



National Industrial Chemicals Notification and Assessment Scheme - Proposal for Regulatory Reform of Industrial Nanomaterials

Public Consultation – Discussion Notes

Sydney 16.11.09 and Melbourne 18.11.09

This table summarises points that were raised during participant discussions in both consultation sessions, and has been published for general information, particularly to inform stakeholders who could not attend of the issues raised in the face to face meetings.

Theme:	Issues for stakeholder consideration:
<p>1. Definition of “industrial nanomaterials”</p>	<p>1.1 The working definition for industrial nanomaterials, supplied in the Discussion Paper, may not be adequate for effective regulatory purposes due to the complexity of these materials. Aspects of the definition that are too narrow include:</p> <ul style="list-style-type: none"> • Size – cut off should not be 100nm because of factors such as agglomeration, therefore should be reconsidered. (e.g: example given of definition that uses 300nm as cut off) • Intentionally produced – does not take into account industrial nanomaterials that may be accidentally produced and present in mixtures of some percentage, as a result of production methods such as grinding. • Mixtures not included – some materials may be a mix of nano and non-nano forms, and may display novel nanoscale properties. <p>1.2 Definition should also include biopersistence/solubility.</p>
<p>2. Whole of government approach</p>	<p>2.1 Greater assurance needs to be given to all stakeholders that there is a whole of government approach to ensuring the effective regulation and responsible development of nanotechnology in Australia.</p> <p>2.2 The government should be clear that health and environmental issues raised by this technology should be treated with a precautionary approach.</p> <p>2.3 Regulatory agencies such as NICNAS, TGA and APVMA must be consistent in the development of a nationally coordinated regulatory framework for all nanomaterials.</p> <p>2.4 As recommended by NSW govt report, to coordinate the whole of government approach effectively, a central overarching steering body should be established.</p> <p>2.5 More attention to responsibility for regulation of articles containing nanoforms of substances is required. For instance, Australian manufacturers of articles who import chemicals are regulated by NICNAS, so there must be equivalent regulation for imported articles that are manufactured overseas to ensure a level playing field.</p> <p>2.6 How can we make sure that effective regulation can keep up with emerging technologies?</p>

<p>3. NICNAS processes</p>	<p>3.1 NICNAS should use wording in regulatory principles that clearly commits to a precautionary approach in the regulation of industrial nanomaterials.</p> <p>3.2 NICNAS must have adequate resources to handle assessments of industrial nanomaterials in a timely manner. Should also have broader legislative powers, power to ban hazardous substances where appropriate and have greater enforcement capability.</p> <p>3.3 Timeframes for reform process should be available to stakeholders for consideration.</p> <p>3.4 Further information on the proposal should detail / clarify how these reforms will fit in with other NICNAS activities, eg;</p> <ul style="list-style-type: none"> • Existing Chemicals Review • Low Regulatory Concern Chemicals <p>3.5 Engagement would be more inclusive with better stakeholder databases and more notice given.</p> <p>3.6 Effective regulation is being assisted by leveraging links with other agencies and organisations, such as the National Measurement Institute, doing work in this area.</p>
<p>4. Assessment of nanomaterials</p>	<p>4.1 Assessments and risk management should take into consideration:</p> <ul style="list-style-type: none"> • Social issues • Economic issues • Potential for synergistic, cumulative effects, end of life persistence.. • Potential for synergies in formulations • Comprehensive lifecycle analysis, including waste phase and risks associated with potential recycling. • How the material is incorporated in a product that suits a consumer need, • Complex nature of nanomaterials, properties that impart novel characteristics or health/ environmental effects, such as clumping, need to be addressed. <p>4.2 Innovations and resulting products should be subject to societal benefits test however, it is acknowledged that this is outside of NICNAS' mandate.</p> <p>4.3 The principle of "No data, no market" (precedent in Europe) should be adopted here in future.</p> <p>4.4 Should a dedicated body or testing certification system be established for testing of industrial nanomaterials in Australia?</p>
<p>5. Supply chain concerns</p>	<p>5.1 The supply chain presents complex challenges that must be considered in regulation of industrial nanomaterials. Aspects that may be problematic include:</p> <ul style="list-style-type: none"> • Downstream users rely on manufacturer of chemicals to properly identify material and supply correct data. • The closer a chemical is to the consumer – the less information becomes available to users. <p>5.2 Industry bodies may help promote cohesive transferal of information/data down supply chain as best practice.</p>
<p>6. Public access to information/ education</p>	<p>6.1 Public access to scientific information on nanomaterials should be maintained, and not patented.</p> <p>6.2 Education of the public on issues of nanotechnology must be balanced and responsible, reflecting the huge range of applications of varying benefit to society.</p>

<p>7. Innovation/ market concerns</p>	<p>7.1 Imposts on industry and R&D should be designed to balance responsible development with the needs of Australian industry. This must aim to create a level playing field where companies are not disadvantaged by 'doing the right thing'.</p> <p>7.2 Regulation of nanomaterials may use the precedent of sustainability in industry sector, by aiming to create opportunities and recognition that will promote compliance.</p>
<p>8. Implementation</p>	<p>8.1 The appropriateness of this proposal is contingent on;</p> <ul style="list-style-type: none"> • More details, some of which will be dependant on international developments i.e. how will nanomaterials be differentiated, by CAS number for instance? • More detail, yet to be provided by NICNAS, such as more detailed data requirements, compliance strategy, definitions etc. <p>8.3 Implementation issues faced now will be complex, and thought should be given about how we can prepare for the next generations of nanomaterials.</p> <p>8.4 Implementation of reforms – should have a steering committee and be auditable across all sectors of industry, including downstream use.</p> <p>8.5 Measures such as mandatory reporting can help industry if effectively implemented by creating a level playing field.</p> <p>8.6 What enforceable conditions can NICNAS introduce to ensure compliance and that costs are recovered from non-compliant companies?</p>