

Table 4 Summary of stakeholder comments on additional issues

Issue	Summary of views	NICNAS response
<p>4.1 Precautionary Principle</p>	<p>Stakeholders expressed that Precautionary Principle is now a 'customary norm' and should be incorporated in NICNAS nanomaterials related activities as according to the Rio and Bahia Declarations, 2008 International Forum on Chemical Safety,</p>	<p>The NICNAS Overarching Principles states "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."</p> <p>This is in line with the <i>Australian Government Objectives for the Responsible Management and Oversight of Nanotechnology</i> principle that states that regulators should "apply a precautionary approach consistent with Australia's international obligations, including the Rio declaration".</p>
<p>4.2 NICNAS overarching principles</p>	<p>The following comments were made in relation to the NICNAS Overarching Principles:</p> <ol style="list-style-type: none"> 1. "Managing the risks posed by new technologies" in (a) must be replaced with "Eliminating, or where not possible, minimising, the risks posed by new technologies" "...as it has been stated and acknowledged here and elsewhere, it is undeniable that there is insufficient 'scientific evidence' to support the safety of the majority of products/chemicals containing NMs. Studies reporting close associations between nanoparticles and their adverse effects on human health are constantly being published. Therefore, it is crucial that the Precautionary Principle (see below) be adopted with regard to industrial NMs. The overarching principles must include the Precautionary Principle. To repeat an often quoted line: "Absence of evidence is not evidence of absence." "...This is crucial, not simply 'prudent', but necessary to ensure that, as in the first point: "Any risk from the use of the nano-form of a chemical is no greater than that posed by the conventional form of the chemical or is at or below the level of acceptable risk i.e. humans and the environment are not exposed to unknown/unacceptable risk." Also, we argue that it is not only "prudent" but again, critical that 'Risk (including uncertainty) is addressed pre-market' (our emphases)" 2. " 'Review undertaken using inclusive and transparent processes' needs to be expanded to ensure that all relevant stakeholders (unions, community) are provided with sufficient information, assistance and opportunity to participate in any such reviews." 3. "Industry innovation is supported through an appropriate level of regulatory oversight', should be eliminated from these principles. There are other government bodies whose main role is to promote innovation in industry, through provision of funding, expertise, etc. NICNAS' stated mission is: 'the integrated regulation of industrial chemicals for the protection of human health and the environment through scientific excellence and regulatory efficiency to deliver the safe and sustainable use of chemicals'. That is, NICNAS should be primarily providing the 'checks and balances' to industry innovation. " 4. "In relation to the point: "Risk assessments should be undertaken on a case-by-case basis". However, it is also important that a standardised nano-specific safety assessment is developed and applied to ensure confidence in individual assessments. Such an assessment is being considered internationally, though not 	<ol style="list-style-type: none"> 1. The essence of these comments is inherent in the Overarching Principles that were developed to deal with the uncertainty that new technologies may pose. 2. The involvement of all stakeholders including the community and unions is implicit in all NICNAS's reform work as evidenced by the composition of its various advisory groups including the NAG and the application of the Community Engagement Charter. 3. NICNAS does not believe that the principle that "Industry innovation is supported through an appropriate level of regulatory oversight" implies promotion of industry innovation, rather it seeks to provide a balance by encouraging responsible development of nanotechnology through adequate regulation. Consistent with the objective of the Act, NICNAS seeks to maintain a level of regulation that maintains health, safety and environmental standards. 4. NICNAS is an active participant in the OECD Working Party on Manufactured Nanomaterials and has bilateral agreements with comparable overseas regulatory authorities that include nanotechnology related activities. These mechanisms facilitate benchmarking our regulatory practices and processes with international best practice.

