

**Meeting date:** 13&14 January 2005**Open Govt. Status:** Fully Open**Type of paper:** For debate and development of a position**Paper File Ref:****Exemptions:**

## WATCH COMMITTEE

### Occupational health aspects of nanotechnologies

#### Issue

1. Nanotechnologies and nanoparticles: positions on hazard, exposure and risk assessment and appropriate risk management approaches.

#### Timing Considerations

2. Routine.

#### Recommendation

3. WATCH is invited to consider the issues noted in this cover paper and to respond to the actions in paragraph 22.

#### Background

4. Nanotechnologies are concerned with the design, characterisation, production and application of structures, devices and systems by controlling shape and size at the nanometre scale. They involve the production and use of materials that have one, two or three dimensions in the nanometre range (defined here as <100 nm). For example, nanoscale surface coatings have a single dimension in the nanoscale, nanotubes have two dimensions at this scale whilst nanoparticles have all three dimensions in the nanometre range.

5. The emergence of nanotechnologies has come about because of advances in our capability to develop and manipulate material at the nanometre scale. This includes the development of novel nanomaterials (e.g. carbon nanotubes), as well as novel applications of existing material in the nanometre range (e.g. use of nanoparticulate titanium dioxide in sunscreens).

6. An integral aspect of the development of nanotechnologies is the occupational health and safety implications of exposure to nanomaterials. HSE focused attention on this aspect in 2003, as part of our horizon-scanning activities. The aim was to assess the current state of knowledge in relation to the human health hazards of nanomaterials, the UK situation in terms of use and application of nanotechnologies, and the likely future impact of these nanotechnologies in the occupational context in the UK. The reviews of the human health hazards and the occupational hygiene aspects are attached at Annexes 1 and 2 respectively. HSE has also published an information note on the health and safety issues surrounding nanotechnologies, aimed at researchers and developers handling nanomaterials. This is attached at Annex 3.

7. An important element of our horizon-scanning work was to organize and host, jointly with NIOSH, the First International Symposium on Occupational Health Implications of Nanomaterials, which was held in Buxton in October 2004. This Symposium was an important first step in developing a dialogue between HSE (and other regulatory authorities) and stakeholders, including scientific researchers and industry, to identify common issues and research/knowledge gaps. The Symposium report is attached at Annex 4.

8. Shortly after beginning our activities, the Government commissioned the Royal Society (RS) and the Royal Academy of Engineering (RAEng) to undertake a wide-ranging review of nanotechnologies, covering their health, safety and ethical implications. HSE took the opportunity to feed into this review, which reported in Summer 2004 (full report available at [www.royalsoc.ac.uk](http://www.royalsoc.ac.uk) and [www.raeng.org.uk](http://www.raeng.org.uk); the report summary and recommendations is attached at Annex 5).

## **Argument**

### Toxicological hazard

9. The potential for toxicity in the occupational setting is relevant for two- and three-dimensional nanomaterials, as these have the potential to become airborne. The toxicological hazard assessment of nanomaterials conducted for our horizon scanning activity therefore focused on these materials, referred to hereafter as nanoparticles.

10. There is extremely limited information on the toxicological hazards associated with novel nanoparticles, although what little information there is suggests that they might possess significant toxicity potential, at least to the lung. There is a considerably larger toxicological database, albeit limited in range, for existing materials (e.g. TiO<sub>2</sub>) produced at the nanometre scale. The available information for such materials consistently shows that for the same material on a mass dose basis, toxicity (measured in terms of indicators of lung damage) is greater when the material is in the nanometre size range compared with the micrometre size range.

11. An important feature of nanoparticles that raises additional toxicological considerations over and above those associated with larger particles, is their potential to cross epithelial barriers (e.g. the lung) and to escape normal biological clearance mechanisms. This raises the possibility that nanoparticles could reach organs and tissues that would not otherwise encounter particulate material, with potential consequences for systemic effects.

12. The properties that determine the toxicity of nanoparticles (certainly when compared with their micrometre counterparts) currently are not fully understood, although they seem to involve particle surface effects, related to surface area and surface activity. However, it is also apparent that different nanomaterials exhibit different degrees of toxicity, at least towards the respiratory tract. Consequently, it is not possible to reach generic conclusions about toxicity based on consideration of nanometre size alone; the potential toxicity of each individual nanomaterial needs to be considered on a case-by-case basis.

