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Ms Nicola Hall
NICNAS
Reply Paid 58
SYDNEY NSW 2001

Dear Ms Hall

NSW DECCW SUBMISSION TO THE NICNAS PROPOSAL FOR REGULATORY REFORM OF INDUSTRIAL NANOMATERIALS.

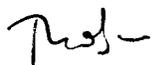
The NSW Department of Environment, Climate Change and Water (DECCW) appreciates the opportunity to comment on the NICNAS Proposal for Regulatory Reform of Industrial Nanomaterials.

Please note that our response is organised into three parts:

- part one describes the current NSW policy approach to nanotechnology,
- part two relates to questions in the NICNAS *Have Your Say Questionnaire*, and
- part three covers issues falling outside this questionnaire.

Should you have any further questions regarding this submission, please contact Dr Robin Walton on 9995 5798.

Yours sincerely .



Tony Hodgson
A/Director Specialised Regulation

15 January 2013

NSW DECCW SUBMISSION TO THE NICNAS PROPOSAL FOR REGULATORY REFORM OF INDUSTRIAL NANOMATERIALS

NSW DEPARTMENT OF ENVIRONMENT, CLIMATE CHANGE AND WATER

January 2010

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- part two relates to questions in the NICNAS *Have Your Say Questionnaire*, and
- part three covers issues falling outside this questionnaire.

1 NSW POLICY APPROACH TO NANOTECHNOLOGY

This submission is supported by the following recent NSW Government documents relating to nanotechnology:

- the NSW Government Submission to the Parliamentary Inquiry on Nanotechnology in NSW available at <http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/8A91F25A0B1F636AC A257426008044FE>
- the Report of the Government Advisory Committee on Nanotechnology available at: <http://www.chiefscientist.nsw.gov.au/Home/Reports.aspx>. This interdepartmental committee assisted the NSW Government in developing its response to the Parliamentary Inquiry. The NSW Government's broad approach to nanotechnology is in line with the seven principles contained in this report; and
- the NSW Government Response to the Legislative Council Standing Committee on State Development Inquiry Into Nanotechnology in NSW (the Government Response) available at: <http://www.parliament.nsw.gov.au/Prod/parlment/committee.nsf/0/35D2E3E37498A908C A2574F1000301BB>)

It also draws upon two recent Commonwealth documents:

- The National Enabling Technologies Strategy Discussion Paper (available at <http://www.innovation.gov.au/Industry/Nanotechnology/Documents/NETSDiscussionpaper.pdf>); and
- The Australian Office of Nanotechnology's Social Inclusion and Engagement Workshop Report (available at <http://www.innovation.gov.au/Industry/Nanotechnology/Pages/socialinclusion.aspx>)

The NSW Government committed to undertake a number of actions in response to the recommendations arising from the Parliamentary Inquiry into Nanotechnology in NSW. Two of these recommendations are directly relevant to the NICNAS proposal for regulatory reform of industrial nanomaterials. One relates to national co-ordination through the Standing Committee on Chemicals and the other concerns mandatory reporting on nanomaterials in the workplace, as set out below.

Oversighting Role of the Standing Committee On Chemicals (SCOC)

The Government Response considered the need for national oversight of the assessment and regulation of nanomaterials and recommended the following:

The NSW Government will raise with the Commonwealth the need for a coordinated response to human health, safety and environmental risk assessment of nano-objects by the TGA, APVMA, FSANZ and NICNAS.

The NSW Government believes there should be an explicit oversighting role for the Standing Committee on Chemicals (SCOC) in coordinating nanomaterials at national level, and that a review of the assessment and registration protocols for nanomaterials and other chemicals should be undertaken under the SCOC mechanism. This assessment regime review would look at, among other things:

- *assessment of nanomaterial-containing products that may not be assessed as chemicals per se under the current regime*
- *mechanisms to enable agencies such as NICNAS to collect and make available human health, safety and environmental risk assessment data of nano-versions of chemicals.*

National Mandatory Reporting Scheme for Nanomaterials Used in the Workplace

The Government Response also recommended the development of a national mandatory reporting scheme for nanomaterials used in the workplace. Some of this information could support the NICNAS proposals for specific use reporting (Streams 1 and 2).

