Consultation on the Proposal for Regulatory Reform of Industrial Nanomaterials

Submission of MADGE Australia Inc

12 February 2010

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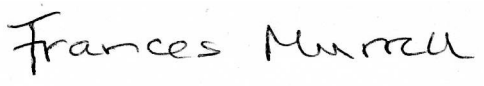

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1. Introduction

MADGE thanks NICNAS for the opportunity to comment on its Proposal for Regulatory Reform of Industrial Nanomaterials. MADGE also recognises NICNAS's efforts to involve a wide range of stakeholders, including the broader community, in developing this regulatory framework.

MADGE Australia Inc is a network of consumers who are concerned about how food and other consumer goods are produced, and the effects they have on our health and the environment. The network currently has around 1100 members.

The MADGE network has a particular focus on **new technologies, such as nanotechnology and genetic modification**. We inform consumers about the issues surrounding these technologies and advocate on their behalf to voice their views to stakeholders in Government and Industry.

2. Summary

MADGE regards the following as essential for consumer confidence in the proposed regulatory reforms:

- There should be a **moratorium on commercial release of nanomaterials** until the validity of risk assessment procedures is established
- The 'Overarching principles of the NICNAS regulatory strategy' should include a **commitment to using the precautionary principle**
- There should be manda**tory reporting and assessment of nanomaterials** - MADGE supports stream 1B and stream 2 of NICNAS's proposed regulatory framework, but does not support stream 1A (voluntary once off, use specific reporting)
- The potential costs of nanomaterials should be judged against the benefits **in the public interest** - social and economic costs should also be considered
- **Consumers' right to know about the presence of nanomaterials in products** should be supported by NICNAS
- There should be a **focus on transparency** in the regulatory process with decisions and risk assessments published in full
- **NICNAS's proposed definition of nanoparticles as particles between 1 – 100 nm is too narrow** and may exclude potentially hazardous substances exhibiting novel, nano-specific properties

3. A moratorium on commercial release of nanomaterials

MADGE believes that Government should implement a moratorium on commercial use of nanomaterials until there is a detailed enough understanding of nanomaterial behaviour and toxicity on which to base appropriate risk assessment systems. Leading institutions such as the European Food Safety Authority (EFSA) recognise current uncertainties surrounding nanomaterial behaviour and consequent difficulties in designing appropriate risk assessment procedures (e.g. EFSA, 2009).

MADGE recognises that nanomaterials are already in commercial use, and that their development is accelerating. In the event that Government does not implement a moratorium on commercial release of nanomaterials, the strongest possible regulatory system is required for protection of public health and the environment.

4. The precautionary principle

The 'Overarching principles of the NICNAS regulatory strategy' should include a commitment to using the precautionary principle.

Currently the overarching principles include a statement that, "where best available scientific evidence is insufficient to support the safety of the product/chemical, measures to protect public health and safety and the environment *can* be adopted". This statement should be strengthened to indicate that in such circumstances, measures to protect public health and safety *will* be adopted. The statement should also make explicit reference to the Precautionary Principle, which underpins key pieces of federal and state legislation on protecting public health and the environment[1], and which is also recognized internationally as being necessary in the management of nanotechnology risks[2].

5. Mandatory reporting and assessment is essential

MADGE supports stream 1B and stream 2 of NICNAS's proposed regulatory framework, but does not support stream 1A - voluntary once off, use specific reporting. Voluntary reporting has been trialled in the United States and the UK as well as Australia, and has not been successful. The EPA (2009) estimates that voluntary reporting in the US resulted in notification of only 10% of commercially available nanomaterials.

NICNAS has made unsuccessful calls for voluntary reporting of nanomaterial use in the past. MADGE believes that NICNAS should now move as quickly as

[1] E.g. the Environment and Protection Conservation Act (1999) and the Victorian Public Health and Wellbeing Act (2008).
[2] E.g. IFCS (2008)

possible to mandatory reporting and risk assessment. Both nano-forms of existing chemicals and nano-forms of new chemicals should be subject to mandatory reporting and assessment.

