



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



THE APVMA AND NANOTECHNOLOGY

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Nanotechnology refers to the design, characterisation and application of materials engineered at the molecular (nanometre) level. There are many naturally occurring instances where nanomaterials are formed, such as in milk (an emulsion) and in lightning strikes (particles). It is not the existence of nanomaterials that is new, but rather the ability to engineer these products at the nano-scale.

Currently, there is no agreed national or international definition of nanomaterials, but the general consensus in the scientific community is that a nanomaterial is anything that has been engineered to measure between 1 and 100nm in at least one dimension. A nanometre is a billionth of a metre, or roughly 1-100,000th the width of a human hair. Many nanotechnologies use nanoversions of common materials, and these nanomaterials have different properties to their larger counterparts. Manufacturers can take advantage of the materials' small size and/or novel properties for use in a variety of applications.

Whole of Government Considerations

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is aware of the potential application of nanotechnology to agricultural and veterinary (agvet) chemicals and chemical products. The APVMA is constantly developing its knowledge regarding nanotechnology, and currently participates on the Nanotechnology Inter-departmental Committee, the Nanotechnology Health Safety and Environment (HSE) Working Group and the Nanotechnology Communications and Public Awareness Network. The purpose of these groups is, among other things, to coordinate national regulatory systems and assess whether the current regulatory framework is appropriate for nanotechnology. The APVMA also contributes to international forums, such as the Organisation for Economic Cooperation and Development (OECD), where the regulation and assessment of nanomaterials and products containing them is being discussed.

APVMA Responses

APVMA assessment of agvet chemicals and chemical products currently registered in Australia has not identified any that contain engineered nanomaterials. To date the APVMA has not received any applications for registration of agvet chemicals or chemical products that contain engineered nanomaterials. The APVMA is continuing to monitor developments of nanotechnologies in relation to agvet chemicals and chemical products and is examining the need for any regulatory mechanisms that may need to be included in the *Agricultural and Veterinary Chemicals Code* (AgVet Code), which is a schedule to the *Agricultural and Veterinary Chemicals Code Act 1994*. At the same time, the APVMA is addressing any necessary changes to operational processes, such as modifying data requirements and the risk assessment framework for agvet products containing nanomaterials.

Potential Impacts

The Australian Government's recently released Monash Report - *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework* - confirmed that the existing APVMA legislation is robust and adequate for differentially regulating the composition of "new" (nanoform) and "existing" (conventional) agvet chemicals and chemical products. The Report however identified four potential gaps in relation to health, safety and environment considerations and these are currently being considered by the APVMA. The potential gaps identified by the report relate to whether:

1. Existing substances reformulated at the nanoscale would be considered as new substances;
2. The existing regulatory framework provides for exemptions to the licensing conditions including experimental use (R&D);
3. The existing regulatory framework assesses substances on the basis of both physico-chemical properties and the effect of product; and
4. The current risk assessment protocols based on conventional methods are suitable for nanomaterials.

APVMA Strategy

The APVMA has formulated a strategy for progressively assessing and addressing the potential gaps in the regulatory framework for agvet chemicals and chemical products in preparation for the regulation of chemicals and chemical products containing nanomaterials. This strategy includes:

- Reviewing the existing regulatory framework against the potential gaps identified in the report *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework*, for its suitability in regulating for nanomaterials in agvet chemicals and chemical products;
- Amending operational procedures to accommodate nanomaterials;
- Publishing a 'Call for Information – Nanomaterials in Agricultural or Veterinary Chemicals, or Agricultural or Veterinary Chemical Products' on the APVMA website and in the APVMA Gazette;
- Providing APVMA staff with appropriate training in the science of nanomaterials and in any changes to operational processes;
- Continuing to be involved in national and international forums on the regulation of nanomaterials; and
- Publishing information on nanotechnology and providing the community and industry with information on any change to the regulatory process.

The APVMA is committed to maintaining a robust regulatory framework that provides for the safe and responsible introduction of effective agricultural and veterinary chemicals and enables the progressive implementation of chemical products containing nanomaterials into Australia.