NSW GOVERNMENT
Office of the
Chief Scientist &
Scientific Engineer

Reference: S28387

Dr Marion Healy
Director
National Industrial Chemicals Notification and Assessment Scheme
PO Box 58
SYDNEY NSW 2001

Dear Dr Healy,

As Chair of the NSW Nanotechnology Policy Coordination Committee (NNPCC), I write in submission to the National Industrial Chemicals Notification and Assessment Scheme's (NICNAS) call for public comment on the Proposal for Regulatory Reform of Industrial Nanomaterials.

The NSW Legislative Council Standing Committee on State Development undertook an Inquiry into Nanotechnology in NSW to better understand the risks and benefits of nanotechnology and its application. The NSW Government then provided a response to the Inquiry, to facilitate opportunities for NSW industry within an appropriately targeted regulatory environment for nanotechnology that will minimise risks to the community's health and the environment.

This submission responds to themes arising from stakeholder consultation discussions held in November 2009, which was distributed to participants on 30 November 2009, see attached.

Definition of "industrial nanomaterials"
There is evidently continued uncertainty in the community about the regulatory environment, particularly the definition of nanoparticles and how the regulatory regime will respond to issues of similarity between nanoparticles and other chemicals. In order to overcome these issues, I believe that a sensible approach would be for the Commonwealth to drive nanotechnology policy through the proposed Standing Committee on Chemicals (SCOC).

Given these issues, the utilisation of SCOC would have the advantage of being able to manage nanotechnology policy in the context of other chemicals and materials. This would not preclude special issues being addressed in relation to nanomaterials that call for additional regulatory actions such as additional toxicology testing based on particle size.

Whole of government approach
The NNPCC charter is to analyse and make recommendations on NSW Government regulations and policy in relation to development, use and disposal of nanomaterials. Of primary concern is that health and environmental safety issues are appropriately addressed in regulation, and that there is a suitable interface between regulations at the federal, state and local government level. I commend NICNAS for the precautionary approach taken health and environmental impacts of nanotechnology.

The Committee believes that the issue of nanotechnology regulation requires a national perspective. To date, the Commonwealth has played a coordinating role regarding nanotechnology regulation and NSW supports this on-going role however there is still more work to be done. I am encouraged to see two current Commonwealth regulatory reform agendas underway, recently the NICNAS reform agenda and the National Enabling Technologies Strategy.

NICNAS processes

NSW has engaged in the NICNAS consultation process and is encouraged to learn that the organisation is committed to a timely and comprehensive review of the existing regulatory framework in relation to nanoparticles in the industrial setting. However, during the Sydney stakeholder engagement session it became clear that clarity is still needed around how this reform agenda fits in with the whole-of-government structure.

I am encouraged to know that in addition to policy reform, NICNAS is also investigating the implementation of technical changes to its processes, including data management through a technical committee. I will raise at the next meeting of the NNPCC opportunities for NSW to support NICNAS efforts in this regard.

Assessment of nanomaterials

The NSW Government recommends a national approach to the coordination of nanomaterials. The Committee is encouraged by the leadership role taken by NICNAS in the national review of the assessment and registration protocols to safeguard the health and safety interests of the community.

The NSW Government's review of nanotechnology highlighted several areas for further consideration. Building on the NSW strength in nanotechnology and metrology, the NSW Government is undertaking a review of nanotoxicology within a NSW and national context. This review will provide a clearer understanding of the breadth of nanotoxicology knowledge and where further research and infrastructure is required in this developing sector.

Public access to information/education

It is critical for the Commonwealth to provide overarching clarity around these complex issues which span across jurisdictions and impact society, the environment and industry. A clear statement about the direction of the regulatory environment for nanoparticles is needed, outlining how the Commonwealth will develop policy and review the current regulatory regime.

The NSW review of nanotechnology recommended the development of a labelling scheme for products featuring engineering nanoparticles. The recommendation encouraged the provision of more information on labels to allow the community to make well-informed decisions about products containing nanoscale ingredients. The NSW Food Authority is working with the Commonwealth on the issue of food labelling. I have also written to the Australian Competition and Consumer Commission to recommend a review of the national labelling code to incorporate nanoparticles.

