

"rüdiger stegemann" [REDACTED]

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To  
nicola.hall@health.gov.au  
cc

bcc

Subject

NICNAS Regulation on Nanotechnology [No Protective Marking]  
DOCUMENT NOT YET CLASSIFIED

Dear Madam,  
dear Sir,

for your ongoing preparation of the Australian Regulation on Nanotechnology we send you our submission, which you find as attachment as well as at the bottom of these lines.

We hope that our proposals will find your due interest and can be considered in the development of the necessary regulations.

We would be very interested in the further work on regulations on nanotechnology and in the results of your deliberations.

We remain,

yours sincerely,

Ruediger Stegemann  
S A N

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SEEDS ACTION NETWORK



SUBMISSION TO NICNAS

Regulation of Nanomaterials

SEEDS ACTION NETWORK (SAN) is a civil society network involved in public

interest matters of agrobiodiversity, agro genetic engineering, nanotechnology, health, environment and related sectors. SAN is active on the national, European and international level.

We submit this statement to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), related to the Australian Government Department of Health and Ageing. We submit it, because the Regulation of Nanomaterials on the one hand is a national issue, but at the same time an international and global issue. Therefore we appeal to the Australian Government and to NICNAS in particular in the following way:

NICNAS must act to close regulatory gaps in order to ensure that both nano-forms of existing chemicals, and nano-forms of new chemicals, face mandatory safety testing before they can be used in products.

There is a strong case for a moratorium on the commercial and other use of nanomaterials until the safety science catches up and risk assessment procedures can be validated. Leading international authorities including the European Food Safety Authority warn that we do not yet know enough about the behaviour of nanomaterials to design reliable risk assessment.

NICNAS should commit itself to the use and application of the precautionary principle in the development and handling of nanomaterials; i.e. for the full life cycle. At the 2008 International Forum on Chemical Safety's meeting in Dakar, 71 governments, 12 international organisations and 39 NGOs have recommended "applying the precautionary principle as one of the general principles of [nanotechnology] risk management".

NICNAS should commit itself to prioritising public interest management of nanomaterials, including the community's and the individual's 'right to know'. Information on the types and quantities of nanomaterials used, as well as their use and application in particular products and industrial chemicals must be made freely available, including through product labelling.

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'. This is necessary because many particles that measure up to 300nm in size present new, nano-specific health and environmental risks.

The definition proposed by NICNAS of <100nm is too narrow and will leave out many nanoparticles that potentially pose new safety hazards. Nanotoxicologist Professor Ken Donaldson has told the UK House of Lords Inquiry into nanotechnologies and food that "there is no toxicological basis whatsoever" to limit the definition of nanoparticles to <100nm.

Nanoparticles should not be defined as insoluble. Nano-solubility is

complex and poorly understood. Further, there is much evidence that partially and even wholly water soluble nanoparticles can be toxic.

Nanoparticles should not be defined as biopersistent. Biopersistence is poorly researched and poorly understood. Importantly, even particles that do not show significant biopersistence may be toxic in the short term.

Aggregates and agglomerates (clumps of nanoparticles) whose primary particles are nanoscale should also be recognised and assessed as nanoparticles.

Voluntary initiatives and codes of conduct on nanotechnology have failed in Australia, the United States and the United Kingdom, as well as on many other subjects and in other policy areas. NICNAS should pursue mandatory regulation of nanomaterials.

Transparency in regulation of nanomaterials is essential. Risk assessment reports should be published in full.

A formal review of the NICNAS regulatory framework should be required 2 years after it begins.

SEEDS ACTION NETWORK - S A N  
Ruediger Stegemann, Coordinator

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