

Table 3 Summary of stakeholder comments on Existing Chemicals proposals

Issue	Summary of views	NICNAS Response
<p>3.1 Voluntary and mandatory reporting measures</p>	<p>Overwhelmingly respondents were in support of mandatory reporting over voluntary measures, assuming requirements were realistic, costs were appropriate and balanced provisions for confidentiality could be provided.</p> <p>This part of the proposal was recognized as being consistent with the Australian Government objectives for responsible management and oversight of nanotechnology.</p> <p>Some submissions recognized that an initial voluntary measure was acceptable as a precursor to mandatory reporting while necessary legislative changes were being made.</p> <hr/> <p>An alternative view was that no more voluntary reporting should be considered, going straight to a mandatory system to enforce the 'no data, no market' principle, that mandatory notification and assessment should be enforced straight away for all nanomaterials and that a secondary notification should go out to all manufacturers of importers whose products may contain a nano component.</p> <p>Further information was requested to fully understand the implication to industry, in terms of data required and resources that would be needed to comply with this part of the proposal.</p> <hr/> <p>A view that NICNAS must avoid duplicating efforts by other agencies, suggesting that one agency takes over regulatory evaluation of certain chemicals via a mechanism that coordinated evaluations between all of the regulators in Australia's framework.</p>	<p>As a result of stakeholder feedback, experience with previous voluntary calls and advice from NICNAS's Nanotechnology Advisory Group, it is clear that it is preferable to move straight to mandatory measures. From experience gained through the 2006 and 2008 Calls for Information, NICNAS recognises that voluntary initiatives may not elicit a comprehensive response from industry. NICNAS's experience is similar to the experience of comparable overseas regulatory authorities.</p> <p>The ability to spread costs across businesses will be limited by confidentiality of the information provided to NICNAS will be protected in accordance with current confidentiality provisions under the Act. Industry will be asked to identify information of a confidential nature when providing information.</p> <hr/> <p>Under the legislation secondary notification is only applicable to a chemical that has been assessed by NICNAS. NICNAS proposes to apply permit conditions or specify secondary notification conditions to conventional chemicals assessed by NICNAS when it can be reasonably assumed that a nano form may be introduced in the future.</p> <hr/> <p>NICNAS's assessment remit extends to chemicals (including nanomaterials) that are used for industrial purposes, whether or not the chemical is used for an excluded purpose (i.e. in medicines, pesticides, veterinary medicines and foods). The NICNAS legislation includes provisions for recognising various components of assessments under taken by other national authorities. There are criteria that must be met in order for an assessment to be eligible for "Acceptable Assessment Report" status. These amendments will apply to nanomaterials.</p>

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	<p>Opinion was expressed that regulatory impact assessment essential as part of a 'stepwise' approach.</p> <hr/> <p>It was noted that workplace reporting for OHS regulation could also assist in data collection.</p> <hr/> <p>Giving industry time to gather information and spread costs were suggested as important factors for success and minimizing burden on industry.</p> <hr/> <p>Opinion was expressed that nanomaterials that have been in use for many years without adverse effect should not have to be subject to mandatory reporting.</p>	<p>NICNAS is committed to complying to Office of Best Practice Regulation procedures processes</p> <hr/> <p>As yet there are no nano-specific OHS reporting requirements. NICNAS is a member of Safe Work Australia's Nanotechnology OHS Technical Advisory Group. These activities provide opportunities to share information and provide a forum where synergies are identified.</p> <hr/> <p>NICNAS is aware of the need for industry to be given reasonable notice when administrative changes or regulatory reforms are introduced. In addition, NICNAS consults with its Nanotechnology Advisory Group to seek advice on matters such as timeframes. NICNAS is also committed to engage industry in workshops, email/telephone support and other outreach activities to assist in compliance.</p> <hr/> <p>In Australia there is currently no comprehensive and coordinated mechanism to obtain data on adverse health and environmental effects from the use of industrial chemicals. As such there is also no formal mechanism that has gathered information on adverse effects that can be relied on to exclude certain nanomaterials. However, this issue may be addressed in the working definition, this defines materials as industrial nanomaterials that have been intentionally produced at the nanoscale to exploit unique properties. Current regulatory arrangements apply to materials that fall outside this scope.</p> <p>NICNAS is also committed to reviewing all reforms after a reasonable period of implementation and any unintended consequences will be identified and rectified through this process.</p>
<p>3.2 Balancing burden of reporting with community HSE expectations</p>	<p>It was generally agreed that this would be balanced, assuming requirements were realistic, costs were appropriate and provisions for confidentiality could be provided.</p> <p>Industry needed more detail on the specifics for proper evaluation of impact. Further information was requested to fully understand the implication to industry, in terms of data required, and resources that would be needed to comply with this part of the proposal.</p>	<p>NICNAS will further explore options for regulating nanoforms of industrial chemicals. Regulatory impact analysis will be undertaken to meet Office of Best Practice Regulation requirements. This reform package for nano-forms of existing chemicals will be subject to a further round of consultation.</p>

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<p>3.3 Mandatory Notification and Assessment</p>	<p>In principle support was generally given to this proposal. It was thought to satisfy community expectations and create a 'level playing field' for industry, however industry recognised that feasibility would be dependant on more information to understand effort required and the resources that NICNAS would need to implement effectively.</p> <p>Opinion was expressed that nanomaterials that have been in use for many years without adverse effect should not have to be subject to this.</p> <p>Success was also thought to depend on how effectively the system could address challenges posed by continued development of knowledge and understanding of the potential hazards associated with nanomaterials, their use, handling and manufacturing processes, consumer use and disposal or recycling.</p> <p>Other elements that were thought to be crucial to the success of such a system include; clear definitions, clear guidance to industry and explanation of what the information would be used for, provisions to protect confidential business information, consideration of resources that would be needed by the notifier and appropriate resources needed by NICNAS to carry out assessments and compliance.</p> <p>To avoid unduly impacting smaller manufacturers and importers, possible creating a trade barrier, it was recommended that testing requirements take into account volume and exposure scenarios.</p>	<p>As for 3.2.</p>

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<p>3.4 Feasibility of an integrated mandatory notification and assessment program</p>	<p>Respondents expressed a view that this concept is worth further consideration.</p> <p>It was recognised that a single approach to regulation is preferable from a community and industry perspective, such a system would be preferable to make the regulation of nanomaterials more simple, and NICNAS would also benefit from not having to administer two separate programs.</p> <p>It was generally agreed that the experience and knowledge for this will be gained in the short term as NICNAS progresses with implementing the initial reforms.</p>	<p>As for 3.2.</p>
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