Innovation

A national focus on regulatory and technical reform in this field will benefit the NSW Government's aim to increase linkage and coordination between industry, researchers and regulators. The NSW Government has proposed a number of initiatives to facilitate opportunities for NSW industry and the research sector to

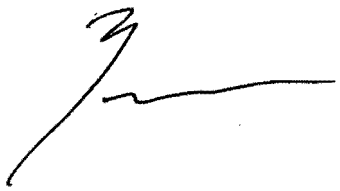
develop nanotechnology related innovations. A commitment to regulatory and technical reform will streamline information flows and speed up the application of new knowledge into practice.

NSW is a leading centre for nanotechnology and metrology, with significant capability located here through Commonwealth facilities, Universities, State Government facilities and the private sector. NSW is hoping to build on this capacity, and ensure that it provides real benefit to industry involved with nanomaterials. A coordinated approach to regulation will aid the development of the nanotechnology industry in NSW.

I would also like to bring your attention to the contribution to this process made by the NSW Department of Environment, Climate Change and Water, a member of the NNPCC, which was submitted to NICNAS in December 2009.

I believe that the Commonwealth and NSW nanotechnology reform agendas are well matched and can therefore provide real benefits to industry, Government and regulators. I thank you for the opportunity to contribute to the NICNAS reform process on behalf of the NSW Nanotechnology Policy Coordination Committee.

Yours sincerely



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NSW GOVERNMENT RESPONSE

TO THE

LEGISLATIVE COUNCIL STANDING COMMITTEE ON STATE DEVELOPMENT

INQUIRY INTO NANOTECHNOLOGY IN NSW

Government's Response to the Recommendations of the Inquiry into Nanotechnology in NSW

Introduction

The NSW Government recognises the benefits to society from research, development and application of nanotechnology. New nanotechnology-based solutions are emerging, with applications in fields including:

- *Health* – cancer diagnosis and therapeutics; diabetes monitoring; surgical aids.
- *Energy* – photovoltaics; hydrogen fuel cells; batteries.
- *Information and Communication Technologies* – semiconductors, supercomputing, electronic displays.
- *Environment* – air purification, water purification and filtration.

The NSW Government requested that an Inquiry into Nanotechnology in NSW be undertaken, so that it could better understand the risks and benefits of nanotechnology and its application. The Legislative Council Standing Committee on State Development undertook the Inquiry and handed down its response on 29 October 2008.

To assist the NSW Government in developing its response to the eighteen recommendations of the Inquiry into Nanotechnology in NSW, the Government established the Government Advisory Committee on Nanotechnology a committee of experts from Government and two independent and eminent researchers, chaired by Professor Mary O'Kane, NSW Chief Scientist and Scientific Engineer.

The Advisory Committee prepared responses to the eighteen Inquiry Recommendations within its report, that was delivered to the Minister for Science and Medical Research on 31 March 2009. This report assisted NSW Government in responding to the Inquiry.

NSW Government Response

The NSW Government supports the thrust of the Recommendations of the Inquiry into Nanotechnology in NSW.

The NSW Government's response to the Inquiry into Nanotechnology in NSW aims to secure innovation and industry development in the context of an appropriately targeted regulatory environment for nanotechnology that minimises risks to health and the environment. In so doing, the NSW Government notes that nanotechnology and its regulation is a complex issue, with no state or national government having fully clarified these issues.

The NSW Government does not support a moratorium on nanotechnology and nanomaterials. The NSW Government believes that the most effective and efficient approach to regulating nanomaterials and nanotechnology would be to adapt, where required, the existing occupational health and safety, waste management, industrial chemical, food and other regulations at the State and Commonwealth levels rather than to develop a set of nanotechnology-specific regulations.

The NSW Government also believes that existing or planned mechanisms that connect Australia with international developments, such as those occurring in the Organisation

for Economic Cooperation and Development (OECD) and the International Organization for Standardization (ISO) should be supported.