6. Cost-benefit assessment in the public interest

The development of nanotechnology is "an ethical as well as a scientific question", as UK Government Minister Ian Pearson has noted[3]. There are potential costs – social, environmental, health-related and economic – as well as benefits. NICNAS's proposed regulatory framework only assesses two kinds of potential 'costs' or risks – health and environmental – and does not recognize broader social costs, such as the potential for widespread use of nano-silver in clothing to lead to anti-bacterial resistance in a medical context[4].

MADGE believes that such potential social and economic costs should be considered within NICNAS's regulatory framework. Potential 'costs' should also be considered against the value of proposed benefits, so that the potential 'cost' of nano-silver's impact on aquatic life[5] is judged against the relatively trivial 'benefit' to society of odour reduction. It was suggested during consultations that such cost-benefit judgments are not part of NICNAS's remit. MADGE contends that the Australian public expects regulators to make such judgments.

7. Consumers' right to know

Consumers' right to know about the presence of potentially toxic chemicals is recognised in several international treaties that Australia is a signatory to (Lloyd-Smith, 2002).

Consumers' right to know about the presence of nanomaterials in products should be supported by NICNAS as the regulatory authority which will in future hold most information about commercial use of nanomaterials in Australia.

The right to know should be supported through publication of easily accessible web-based data about commercial use of nanomaterials and through full labelling of products containing nanomaterials. While we understand that NICNAS has no formal responsibility for product labelling, it is ideally placed as the primary repository for information about nanomaterials to initiate a joint labelling initiative with the ACCC.

[3] In Macnaghten et al (2010)
[4] See http://www.abc.net.au/science/articles/2009/06/12/2594441.htm
[5] See Asharani et al (2008)

8. Regulatory transparency

Transparency in the regulatory framework for nanotechnology is essential to consumer confidence in the technology. Recent research by Swinburne University shows that consumers' lack of confidence in GM foods is partly due to a lack of confidence in the processes of commercialisation, and it calls for increased "transparency, participation and communication"[6].

Transparency should include publication of risk assessment reports in full and information about permits issued. Transparency should also include visibility of *how decisions are made* at NICNAS regarding issuing of permits. MADGE directs NICNAS's attention to the UK Food Standards Agency (FSA) as a regulatory body which has improved transparency in decision-making in order to increase public confidence. The FSA holds decision-making meetings in public, (with web and audio cast) and publishes meeting minutes and papers tabled, as well as publishing risk assessments and decisions[7].

9. Definition of nanoparticles

Appropriate definition of 'nanoparticles' within the regulatory framework is essential to overall consumer confidence. If nanoparticles are defined too narrowly, such that substances with novel nano-specific properties (and potentially adverse impacts on public health and the environment) are excluded from notification and assessment, this is likely to undermine consumer confidence in the entire regulatory framework. Defining nano-particles too narrowly may also encourage companies to actively develop nanomaterials that fall just outside of the definition triggering notification and assessment in order to reduce their 'regulatory burden'.

NICNAS's proposed definition of nanoparticles as particles between 1 – 100 nm is too narrow and may exclude potentially hazardous substances exhibiting novel, nano-specific properties.

- The size of nano-particles should be defined as 0.3 – 300 nm because particles of up to 300 nm have been shown to have novel, nano-specific properties (e.g. Garnett and Kallinteri, 2006)
- Soluble nano-particles should not be excluded from the definition as nano-solubility is currently poorly understood (SCENIHR, 2009)
- Nano-particles should not be defined in terms of biological persistence – little research has been done into biopersistence and some studies have

[6] Whitfield et al (2010). See http://www.swinburne.edu.au/chancellery/mediacentre/media-centre/news/2010/02/attitudes-to-gm-agriculture-unchanged

[7] For information about how the FSA works, see http://www.food.gov.uk/aboutus/how_we_work/copopenbranch/

suggested that particles that do not show biopersistence may still have short term toxic effects (e.g. Bai et al, 2009)

- Agglomerates and aggregates with primary particles that are nano-scale should be included within the definition of nano-particles – many nanomaterials have particles that are present as agglomerates or aggregates rather than single particles (SCENIHR, 2009)

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