PO Box 173 Bangalow
NSW 2479 Australia
info@ntn.org.au



**Submission to NICNAS Regulatory Consultation - Nanotechnology**
**8 February 2010**

Prepared by: Dr Mariann Lloyd-Smith

**General Comments**

The National Toxics Network (NTN) considers there is a strong case for a moratorium on the commercial use of nanomaterials until specific risk assessment procedures can be validated and the safety of nanomaterials can be better ensured and an effective regulatory regime is in place.

While we acknowledge NICNAS's public consultation process, we would also encourage NICNAS to further utilise the Community Engagement Forum (CEF) to ensure a broader approach to community engagement on nanomaterials.

We support our NGO colleagues in their calls for further face-to-face consultations with interested stakeholders and members of the public to discuss and further develop the technical details of the NICNAS regulatory strategy. We believe this should take place before the finalisation and release for consultation of the second version of the NICNAS proposed regulatory framework.

**Risk assessment**

Leading international authorities including the European Food Safety Authority (2009)[1] have warned that not enough is known about the behaviour of nanomaterials to design reliable risk assessment.

The gaps in the understanding of nanomaterials' biological behaviour and new toxicity risks are large, and the capacity to measure, assess, compare and mitigate these risks is still in its infancy.

There is an urgent need to address the safety aspects of nanomaterials before allowing their widespread dissemination in the environment. This has been made all the more urgent by the growing awareness of the ability of some nanoparticles to cross the placental barrier, thereby contaminating future generations.

[1] EFSA. 2009. Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety; EFSA-Q-2007-124a, Brussels. EFSA. Available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm (last accessed 3 February 2010).

In 1996, researchers showed that *'fullerenes'*, a common nanoparticle used in women's makeup, move into mouse embryos via maternal blood, severely disrupting foetal development.[2] In 2009, researchers confirmed that nanosized titanium dioxide, which is used in a wide range of consumer products, passes from pregnant mice to their offspring, resulting in damage to the genital and cranial nerve systems.[3] This research demonstrates that once nanoparticles enter the mother's body, through any means - inhalation, ingestion or via skin - harmful nanoparticles can be passed on to her offspring during the crucial early stages of foetal development.

The special vulnerability of children and pregnant women to the hazards of manufactured nanomaterials must be addressed as a priority prior to their production, assessment, use, transport and disposal.

**COMMENTS ON THE OVERARCHING PRINCIPLES**

NTN, along with over 1000 other NGOs globally, has committed to the World Summit on Sustainable Development 2020 goal. We committed *"to work for and achieve by the year 2020, a Toxics-Free Future, in which all chemicals are produced and used in ways that eliminate significant adverse effects on human health and the environment.*

To achieve this, the four pillars of chemical reform need to be implemented in any regulatory regime:

- Right to Know
- No data / no market
- Precautionary Principle
- Principle of substitution

It is these four principles, which should underpin the regulatory framework for nanomaterials. This is essential in order to ensure that future generations do not pay the costs of our lack of diligence, as has occurred with persistent organic pollutants (POPs), asbestos and agent orange, to name only a few.

The public interest in the assessment and management of nanomaterials, including the community's 'right to know' must be paramount. The level of regulatory oversight should not be defined by support for industry innovation, rather by the protection of human health, the environment and future generations.

**Community and Worker 'Right to Know'**

The proposed principles do not include a commitment to transparency, and the public and workers' right to know in relation to nanomaterials regulation and assessment. The need for

[2] Tsuchiya et al, Novel harmful effects of [60] fullerene on mouse embryos in vitro and in vivo. *Fed. of European Biochemical Societies (FEBS) Letters 393* [1996] 139-145
[3] Takeda et al, Nanoparticles Transferred from Pregnant Mice to their Offspring Can Damage to the Genital and Cranial Nerve Systems. *J. Health Sciences*, 55(1) 95-102 (2009)

communities to have information on toxic chemicals has been well recognised internationally in several treaties to which Australia is a signatory.[4]

Right to know is an essential principle of chemical management, and information on the types and quantities of nanomaterials used, and their use in particular products and industrial chemicals should be a priority. Right to know was enshrined in Agenda 21 and reiterated in the 'Bahia Declaration on Chemical Safety'[8] by the Intergovernmental Forum on Chemical Safety (IFCS) in Brazil, 2000. The declaration affirmed that an informed public is vital for effective chemical management and called on all governments to not only increase access to information in chemicals, but to recognise the community's right-to-know about chemicals in the environment and to recognise the community's right to participate meaningfully in decisions about chemical safety that affect them.