A proposed mandatory scheme would need to be broadly sufficient to capture information on nanomaterial lifecycle.

The NSW Government supports the recommendation to work in cooperation with federal agencies on the development of a national mandatory reporting scheme for companies who use, manufacture, transport or dispose of nanomaterials.

The NSW Government will raise with the Commonwealth through the Standing Committee on Chemicals, the issue of a mandatory reporting scheme for companies that use, manufacture, transport or dispose of engineered nanomaterials.

2 HAVE YOUR SAY QUESTIONNAIRE

What is the significance and/or consequence of this working definition for 'industrial nanomaterials'?

DECCW is aware that some stakeholders are concerned that a threshold of 100 nm may not be broad enough to capture all materials with very different physicochemical and toxicological properties compared to bulk materials of the same composition. DECCW believes that consistency between jurisdictional definitions for nanomaterials is highly desirable. However, this objective should be balanced against the need to prevent loopholes for slightly larger materials that have demonstrated critical properties similar to those meeting the 100 nm criterion, for example, the ability to cross cell membranes. The definition should also be sufficiently broad to capture nano-sized materials that are unintentionally produced, for example, through processing and transportation. Additional definitional issues requiring deliberation include how to deal with mixtures of nano and non-nano forms of a chemical.

How do you think the proposal to limit access to exemptions for nanoforms of new chemicals will contribute to protecting health and the environment?

DECCW believes this is an important step in addressing some of the gaps identified in the Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework (the Monash Report). However, it depends heavily on having adequate toxicology and exposure data utilised in conjunction with appropriate assessment methodologies. Strong efforts to fill these data gaps must be made, however, it may be some time before enough data is available to support the application of current risk assessment methodologies, particularly quantitative methods, to the assessment of nanoforms. Alternative assessment methodologies may need to be developed and/or used to avoid delay in providing regulatory oversight. See Part Three for more discussion of risk assessment methodologies.

Describe any ways in which you think self-assessment by an independent third party could be used to effectively achieve the same results?

This question is unclear - DECCW understands that self-assessments are undertaken by notifiers proposing to use new chemicals that meet certain criteria. An independent third party would then conduct an audit of selected self-assessments.

What are your views on the impact of the proposal to regulate nanoforms of new chemicals with the above changes to the permit and certificate categories? Can you identify additional advantages or disadvantages?

DECCW considers that the proposed changes to the permit and certificate categories will be beneficial provided:

- suitable use, characterization, toxicity and exposure data is provided;
- an effective assessment methodology is available; and
- NICNAS staffing levels are adequate to support a rigorous assessment of the nanomaterials.

Without these supporting resources, the proposed assessment process may give regulators and the public a false sense of assurance that potential risks to the public, workers and the

environment have been effectively identified prior to marketing and exposure. Should any significant post-assessment risk emerge - it could damage public confidence in the regulatory process and weaken widespread support for nanotechnologies and the many environmental and public health benefits they promise.

Unless NICNAS is provided with adequate staffing to cope with increased numbers of new chemical assessments it is possible that a backlog of nanomaterials requiring assessment might emerge. This could lead to increasing pressure on assessors to rush the assessment process of new nanomaterials. On the other hand, the sheer number of nanomaterials requiring assessment in the future might lead to delays in market entry of useful, low-risk nanomaterials (e.g. possibly those which are readily biodegradable).

What are your views on a system that is sufficiently flexible to amend permit conditions where new data indicate a new risk profile?

DECCW considers that a key requirement for effective, timely regulation of nanomaterials is the capacity to respond quickly to emerging science regarding potential human health or environmental risks. Given the evolving nature of our understanding of potential risks associated with the use of nanomaterials and the current paucity of robust toxicological data for the environment and human health, it appears that the permit system is more appropriate for nanomaterials, particularly given that it is not clear whether secondary notification will provide adequate regulatory controls for those new chemicals with assessment certificates which eventually are added to the Australian Inventory of Chemical Substances (AICS).

What are your views on the impact of the proposal for mandatory once-off, use specific reporting for nanoforms of 'existing chemicals'? Can you identify additional advantages or disadvantages?

