Nanotechnology

Department of Trade and Industry. October 2006. URN 06/1992
'Nanoscience and Nanotechnologies: Opportunities and Uncertainties'. Two-Year Review of Progress on Government Actions

The government initiatives on nanotechnology have identified several difficulties with risk assessment and regulation of risk. Work is progressing towards developing a language and methodology for risk assessment, focussing mainly on potential human health effects. In our view, current regulations are not well adapted to the proactive risk assessment of these engineered nanoparticles and the prediction of liability risk exposure remains highly uncertain. Most of the relevant regulations have the capacity to support retrospective interventions e.g. restrictions on supply after a harmful event has occurred.

The Government is promoting the development and exploitation of nanotechnologies, balanced by work to identify, evaluate and control risks. This paper reports on the mechanisms in place.

The Nanotechnology Research Coordination Group (NRCG) oversees policy setting research into human and environmental health issues and the management of risk [by which they mean prevention and, possibly, clean-up]. Meetings are attended by representatives from across Government Departments, Regulatory Agencies and the Research Councils:

- Biotechnology and Biological Sciences Research Council
- Department for Environment, Food and Rural Affairs (Chair)
- Department of Health
- Department of Trade and Industry
- Economic and Social Research Council
- Engineering and Physical Sciences Research Council
- Environment Agency
- Food Standards Agency
- Health and Safety Executive
- Health Protection Agency
- Medical Research Council
- Medicines and Healthcare Products Regulatory Agency
- National Physical Laboratory
- Natural Environment Research Council
- Office of Science and Technology

The group identified five work areas of note for the purposes of regulation:

- metrology, characterisation and standardisation; what to measure, how and what to compare it with? Of note is that current techniques have difficulty differentiating between engineered and adventitious nanoparticles of the same chemical composition.
- exposure, sources, pathways and technologies; what is good practice with respect to exposure control? Do nanoparticles present an explosion risk?
- human health hazard and risk assessment; is there enough information for the establishment of a toxicology assessment service?
- environmental hazard and risk assessment; co-toxicity, bioaccumulation, persistence, toxicity specific to size etc.
  and,
- social and ethical dimensions of nanotechnologies. Probably not specific to nanotechnology; issues such as public confidence, research priorities (e.g. health vs. wealth), upstream engagement, ethics, potential changes in work and leisure,

In their view, the principal exposures to engineered nanoparticles are currently in research laboratories. It is the responsibility of commercial companies to fund the research necessary to identify potential hazards of specific products that they intend to market. The report does not emphasise development of data or methods for the financial risk management of nanoengineered products or the companies that produce them, and their insurers.

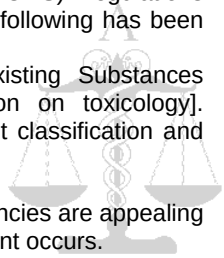
Funding for research and development will be available from the EU Framework Programme 7 (FP7) part 4: *Nanosciences, nanotechnologies, materials and new production.* This has a budget of ~€1,200 million starting in 2007. Some of this will be for toxicology research but most will be concerned with obtaining economic advantage.

Regulations
Existing regulations provide opportunity for risk control:

Novel foods and novel food ingredients should first be approved. Regulation No 258/97. However, the definition of 'novel' may not automatically identify particle size as a regulatory issue; this is being addressed as part of a review of the Regulation. The Food Safety Act makes it an offence to sell food which is injurious to health and thereby provides an incentive for self regulation through risk assessment and testing. The authorities would not know in advance whether a regulation had been breached. They do have emergency powers if an incident occurs.

New substances should be notified under the Notification of New Substances (NONS) Regulations (which implement Directive 67/754/EEC). This will be superseded by REACH. The following has been agreed:

> When a nanomaterial is derived from an existing substance, the Existing Substances Regulation (EC) No 793/93 applies [usually requiring less information on toxicology]. Otherwise, if the properties are very different, they may require a different classification and labelling compared to the bulk material.



So far it is very unclear whether current regulations are adequate or inadequate. Agencies are appealing to industry to volunteer any information. They do have emergency powers if an incident occurs.

Health and Safety risks should be controlled in the light of suitable and sufficient risk assessments [Health and Safety at Work etc Act 1974]. This 'failsafe' wording should be sufficient to ensure the HSE can act in all circumstances where harm has been done. Prediction of harm, however, remains elusive. Failure to undertake a risk assessment can be an offence and can be used as evidence in support of a civil claim.

All cosmetic products sold in the UK must comply with the Cosmetic Products (Safety) Regulations 2004 and must be safe under normal or reasonably foreseeable conditions of use. Similarly, the General Product Safety Regulations 2005 place an obligation on suppliers of other consumer products to supply only products that are safe for normal or reasonably foreseeable use. Strict liability applies; the development risk defence is still available [and likely to remain so].

Comment
The focus of current activity with respect to risks from nanotechnology is on input activities e.g. product development [how to make money of the new technology] and data gathering on the likely exposures and any toxicologically relevant information. End of product life/disposal issues are mentioned but are clearly not a priority. Systematic assessment of toxicology has barely begun.

Financial quantification of risk, the cost of control or mitigation, compensation and manifestation timescales are not being tackled in a systematic way. Interest in economic and social consequences is limited to issues concerned with democracy and funding priorities, and with economic growth and lifestyle issues. There are no compensators on the NRCG. It is probably considered too early to be concerned with such matters until the products etc. have proved themselves to be competitive. Sustainability will only be fully assessed if problems, and their costs, begin to emerge.

In our view, the current regulation of harmful exposures is not well adapted to the unpredictable toxicological properties of engineered or adventitious nanoparticles. There are no definitions which would enable the generator of the particles, or the regulator, to predict which regulation would apply, if any. Regulators can only urge that developers adopt a precautionary approach. Breach of duty and probable causation would be identified retrospectively.

Industry is invited to join a voluntary reporting scheme to allow central accumulation of extant hazard, control, manufacturing and exposure parameters for free engineered nano particles (DEFRA 29th Sept 2006).

A report on the UK government action to characterise the human health and environmental health risks posed by engineered nanoparticles is available: *Characterising the potential risks posed by engineered nanoparticles*. DEFRA October 2006. It describes efforts to develop measurement techniques, standard reference materials, toxicological parameters e.g. solubility, likely exposure routes etc.

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