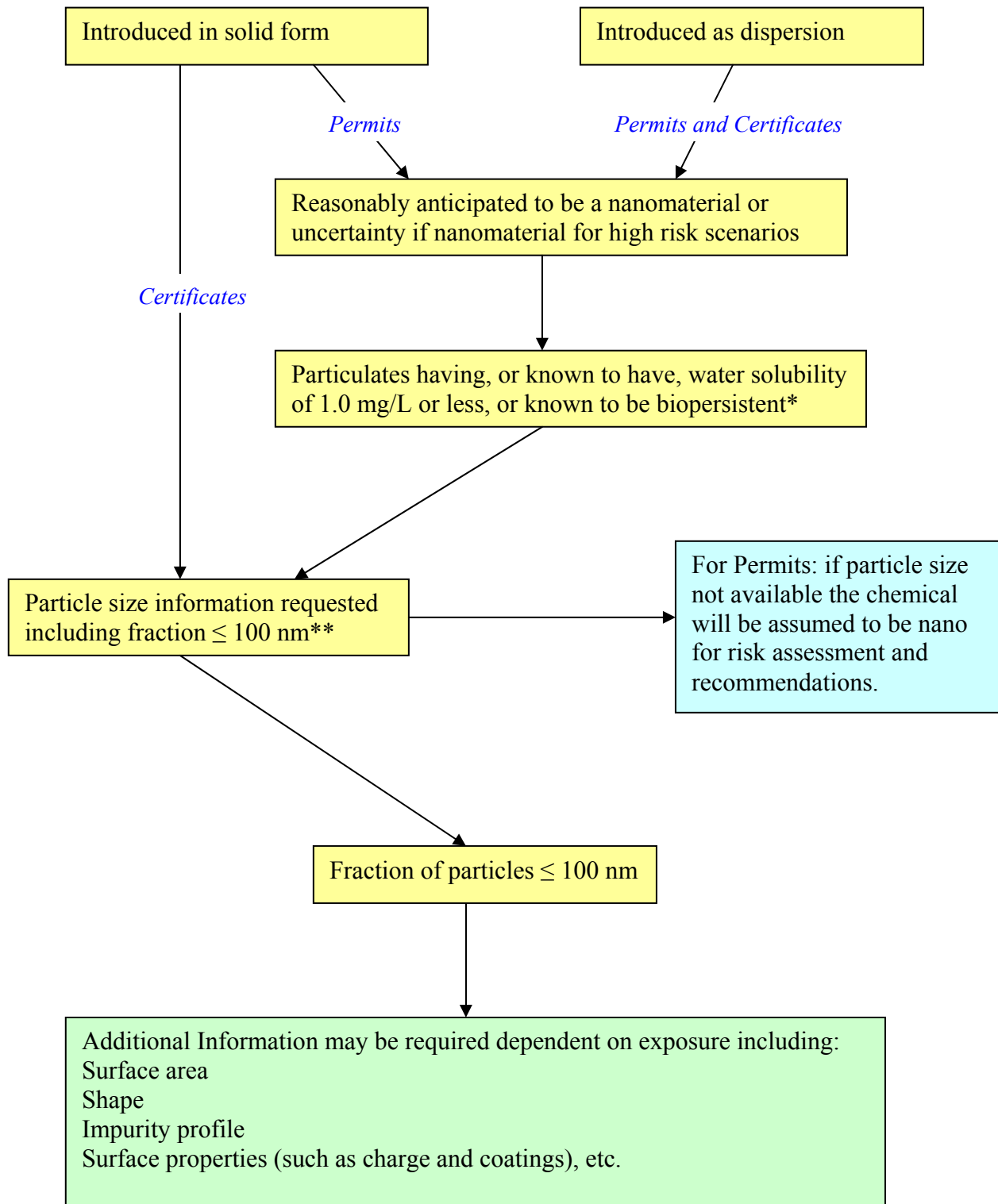
<sup>1</sup>Limited (LTD) notifications – toxicity data not a scheduled data requirement, therefore chemicals under this category generally have limited or no toxicity data.

<sup>2</sup>Volume restriction does not apply to synthetic polymers with NAMW > 1000 Da.

<sup>3</sup>Currently it is a requirement of notifiers to submit information on particle size for all certificate categories where the chemical is introduced as a solid  
Particle size information will be requested in the following cases:

- where it can reasonably be anticipated that the chemical could be a nanomaterial; or
- in cases where there is uncertainty regarding whether the chemical could be a nanomaterial for high risk scenarios i.e. uncontrolled exposure; and
- the particulates are insoluble or biopersistent.