Right to know is also called for in the Strategic Approach to International Chemical Management (SAICM) in order to ensure information about chemicals throughout their life cycle, including chemicals in products, is available to all stakeholders. Based on the SAICM Overarching Policy Strategy, appropriate information should encompass nanomaterials' effects on human health and the environment, their intrinsic properties, potential uses, protective measures and relevant regulations,[5] stressing that in this context, information relating to the health and safety of humans and the environment should not be regarded as confidential.[6] A further SAICM objective is to ensure that the available information is sufficient to adequately assess and manage chemicals safely throughout their life cycle.[7]

NICNAS's regulatory proposal must address the need to ensure easy accessibility of information on the use and risks associated with the life cycle of manufactured nanomaterials to the general public and workers. As nanomaterials may be toxic in minute amounts and may persist for long periods in the environment, the food chain or human tissue, it is particularly important that accurate information concerning their quantities, properties, use, location, and regulatory status be freely exchanged and widely accessible to the public. Producers must provide comprehensive information about the content of manufactured nanomaterials in order to inform consumers about potential risks through product labeling and, as appropriate, websites and databases.

***It is therefore essential to enshrine the public's right to know in both the overarching principles and the regulatory framework. The use of confidentiality listing and commercial business information provisions are not appropriate to the management of nanomaterials through their assessment and life cycle.***

**'No Data, No Market' Principle**

The implementation of the "no data, no market" principle, requiring submission of comprehensive hazard assessment including toxicology and ecotoxicology data prior to commercialization of nanomaterials is essential to avoid the mistakes of the past and to ensure public trust and acceptance. This must include information on the byproducts and effects of the waste phase of nanomaterials. Most importantly, the toxicological testing methodology used must be in step with current thinking in the new ways of assessing

[4] Lloyd-Smith, M., 'Rights and Wrongs of Knowing in Chemical Conflict.' Vol.2 No 3: March 2002 *The Drawing Board, An Australian Review of Public Affairs.*
[5] SAICM Overarching Policy Strategy, para 15 (b) (i)
[6] SAICM Overarching Policy Strategy, para 15 (c)
[7] SAICM Overarching Policy Strategy, para 15 (a)

toxicological effects[8] and should incorporate international peer reviewed research in nanomaterial assessments. It should also encompass an assessment of intergenerational effects, nonmonotonic dose response associated with endocrine disrupting chemicals (EDCs) and indirect mesocosm effects for the chemical(s) being tested.

**Precautionary Principle**

The proposed overarching principles do not include a commitment to use the precautionary principle. The critical role of the precautionary principle needs to be acknowledged when assessing nanomaterials and throughout their life cycle to their final disposal and destruction. The precautionary principle is clearly warranted by the growing scientific evidence of threat of serious harm[9] and the extent of uncertainty that surrounds nanomaterials behaviour and biological risks.[10]

The precautionary principle is an integral part of Australian law[11] and is included in the *National Strategy for Ecologically Sustainable Development* (Commonwealth of Australia (1992), the *Environment Protection and Biodiversity Conservation Act* (1999) and the *National Environmental Protection Council Act* 1994 (Cth), responsible for developing National Environment Protection Measures for soil and air. By 2004, the consideration of ESD principles including precaution was required by over 23 pieces of Commonwealth legislation and at least, 47 State Acts in New South Wales (NSW) alone.[12] In 1999, the Australian government argued before the international Tribunal for the Law of the Sea that the precautionary principle was a 'customary norm'.[13] As such there can be no excuse for not including the precaution principle as an integral part of NICNAS's regulatory regime for nanomaterials.

---

[8] See Myers, J.P., Zoeller, R.T. anf vom Saal, F.S. "A Clash of Old and New Scientific Concepts in Toxicity, with important implications for public health", *Environmental Health Perspectives*, Volume 11, November 2009 pages 1652-1655

[9] For example see EFSA. 2009. Scientific Opinion: The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety; EFSA-Q-2007-124a, Brussels. EFSA. Available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm; Hansen, S. (2009), Regulation and Risk Assessment of Nanomaterials – *Too Little, Too Late?* PhD Thesis February 2009, Copenhagen: Technical University of Denmark. Available at http://www2.er.dtu.dk/publications/fulltext/2009/ENV2009-069.pdf

[10] For example see Maynard, A.D., Aitken, R.J., Butz, T., Colvin, V.L., Donaldson, K., Oberdörster, G., Philbert, M.A., J. Ryan, A. Seaton, V. Stone, S.S. Tinkle, L. Tran, N. Walker and D.B. Warheit (2006), 'Safe Handling of Nanomaterials', Nat 444: 267-269; Oberdörster G, Stone V, Donaldson K. 2007. Toxicology of nanoparticles: An historical perspective. *Nanotoxicol* 1(1):2-25.

[11] Peel, J., The Precautionary Principle in Practice: Environmental Decision-Making and Scientific Uncertainty (Federation Press, Sydney, 2005); Also see Lloyd-Smith, M., Precautionary Principle Gets Real, Proceedings of the Environmental Grantmakers Conference, Kaui, Hawaii 2004

