Annex 1

Nanotechnology - Provisional Information Note vers2.0

This note gives information on the health and safety issues surrounding some aspects of nanotechnology. The Royal Society and the Royal Academy of Engineering are undertaking a review of the benefits and possible problems associated with nanotechnology. The review is considering the implications for health, safety and environmental regulation and is expected to report in June 2004. This information note will be reviewed in the light of the recommendations in the report.

Introduction

1. Nanotechnology and Nanoscience involve the creation and manipulation of materials at the submicron level to create products that exploit novel properties. There has been a rapid development in this area of science with an increasing number of organisations developing a range of new materials and products.
2. When such new particles, materials and devices are first developed there is limited robust scientific evidence about potential hazards that may exist or the risks to an individual or group of individuals being exposed to them. This information note is intended to raise awareness of the potential hazards of these materials and to help people using such materials to sensibly manage the attendant risks.
3. Currently, the aspects of nanotechnology of most immediate concern involve new and existing materials being formed into nano-particles and nano-fibres. This information note addresses the health and safety risks from these and not the physical or chemical processes used to create them.

Risk Assessment for Nanotechnology

4. A risk assessment should be the first step in ensuring that work activities are appropriately and effectively controlled. HSE produces a number of documents to help guide you through this process[1]. The most likely hazards from nanopowders and nanofibres are toxic effects, catalytic effects and fire/explosion.
5. The legislation dealing with the control of exposure to harmful chemicals is the Control of Substances Hazardous to Health Regulations 2002. An Approved Code of Practice (COSHH)[2] and guidance on COSHH risk assessments is available from HSE[3].
6. The Dangerous Substances and Explosive Atmosphere Regulations 2002 deal with the fire and explosion risks from dangerous substances. An ACoP (DSEAR)[4] is available. Specific guidance for dealing with the fire and explosion risk of dusts is also available from HSE[5].

Scientific Uncertainty

7. Risk assessment should be undertaken using both sound scientific information and past experience. Due to the developmental nature of much of nanotechnology this information may be incomplete but you should make thorough enquiries to obtain as much information as possible. Where significant gaps in knowledge remain your risk

assessment and risk management decisions should be suitably precautionary, providing higher levels of protection as the significance and level of uncertainty about the risk increases.

8. You should also take steps e.g. initiate further focused research, to address the gaps in information to allow your risk assessment to be refined. Risk assessments should be reviewed on a regular basis and whenever new information becomes available.

HEALTH RISKS

Human Health

9. For most particulate materials that can become airborne and be breathed in, particularly those that are poorly soluble, the primary health concern is for effects on the lung. This should be the first consideration for any nanomaterial that you are using, where there is any potential for inhalation exposure. However, you should also give some thought to other aspects, such as skin contact or ingestion.

10. Novel nanomaterials (eg single-walled carbon nanotubes) will vary in terms of their physical form, chemical composition and physical properties. Therefore it is not possible to apply generic rules about their potential health effects. The situation is compounded by the fact that published information on the potential health effects of some of these novel nanomaterials is very limited. The absence of knowledge about the health hazards of new nanomaterials and the uncertainty that is therefore introduced into any risk assessment means that, when working with them, you should implement stringent controls on exposure.

11. For some more familiar materials that are now being manufactured in the nanometre size range (eg titanium dioxide), a significant body of relevant hazard information is available. This information may be used as a starting point, for assessing the risk and the exposure levels at which the risk of harm becomes a concern. In the absence of any other evidence you should assume that the nanoparticle or fibre is at least as harmful as larger particles and may be more harmful. Particles or fibres that are benign in sizes above the nanoscale may be harmful if inhaled as nanoparticles or nanofibres.

