

## CHEMICALS CLEARING HOUSE

CCH 80 – 7 June 2011

**Agenda Item: \*\***

**Originator: NICNAS**

**Title: Update on NICNAS Strategy for Industrial Nanomaterials**

**Purpose:**

To provide CCH with an update on NICNAS's progression of its strategy addressing potential risks and public concerns arising from the introduction of industrial nanomaterials.

**Background:**

- In November 2009 NICNAS developed a proposal for regulatory reform of industrial nanomaterials. The main elements of the proposal that NICNAS developed in 2009, in consultation with the NAG, were:
  - regulation of nano-forms of new chemicals
  - regulation of nano-forms of existing chemicals
  - principle of an integrated approach for industrial nanomaterials within the NICNAS framework.
- The public consultations on this proposal in 2009-10 indicated broad support for the proposed reforms across the range of NICNAS stakeholders. NICNAS has published on its website written submissions together with responses to the issues raised in these submissions, and these can be located at -  
[http://www.nicnas.gov.au/Current\\_Issues/Nanotechnology/Stakeholder\\_Consultation\\_2009\\_10.asp](http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Stakeholder_Consultation_2009_10.asp).
- NICNAS discussed the views received from the 2009-10 consultation on its proposal for regulatory reform of industrial nanomaterials with its Nanotechnology Advisory Group (NAG). Reflecting general stakeholder views, the NAG expressed strong support for the New Chemicals proposals but requested further information on some aspects for reform of nanoforms of existing chemicals.
- From 1 January 2011, as the result of stakeholder support and with the advice of the NAG, NICNAS introduced new administrative processes for the notification and assessment of industrial nanomaterials that are considered to be New Chemicals. The new arrangements apply to any new chemical, not already notified to NICNAS, falling under the NICNAS working definition of 'industrial nanomaterial' (see the January 2011 NICNAS Gazette Notice for more information, [Attachment 1](#)).

**Issues:**

*Changes to administrative arrangements for nanoforms of New Chemicals*

The changes, introduced from 1 January 2011, ensure that pre-market evaluation of all new nanomaterials will be conducted by NICNAS by restricting the introduction of nanoforms of new chemicals from certain exemption categories as well as self assessment certificate categories.

NICNAS has also modified its New Chemicals Program administrative forms to include a declaration that states if the notified chemical is a nanomaterial, or not. If a company is unsure, NICNAS will make this determination for them. When a nanomaterial is notified NICNAS may require additional information on the substance to conduct its risk assessment.

Since January, all New Chemicals notifications have been monitored to ensure conformity with new administrative processes. No notifications have been received for an industrial nanomaterial to date. NICNAS is also monitoring for the potential for conventional chemicals that are notified to be introduced as nanomaterials in the future.

To support these changes, NICNAS has published a guidance document to assist notifiers (Attachment 2) and has been conducting information sessions on these changes at outreach seminars for industry around Australia.

Compliance activities commenced in April 2011 to assess industry understanding of the new changes. Ongoing compliance activities for nanomaterials will be rolled out pending consultation with major stakeholder groups and in light of NICNAS's audit, monitoring and outreach priorities for 2011-12.

NICNAS has responded to several queries received in regard to these changes since introduction, but no significant concerns have been raised by stakeholders.

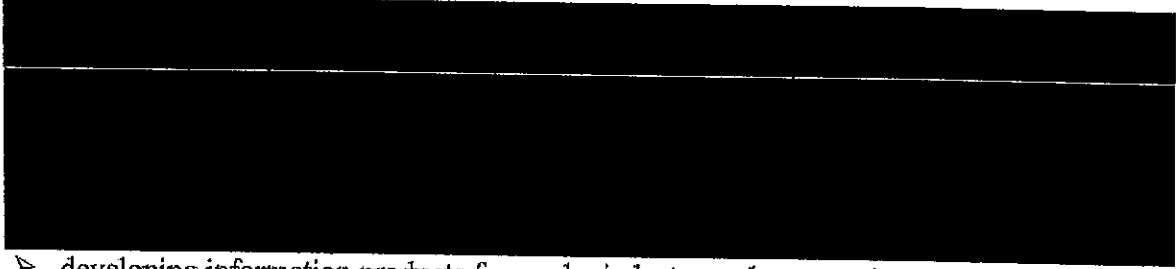
These administrative arrangements will be reviewed following a reasonable period of implementation. Experience gained through administrative amendments will inform any future legislative amendments.



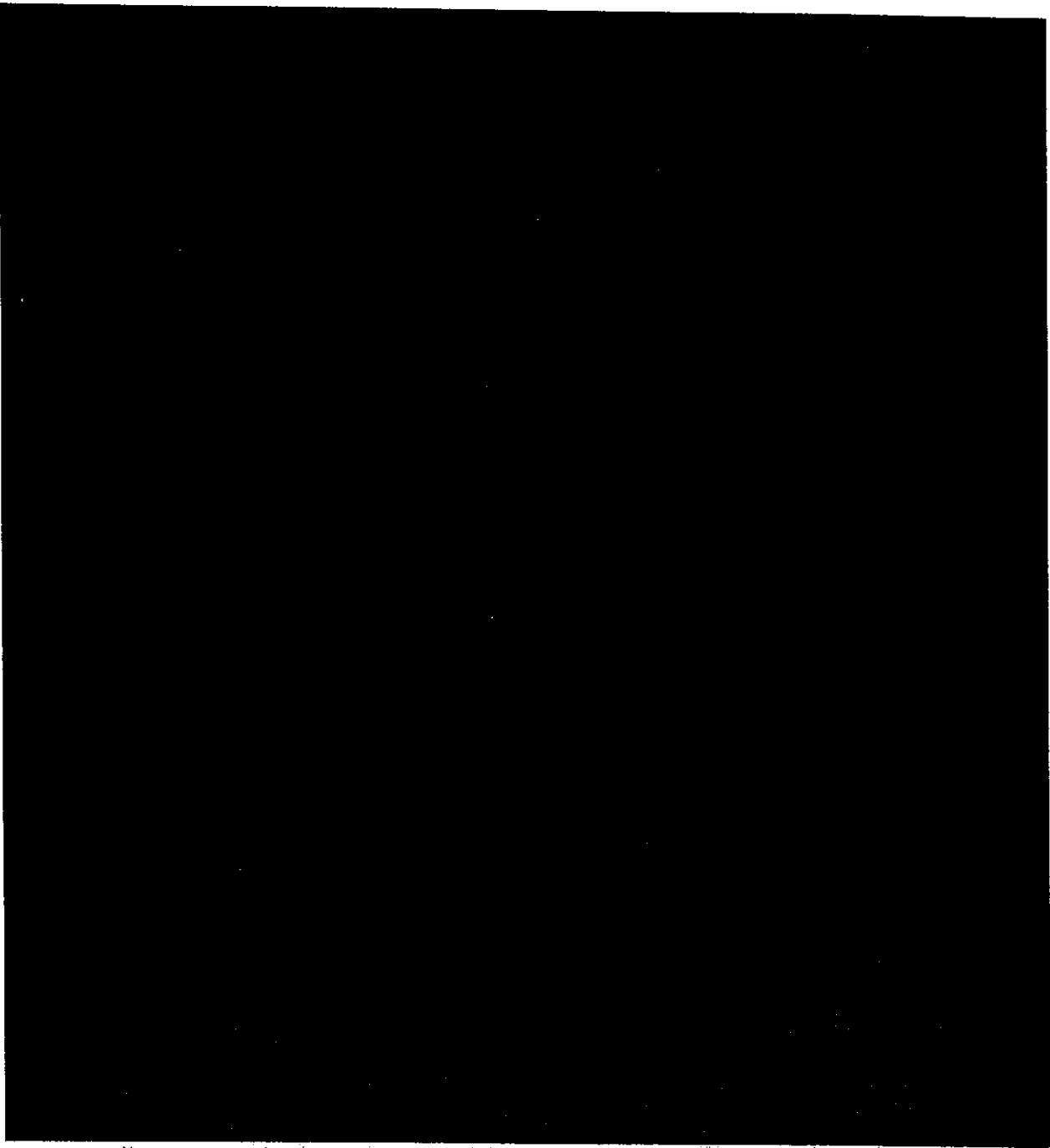
*NICNAS technical activities for industrial nanomaterials*

As part of the NICNAS Nanotechnology Strategy, NICNAS has been continuing to build on the technical capability of the organisation to provide for the use of best available scientific evidence concerning the hazards and risks of industrial nanomaterials, and the ability to review regulatory decisions as new information becomes available. These activities include:

- developing risk assessment and modelling capabilities for NICNAS staff that meet international best practice
- compiling toxicity information from published literature on six nanomaterials of interest to NICNAS - TiO<sub>2</sub>, ZnO, CeO<sub>2</sub>, nanosilver, CNTs and fullerenes (See 5B – Toxicity summaries)



- developing information products for use by industry and community






**Recommendation:**

Members to note that

- NICNAS has published on its website individual written submissions from its public consultation on this matter, together with responses to the issues raised in these submissions.
- NICNAS has introduced administrative adjustments to the New Chemicals Program for Industrial Nanomaterials from 1 January 2011

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- NICNAS technical activities are ongoing, and hazard information sheets on four nanomaterials of interest to NICNAS will be published later in 2011/12.

## Attachment 1

### **NOTICE OF ADJUSTMENTS TO NICNAS NEW CHEMICALS PROCESSES FOR INDUSTRIAL NANOMATERIALS FROM 1 JANUARY 2011**

This Notice is directed to introducers of nanomaterials that are new chemicals. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has introduced new administrative processes for the notification and assessment under Part 3 (Notification and Assessment of Industrial Chemicals) of the Industrial Chemicals Notification and Assessment Act 1989 (the Act) of industrial nanomaterials that are considered to be New Chemicals.

As published in the October, November and December 2010 issues of the *Chemical Gazette* these new administrative arrangements are effective from 1 January 2011. They apply to any New Chemical that falls under the following working definition of 'industrial nanomaterial'.

#### **WORKING DEFINITION**

NICNAS has developed the following working definition of "industrial nanomaterial":

**... industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"**

Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications.
- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.

#### **ADJUSTMENTS TO NICNAS NEW CHEMICALS PROCESSES FOR INDUSTRIAL NANOMATERIALS**

The outlined adjustments, below, only apply to nanomaterials that are new chemicals. That is a chemical meeting the above definition of a nanomaterial, and that is not listed on the Australian Inventory of Chemical Substances. (*Nanomaterials that have a conventional, bulk form listed on the AICS, e.g. titanium dioxide, are considered to be existing chemicals and are not subject to these adjustments.*)

Specific amendments to current processes and practices vary between new chemicals exemptions and new chemical certificates and permits as follows:

**i) Exemption categories:**

New chemical exemptions are underpinned by S 21 (4) and (6) of the Act. S 21AA imposes annual reporting obligations on persons introducing chemicals under S 21 (4) and (6) of the Act.

From 1 January 2011, nano-forms of new chemicals are not permitted under exemption categories where human and/or environmental exposure can reasonably be anticipated, these being:

- Low volume cosmetic and non-cosmetic exemptions (S21(4))
- Low concentration (<1%) non hazardous cosmetic exemption (S21(6c)).

Introducers who advise NICNAS of introductions under these exemption categories are required to declare that their chemicals are not nanomaterials, according to the NICNAS working definition above.

The following exemption categories remain available for nanoforms of new chemicals:

- Transshipment exemptions – current conditions of introduction remain unchanged (S21(6b))
- R&D exemptions S21(6a) – with some amendments to the annual reporting requirements. All nanomaterials introduced in volumes over 100g/year need to be identified as nanomaterials and their full chemical name provided.

