

## February 2007

# Presentation by Brian Fullam, HSE Bootle

## Nanotechnology – the Regulatory challenge!

Brian leads a team of 14 Chemical Engineers, Chemists and Mechanical engineers, working mainly with the Chemical Industry and he has worked in the HSE for over 30 years!

He explained that nanostructures were only nanometre thick (or thin!) and, to put some sort of comprehensible scale to that, he went on to say that in contrast the average human hair was 10,000 times as thick! They are produced by the manipulation of Atoms to give materials different properties from their conventional characteristics. As an example, Brian cited Gold as an inert substance in its normal form and mass, but Toxic in its Nano-particle form.

He added that it was important to achieve an understanding of nano-particles in order to establish a regime of sensible risk management of these new materials! Otherwise, risk aversion might occur as had happened with Genetically Manipulated Organisms. The important principles are: -

- To protect people's health and safety and the environment by ensuring risks from the new technologies are properly controlled
- To do this by dialogue, regulation and enforcement, where necessary
- It requires the understanding and consent of the public

Brian went on to say that there were new hazards from existing materials, with new properties, new processes and machinery, which posed different risk-control measures that were unproven! He commented that nano-particles are like "Carbon-black", whereas "Nano-tubes" are fibrous, rather like Asbestos and stronger than steel. This means that there is uncertainty about these risks and the priorities for action, therefore, are: -

- Reduce uncertainty
- Fill the knowledge gaps
- Engage openly with researchers and workers in the field
  - Be clear about what is known and what is just opinion
  - Share information with the public and each other
  - Engage with the public – a true dialogue is needed
- Promote a sensible, proportionate and precautionary risk management so that:
  - We err on the side of safety
  - The degree of caution is proportionate to the degree of uncertainty
  - Best health and safety practice is followed
- Research to reduce uncertainty
- Review the Regulatory framework and amend, if necessary, ie –
  - **Legislation** (Regulations, ACOPs)

- **Guidance and Standards to establish good practice** (Developed by stakeholders in (Industry/Academia/Professional institutions) with regulatory input
- **Voluntary Action by Industry** (Often undertaken in the early stages of technology development BUT rarely acceptable to public in the longer term
- **Robust enforcement**

When looking at the task addressing Workplace and environmental risk control, Brian said that the main issues were as follows: -

- Legislation is risk-based and can, in principle, be applied to the hazards from nanomaterials
- Lack of understanding of the hazards hampers proportionate regulation
- There is a lack of common nomenclature
- There is no agreed test regime to determine risks
- Many existing measures to control exposure are thought to be adequate for nanomaterials

In a similar manner to COSHH and CHIP, where it is also important to manage the supply of chemicals to the marketplace, in this case the following are relevant: -

- Regulation is based on EU Directives
- There are some potential weaknesses in *existing* regimes for controlling existing and new substances
- The proposed Registration Evaluation, Authorisation and Restriction of Chemicals (REACH) may not fully address the matter.
- control of nanomaterials will only be important if they prove to be more hazardous, or have markedly different hazards, than micron-sized materials

