Response to nano silver media enquiry

Chris Lemke → Kay McNiece via email

2/8/07

4.39pm.

Question: How is nano silver regulated in Australia?

- How nano silver is regulated in Australia depends on what product it is used in.
- For example, if nano silver was used in food packaging material it would be regulated by Food Standards Australia New Zealand.
- In relation to medical devices, the Therapeutic Goods Administration (TGA) has assessed wound dressings containing silver. In ensuring that medical devices met acceptable risk benefit profile compatible with patient protection, the TGA paid particular attention to the chemical and physical properties of the materials used in the device, the compatibility between the materials used and biological tissues, cells and body fluids, having regard to the intended purpose of the device.
- The Australian Government already has in place robust regulatory arrangements to ensure the safety of food, chemicals and medicines.
- Regulation of nanotechnology products is currently included in extensive Commonwealth legislation, including the:
  - *Food Standards Australia New Zealand Act 1991;*
  - *Gene Technology Act 2000;*
  - *Industrial Chemicals (Notification and Assessment)Act 1989; and*
  - *Therapeutic Goods Act 1989.*
- Regulatory agencies have been aware of nanotechnology in food, chemicals and medicines for some time and are continually considering the risks of products that fall under their legislation.
- All the regulatory agencies are well connected internationally and are aware of international decisions being made about nano-products. For example, the National Industrial Chemicals Notification and Assessment Scheme is actively engaged in the OECD Working Party on Manufactured Nanomaterials.
- In addition, the Department of Health and Ageing, through its portfolio agencies with responsibility for health, safety and environment issues, is working with the Department of Industry, Tourism and Resources on applicability of existing health and safety regulatory frameworks to nanotechnology.
- The Australian Government has contributed $4.6 million over four years to strengthen the health portfolio's regulatory frameworks relevant to nanotechnology.
- If, in the future, any gaps in regulatory arrangements are identified, the Department of Health and Ageing and its portfolio agencies will act swiftly to redress these issues.

If asked about the National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

Nanomaterials, as industrial chemicals, fall within the remit of NICNAS, and have been traditionally used as catalysts, pigments etc by the chemicals industry. NICNAS is engaging with the National Nanotechnology Strategy via a cross-portfolio working group on health, safety and environment (HSE) issues, and is also examining nanotechnology as an emerging issue in its own right to determine if and how it needs to adapt its processes to ensure the safe and sustainable use of nanomaterials when used as industrial chemicals.

To this end, NICNAS is engaged in such activities as:

- keeping abreast of, and influencing, international developments in nanomaterials by active participation in the OECD Working Party on Manufactured Nanomaterials. Specifically, NICNAS is assisting with the development of a database on HSE research and the selection of representative classes of nanomaterials around which testing protocols can be developed;

- assessing the volumes and types of nanomaterials that are being used within Australia as industrial chemicals via a voluntary call for information directed to industry. The 2006 call provided a useful baseline against which any future calls can be compared, and can be found at http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Call_for_info_Nanomaterials.pdf. Companies reported introducing approximately 21 types of organic (eg. polymers) and inorganic (eg. metal oxides) nanomaterials, involving mainly surface coatings, printing, water treatment, catalysts, domestic products and cosmetics;

- creating a NICNAS Nanotechnology Advisory Group, to advise on strategic directions NICNAS might take in addressing the potential impacts of nanomaterials as industrial chemicals. The Group, which is currently being formed, will include representatives from the community and industry, and will also draw on expertise in nanoscience and toxicology; and

- undertaking on-going reform of its chemicals programs to ensure they remain at the forefront of international best practice and are readily adaptable to emerging challenges in industrial chemicals regulation.

If asked about Food Standards Australia New Zealand (FSANZ)

- Food Standards Australia New Zealand (FSANZ) has established a taskforce to keep up to date with international and national developments relating to the use of nanotechnology in the food and food packaging industries.

- FSANZ is aware of the development internationally of food packaging systems which consists of a multilayer plastic film which contains within these layers

nanoparticles of silver (or other microbial inhibitors) whose purpose is to inhibit the formation of microbial spoilage organisms on the contained food.
    - The silver particles are separated from the food by plastic layer of film, though it is not clear if the silver would transfer through the plastic to directly contact the food.
    - FSANZ is not aware of the use of this technology currently in the Australian market.

- The *Australia New Zealand Food Standards Code* requires that articles and materials in contact with food do not cause bodily harm, distress or discomfort. They also need to comply with all relevant legislation.

- For more information about FSANZ please contact Lydia.Buchtmann@foodstandards.gov.au.