DECCW is concerned that the number of applications for nanotechnology is expanding at such a fast rate that a once-off reporting initiative would be unlikely to provide the use specific information which regulators and assessors will need to make informed decisions about the potential risks and benefits of nanomaterials.

Note that the NSW Government supports development of a mandatory reporting scheme (see Part One) for nanomaterials used in the workplace and some of this information could contribute to the NICNAS proposal for collecting specific use data.

Explain how you think the potential burden of once-off, use specific reporting could or could not balance community expectations in relation to health and environmental standards?

DECCW and the community expects that the Australian Government will provide robust regulatory oversight of nanomaterials underpinned by the most recent and accurate information available. This needs to be balanced by considering the cost and practical difficulties associated with specific use reporting by industry. That is, a reporting frequency which provides meaningful information that is not overly onerous or expensive to provide must be determined. A once off reporting initiative would be appropriate for a stable product which has been used for similar purposes in the same volume for some years. It is unlikely to be suitable in the case of nanomaterials, given the large and diverse range of applications that have already emerged in the marketplace and those applications that are expected to follow.

What are your views on making the information gathered through streams 1A and 1B publicly available?

DECCW considers that communities will have more confidence in regulatory regimes, which are based on publicly accessible data. Accordingly an important component in the regulation of nanotechnology and the application of the principles of open government is to make specific use information pertaining to nanomaterials publicly available.

What are the advantages and disadvantages of the introduction of a system that required a mandatory notification and assessment program for nano-forms of existing chemicals? What are the reasons for this answer?

DECCW has strong reservations about voluntary notification initiatives for nanomaterials given that this approach has proven largely ineffective in Australia and overseas as demonstrated by the poor response rates to voluntary requests by NICNAS, the U.S. Environmental Protection Agency and the UK government for data on nanomaterials for assessment purposes.

Options for a mandatory scheme would need to be carefully designed to ensure benefits and costs are balanced and regulatory objectives are achieved. Not all nanoforms may require the same level of assessment.

What are current issues that affect the feasibility of such a program?

This program would involve consideration of many issues including: determining what information needs to be provided, how this could be used, how often it should be provided, the cost of obtaining new data, the ability of smaller enterprises to pay for this data, commercial-in-confidence issues and how these could be reconciled with the public right-to-know and finally, the possibility that some physicochemical characteristics of nanomaterials could change depending upon how they have been processed or formulated.

What are your views on making information gathered from assessments of nano-forms of existing chemicals publicly available?

See previous comments regarding the information gathered through streams 1A and 1B.

How might an integrated approach provide for more effective regulation of industrial nanomaterials compared to the package proposed (for nano-forms of new and existing chemicals) in sections 3a and 3b?

There are approximately 40,000 chemicals on the Australian Inventory of Chemical Substances (AICS) and any one of these could be imported or manufactured in Australia in nano-form and marketed without any assessment by NICNAS. DECCW believes that one of the key objectives of integrating the assessment of existing and new industrial nanomaterials into a single system is to ensure that nano-forms of existing chemicals are appropriately assessed.

3 OTHER ISSUES

A number of other important issues fall outside the *Have Your Say Questionnaire*. DECCW offers the following comments on them.

National approach

A consistent, co-ordinated approach to assessing and regulating nanomaterials across different end use categories needs to be implemented in Australia. NSW considers that the appropriate body to facilitate this is the national Standing Committee on Chemicals (SCOC) (see Part One).

Regulatory powers of NICNAS

NICNAS must have the regulatory powers it requires to undertake its responsibilities in a credible and effective way including the powers to:

- collect information from chemical users - even if a chemical is not under consideration as a potential priority existing chemical,
- require additional testing for chemicals of particular concern, prior to further assessment and marketing, and
- prohibit uses of certain chemicals.

This is in keeping with the powers of other Australian chemical regulators such as the Therapeutic Goods Administration and the Australian Pesticides and Veterinary Medicines Authority as well as comparable chemicals regulators overseas.

The Overarching Principles of the NICNAS Regulatory Strategy

Given the great uncertainties regarding health and environmental risks and benefits associated with the use of nanomaterials, DECCW strongly encourages NICNAS to commit to applying the precautionary principle in the Overarching Principles of the NICNAS Regulatory Strategy set out in Attachment 1.