[12] For examples see Agricultural Tenancies Act 1990 (s 3), Coastal Protection Act 1979 (s 3), Contaminated Land Management Act 1997 (s 3), Energy Services Corporations Act 1995 (s 5), Fisheries Management Act 1994 (s 3), Gas Supply Act 1986 (s 3), Landcom Corporation Act 2001 (s 6), Local Government Act 1993 (s 7), National Parks and Wildlife Act 1974 (s 2A), Native Vegetation Conservation Act 1997 (s3), Pesticides Act 1999 (s 3), Plantations and Reafforestation Act 1999 (s 3), Protection of the Environment Operations Act 1997 (s 3), Rural Fires Act 1997 (s 3), State Owned Corporations Act 1989 (s 8, s 20E), Sydney Water Act 1994 (s 21), Sydney Water Catchment Management Act 1998 (s 14), Threatened Species Conservation Act 1995 (s 3), Transport Administration Act 1988 (s 5, s 18B, s 19D, s 20), Water Avoidance and Resource Recovery Act 2001 (s 3), Waste Recycling and Processing Corporation Act 2001 (s 5), Water Management Act 2000 (s 3), Western Lands Act 1901 (s 2), Independent Pricing and Regulatory Tribunal Act 1992 (s 15(1)(f)), Local Government Act 1993 (s 89(1)(c) and (2)), Natural Resources Commission Act 2003 (s14(a))

[13] Southern Bluefin Tuna Cases (*New Zealand v Japan; Australia v Japan*) Request For Provisional Measures, The International Tribunal For The Law Of The Sea, 27th of August 1999

In 2004, Swiss Re, one of the world's largest reinsurance agents, called for application of the precautionary principle in management of nanotechnology risks; "In view of the dangers to society that could arise out of the development of nanotechnology, and given the uncertainty currently prevailing in scientific circles, the precautionary principles should be applied whatever the difficulties".[14]

In 2008, the application of the precautionary principle as one of the general principles of nanotechnology risk management was recommended by 71 governments, 12 international organisations and 39 NGOs at the Intergovernmental Forum on Chemical Safety, Senegal meeting in September in 2008.[15]

***The Overarching Principles must include a clear commitment to the precautionary principle for the assessment of nanomaterials and to ensure adequate followup environmental monitoring and human biomonitoring on nanomaterials used in industry and or released to the market place.***

**Substitution Principle**

The 'substitution principle' calls for the replacement of hazardous substances of concern by suitable alternative substances or technologies.[16] 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.

**DEFINITIONAL ISSUES**

***Nanomaterials should be defined as 'particles having one or more external dimensions measuring approximately 0.3 nanometres (nm) to 300 nm, or particles which have internal structures that exist at this scale'.***

Particles that measure >100nm still have novel nano-specific properties and display novel nano-specific toxicity. Professor Ken Donaldson from the UK House of Lords found in 2009 that "there is no toxicological basis whatsoever" to define a nanoparticle as <100nm. There is no difference between a 90 nm and a 110 nm particle in its ability to have an adverse effect and little evidence exists for the 100nm cut off point for the ultrafine effect.

Nanoparticles should not be defined as insoluble as nano-solubility is poorly understood. Further more, there is much evidence that partially and even wholly water soluble nanoparticles exert both ion and particle-mediated toxicity which can be greater than that of ions alone.

Nanoparticles should not be defined as biopersistent. Biopersistence remains poorly researched and poorly understood. Furthermore, even particles that do not show significant biopersistence may pose acute nano-specific toxicity. Aggregates and agglomerates whose primary particles are nanoscale, and particles which possess nano-structures, must also be defined and assessed as nanoparticles.

[14] Nanotechnology: Swiss Re investigates the opportunities and risks of nanotechnology from an insurance perspective, London / Zurich, 10 May 2004 p 47
[15] Forum 6, Intergovernmental Forum on Chemical Safety, Senegal, Dakar, September 2008 Available at http://www.who.int/ifcs/forums/six/en/index.html
[16] SAICM Overarching Policy Strategy, paragraph 14 (d)(i)

***It is important to stress that the issues raised in NTN's submission relate to nano-forms of both new and existing chemicals.***

NICNAS must ensure that nano-forms of existing chemicals also face mandatory notification and assessment. This may require NICNAS to issue secondary notifications to all manufacturers/ notifiers whose products may contain a nano-component.

**REGULATORY RESPONSES**

It is clearly apparent that voluntary initiatives on nanotechnology have failed.[17] Co-regulatory options for NICNAS' oversight of nanomaterials should not be introduced and mandatory measures should begin immediately.

Neither the current NICNAS permit nor certificate system is appropriate for nanomaterials. NTN recommends a new permit category for nanomaterials. This should require full, standardised nano-specific health and environmental assessment and physico-chemical characterisation. It should also require notification and listing on a publicly available database to alert potentially exposed workers and consumers.

Labelling consumer goods in which nanomaterials occur is essential for public health and safety, environmental sustainability and consumer choice reasons. NICNAS should initiate a joint program with ACCC to ensure that nano-labelling proceeds in a timely way.

A formal review of the NICNAS regulatory framework should be required 2 years after its commencement.

[17] See Breggin L, Falkner R, Jaspers N, Pendergrass J, Porter R. 2009. Securing the promise of nanotechnologies: Towards transatlantic regulatory cooperation. Chatham House (the Royal Institute of International Affairs), London. Available at: http://www.chathamhouse.org.uk/files/14692_r0909_nanotechnologies.pdf ; Also see U.S. EPA. 2009. Nanoscale Materials Stewardship Program Interim Report. January 2009. Available at: http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf