



Australian Government
Department of Health and Ageing
NICNAS

Proposal for regulatory reform of industrial nanomaterials
NICNAS summary of Business Impact Surveys (BIS)

The BIS formed part of the package for public consultation on NICNAS's proposal for regulatory reform of industrial nanomaterials.

While we received 41 written submission we only received 4 BIS, of which one was a confidential submission.

General

All respondents (4) were registered with NICNAS, Tier 1 (n=2), Tier 2 (n=1) and Tier 3 (n=1) companies. They were either importers of nanomaterials (n= 1) importers of products containing nanomaterials (n=2) and manufacturers of nanomaterials (n=1).

Six nanomaterials were declared as being currently introduced into Australia, 5 nano-forms of existing chemicals and one nano-form of a new chemical for R&D purposes.

New chemicals proposals

Respondents stated that if introducing nano-forms of new chemicals they would introduce under low volume or low concentration exemptions (n=2) and R&D exemptions (n=2). One response did not address this question and one company used two categories.

Respondents nominated both permits (n=1) and certificates (n=2) as categories they may use for new chemicals, one respondent did not specify their preferred notification category.

Removal of self assessments as a notification option for nanomaterials was seen as having a potential impact on 2 respondents while the others (n=2) responded to say that it will not have an impact. The reason for why it would potentially impact was claimed to be the fact that there were many safe uses of nanomaterials and that companies could make an appropriate self assessment, however the same respondent went on to say that "NICNAS may want to have these self-assessed materials reported under one of the proposed or other reporting program". The other respondent who claimed that this would impact on their business did not provide reasons for this determination.

All respondents indicated that proposed changes to the new chemicals processes may negatively impact on their ability to introduce nano-forms of new chemicals. The reasons provided and NICNAS responses to these are as follows:

- extra reporting burden – the reporting burden will be either reduced or remain unchanged as annual reporting requirements apply to exemptions and self- assessed

categories so removal of these options will potentially minimise annual reporting burden

- uncertainty of restrictions – restrictions will be recommended on a case by case basis and NICNAS’s approach is consistent across all assessment categories – restrictions on exemptions are specified in legislation
- timing of approval – legislated timeframes give industry certainty of timeframes from submission of the complete application, incomplete data provision is the responsibility of the notifier
- high expense for business – exemptions do not incur fees however, to introduce the same quantity of a nanomaterial under a permit, the cost will be no more than \$AU 3730 per substance in 2010-11. Moving from self-assessments to permits would cost between \$AU 3988 and 6713 depending on the assessment category chosen.
- *“While the proposed approach is appropriate and prudent for truly new nanomaterialsthere is a need [to] differentiate between current safe applications of nanomaterials and uses that need additional assessment and a phase in time to collect data and evaluate before implementing restrictions that may be warranted based on risk.”*- these proposals apply only to new substances not those chemicals that are in commerce at present (‘existing chemicals’ – list on the AICS) and administrative amendments are foreshadowed to be implemented in January 2011.

Existing chemicals proposals

A mandatory notification and assessment program for existing chemicals was supported conditions by 2 respondents while the other 2 did not support this proposal.

Three respondents indicated that these proposals will incur a regulatory burden on industry while two indicated that the burden would not be unacceptable. One of these respondents estimated cost to be around \$ AU20-30,000 per chemical, while another business stated a figure of \$AU1,000,000 per ‘product’. The third respondent pointed out that cost would be dependant on the extent and depth of the reporting scheme, and made several suggestions that could minimise impact.

All respondents indicated that the existing chemicals proposals will negatively impact on their ability to introduce these substances into Australia.

Two respondents indicated that these proposals will affect competition, while the other two did not feel that they would affect competition.

General Impact

Responses varied on whether or not these proposals would effect competition and how it might affect consumers. Concerns were raised that global manufacture may eliminate local manufactures and may result in an increase in costs to consumers for products containing nanotechnology. Another view was expressed that it may slow down introduction of these materials until appropriate testing has determined the safety of these materials.