The NSW Government's broad approach is in line with the principles put forward by the Advisory Committee, namely to:

- *Maximise the benefits and minimise the risks*
- *Adopt the precautionary principle*
- *Research both the innovative applications and the health and environmental safety aspects of nanotechnology*
- *Open government and access to information* – principles of open government with regard to nanotechnology should be subscribed to.
- *Avoid delay* – don't delay in promoting and setting in place effective and appropriate regulation for nanomaterials.
- *Take a national approach* – so as to avoid duplication and to simplify compliance issues.
- *Utilise mechanisms that are already in place or planned* – for example the establishment of the Standing Committee on Chemicals (SCOC) recommended by the Productivity Commission and recently endorsed by COAG, would be an appropriate body to coordinate regulation of nanomaterials nationally.
- *Implement best practice regulation* – in compliance with the requirements of the Office of Best Practice Regulation's principles of best practice regulation.

Accordingly, to operationalise these principles, the NSW Government will work with relevant Governments and organisations to establish:

1. National Nanotechnology and Nanoscience Laboratory – a networked virtual hub of public and private sector facilities that provides a one-stop-shop for industry to access leading research and testing infrastructure (Attachments 1). NSW Government, through the Department of State and Regional Development will establish a pilot of several NSW-based metrology facilities to test the feasibility of this network.
2. An enhanced presence in NSW of the NanoSafe Australia network – networked with the National Nanotechnology and Nanoscience Laboratory to provide services and advice to NSW research and industry sectors on matters related to health and environmental safety of nanomaterials (Attachments 1)
3. National Council for Ultrafine Particles – a peak body with membership from government, industry, research sector and unions would have a leading role in: (1) identifying and addressing gaps in understanding about the potential risks and benefits of nanotechnology; (2) communicating the latest knowledge around nanomaterials to industry, government and other stakeholders; (3) coordinating research on specific questions (Attachments 1).
4. The NSW Nanotechnology Policy Coordination Committee – bringing together NSW Government agencies with a role in nanotechnology regulation and policy to review and make recommendations on NSW Government regulatory environment in respect of nanotechnology (Attachments 1).

In line with the Inquiry's recommendations, we will also undertake the following work:

- A study into the metrology and characterisation requirements and capabilities in NSW
- A study into the nanotoxicology requirements and capabilities in NSW

- A study of the industry skills requirements and delivery mechanisms for nanotechnology
- A website that acts as a central information point for nanotechnology policy, regulation, programs and contacts in NSW Government.
- Access by industry to research and development infrastructure of relevance to nanotechnology, through the Collaboration and Infrastructure Access Program (CIAP)
- An assessment of the availability and feasibility of automated web-based data mining tools to provide a mechanism to track developments in the risk profiling of nano-objects, through *Science Commons* or another appropriate portal.

The full response is at Attachment 1.

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Inquiry recommendation	NSW Government's Response
Recommendation 1: *That the New South Wales Government recommend that nano-versions of existing chemicals are assessed as new chemicals, during the review of the national regulatory frameworks.*	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 Should a review of the assessment and registration protocols fail to result in an enhancement of the regulatory assessment framework in relation to nanomaterials, NSW Government would raise with the Commonwealth and other jurisdictions the need to promote the need for designers, manufacturers, importers and suppliers of nanoscale versions of existing chemicals to utilise all relevant data to inform end-users and supply chain intermediaries about possible adverse health, safety, environmental and/or product quality issues. NSW Government, through the Department of State and Regional Development, will investigate the availability and feasibility of automated web-based data mining tools to provide a mechanism to track developments in the risk profiling of nano-objects. NSW Government, through the Department of State and Regional Development, will promote the establishment of a National Council for

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	Ultrafine Particles to the Commonwealth and other State and Territory Governments. The Council would have membership from stakeholder organizations such as unions, industry associations, universities non-government organisations and other research organisations. The Council would coordinate the development and dissemination of the latest knowledge on engineered nanotechnology and related materials and products, including health safety and risk data, ecotoxicology information, international developments, skills and training requirements.
Recommendation 2: *That the NSW Government ensure that all relevant State regulatory agencies be involved in developing a coordinated and cohesive position on what amendments, if any, are required to the current regulatory frameworks in order to best regulate nanomaterials over their life-cycle.*	The NSW Government will establish a NSW Nanotechnology Policy Coordination Committee (NNPCC), with membership from the NSW Better Regulation Office, Department of Primary Industries, NSW Health, WorkCover NSW, Department of State and Regional Development, Department of Environment and Climate Change and the NSW Food Authority and Department of Premier and Cabinet. The Committee will be chaired by the NSW Chief Scientist and Scientific Engineer. The Committee would also include relevant Commonwealth Government agencies with relevant interests, for example the Australian Nuclear Science and Technology Organisation (ANSTO), which has considerable expertise in nanotechnology. This Committee would consult with other NSW Government agencies, Local Government and the Commonwealth to encourage a coordinated approach to policy and regulation of nanotechnology and related materials and products. The Committee will review NSW Government regulations in relations to nanotechnology in the light of the latest research findings, and also with regard to regulatory developments in Australia and overseas. In order to develop a knowledge hub for nanomaterials characterisation and toxicology and facilitating strong links between policy development