Any substance that meets the working definition of 'industrial nanomaterial' (above) previously introduced under an exemption category requires a NICNAS permit or certificate from 1 January 2011 if introduction is to continue. Introducers should contact NICNAS to determine the most appropriate notification category for their nanomaterial(s).

**ii) Permit categories:**

All permit categories under Part 3 of the Act remain available for use by introducers of nano-forms of new chemicals. Some changes to notification forms and information requirements may apply as follows:

- Addition of a declaration by the notifier on the permit application forms stating that the chemical is a nanomaterial.
- More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions (see Requirements to Provide Additional Data, below).

To complement these changes NICNAS may stipulate permit conditions for conventional chemicals where it can be reasonably assumed that a nano-form may be introduced in the future.

**iii) Certificate categories**

Of currently available certificate categories, all except self-assessment categories are available for use by introducers of nano-forms of new chemicals. Introducers who annually report introductions under self-assessed certificate categories are required to declare that their chemicals are not nanomaterials, according to the NICNAS working definition above.

Some changes to notification forms and information requirements apply as follows:

- Addition of a declaration by the notifier on the certificate application forms stating that the chemical is a nanomaterial or not.
- More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions (see Requirements to Provide Additional Data, below).

Complementing these changes, NICNAS may stipulate specific secondary notification conditions to the assessment of conventional chemicals where a nano-form may be introduced in the future.

## **REQUIREMENTS TO PROVIDE ADDITIONAL INFORMATION**

Information additional to those items specified in the Schedule to the Act may be required on a case-by-case basis. The Act provides for the Director, NICNAS to require further information where he/she considers it necessary for the purpose of assessing the chemical.

Additional information may be required on the nano-specific characteristics of chemical. For example, where the nanomaterial is introduced as a solid/powder or as a dispersion and is insoluble or known to be biopersistent, then as a minimum requirement the primary particle size distribution of the nanomaterial will be required.

Further additional data may be required such as surface area, impurity profile and surface properties (such as charge and coatings), on a case-by-case basis.

Guidance on data requirements for notifiers is available on the NICNAS website and the NICNAS Handbook for Notifiers in the *Current Issues - Nanotechnology* section, see: [http://www.nicnas.gov.au/Current\\_Issues/Nanotechnology.asp](http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp).

## **REASONS FOR ADMINISTRATIVE CHANGES**

These administrative amendments to the new chemicals notification and assessment framework are components of the NICNAS strategy for regulating industrial nanomaterials. They address the uncertainty surrounding the risks posed by industrial nanomaterials and the appropriateness of current risk assessment protocols and practices and aim to maintain or enhance existing levels of public health, worker safety and environmental protection in relation to industrial nanomaterials,

The changes to the notification and assessment of nano-forms of new chemicals have been developed in consultation with the NICNAS Nanotechnology Advisory Group, comprising industry, community, government and scientific experts. Changes to the new chemicals

framework for nanomaterials included in NICNAS's *Proposal for Regulatory Reform of Industrial Nanomaterials*, was strongly supported by stakeholders.

These administrative arrangements will be reviewed following a reasonable period of implementation. Experience gained through administrative amendments will inform any future legislative amendments.

For information on NICNAS's consultation on the Proposal for Regulatory Reform of Industrial Nanomaterials, please see:

[http://nicnas.gov.au/Current\\_Issues/Nanotechnology/Stakeholder\\_Consultation.asp](http://nicnas.gov.au/Current_Issues/Nanotechnology/Stakeholder_Consultation.asp)

### **NEED MORE ADVICE?**

Training for notifiers will continue after introduction of these changes and further information on such activities will be detailed via notices on the NICNAS website in coming months. Alternatively, please contact NICNAS for more guidance and/or advice on this matter.