### Occupational exposure

13. In the UK there are about 2000 people employed in sectors/companies associated with nanotechnologies. Considerably more are employed in industry sectors where exposure to nanomaterials may occur, but which are not nanotechnologies (e.g. exposure to nanoparticles via incidental production in processes such as welding). It is anticipated that these numbers will increase, with perhaps a doubling of the numbers employed in nanotechnologies over the next five years.

14. There has been no adequate assessment of worker exposure to nanoparticles in the nanotechnologies sector. This, in combination with the lack of understanding of the health hazards of nanoparticles, means that risk assessment is extremely uncertain.

15. One factor influencing the acquisition of exposure information is the metric for assessment of exposure to nanoparticles. Current thinking points towards surface area as the most appropriate exposure metric. However, there are no effective methods currently available by which particle surface area can be assessed for air samples taken in the workplace. HSE is funding a research project which aims to determine the inter-relationships between particle mass, number and surface area. It is anticipated that the research findings could underpin the development of a suitable measurement technique.

16. In terms of control, although current approaches and methods may be suitable for nanoparticles, the effectiveness of these existing control approaches has not been evaluated. For example, for dermal exposure, control methods based on personal protective equipment may not be as effective for nanoparticles as they are for larger particles.

### The RS/RAEng report

17. The RS/RAEng published its report 'Nanoscience and nanotechnologies: opportunities and uncertainties' in July 2004. The report contained a number of recommendations, some of which relate directly to the regulatory framework for occupational health, and therefore fall directly within HSC/HSE's area of responsibility (see Annex 5). HSE has been working together with other Government Departments and regulatory agencies to prepare the Government's response to the report and its recommendations. The Government's response will be published in December by Lord Sainsbury, Minister for Science and Innovation. Discussion of the recommendations that relate to occupational health formed the basis for workshop sessions at the Buxton Symposium.

### Regulatory issues

18. HSE's horizon-scanning work and the RS/RAEng review have identified the emergence of nanotechnologies as a significant new scientific development. However, they have also highlighted the gaps in our understanding of occupational health issues related to exposures arising from nanotechnologies. Consequently, there is a need to consider the robustness and adequacy of the existing regulatory position for the assessment and

management of any risks arising from workplace exposures to nanoparticles. In this context, issues relating to the appropriate measurement and control of exposure to nanoparticles are a primary consideration.

### **Link to HSC Strategy**

19. This area of work is a reflection of the 'horizon-scanning' element of HSE's Chemicals Strategy.

### **Consultation**

20. No wider consultation on the content of this cover paper beyond HSE has been undertaken at this stage. The issues involved have been discussed with interested stakeholders at the First International Symposium on Occupational Health Implications of Nanomaterials.

### **European Context**

21. There are no direct links to any EU procedures or activities. This area is one of international significance, and any progress towards common aims has to be made in that context. HSE will therefore be working with other regulatory authorities and stakeholders at an EU and wider international level to secure a common approach to developing a clearer scientific basis for the appropriate regulation of nanotechnologies.

### **Action**

22. WATCH is asked to consider the issues described in this paper and the attached annexes and to:

- a) endorse or suggest any necessary modifications to HSE's assessment of the current state of knowledge about the human health hazards of nanoparticles (Annex 1);
- b) take a position on what exposure metric(s) should be pursued in relation to assessing workplace exposure to, and control of nanoparticles (e.g. mass, surface area, particle number);
- c) express its opinion on the adequacy of the existing regulatory framework to accommodate the scientific and technological features of nanoparticles, and the appropriate deployment of conventional approaches, including the possible role of WELs;
- d) recommend whether or not new risk management approaches need to be developed and implemented (for example, approaches that can take account of the paucity of hazard and exposure data).

**Contact:**  
Nicola Gregg  
WATCH Secretariat

## **References / Attachments**

Annex 1 - Human health effects of particles intentionally produced for use in nanotechnology applications

Annex 2 - Nanoparticles: an occupational hygiene review

Annex 3 - Horizon scanning information note (HSIN1)

Annex 4 - Report of the First International Symposium on the Occupational Health Implications of Nanomaterials

Annex 5 - Nanoscience and nanotechnologies: opportunities and uncertainties. Report Conclusions and Recommendations.