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	and latest knowledge, NSW Government will test the feasibility of a network that brings together relevant research infrastructure capacity, to be called the National Nanotechnology and Nanoscience Laboratory. This is further discussed in responses to Recommendations 8 and 10.
Recommendation 3: *That WorkCover NSW work with those companies, or premises of which it is aware, that manufacture or use engineered nanomaterials of 300 nanometres or less in size in one or more dimensions, to promote workplace safety in the use of nanotechnology.* *That WorkCover NSW advertise its intention to undertake this endeavour and calls for companies manufacturing or using engineered nanomaterials of 300 nanometres or less in size to contact it to participate in this workplace safety endeavour.*	The NSW Government notes that WorkCover NSW already has a number of initiatives in place to promote workplace safety in the use of nanomaterials. WorkCover NSW has specific technical resources to develop the capacity of the inspectorate and industry through initiatives such as training for inspectors and the development of an audit framework for nanotechnology facilities. WorkCover NSW will continue to work with industry to raise awareness of the safe management of nanomaterials. The NSW Government considers that a nationally coordinated approach to promoting workplace safety in the use of nanotechnology would be more appropriate than an initiative limited to NSW. The NSW Government recommends that the Safe Work Australia Council in liaison with the Heads of Workplace Safety Authorities, consider a nationally coordinated program to promote workplace safety in the area of nanotechnology. NSW Government recommends that public sector research laboratories be included in these safety promotion initiatives, given the significant proportion of nanotechnology research and development occurring in public organisations.
Recommendation 4: *That the New South Wales Government work in cooperation with federal agencies on the development of a national mandatory labelling scheme for engineered nanomaterials used in the workplace, and that in the absence of a national scheme, NSW should proceed with investigating the development of its own mandatory labelling scheme.*	The NSW Government supports the recommendation to work in cooperation with federal agencies in the development of a national mandatory labelling scheme for engineered nanomaterials used in the workplace. The NSW Government agrees to make recommendations to the Commonwealth that a national labelling scheme be supported for engineered nano-objects and nano-object containing materials used in the

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	workplace. Given the need for a nationally coordinated approach to nanotechnology, the NSW Government does not support investigating the development of a state based mandatory labelling scheme in the absence of a national scheme.
Recommendation 5: *That the NSW Food Authority develop an application to seek an amendment to the national Food Standards Code to require that food labels identify the presence of nanoscale materials.*	In view of the November 2008 COAG agreement for a comprehensive review of food labelling law and policy, and on-going Commonwealth initiatives, the NSW Government will not at this time develop a separate application to amend the Australia New Zealand Food Standards Code. Rather, the NSW Government will continue to work in cooperation with federal agencies to ensure that the most feasible regulatory and non-regulatory options for addressing nanotechnology and food takes into account all available information.
Recommendation 6: *That the New South Wales Government recommend that ingredient labelling requirements for sunscreens and cosmetics include the identification of nanoscale materials, during the review of the national regulatory frameworks.*	The NSW Government agrees to raise with the Commonwealth, during the review of the national regulatory frameworks, the possibility of introducing ingredient labelling requirements for sunscreens and cosmetics that include the identification of nanoscale materials. While wishing to encourage the provision of more information on labels to allow the community to make well-informed decisions about products containing nanoscale ingredients, it is necessary to thoroughly consider the potential impact, in light of high and increasing rates of melanoma in Australia. Any changes to labelling should be accommodated within current frameworks and could fit with a more wide-ranging review of the standards governing sunscreen. The NSW Government recommends a health impact assessment be conducted prior to any changes being made to labelling requirements,