For further information, please contact:

Nicola Hall

Phone: (02) 8577 8871

Fax: (02) 8577 8888

Email: [Nicola.hall@nicnas.gov.au](mailto:Nicola.hall@nicnas.gov.au)



## Attachment 2

### **GUIDANCE ON NEW CHEMICAL REQUIREMENTS FOR NOTIFICATION OF INDUSTRIAL NANOMATERIALS**

A new industrial chemical that falls under the working definition of an 'industrial nanomaterial' will not be permitted to be introduced under some exemption and self-assessment categories. These processes apply to any *new chemical* that meets the following working definition of 'industrial nanomaterial':

#### **NICNAS WORKING DEFINITION<sup>1</sup> OF INDUSTRIAL NANOMATERIAL**

*... industrial materials intentionally produced, manufactured or engineered to have unique properties or specific composition at the nanoscale, that is a size range typically between 1 nm and 100 nm, and is either a nano-object (i.e. that is confined in one, two, or three dimensions at the nanoscale) or is nanostructured (i.e. having an internal or surface structure at the nanoscale)"*

[Notes to the working definition:

- intentionally produced, manufactured or engineered materials are distinct from accidentally produced materials
- 'unique properties' refers to chemical and/or physical properties that are different because of its nanoscale features as compared to the same material without nanoscale features, and result in unique phenomena (e.g. increased strength, chemical reactivity or conductivity) that enable novel applications.
- aggregates and agglomerates are considered to be nanostructured substances
- where a material includes 10% or more number of particles that meet the above definition (size, unique properties, intentionally produced) NICNAS will consider this to be a nanomaterial.]

#### **EXEMPTION CATEGORIES**

New chemical exemptions are underpinned by S 21 (4) and (6) of the Act. S 21AA imposes annual reporting obligations on persons introducing chemicals under S 21 (4) and (6) of the Act.

From 01 January 2011, nano-forms of new chemicals will not be permitted to be introduced under exemption categories where human and/or environmental exposure can reasonably be anticipated, these being:

- Low volume cosmetic and non-cosmetic exemptions (S21(4))
- Low concentration (<1%) non hazardous cosmetic exemption (S21(6c)).

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<sup>1</sup> NICNAS will actively monitor progress of national and international reviews and other scientific developments and regularly re-assess this working definition.

Introducers who advise NICNAS of introductions under these exemption categories will be required to declare on their Annual reporting form, that their chemicals are not nanomaterials, according to the NICNAS working definition above.

The following exemption categories will remain available for nanoforms of new chemicals:

- Trans-shipment exemptions – current conditions of introduction remain unchanged (S21(6b))
- R&D exemptions S21(6a) – with some amendments to the annual reporting requirements. All nanomaterials introduced in volumes over 100g/year will be identified as nanomaterials and their full chemical name provided.

Any substances that meet the working definition of ‘industrial nanomaterial’ (above) currently introduced under exemption categories will require a NICNAS permit or certificate if introduction is to continue after 01 January 2011. Introducers should contact NICNAS prior to this date to determine the most appropriate notification category for their nanomaterial(s).

## PERMIT CATEGORIES

All permit categories under Part 3 of the Act will remain available for use by introducers of nano-forms of new chemicals. Some changes to notification forms and information requirements may apply as follows:

- Addition of a declaration by the notifier on the permit application forms stating that the chemical is a nanomaterial or not.
- More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions (see “Specified conditions for requesting additional data requirements”).

To complement these changes NICNAS may stipulate permit conditions for conventional chemicals where it can be reasonably assumed that a nano-form may be introduced in the future.

## CERTIFICATE CATEGORIES

Of currently available certificate categories, all except self-assessment categories will be available for use by introducers of nano-forms of new chemicals. Introducers who annually report introductions under self-assessed certificate categories will be required to declare that their chemicals are not nanomaterials, according to the NICNAS working definition above.

Some changes to notification forms and information requirements may apply as follows:

- Addition of a declaration by the notifier on the certificate application forms stating that the chemical is a nanomaterial or not.
- More specific information (such as particle size, shape and other specific information on properties) may be required under specified conditions (see “Specified conditions for requesting additional data requirements”).

Complementing these changes, NICNAS may stipulate specific secondary notification conditions to the assessment of conventional chemicals where a nano-form may be introduced in the future.