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<p>4.3 Risk assessment</p>	<p>It was expressed that 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, <p>Other considerations requested o be included in the risk assessment process were:</p> <ul style="list-style-type: none"> • That the complex nature of nanomaterials, properties that impart novel characteristics or health/ environmental effects, such as clumping, need to be addressed • Vulnerability of pregnant women and children. • Priority should be given to nanomaterials already in use and assess first. <p>It was suggested that NICNAS observe the European Food Safety Authority (EFSA 2009) recommendation that nano-specific risk assessment characterise the following:</p> <ul style="list-style-type: none"> • Particle size (including distribution of particle size within the sample) • Surface area and specific surface area of particles • Shape (including aspect ratios such as fibre-like structures where appropriate) • Chemical composition (including impurities and processing chemicals) • Surface properties (e.g. coating, charge, surface adsorption properties) • Solubility (in fats and water) • Agglomeration/ aggregation and • Biodegradability and biopersistence <p>It was suggested that NICNAS observe the European Commission’s SCENIHR (2007) suggestion that the following properties are necessary for hazard characterisation:</p> <ul style="list-style-type: none"> • Elemental composition; • Density; • Crystal structure; • Solubility; • Charge; • Conductivity; 	<p>NICNAS undertakes risk assessments consistent with the objects of its Act. Information on all risk assessment methodology and data requirements is included in the NICNAS Handbook for Notifiers.</p>

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	<ul style="list-style-type: none"> • Melting point; • Hardness; • Magnetic and optical properties; • Morphology; • Size and size distribution; • Surface area and surface layer composition; • Photo-activation; and • Potential to generate reactive oxygen species. <p>Additional comments on this issue were:</p> <ul style="list-style-type: none"> • Assessments should be done in an 'iterative regulatory loop' any information supplied by manufacturers should be critiqued by government and academia. • Standardised, nano specific characterizations and standard tests need to be transparent and not just case by case. • Public should be involved to decide on appropriate parameters for hazard characterization and the range of safety tests. • The substitution principle must be applied to NICNAS assessment of nanomaterials and if there are less hazardous options to a nanomaterial, that nanomaterial should not be listed. 	<p>See above.</p>
<p>4.4 Government's Standing Committee on Chemicals (SCOC)</p>	<p>It was suggested that SCOC should determine definition and may be interested in commenting at the RIA stage, therefore should be advised on outcomes of consultation for cross jurisdictional implications.</p> <p>SCOC mechanism should be used of coordinated regulation of nanomaterials at a national level across agencies, looking at assessment mechanisms, data collection mechanisms for agencies such as NICNAS.</p>	<p>The department is represented on the SCOC via the Office of Health Protection (OHP) NICNAS is a member of its sub-committee, the Chemicals Working Group. These mechanisms will be used to provide input into SCOC deliberations as required.</p>
<p>4.5 Whole of government approach</p>	<p>Stakeholders emphasised that here should be a coordinated approach to evaluations between all of the regulators in Australia's framework.</p> <p>A submission expressed that NICNAS's work the area should continue to be in line with the Governments' guiding principles to enabling technologies 1) Using evidence based approach to making decisions, 2) Using the regulatory frameworks to deliver efficient and effective response, 3) Ensure schemes are reviewed, 4) Apply a precautionary</p>	<p>NICNAS has developed overarching principles to guide its nanotechnology related reforms, these are available in the Nanotechnology section of the NICNAS website, under <i>"What is NICNAS doing in Nanotechnology?"</i></p>

Consultation results on NICNAS Proposal for Regulatory Reform of Industrial Nanomaterials