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	including consultation with consumers, clinicians and industry. Continued public education campaigns are essential to ensure the public is aware of the dangers of harmful Ultra Violet light exposure and are well informed of the means to protect themselves.
Recommendation 7: *That the New South Wales Government 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, and that in the absence of a national scheme, NSW should proceed with investigating the development of its own interim reporting scheme.*	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. A proposed mandatory scheme would need to be broadly sufficient to capture information on nanomaterial lifecycle. Given the need for a national approach to nanotechnology, the NSW Government does not support the investigation of a state based reporting scheme in the absence of a national reporting scheme.
Recommendation 8: That the NSW Government actively seek, through the use of leverage funding, the establishment of additional metrology infrastructure within the State to build on the current metrology strength and to provide additional benefit to industry, research and development.	NSW Government, in the context of the recent response to the NSW Jobs Summit, will look at opportunities to promote Sydney and NSW to the world as location for scientific services, in particular measurement and characterisation of nanomaterials. The NSW Government, through the Department of State and Regional Development will undertake a mapping exercise of state, national and Asia-Pacific nanometrology capabilities. Through this exercise the infrastructure requirements of industry and the research sector will be ascertained. From there an assessment of the capability and

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	infrastructure gaps will be made; priority areas will be identified and taken forward in future Commonwealth funding rounds where appropriate. The NSW Government will undertake a pilot project to bring together a group of metrology and nanotoxicology facilities to test the feasibility of the National Nanotechnology and Nanoscience Laboratory network, in providing a one-stop-shop for industry seeking access to infrastructure for research and assessment. The NSW Government will establish the Collaboration and Infrastructure Access Program to provide support to NSW industry seeking to access research infrastructure and to develop research partnerships with public sector organisations.
Recommendation 9: *That the Office of Science and Medical Research, through investigation and consultation, determine what are the nanotoxicology research needs of most importance to the industry and research sectors in New South Wales.*	The NSW Government will commission the Department of State and Regional Development to undertake a mapping exercise of state, national and regional nanotoxicology requirements and capabilities to address the current knowledge gap, identify priority areas and to provide the basis of infrastructure funding bids.
Recommendation 10: *That the New South Wales Government provide financial support to create enhanced nanotoxicology assessment capacity relevant to research and industry sectors in the State*	The NSW Government will discuss with the Commonwealth, the feasibility of broadening the toxicology infrastructure proposed in the Commonwealth's Strategic Roadmap for Australian Research Infrastructure (August 2008) to include nanotoxicology, or through the most relevant Commonwealth mechanism, should there not be a further funding round associated with the Roadmap. Currently the Roadmap makes a recommendation that a set of *preclinical* testing facilities, including for toxicology be established. Expanding this capability beyond preclinical toxicology testing to also include toxicology facilities of relevance to nano-objects and expertise in designing toxicology experiments of relevance to nano-objects, whether they are for clinical or non-clinical applications.

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	The proposed mapping exercise in Recommendation 9 would identify areas of greatest need in terms of research priorities for the State. As set out in the response to recommendation 8, the Government will undertake a pilot project to bring together a group of metrology and toxicology facilities to be known as the National Nanotechnology and Nanoscience Laboratory, to test the feasibility of a network to provide a one-stop-shop for industry seeking access to infrastructure for research and assessment. The Government will discuss with NanoSafe Australia opportunities to expand its network in NSW and develop linkages to the National Nanotechnology and Nanoscience Laboratory.
Recommendation 11: *That New South Wales Government agencies that provide funding grants for research and development of nanomaterials or products containing nanomaterials with a view to their commercialisation require that a component of that funding be used to assess the health, safety and environmental risks of the material or product when those risks have not yet been tested or confirmed*	NSW Government agencies that make grant funding available for the development of nano-objects or nano-object containing materials that will be used in commercial settings, will require grantees to report on the assessment of health, safety and environmental risks as a component of their reporting on the utilisation of the grant. Where this information is not available for the nano-objects under consideration, the grantee will be required to fund research of the health, safety and environmental risks of the nano-objects, using a portion of the NSW Grant. NSW Government agencies that provide research funding will ensure that grant application forms include a check-box for nanotechnology.
Recommendation 12: *That the NSW Department of State and Regional Development enter into detailed discussions with the Commonwealth Scientific and Industrial Research Organisation, the Australian Nuclear Science and Technology Organisation and New South Wales Government agencies to explore the feasibility of and*	As part of the mapping activity outlined in the response to Recommendation 9, the Department of State and Regional Development will consult with CSIRO, ANSTO and relevant NSW Government agencies, that have toxicological research capabilities. The Department of State and Regional Development's mapping study will provide advice as to the preferred method for taking this capability forward