NICNAS has successfully applied stakeholder engagement principles in developing proposals for reform. DECCW considers that this is particularly important in the case of nanotechnology because of the potential of this technology to provide many benefits and pose unknown risks to a large number of people and the environment. The Commonwealth Office of Nanotechnology has developed a set of principles for deliberative and inclusive public engagement (see Part One) that could enhance work undertaken by NICNAS and these should be reflected in the Overarching Principles of the NICNAS Regulatory Strategy. These public engagement principles would be particularly relevant in developing how the precautionary principle could be applied to stimulate and support innovation in nanotechnology while taking timely, effective action to prevent riskier applications from widespread uptake altogether or, for less risky products, ensuring additional controls are in place. The European Environment Agency's report *Late lessons from early warnings: the precautionary principle 1896-2000* (available at: http://www.eea.europa.eu/publications/environmental_issue_report_2001_22) may be a useful reference for developing an Australian approach. The report makes a number of recommendations relevant to chemical assessments.

Risk assessment methodology

Concerns have been raised in recent reports regarding the suitability of current toxicity tests and risk assessment methodology to evaluate nanomaterials including:

- the Monash Report,

- the *European Commission's Opinion On The Appropriateness of the Risk Assessment Methodology in Accordance with the Technical Guidance Documents for New and Existing Substances for Assessing the Risks of Nanomaterials* (available at: http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_010.pdf); and
- the Royal Commission on Environmental Pollution's report *Novel Materials In The Environment: The Case of Nanotechnology* (available at http://ec.europa.eu/health/ph_risk/committees/04_scenihhr/docs/scenihhr_o_010.pdf)

Quantitative risk assessment methodologies currently in use rely heavily on sufficient data to underpin the assessments, data that is lacking for most nanomaterials and not readily generated. The Royal Commission on Environmental Pollution states in its report on nanomaterials (listed above) that:

Scientists and regulators, as well as the wider public, invariably use world views to interpret data or other kinds of evidence. But where information is missing or evidence is ambiguous, people draw even more heavily on more general world views to inform their decision making. For example, those who believe that nature is maintained in a delicate balance are more likely to regard any discharge into the environment as a dangerous insult than those who see nature as robust and forgiving.

As a consequence, many reports discussing best practice risk assessment encourage public engagement throughout the whole risk assessment process including the technical aspects not just the risk management and communication stages. See for example, the reports on risk assessment by the National Research Council (*Science and Decisions: Advancing Risk Assessment* and *Understanding Risk: Informing Decisions in a Democratic Society* available at http://www.nap.edu/openbook.php?record_id=12209&page=1 and <http://www.nap.edu/openbook.php?isbn=030905396X> respectively). Few assessment methodologies currently used by government assessors have been able to effectively implement this in practice yet it is still worthy of serious consideration, particularly in relation to how public values could be incorporated into the process.

As noted earlier (see response to the second question in Part Two) alternative assessment methodologies may need to be developed and used for assessing nanomaterials. Important aspects that methodologies should address in addition to public values, include careful attention to:

- the potential impacts of the nanomaterials throughout their lifecycle, particularly during use and end-of-life;
- cumulative and synergistic effects;
- nanomaterials that are likely to be persistent, bioaccumulative and toxic, in line with the Stockholm Convention on Persistent Organic Pollutants; and
- evaluation of claimed benefits along with risks. In the Government Response, the point was made that "careful assessment of nanotechnology will be required to determine whether potential net benefits are likely to outweigh the risks associated with the life cycle of nanomaterials." Note that this approach is also in line with the European Environment Agency's *Late Lessons* report on implementing precaution through "systematically scrutinising and justifying the claimed 'pros' and 'cons' of a technology". However, current assessment methodologies used by NICNAS exclude evaluation of the claimed benefits of using a particular chemical. A suitable assessment methodology for nanomaterials would allow consideration of this aspect. For example, the nano-silver used in numerous products such as socks may prove to offer dubious consumer benefits while increasing the chemical

loading to the environment and associated risks, as it appears that it is lost from the fabric within a few washes.