

Nanotechnology regulation in Australia



What are nanomaterials?

Nanomaterials are objects with one or more dimensions, or surface structures, on the nano-scale. The nano-scale ranges from approximately 1-100 nanometres - with one nanometre being one billionth of a metre. There is, however, no legislated definition of nanomaterials in Australia, raising concerns that regulations relating to nanomaterials may not be enforceable.¹

Nanomaterials can behave quite differently to bulk particles of the same substance. They are more chemically reactive - and potentially more toxic - than larger particles

Nanomaterials are being used in a host of sectors and products, including medicine, cosmetics, food, clothing, agriculture, diverse consumer products, aviation and energy.

Why should nanomaterials be regulated?

There is a growing body of peer-reviewed research indicating potentially serious environmental and health concerns with some nanomaterials.

Nanomaterials are generally more chemically reactive than larger particles of the same chemicals and much more likely to be taken up into our cells and tissues than larger particles.² Numerous studies have shown nanoparticles can be absorbed through the skin, lungs and intestine and often accumulate in the liver, kidney, spleen, lung and brain.³

Nanoparticles have been associated with immune dysfunction and colon cancer and there is evidence that nanoparticles may remain in the body for extended periods.⁴

Although environmental impacts have been poorly studied, there is increasing evidence that some nanomaterials could cause harm. Nano-silver, for example, has adverse impacts on plants, microorganisms and aquatic organisms.

In many cases, a lack of data makes an assessment of the safety of products containing nanomaterials impossible, yet only a handful of nanomaterials are subject to any regulation at all.

Who is responsible for regulating nanomaterials?

In Australia, at least seven Federal regulatory agencies have some responsibility for regulating nanomaterials - depending on the material and where it is in the supply chain. State agencies are responsible for regulating nanomaterials in the waste stream, but have not yet used those powers.

A 2008 review of Australia's regulatory framework concluded that there were significant regulatory gaps that need to be filled. These include the fact that most regulators don't require the separate risk assessment of nano forms of existing substances - even if those nanomaterials behave differently to bulk forms of the substance.⁵ Six years on the majority of these gaps remain unaddressed.

NICNAS (National Industrial Chemicals Notification and Assessment Scheme) regulates industrial chemicals, including formulations and cosmetics. NICNAS requires the registration of 'new' nanomaterials but this doesn't include the nano forms of chemicals that are already registered.

The Department of Environment is responsible for regulating releases that may impact on 'matters of national environmental significance'. Although they looked at the issue in 2010 they have not taken any regulatory steps to date.⁶

The APVMA (Australian Pesticide and Veterinarian Medicines Association) is responsible for nanomaterials in pesticides or veterinary medicines.⁷ The APVMA has "not yet published any detailed guidelines specifically about the registration and regulation of products containing nanomaterials," although agricultural products containing nanomaterials are available in Australia.⁸

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The TGA (Therapeutic Goods Association)

regulates any therapeutic good (including supplements and sunscreen) and medical devices. Decisions on household chemicals are made by the Secretary to the Department of Health who is advised by a committee formed under the Therapeutic Goods Regulations.⁹ According to the TGA, if nanomaterials are added to existing therapeutic goods they will require re-assessment, and manufacturers must submit or hold safety data on new products.¹⁰ However that requirement does not appear to be reflected in the Therapeutic Goods Act Regulations, nor do any sunscreens or other therapeutic goods known to contain nanomaterials¹¹ appear to be listed in the Register of Therapeutic Goods.¹²

Safe Work Australia is responsible for nanomaterials in the workplace. Apart from carbon nanotubes, no other nanomaterials are subject to workplace health and safety requirements.