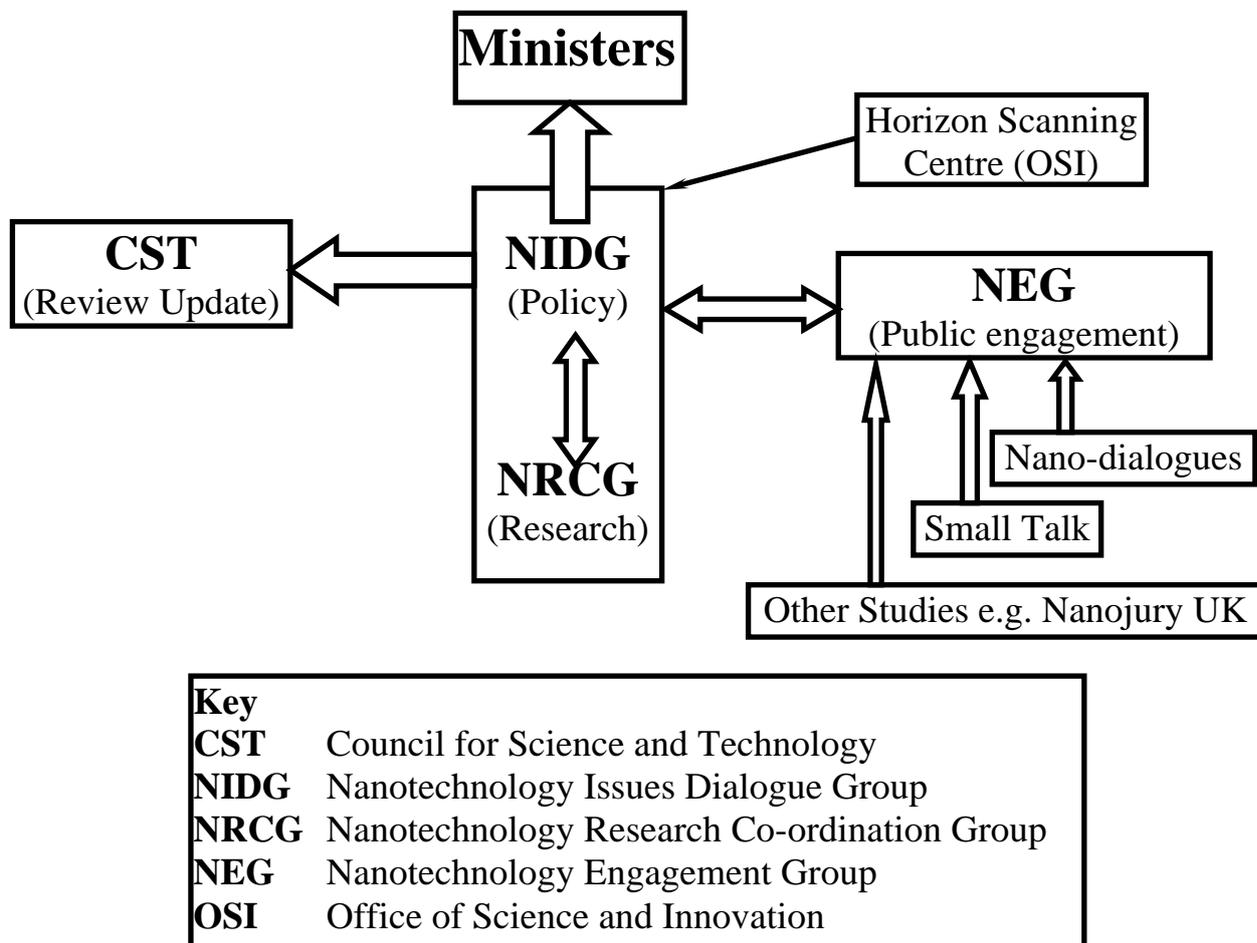
So what are the new ‘Nano’ workplace health risks? Brian suggested this selection: -

- Enhanced toxicity because of their increased surface area
- A raised potential to cross the blood/brain barrier, if inhaled.
- Potential for migration throughout the body
- Persistence in the workplace and the environment
- Existing control measures are unproven on these new risks

This gave the HSE an interesting set of research priorities: -

- Measurement of particle properties and their presence in the environment
- Exposure control
- Relating the fundamental properties of materials to hazard (**NOT** the toxicology of individual substances)

All of these developments come under a collection of interlinked regulatory bodies, as shown in this block diagram of the “Joined-up-Government Approach”: -



Brian explained that the NIDG co-ordinated Government Activities, including the work of the NRCG, and provided a forum for discussion as well as a mechanism for referring unresolved issues to ministers. It also monitors progress and delivery of Government Commitments. Brian said that his work was within the NRCG, where he chaired Task Force Number 2, of a total of five such task forces: -

- First Metrology, Characterisation and Standardisation, Reference Materials
- Second Research Areas
  - a. Sources of Nanoparticles
  - b. Technologies for measurement of particles in air
  - c. Fate and behaviour of particles in air
  - d. Exposure control devices
  - e. Environmental fate and behaviour of nanoparticles in soil and water
- Third Human Health Hazard and Risk Assessment
- Fourth Environmental Hazard and Risk Assessment
- Fifth Social Dimensions of Nanotechnologies

Brian concluded by illustrating the breadth of his Task Force interests in the list of its membership, which comprised HSE (2), Health and Safety Laboratory, Environment Agency, Food standards Agency, Institute of Occupational Medicine, York University, Natural Environmental Research Council, British Occupational Health Society, Department of Trade and Industry and Department of Environment, Food and Rural Affairs

## *Members' Questions*

**Ed Friend** asked about the amount of exposures to Nanoparticles and Brian answered that it was about 3 – 5,000, not nearly as much as Asbestos, for example.

**Michelle** of Wolverhampton University enquired about enclosure of operations involving nanoparticles. Brian indicated that suitable control measures should include enclosures and Local Exhaust Ventilation.

**Dennis Walley** of Homeserve plc said that, in his experience, HEPA filters gave a 90 – 97% efficiency with Carbon Black and asked if they were acceptable for Nanoparticles. Brian commented that there was no data available yet but they should be suitable as they were designed for micro-organisms.