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	<p>approach, 5) Ensure that information is based on scientific facts.</p>	
<p>4.6 Supply Chain</p>	<p>It was stated that the supply chain presents complex challenges that must be considered in regulation of industrial nanomaterials.</p> <p>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>Industry bodies may help promote cohesive transferral of information/data down supply chain as best practice.</p>	<p>NICNAS is part of an overall chemical regulation management framework in Australia. NICNAS regulates the introduction, through manufacture or importation, of industrial chemicals into Australia. NICNAS undertakes risk assessments and makes recommendations for safe use under the national OHS, public health and environment framework. State and Territory agencies regulate and control the use of industrial chemicals.</p>
<p>4.7 Labelling</p>	<p>Stakeholder opinions expressed that:</p> <ul style="list-style-type: none"> • NICNAS should work with the ACCC to ensure all labeling of nano on consumer products, especially cosmetic and domestic products. • NICNAS should work with SWA to ensure all labeling of nano in workplace materials. • Labeling should include product type and quantity in product for user information 	<p>NICNAS does not administer a labelling code. Labelling of industrial chemicals is a matter for the ACCC (in the case of cosmetics) and state territory regulatory authorities with responsibility for OHS and public health legislation.</p>
<p>4.8 Guidance/ further information</p>	<p>It was expressed that timeframes for reform process should be available to stakeholders for consideration</p> <p>It was requested that further information on the proposal should detail / clarify how these reforms will fit in with other NICNAS activities, e.g.; Existing Chemicals Review and Low Regulatory Concern Chemicals</p>	<p>NICNAS has developed a comprehensive communication strategy for this reform activity. Consistent with current practice, NICNAS will develop guidance material and information products as the various regulatory proposals are finalised and implemented. Stakeholder education and outreach will continue through each stage of the process. NICNAS will inform stakeholders of the timetable for implementation through its communication strategy.</p>
<p>4.9 Review of implemented reforms</p>	<p>Should have a steering committee and be auditable across all sectors of industry, including downstream use.</p> <p>Reforms should be reviewed, every twelve months or two years.</p>	<p>It is normal practice for NICNAS to review its regulatory reform activities, following an adequate period after implementation.</p>
<p>4.10 “No Data, No Market”</p>	<p>No data no market principle should be adopted, requiring submission of comprehensive hazard assessment including toxicology and eco-toxicology data prior to commercialization of nanomaterials.</p> <p>Must include information in addition to toxicological data on by products, effects of waste phase, toxicity testing methodology, peer reviewed research, assessment of intergenerational effects, nonmonotonic dose response associated with endocrine</p>	<p>‘No Data, No Market’ approach is already encompassed by the current framework for new chemicals. For conventional chemicals, exemption for this is only permitted for low risk chemicals and it is balanced by post market obligations. The proposed reforms would also serve to strengthen this approach by excluding exemption categories where human and/or environmental exposure can reasonably be anticipated. It also provides a mechanism to gain use specific data on nano forms of existing chemicals that, if progressed from the call for information stage to the notification and assessment stage, will require that data are provided and assessed in order to gain the right to introduce these nanomaterials into the</p>

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	disrupting chemicals and direct mesocosm effects for the chemical being tested.	Australian market.
4.11 Monash Report	Disagreement as to whether or not conclusion that current regulatory framework is "generally well suited to allowing adequate management and control of ...nanomaterials".	The NICNAS regulatory proposal addresses the triggers identified in the Monash Report.
4.12 Stakeholder engagement	CEF should be further utilized in consultation Need more face to face consultation before reforms are finalised.	NICNAS's communications strategy includes consultation with the community sector, this includes the CEF and NAG.
4.13 Moratorium on nanomaterials	There should be a moratorium on nanomaterials commercialised/ used in products until more is known.	A moratorium would be a whole of government decision.
4.14 Principle of substitution	Call for the replacement of hazardous substances of concern by suitable alternative substances or technologies. The substitution principle must be applied to NICNAS assessment of nanomaterials and if there are less hazardous options to a nanomaterial, that nanomaterial should not be listed [sic].	NICNAS assesses industrial chemicals and does not identify suitable alternatives. Industry is required to identify alternatives and notify them to NICNAS if they are new chemicals.
4.15 NICNAS powers	These should be broadened so NICNAS can ban toxic nanomaterials, or those that have insufficient data.	At present, NICNAS does not have the power to ban chemicals. The Act requires NICNAS to make recommendations for safe use. However chemicals subject to international conventions such as the Rotterdam Convention may be subject to bans or restrictions under the conditions of the specific convention.
4.16 National testing laboratory	Comment was made that a dedicated body or testing certification system should be established for testing of industrial nanomaterials in Australia, and this should be established also to build young scientist's capability in this area.	The Australian Government, through its National Enabling Technology Strategy (NETS) supports the work of the National Measurement Institute's nanometrology facilities.