### **SPECIFIED CONDITIONS FOR REQUESTING ADDITIONAL DATA REQUIREMENTS**

As a minimum requirement particle size information (**primary particle size and number-weighted size distribution**) will be required in the following cases:

- where the chemical is an industrial nanomaterial
- where it can be anticipated or there is uncertainty that the chemical could be a nanomaterial and exposure to human health or the environment is expected based on use scenarios

AND

- the chemical is introduced as a solid/powder or as a dispersion and is insoluble (e.g. water insolubility < 1 mg/L); and/or known to be biopersistent\*.

*Note 1: If particle size information cannot be supplied for a chemical which meets certain conditions outlined above (other than where it has been declared as a nanomaterial), the chemical will be assumed to be an industrial nanomaterial for risk assessment and recommendations.*

*Note 2: The following chemicals that meet the circumstances outlined above may not be subject to the additional data requirements.*

- *compounds that dissociate in water to form ions*
- *colloidal polymers*
- *micelles*
- *biological materials*

*Please contact NICNAS for advice on notification requirements for these chemicals.*

In addition to the particle size information, the following additional data, above that which is normally required for the notification category may also be requested (where applicable) under certain circumstances (see Flow Chart). Specific guidance on physico-chemical characteristics and toxicity testing are provided below:

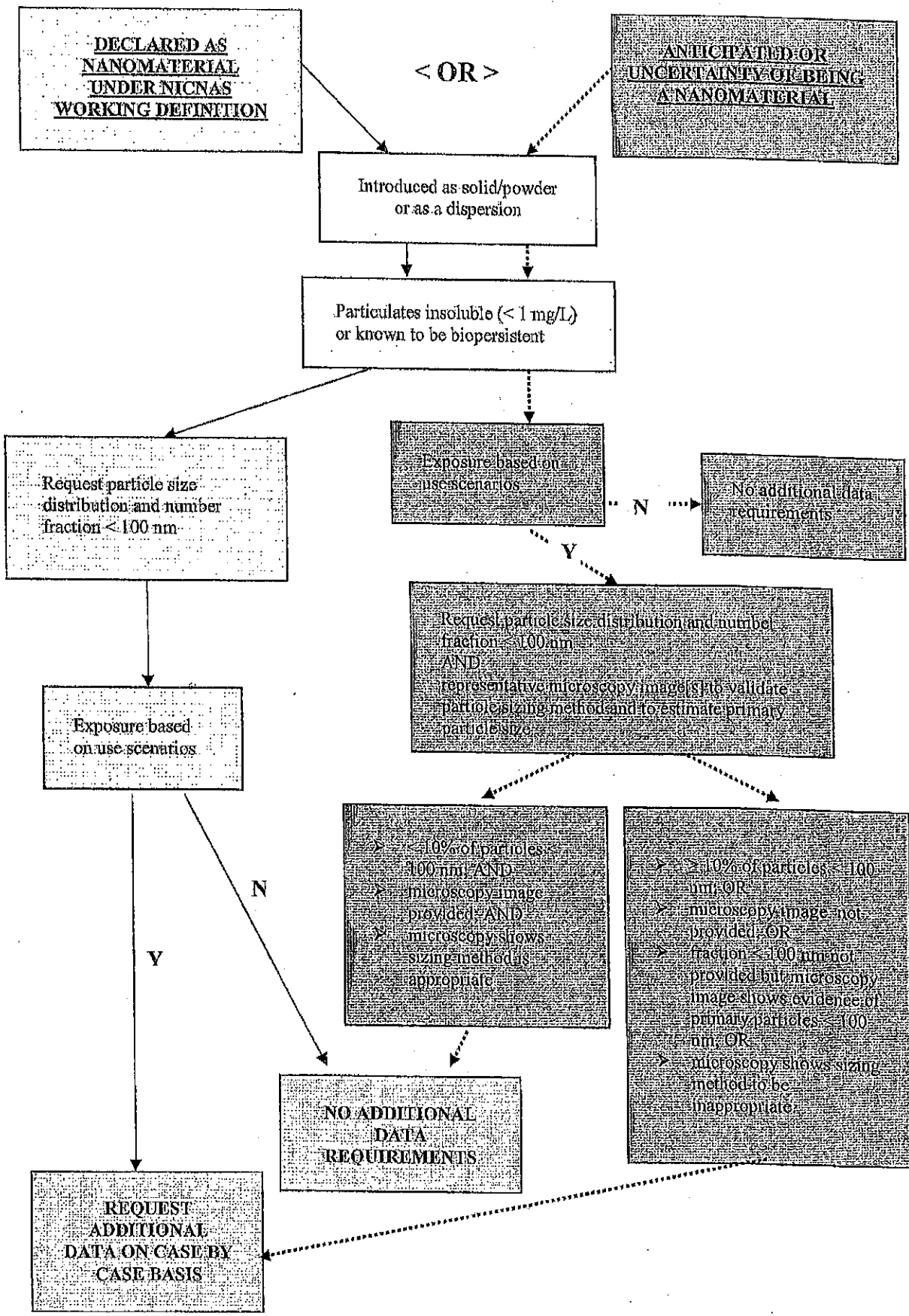
- method of production
- medium identity
- medium conditions (identity and concentration of stabilizers, ionic strength and ionic composition)
- shape
- crystalline phase
- agglomeration/aggregation state
- composition (purity/impurities)
- surface area
- surface charge
- surface chemistry (such as coatings and modifications)
- toxicity data will be requested on a case-by-case basis

