

Table 2 Summary of stakeholder comments on New Chemicals proposals

Issue	Summary of views	NICNAS Response
<p>2.1 Exemptions – administrative exclusion of exemptions where human and /or environmental exposure can reasonably be anticipated</p>	<p>Most submissions were supportive of this approach, if rigorously implemented, and believed that these proposed amendments to the current system were a reasonable measure, reflecting a precautionary approach and should be implemented in a timely manner.</p> <hr/> <p>Protection of confidential business information was requested.</p> <hr/> <p>Transshipment exemptions were agreed to, but it was emphasized that nanomaterials in this category should be labeled properly and suitably contained in case of spillage due to accident. Following on from the transshipment exemption category, a submission asked if NICNAS had a proposal about domestic movements of nanomaterials inside Australia.</p> <hr/> <p>In regard to changes to R&D annual reporting obligations, most respondents did not believe that this would incur a substantial additional burden on R&D facilities. For the R&D exemption it was recommended that NICNAS adopt a similar system that is in place for governing the use of Scheduled Carcinogens.</p> <hr/> <p>Working with OHS agencies to give practical handling and disposal guidance and incident reporting for the R&D environment was recommended.</p>	<p>NICNAS will monitor the appropriateness of this administrative approach and amend it in the future if warranted.</p> <hr/> <p>Current provisions for maintaining commercially sensitive material under the Act will be maintained.</p> <hr/> <p>NICNAS legislation does not cover labelling provisions or transport of chemicals in Australia. These comments will be referred to the relevant agencies.</p> <hr/> <p>OHS requirements in laboratories and research organisations are enforced by state and territory OHS agencies, under the Occupational Health, Safety and Welfare Act 1986 and the Occupational Health, Safety and Welfare Hazardous Substance Regulations 1995.</p> <p>Information requirements for annual reporting of exemptions are specified in NICNAS legislation. The Act specifies that for R&D exemptions companies/organisations are required to report on the chemical name and volume introduced during the reporting period.</p> <p>NICNAS actively collaborates with Safe Work Australia (SWA) in the area of nanotechnology safety as part of SWA's Nanotechnology Technical Advisory Group and will refer these comments to Safe Work Australia for their consideration.</p>
<p>2.2 Certificates and Permits</p>	<p>Generally, support was given to the proposal for changes to permit and certificate categories as reflecting a precautionary approach, with an emphasis on the fact that much of the burden will fall on NICNAS, requiring adequate resources to implement effectively.</p>	<p>NICNAS undertakes risk assessment prior to issuing permits and certificates. This practice will also apply to nanomaterials. NICNAS has outlined triggers for requesting particle size distribution and other nanospecific characteristics for permit and certificate categories. More specific information such as particle size, shape and other specific information on properties will be required:</p> <ul style="list-style-type: none"> • when it is anticipated that the chemical is a nanomaterial; or • in cases where there is uncertainty regarding whether the chemical could be a nanomaterial for use in high risk scenarios i.e. uncontrolled exposure; and • the particulates are insoluble or biopersistent.