**FLOW CHART: Proposed strategy for requesting particle size distribution information for permit and certificate categories.**

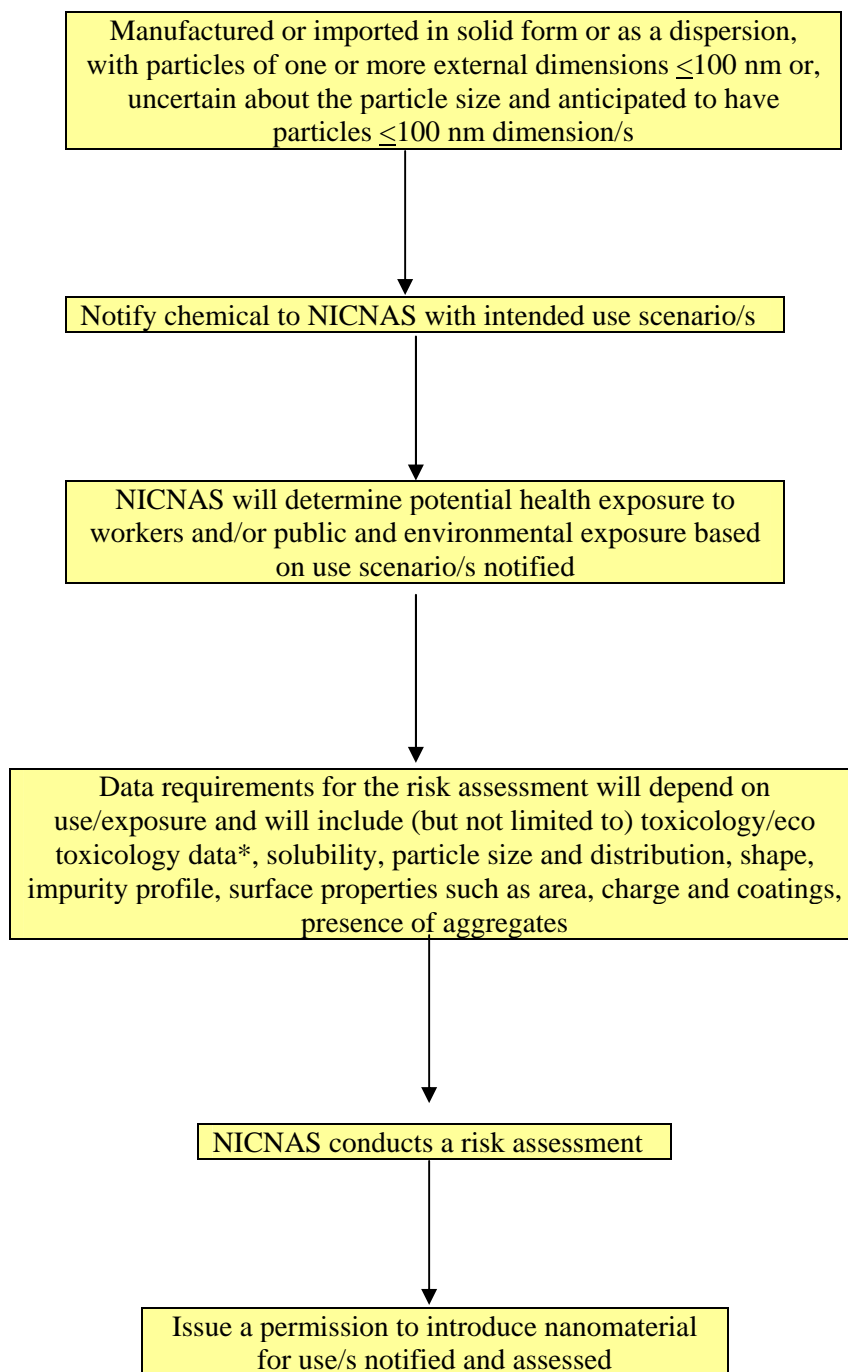


\* “biopersistent” is defined as the ability of a substance to remain in the body in spite of physiological clearance mechanisms

\*\* fraction ≤ 100 nm only required if particulates have, or known to have, water solubility of 1.0 mg/L or less, or known to be biopersistent\*

**Attachment 7:**

**Proposed model for a mandatory notification and assessment program.**



\* All available toxicological and eco-toxicological data should be provided. NICNAS may request additional data if they are deemed necessary to determine the risk.