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

*Note 3: These additional data requirements will be determined on a case by case basis and are subject to variation as new knowledge regarding toxicity of nanomaterials is developed.*

**FLOW CHART: Conditions for provision of particle size information and additional data requirements for permit and certificate categories**



**DECLARED AS  
NANOMATERIAL  
UNDER NICNAS  
WORKING DEFINITION**

**< OR >**

**ANTICIPATED OR  
UNCERTAINTY OF BEING  
A NANOMATERIAL**

Introduced as solid/powder  
or as a dispersion

Particulates insoluble (< 1 mg/L)  
or known to be biopersistent

Request particle size  
distribution and number  
fraction < 100 nm

Exposure based on  
use scenarios

No additional data  
requirements

Exposure based  
on use scenarios

Request particle size distribution and number  
fraction < 100 nm  
AND  
representative microscopy images to validate  
particle sizing method and to estimate primary  
particle size

> < 10% of particles < 100 nm AND  
microscopy image  
provided AND  
microscopy shows  
sizing method as  
appropriate

> > 10% of particles < 100  
nm OR  
> microscopy image not  
provided OR  
> fraction < 100 nm not  
provided but microscopy  
image shows evidence of  
primary particles < 100  
nm OR  
> microscopy shows sizing  
method to be  
inappropriate

**NO ADDITIONAL  
DATA  
REQUIREMENTS**

**REQUEST  
ADDITIONAL  
DATA ON CASE BY  
CASE BASIS**

## GUIDANCE ON PROVISION OF ADDITIONAL DATA REQUIREMENTS

The following provides guidance on the physico-chemical characterisation and reporting requirements for the additional data requirements (i.e. above that which is normally required for the notification category). Recommended test methods are identified for the physico-chemical data informed by ISO's Technical Report ISO/PDTR 13014 on Nanotechnologies – *Guidance on physico-chemical characterisation for manufactured nano-objects submitted for toxicological testing*<sup>2</sup> and the OECD Sponsorship programme *Guidance manual for the testing of manufactured nanomaterials*<sup>3</sup>. Please refer to these documents for further details and alternative methods.

Where specific data are requested by NICNAS and it is not feasible or not considered to be applicable to provide the additional physico-chemical data, a scientific rationale for not providing these test results must be provided.

The physico-chemical data should be supplied for the nanomaterial as manufactured (i.e. at the point on completion of manufacture or as the sample is removed from the manufacturer's container) and, where data available, in the end-use product formulation.