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need for a specialised facility for assessing the toxicity of engineered nanomaterials, and the case for and benefit of it being located within New South Wales	including the preferred model for governance, co-location, funding, linkages and access for industry and public sector workers.
Recommendation 13: *That a user-friendly, accessible and continually updated directory of research and research infrastructure capacity that is publicly available via an easily accessible website be maintained by a relevant Government agency or department.*	The NSW Government has commissioned the NSW Chief Scientist and Scientific Engineer to oversee the development of a user-friendly, accessible and continually updated directory of research and research infrastructure capacity.
Recommendation 14: *That the New South Wales Government develop, publish and endorse a comprehensive statement on nanotechnology, referring, among other matters, to current issues relating to nanotechnology, activity being undertaken at the State and national levels, and advice on where further information is available.*	The NSW Government will publish a statement on nanotechnology, in which it articulates its approach to providing stewardship, managing risks, reviewing regulation, engaging the public, supporting the development of new knowledge and providing opportunities for technological advancement. This statement will be published on the Nanotechnology webpage to be maintained by the Department of State and Regional Development.
Recommendation 15: *That the NSW Government establish a NSW Nanotechnology Unit within an existing department or agency to act as a coordination point for all other NSW agencies dealing with issues relating to nanotechnology, provide a central point for whole of government information on or enquires relating to nanotechnology, and proactively engage with industry in the promotion of nanotechnology.*	The NSW Government will not at this time create a dedicated nanotechnology unit. Nanotechnology activities, coordination, funding and regulations are part of the general core business of NSW Government in agencies including Department of State and Regional Development, WorkCover NSW, NSW Health, Department of Environment and Climate Change, NSW Food Authority, and NSW Department of Primary Industries. Instead, the NSW Government will put in place mechanisms to coordinate review of NSW regulations in respect of nanomaterials through the NSW Nanotechnology Policy Coordination Committee. The NSW Government will establish and coordinate a webpage with information of NSW Government's activities in nanotechnology, including

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	regulatory overview and available funding programs. This webpage would be maintained by the Department of State and Regional Development.
Recommendation 16: *That the New South Wales University-Government working group, with representation from the vocational and technical education sector, examine the education, skill and knowledge requirements to support nanotechnology.*	A mapping study of the skills requirements of industry, government and universities in relation to nanotechnology will be undertaken. NSW Government will then ask the NSW Vice Chancellors Committee to establish a working group with representation from the NSW Board of Vocational Education and Training that will determine nanotechnology education and training delivery mechanisms and to design appropriate mechanisms to deliver the education and training courses identified through the skills study.
Recommendation 17: *That the Office of Science and Medical Research, in collaboration with the Department of Education and Training, examine and develop a strategy to ensure greater access for regional students to the Science EXPOsed programme.*	Government has asked the NSW Chief Scientist and Scientific Engineer to work with the Department of Education and Training, the Department of State and Regional Development, the Australian Museum and the Powerhouse Museum to determine the most effective and equitable model for delivering Science EXPOsed and related activities so as to maximise the opportunities for regional and remote students in NSW.
Recommendation 18: *That the NSW Government, or the NSW Nanotechnology Unit as recommended by the Committee, create and maintain a website that provides information, or links to information, on nanotechnology.*	The NSW Government will discuss with the Commonwealth the most appropriate mechanism to maintain an enhanced national nanotechnology web-based communication function. As indicated previously, the NSW Government, through the Department of State and Regional Development, will establish and maintain a webpage to provide updates on the policy, programs and regulatory activity of NSW Government in relation to nanotechnology.