FSANZ (Food Standards Australia New Zealand)

regulates foods, food packaging and food contact materials. The agency has stated that it will require a risk assessment of “novel nanoparticles in food should FSANZ receive an application to amend the Code.”¹³ However FSANZ says no applications have been made and FSANZ has taken no steps to determine whether nanomaterials are currently being used in food and food contact materials in Australia.¹⁴ FSANZ’s position on food packaging is even weaker. The unenforceable standard that “retailers must ensure their products are safe”¹⁵ is viewed by industry as equivalent to “not having any legislation for packaging in contact with food.”¹⁶

The ACCC (Australian Competition and Consumer Commission) is responsible for all consumer products containing nanomaterials that are not subject to other regulatory jurisdiction. They have neither a policy nor regulations in place.

What needs to happen?

Friends of the Earth is calling for:

1. A mandatory register of nanomaterials to allow the tracking of nanomaterials through the supply chain and risk assessments to be conducted;
2. A moratorium on the commercial release of products containing nanomaterials until testing has determined that they are safe;
3. The labelling of all products containing nanomaterials to allow consumer choice.

¹ Friends of the Earth (2013) ACCC refuses to tackle widespread misleading conduct in the sunscreen industry, http://emergingtech.foe.org.au/?s=accc&silverghyll_tpicker=s=accc,

² Friends of the Earth (2014) Way too Little: Our Government’s failure to regulate nanomaterials in food and agriculture, http://emergingtech.foe.org.au/wp-content/uploads/2014/05/FOE_nanotech_food_report_low_res1.pdf

³ *Ibid.*

⁴ Buzea *et al.* (2007) Nanomaterials and nanoparticles: Sources and toxicity, *Biointerphases*, 2(4):MR17 - MR172, available at: <http://arxiv.org/ftp/arxiv/papers/0801/0801.3280.pdf>; Elsaesser, A. & Howard, C.V. (2012) Toxicology of nanoparticles, *Advanced Drug Delivery Reviews* 64:129-137 C

⁵ Ludlow, K., Bowman, D. & Hodge, G. (2007) *A Review of Possible Impacts of Nanotechnology on Australia’s Regulatory Framework*, <http://www.industry.gov.au/industry/nanotechnology/NationalEnablingTechnologiesStrategy/Documents/MonashReport2007.pdf>

⁶ CSIRO (2010) *Fate of Manufactured Nanomaterials in the Australian Environment*, <http://www.environment.gov.au/system/files/pages/371475a0-2195-496d-91b2-0a33f9342a6d/files/manufactured-nanomaterials.pdf>

⁷ Friends of the Earth (2014) Nanomaterials and agriculture fact sheet, <http://emergingtech.foe.org.au/wp-content/uploads/2014/09/Nanomaterials-and-agriculture-Fact-Sheet-23sept14.pdf>

⁸ Friends of the Earth (2014) *Way too Little*

⁹ Advisory Committees on medicines and chemicals scheduling (ACMS and ACCS), <http://www.tga.gov.au/committee/advisory-committees-medicines-chemicals-scheduling-acms-accs#role>

¹⁰ Nanotechnology and Therapeutic Products, <http://www.tga.gov.au/industry/nanotechnology-qa.htm#.VCO-PRbz7sQ>

¹¹ Sunscreens: Information for consumers, <http://www.tga.gov.au/consumers/sunscreens-2012.htm#.VCiXVRbz7sQ>

¹² Australian Register of Therapeutic Goods, <http://www.tga.gov.au/industry/artg.htm#.VCiYtRbz7sQ>, searched 29 September 2014

¹³ Fletcher, N. & Bartholomaeus, A. (2011) Regulation of Nanotechnologies in Food in Australia and New Zealand, *International Food Risk Analysis Journal* 33, available at: <http://cdn.intechweb.org/pdfs/26273.pdf>

¹⁴ Answers to Questions on Notice, Health Portfolio, Questions SQ14-000075, http://www.aph.gov.au/-/media/Estimates/Live/clac_ctte/estimates/add_1314/Health/Answers/SQ14-000075.pdf, SQ14-000080, http://www.aph.gov.au/-/media/Estimates/Live/clac_ctte/estimates/add_1314/Health/Answers/SQ14-000080.pdf, 26/2/14.