

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.

Exemption	Volume restriction	Other criteria	Advice required prior to introduction	Annual reporting requirements	Proposal for nanomaterials
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 ¹	< 1 tonne/yr ² < 10 tonne/yr ² for site limited chemicals		Under certain circumstances ³ , 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

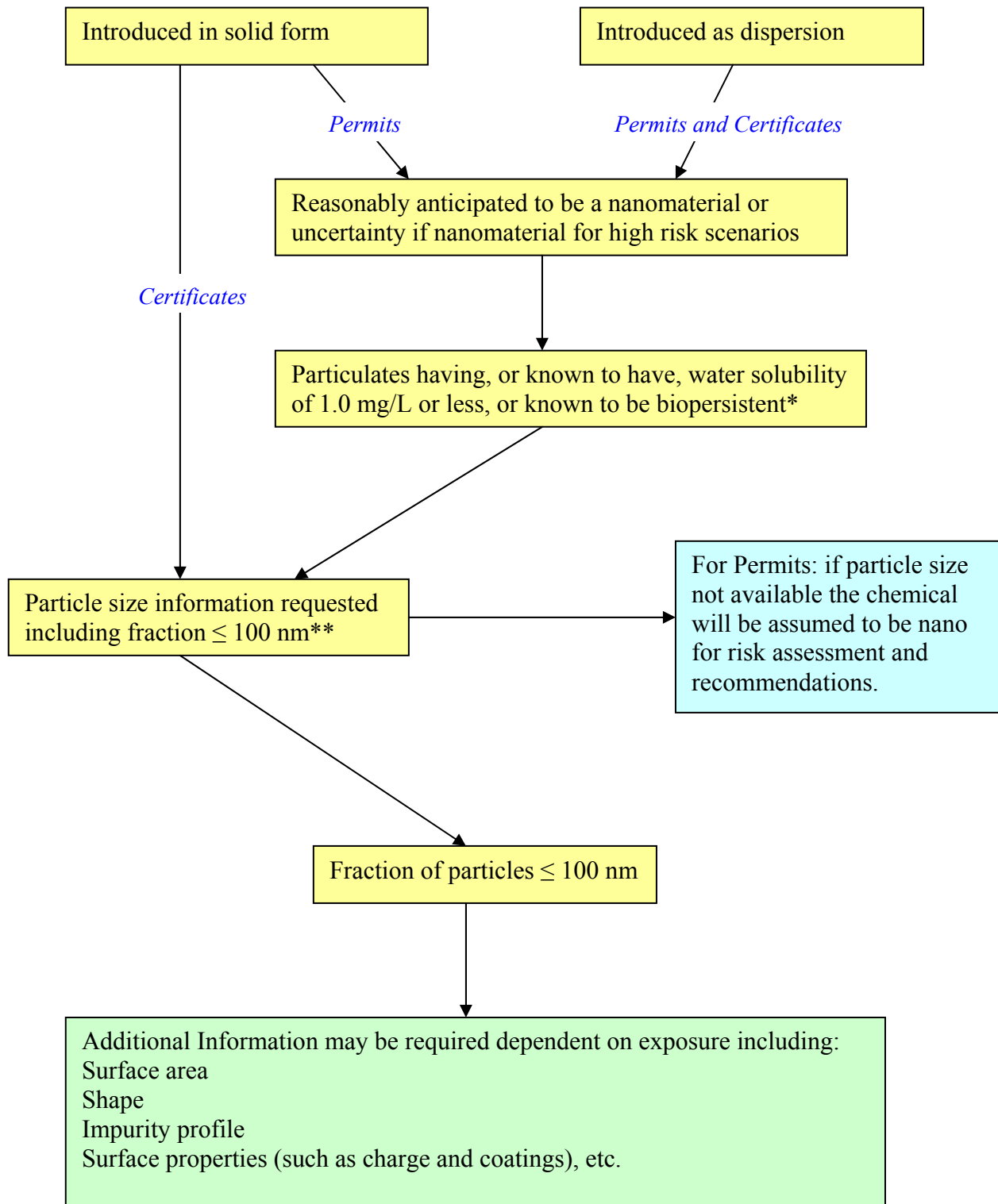
¹Limited (LTD) notifications – toxicity data not a scheduled data requirement, therefore chemicals under this category generally have limited or no toxicity data.

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

³Currently 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*