Australian Government
Australian Pesticides and
Veterinary Medicines Authority

29 June 2008

John Young
Principal Council Officer
Parliament House
Macquarie Street
NSW 2000 Australia

Dear John

APVMA RESPONSE TO QUESTIONS ON NOTICE: NANOTECHNOLOGY INQUIRY IN NSW

1. **In relation to the existing regulatory framework, there were some assessment protocols and regulatory triggers that are to be reviewed to deal with nanosized products. Provide the Committee with more specific detail on the triggers and that whole area so that we can be sure we are across the regulatory side and where you consider there to be potential problems?**

(a) Triggers on the Basis of Name – 'New' or 'Existing' Substances or Products?

The existing APVMA legislation has provisions for assessing the compositional form of both substances (active constituents) and agvet chemical products. This means that the conventional form and the nanoform of a substance or an agvet chemical product may be assessed as distinct chemical entities or chemical products. In situations where it is deemed to be necessary, different risk assessment protocols may then be applied to the conventional form and the nanoform. An example might be the reformulation of an agvet chemical product whereby a conventional form is replaced with a nanoform of the chemical in order to achieve an improved efficacy profile.

Therefore, provisions in the existing legislation are robust and adequate for differentially regulating the composition of "new" (nanoform) and "existing" (conventional) agvet substances and products.

(b) Triggers on the Basis of Weight or Volume

This triggers are considered in the responses for 1(d) and 1(e).

(c) Triggers Requiring Knowledge of Presence or Implications of Presence of NMs

An application must be made to the APVMA to register a new substance or agvet chemical product, or to vary the registration of a substance or existing product. The data required to register a new product with a new active constituent must address: Chemistry and manufacture; Toxicology; Metabolism and Toxicokinetics; Residues; Overseas Trade Aspects of Residues in Food; Occupational Health and Safety; Environmental studies; Efficacy and target safety; Other trade aspects; and Special data requirements (eg. data required for assessment by OGTR, AQIS or NP&WS).

These data requirements apply to both conventional and nanoforms of substances and agvet chemical products.

18 Wormald Street, Symonston ACT 2609
PO Box 6182, Kingston ACT 2604 Australia
Tel: +61 2 6210 4700 Fax: +61 2 6210 4874
www.apvma.gov.au ABN 19 495 043 447

From a workflow perspective, the conduct of differential risk assessments depends on ‘nano’ applications being identified early and in this respect, APVMA is revising its application requirements in order to identify ‘nano’ applications at the time an application is lodged. Once identified, the substance or agvet chemical product is assessed under the appropriate risk assessment regime.

(d) Triggers Reliant on Risk Assessment Protocols or Conventional Techniques

Legislative bodies like APVMA regulate substances and agvet chemical products utilising known processes. In the case of nanotechnology, it is novel for the science underpinning it, and for a framework to regulate it, to be developed at the same time. This represents unique challenges to regulatory agencies.

The novel toxic properties attributable to materials engineered at the nanoscale are constantly being reviewed both nationally and internationally, including by the OECD. APVMA outsource its public health and OHS assessments to the Office of Chemical Safety (DoHA) and its environmental assessments to DEWHA; both of these agencies are across the regulatory developments relating to nanomaterials, including characterisation of the toxic properties of nanomaterials. Risk assessments of nanomaterials have already shown that minor changes to surface characteristics may potentially alter the hazard.

Importantly, risk assessments of nanoform materials have already identified a need for new data requirements to enable the agencies to conduct appropriate risk assessments. This will ensure that substances and agvet chemical products are both safe (people, animals and the environment) and effective.

(e) Research and Development Exemptions

The quantities of agvet chemical product for conventional material referred to in the Agvet Code Regulations (1995): Part 4 (Control of chemical products), Division 1 (General), Regulation 40 (Supply of substances for research etc for chemical products), Sub-regulation 5, may not be appropriate for nanomaterials. This may require that the Regulations are amended.

(f) Triggers Reliant on International Documents

Reports such as the Joint FAO/WHO Meeting on Pesticide Specifications (JMPS) include standards of composition, which are used in toxicity and residue assessments,. In the past, these reports have not dealt with the characterisation of pesticides containing nanomaterials. As these reports are prepared for international use, they will need to accommodate conventional and nanoform substances and agvet chemical products.

2. **How you define nanomaterials on your registration form. Could you provide us with a copy of that and, specifically, do you provide any guidance in that form as to what constitutes a nanomaterial in your definition? You mentioned the OECD definition but is size enough in relation to that form? Is that sufficient to warrant that form to note it is nanomaterial or do you actually say to them, "The OECD definition of a materially is …….. If you are in that area, then fill in this part of the form." I want to understand that process in more detail.**

There are 25 categories of applications for agvet chemical products and only categories 1 and 2 are discussed here,

- Two pages of a proposed application form, is attached in a separate file.
- The nanomaterial question that APVMA has proposed to include on their agvet product application form is highlighted and reads:

  Does the product contain material engineered to be <100nm in one or more directions. Yes ☐ No ☐
- Not all nanomaterials will require a differential assessment. As the Regulator of substances and agvet chemical products, it is the risk assessment provided by the agencies that determines whether the nanomaterial has toxic properties. For this reason, the nanomaterial definition needs to be as broad as possible, so that the risk assessment process determines the toxicity of the nanomaterial.
- Being an engineered substance, it is possible to manufacture materials to be just outside the size range captured by the nanomaterial definition. To offset this, it is likely that the defined size range of nanomaterials will be considered as a guide, with the focus being on engineered materials and the risk assessment.

3. **You mentioned about the Administrative Appeals Tribunal, the stay of proceedings and some frustration in that regard. Can you elucidate that a little bit more? Are there valid grounds here or is it just because your legislation is drafted too widely? What is the nature of your concerns?**

The response for this question was provided by Mr Suter during the Inquiry and is recorded on pages 32 (beginning 12 lines up from the bottom of the page) and 33 (first three lines at the top of the page) of the transcript. APVMA is willing to provide additional material if the NSW Standing Committee on State Development deems it necessary.

Thank you for this opportunity to provide a response to the Inquiry.

Yours sincerely,

Dr Jamie Nicholls
Regulatory Strategy Project Officer
Tel: (02) 6210 4761
Fax: (02) 6210 4840
Email jamie.nicholls@apvma.gov.au