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	<p>Some respondents argued that a new permit system should be established specifically for nanomaterials that relied on a demonstration of no unreasonable risk by full health safety and environmental assessment along with comprehensive physicochemical characterization, before the issue of a permit.</p> <hr/> <p>It was argued that insolubility and biopersistence should not be as relied on as triggers to request more information, as substances classed as soluble or not biopersistent may still be toxic.</p> <hr/> <p>Other submissions expressed the view that changes to the certificate and permit system for nanomaterials could potentially stifle innovation if not implemented in an efficient manner, with appropriate NICNAS resources to make processes efficient and a system that distinguishes between the different levels of risk associated with different types of nanomaterials.</p> <hr/> <p>One view expressed an opinion that eliminating certificate categories is unjustified for certain nanoscale chemicals that present low hazard, and that certificates also have more onerous data requirements in some instances that may be advantageous.</p> <hr/> <p>A concern was expressed that a permit system with additional data requested would make estimating costs of introduction impossible to determine especially if risk methodology applied is not transparent. Another view was that more information is needed on the data requirements to decide if this would be a factor.</p> <hr/> <p>Lack of certainty may affect introduction, as lack of certificates indicates that new nanomaterials will never be on AICS this will mean an uncertain supply chain and could have a downstream impact.</p> <hr/> <p>The issue of labeling, determination of no unreasonable risk by public consultation, permits or certificates to apply based on potential for exposure, the need for further detail on the proposed system and alignment with other regulatory agencies within Australia were</p>	<p>Establishing a new permit system specifically for nanomaterials (new and existing forms together) will be considered under the longer term proposal described as the principle of an integrated approach within the NICNAS framework.</p> <hr/> <p>NICNAS will screen all permit and certificate applications to establish whether or not they are nanomaterials. Insolubility and/or biopersistence are used as triggers to identify potential health hazards but these two parameters are not the only triggers that will be used in the screening process. As stated above, NICNAS has the power to seek additional information for assessment on a case-by-case basis if required.</p> <hr/> <p>NICNAS's discussion paper recognised that one of the disadvantages of this proposal will be an increased burden on introducers when additional data are required, however this information should be required on a case-by case basis and is intended to be based on the level of risk to the extent that this can be determined upfront. It is expected that introducers should have access to this information to support the safety of intentionally produced nanomaterials being introduced into the marketplace.</p> <hr/> <p>NICNAS only proposes to administratively exclude self assessment options for certificates. Standard, Limited and Polymer of Low Concern notification certificate categories will be available for nanomaterials.</p> <hr/> <p>The vast majority of certificate and permit categories will be available for use by industry. Exclusion of self assessments is seen as reasonable as it will take the responsibility off industry to demonstrate no unreasonable health and or environmental risk and transfer this responsibility to NICNAS potentially resulting in greater stakeholder confidence in the safety of these materials. Standard New Chemicals fees will apply to these assessments.</p> <hr/> <p>NICNAS can amend permit conditions or revoke a permit if new information becomes available to indicate a health and/or environmental risk. Under such circumstances NICNAS believes that it is appropriate to take regulatory action to protect health, safety and environmental standards.</p> <hr/> <p>In general permits are designed for lower volumes and shorter overall use periods as well as lower</p>
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	<p>expressed as important considerations.</p>	<p>risk chemicals. Certificates are used for higher volume and higher hazard chemicals (except polymers of low concern). It is however an industry prerogative to choose certificates over permits even in instances where permits categories are available.</p> <p>NICNAS is committed to reviewing these administrative changes after a reasonable period of implementation.</p>
<p>2.3 Self assessment with third party certification as an alternative to NICNAS proposal</p>	<p>While self assessments that were validated by a credible third party were thought to be generally acceptable in the context of low risk nanomaterials, this concept was generally not supported because of issues of feasibility. Key issues here were costs and dependence on establishing a competent authority.</p> <p>One suggestion was to investigate a model such as that used by the Pharmaceutical Benefits Scheme.</p> <p>NICNAS was generally thought to be better placed to assess nanomaterials, especially when businesses may want to disclose confidential business information to an independent third party.</p> <p>It was suggested that a dedicated body or testing certification system should be established for testing of industrial nanomaterials in Australia.</p>	<p>The proposal was to remove the self assessment option for nanomaterials on the basis of uncertainty concerning their hazard. In light of stakeholder views NICNAS will progress this approach to restrict self-assessment for nanoforms of new chemicals.</p>
<p>2.4 Concept of a flexible permit system where permit conditions can be changed if new data indicates a new risk profile.</p>	<p>Flexibility as a concept was generally supported, and compared to overseas measures.</p> <p>More in depth review was requested to estimate what the potential downstream consequences could be of revoking a permit.</p> <p>The importance of transparency, appropriate costs and reliance on robust information as well as effective compliance/cross checking were recommended as important factors to consider in this context.</p>	<p>Flexibility is a key component of the NICNAS permit system. Permits can only be revoked if there is scientific evidence of adverse health and environmental effects.</p>