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VERSION 9

HEALTH AND SAFETY COMMISSION

Managing the Risks from Nanotechnology

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Cleared by Paul Davies on 22 March 2004

Issue

1) A new technology 'nanotechnology' may result in new hazards and risks in the work environment. In the absence of complete and robust evidence of the risks HSC/E must decide how to work with the relevant stakeholders to promote and assure risk management of this technology without unnecessarily stifling innovation and wealth creation.

Timing

2) In response to public concern the UK Government commissioned the Royal Society and the Royal Academy of Engineering (RS/RAE) to carry out an independent study of likely developments in nanotechnology and whether it raises or is likely to raise new ethical, health and safety, environment or social issues which are not covered by current regulation.

3) HSE has worked closely with the study group who propose to publish their report in June 2004. Endorsement in the report of HSC/E's approach to regulating the health and safety risks of nanotechnology would be practicably valuable and would enhance HSC/E's reputation.

Recommendation

4) The commission comment on the suggested approach set out in paragraph 16 in light of the risks summarised in paragraph 17.

Consultation

5) This paper been circulated for comment to ACTS, ACDS and ACDP, the relevant Corporate Science Topic Groups, FOD Safety Unit and the heads of the operational directorates. There will also be further attempts at consultation with worker representatives prior to the Commission meeting on the 6th April 2004, the results of which will be reported at the meeting.

What nanotechnology is

6) Annex 3 explains what nanotechnology is. **It is not essential for commissioners to read this annex** – the chief scientist will cover this at the meeting. But essentially, nanotechnology is the production and use of materials/devices of the order of millionths of a millimetre in size.

7) The possible uses of nanotechnology are extremely wide and it is likely that ultimately every industry sector will exploit its potential. A possible timeline of the wide scale use of nanotechnology is contained in the table in Annex 2.

8) Annexes 4 & 5 – **again for reference and not essential reading** – amplify the table in Annex 2. They summarise the history of the development of nanotechnology and outline future investment and development plans. The overall picture is one of potentially massive growth. But currently much nanotechnology is at the early development, pilot or niche market stage. It is composed of advances in material design, sensor development, microelectronics and high performance coatings. Much of this work is currently being done in universities and industrial research and development laboratories rather than in manufacturing plants.

What the risks are

9) The routes to harm posed by nanotechnology closest to commercial production are those commonly seen in all work involving fine particulates: human exposure, either by inhalation, ingestion or dermal exposure and the risk of unexpected chemical reactions, fire and explosion.

10) However, the defining characteristic of nano-scale materials is that they can have very different physical, chemical or biochemical properties from those same materials at the macro scale. Or they maybe entirely new materials (e.g. carbon nanotubes) whose physical, chemical or biochemical characteristics are, as yet, unknown.

11) With nanomaterials, therefore, there can be considerable **uncertainty** in any assessment of the health and safety risks because of lack of knowledge about the hazards. Similarly there may also be a lack of knowledge about the effectiveness of risk control measures.

The Implications of Uncertainty

12) Broadly all modern health and safety legislation is based upon the principle of suitable and sufficient assessment of the risks leading to the implementation of proportionate preventative and protective control measures. Proportionate in this context means erring on the side of safety (i.e. the gross disproportion element in the ALARP/SFAIRP

tests). Partly this is for moral or ethical reasons. But it also allows for uncertainty both in the risk assessment and in the effectiveness of the control measures – **the greater the uncertainty the more precautionary the duty holder needs to be**.

Implications for HSC/E

13) HSE has presented arguments to the RS/RAE review that existing risk-based health and safety legislation is suitable for regulating the risks from nanotechnology as currently understood[1]. The RS/RAE report is likely to endorse this view. However faced with the uncertainties described above HSC/E has to decide **how precautionary** duty holders need to be to comply with the HSWA and the relevant statutory provisions, principally COSHH, DSEAR & GMO(CO).

14) If we take an over precautionary approach (e.g. prohibiting activities until such time that safety can be assured) we run the risk of stifling the development of new wealth/job creating technology which may itself lead to long term improvements in health & safety (e.g. self cleaning window glass, reducing the need for working at height). We would also earn the opprobrium of the government, which is strongly committed to the development of nanotechnology.

15) At the other extreme if we were to take the view that we should only act once there was evidence of harm, then we would be failing in our statutory duty and subject to intense, high profile criticism from stakeholders.

Proposed Way Forward

16) Taking account of all of the above the following action is proposed:

i. HSC/E should publish an interim information note on Nanotechnology which sets out the legal position and gives advice on how to comply, including how to deal with uncertainty (draft at annex 1)

ii. A communication plan is implemented to capitalise on the publication of the RS/RAE report and with the aim of:

- raising awareness of the Information Note.
- Dealing proactively with the issue of uncertainty in risk-based regulation
- Enhancing our reputation as a sensible, proportionate risk regulator.

iii. HSE completes and publishes the results of 3 ongoing reviews on nanotechnology:

- Fire and explosion risks
- Toxicological hazards
- Occupational exposure

iv. Using the results of the above reviews HSE works with OGD, the Research Councils and Industry to prepare a research strategy to reduce uncertainties

[1] There are issues relating to the adaquancy of regulations on the supply of dangerous substances that need to be addressed at the European level – Annex 6 gives details.

in nanotechnology health and safety risk management. The most immediate targets being the measurement of the airborne concentration of nanoparticles along with other aspects of metrology and toxicology. This research strategy should take account of and link with both European and International (currently mainly USA) research strategies to avoid duplication and unnecessary expenditure of resources.

We have shared with the RS/RAE the reasons for and purpose of the Interim Information Note and the work in (iii) above with the aim of them citing them in their report as a good example of sensible and pragmatic regulation. Early indications are that our proposed approach is in line with the emerging recommendations of the study.

Policy Risk Assessment

17) The main risks of this approach are summarised below:

Table 1: Policy risk analysis

Risk	Controls	Residual Risk
Criticism that we are being insufficiently precautionary	▪ Communications plan ▪ Approach accords with Precautionary Principle; best practice in health & safety risk management is being required; position continually monitored; research will be done to reduce uncertainty	Medium
A nano-material becomes widely used which has serious health effects but a very long latency period (e.g. like asbestos and mesothelioma)	- ditto -	Low
We are overwhelmed with inquiries and requests for advice	▪ Information note on web ▪ Infoline briefed ▪ Field staff briefed and supported by specialist inspectors	Low
Expectation that HSC/E will fund major programmes of research	Research strategy	Medium to Low