In general, all physico-chemical data should specify:

- the grade of the nanomaterial tested, including its purity
- the testing authority or organisation
- the method of preparing the test sample
- the physical conditions used for all test data, for example, agitation method (dispersing aids), pH, ionic strength, ionic composition, temperature or pressure.

The standard of testing to obtain data should be performed in compliance with GLP standards. Notifiers may refer to the OECD Principles of Good Laboratory Practice for information on this matter.

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<sup>2</sup> ISO (2010) Nanotechnologies – Guidance on physico-chemical characterisation for manufactured nano-objects submitted for toxicological testing, ISO/PDTR 13014. The International Organisation for Standardisation, [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_tc\\_browse.htm?commid=381983&development=on](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=381983&development=on), Accessed 17<sup>th</sup> November 2010.

<sup>3</sup> OECD (2009a) Guidance manual for the testing of manufactured nanomaterials: OECD's sponsorship programme; First Revision, ENV/JM/MONO(2009)20/REV. In: OECD Environment, Health and Safety Publication, Series on the safety of manufactured nanomaterials. OECD Paris, Organisation for Economic Co-operation and Development, No. 25, 92 pp.  
<[http://www.oecd.org/document/53/0,3343,en\\_2649\\_37015404\\_37760309\\_1\\_1\\_1\\_1,00.html](http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1,00.html)>, Accessed 17<sup>th</sup> November 2010.

*Note: The OECD Working Party on Manufactured Nanomaterials (WPMN) reviewed all 22 OECD test guidelines for physical-chemical properties for their applicability to the testing of nanomaterials<sup>4</sup>. The review concluded that all but two of the current tests may provide information that is applicable to nanomaterials. The two tests not considered to provide useful information are TG 103 Boiling Point and TG 114 Viscosity of Liquids.*

*It was also recognised that some tests would only be applicable to a sub-set of nanomaterials depending on their physical form and chemical composition. For example, it was concluded that the three test guidelines for physical-chemical properties of polymers (OECD TGs 118-120) would only be applicable to polymeric manufactured nanomaterials.*

*The key physical-chemical properties that require characterisation when considering aquatic environmental exposure of chemicals are water solubility, water-soil and water-oil partitioning, hydrolysis and dissociation constants. All of the standard test guidelines for these properties are considered to be potentially applicable to nanomaterials. However, it is noted that the applicability will depend in part on the presence of colloidal dispersions of nanomaterials in water which may complicate both the conduct and/or the interpretation of studies.*

#### (i) Particle size and size distribution

The mean primary particle size and number weighted primary particle size distribution with number fraction < 100 nm should be provided. In addition, a representative microscopy image at a magnification capable of resolving features < 100 nm should be provided to validate the particle sizing method.

When measuring the particle size distribution an effort should be made, for example, through sonication or the use of dispersing aids to fully disperse the nanomaterial, to break down any loose agglomerates including those of fibres. The method of dispersion and sample preparation should be reported.

Where the size distribution and the number weighted percentage of particles < 100 nm have not been provided, the chemical will be assumed to be a nanomaterial under the NICNAS definition if there is evidence of primary particles of < 100 nm in the representative microscopy image.

#### Fibre-like nanomaterials

For nanomaterials that are fibre-like such as carbon nanotubes, the aspect ratio (fibre length range and diameter range) is required. For guidance on measurement please refer to the OECD technical guidance document No. 10 Particle Size Distribution/Fibre Length and Diameter Distributions.

<sup>4</sup> OECD (2009b) Preliminary review of OECD test guidelines for their applicability to manufactured nanomaterials. In: OECD Environment, Health and Safety Publication, Series on the safety of manufactured nanomaterials, No. 15, ENV/JM/MONO(2009)21. OECD Paris, Organisation for Economic Co-operation and Development, 71 pp.  
<[http://www.oecd.org/document/53/0,3343,en\\_2649\\_37015404\\_37760309\\_1\\_1\\_1\\_1.00.html](http://www.oecd.org/document/53/0,3343,en_2649_37015404_37760309_1_1_1_1.00.html)>, Accessed 17<sup>th</sup> November 2010.