Australian Government
Department of Health and Ageing
NICNAS

National Industrial Chemicals Notification and Assessment Scheme

Proposal for Regulatory Reform of Industrial Nanomaterials

Stakeholder comments – Public Consultations November 2009 – SYDNEY 16.11.09

A. Theme:	B. Comments from participants:	C. Issues for public consideration: To be published
1. Definition of "industrial nanomaterials"	Definition in Discussion Paper not satisfactory: • Size – <100nm too narrow i.e.: could potentially miss out on agglomerated nanoparticles • Use of "intentional" would not take into consideration nanoparticles that are formed unintentionally, i.e. in grinding processes where a grade may be for micro scale but contains proportion of unintentional nano scale particles. • Mixtures? At what % w/w would something be classified as nano?	***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:*** • ***Size – cut off should not be 100nm because of factors such as agglomeration,*** • ***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.***
2. Whole of government approach	Why isn't there a whole of government approach, given uncertainties and risk? Community has expectation that there is a whole of government approach. →Concern over lack of Precautionary approach. Need to have national consistency with NICNAS, APVMA, TGA How/what are TGA and APVMA doing and will it be harmonised with the NICNAS system? What are the 'gaps'? Community expectation is that there should be a central, overarching oversighting body. As according to NSW recommendation→ Standing Committee on Chemicals – yet to meet. How will this topic be dealt with? nb: no community/industry reps.	***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.*** ***2.2 The government should be clear that health and environmental issues raised by this technology should be treated with a precautionary approach.*** ***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.*** ***2.4 As recommended by NSW govt report, to coordinate the whole of government approach effectively, a central overarching steering body should be established.***
3. NICNAS processes	Application of precautionary principle in Attachment 1 "Overarching	***3.1 NICNAS should use wording in regulatory principles that clearly***

	Principles" too weak – "precautionary" not actual text included, reference to it: '***can be'*** should be '***will be adopted'.*** Resourcing – need to make sure NICNAS can ensure assessments are handled in a timely way NICNAS needs greater powers by legislation - to refuse hazardous substances, greater enforcement capability. Tiimeframes should be supplied for each stage of process Low Regulatory Concern Chemicals? (Low concentration/ low volume) How applied to nanomaterials? Better links with Existing Chemicals Review and work happening there? – should be elaborated. New Chemicals: Better more inclusive community engagement, especially with NGO sector needed. Existing chemicals: • EC review (not mentioned) but now - will nano reg proposals to be integrated in this review? (not mentioned) • Downstream user info • Adverse effects reporting scheme • E(?) database on reporting • Selection and prioritisation process NICNAS needs to generate better stakeholder databases for more inclusive engagement, more notice.	***commits to a precautionary approach in the regulation of industrial nanomaterials.*** ***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 refuse hazardous substances and have greater enforcement capability.*** ***3.3 Timeframes for reform process should be available to stakeholders for consideration.*** ***3.4 Further information on the proposal should detail / clarify how these reforms will fit in with other NICNAS activities, eg;*** • ***Existing Chemicals Review*** • ***Low Regulatory Concern Chemicals*** ***3.5 Engagement would be more inclusive with better stakeholder databases and more notice given.***
4. Assessment of nanomaterials	Social, economic factors need to be considered in risk management Balance of economic and safety considerations What about synergies, cumulative, additive effects and end of life persistence? (Grossly underestimated in current assessments) Will assessment consider this? Will/ should formulations be assessed? (Synergistic effects) Problem re: measurement – who would test? Labs? Certification of labs currently low. NATA accreditation exists. How appropriate for nano? Need to liaise. Dedicated body for testing, measuring and assessment of nano/appropriate certification of lab i.e. NATA accreditation. Lifecycle of these materials needs to be addressed somehow – research, assessment on risks in waste phase and potential recycling.	***4.1 Assessments and risk management should take into consideration:*** • ***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.*** ***4.2 Should a dedicated body or testing certification system be established for testing of industrial nanomaterials in Australia?***
5. Implementation	Implementation – when will new system start?	***5.1 Implementation of reforms – should have a steering committee and***

	Auditor needed across all sectors, check downstream use. Need overarching steering committee (COAG standing com?) Compliance issues - Enforceable conditions? What can be enforced? How? (Currently NICNAS is not fully aware of uptake of PEC recommendations?) How can NICNAS get cost recovery from companies that are not doing the right thing?	***be auditable across all sectors of industry, including downstream use.*** ***5.2 Measures such as mandatory reporting can help industry if effectively implemented by creating a level playing field.*** ***5.3 What enforceable conditions can NICNAS introduce to ensure compliance and that costs are recovered from non-compliant companies?***