Exposure Potential

12. Factors that can alter the risk from nanoparticles will include:
    a. Amount of material (mass/number of particles) – more material can mean more risk of human exposure or of fire and explosion.
    b. Dry powder or in solution – loose powders can easily be dispersed increasing the risk of exposure whilst those in solution are much more contained.
    c. Degree of containment – in terms of human exposure, it is only what you may be exposed to that creates the risk. If it cannot get out and you do not go in, the risk is low.
    d. Duration of use – If there is exposure to a material during work activities then a longer exposure will result in a larger personal dose. It will also increases the level of surface contamination.

Control Measures

13. Control measures must be proportionate to the risk. However, as the risks arising from exposure to many nanoparticles are, as yet, not completely understood control strategies should be based on the principle of reducing exposure to as low a level as is reasonably practicable. If your control measures are based on pre-existing standards then you should ensure that that standard is relevant for nanoparticles.
14. You should first seek to remove/reduce the hazard by substituting a lower risk material. If this is not possible then engineering solutions should be sought, such as containment or effective and appropriate local exhaust ventilation e.g. fume cupboards. If these do not provide sufficient degrees of control or for some reason are not suitable, then personal protective equipment may be needed. More detailed information on the hierarchy of control is given in the COSHH ACoP[2].

Personal Protective Equipment (PPE)

15. Whilst suitable PPE[6] and Respiratory Protective Equipment (RPE)[7] have their place in providing risk control, the COSHH Regulations require that PPE/RPE should be the last option considered to control exposure to substances hazardous to health. It should also be remembered that effective engineering control, in addition to potentially supplying a much higher degree of control, is often more reliable in practice and will often prove more cost effective over time. PPE/RPE is only capable of providing the intended level of protection if they have been correctly specified or fitted. If you are using filtering respiratory protective devices (respirators), always check with the manufacturer that they will perform adequately against the type and size of particle you may be exposed to. Where this information is not available, or where very high concentrations may be encountered (e.g. where containment or local exhaust ventilation are impracticable, such as dealing with a spillage) use of breathing apparatus (BA), which is provided with clean air from an independent source, would be preferable. For the highest levels of protection, BA having a correctly fitted full-face mask and positive demand compressed air supply will be required.

Health Monitoring

16. You should consider whether it is necessary to undertake some form of health monitoring[8]. The need for and the specific type of health monitoring required should arise from your risk assessment. The aim of health monitoring is to ensure that if a health effect does occur it will be detected at an early stage. This could allow action to be taken to reduce the likelihood of long-term harm. It is not a substitute for effective control.

SAFETY RISKS

Catalytic Effects

17. Many chemical processes can be catalysed by small amounts of material, and if the potential catalyst is a solid, while the reactants are liquids or gases, the effectiveness of the catalyst may depend on the surface area of the particles. So nanometric products

could cause rapid reactions that would otherwise only proceed very slowly. Small scale testing can help identify such effects.

Fire and Explosion

18. There is almost no data relating to the fire and explosion hazard of nanoparticulates. Whilst it is unlikely that very small amounts of material will create a risk, larger amounts of combustible powder could. Nano-particulate products could be raised from a layer into suspension more easily than coarser products, and may remain in suspension almost indefinitely. Conventional methods of measuring dust concentration may give incorrect results. Dense clouds of nanometric powder may be impossible to see, even though a suspension of the same product at the same concentration at a courser grade is easily visible. If your nanoparticulate is composed of combustible materials it is likely to pose such a hazard.
19. Your risk assessment should have addressed all foreseeable ways by which a fire or explosion could be initiated, including its ignition energy, ability to self-charge or auto-ignite and its settling time.

Control Measures

20. You must consider if the basis of the protective measures being used are still appropriate from this new material, if it is based on a standard is this relevant for nano-particulate e.g. for electrical equipment in 'nano' dusty areas should it be dust-protected or dust-tight. In areas of high risk, due to the small size of the particles and the long settlement times you should consider if such equipment should be gas tight also. In addition, is the temperature rating of the equipment appropriate to prevent ignition.
21. Guidance for dealing with the fire and explosion risk of dusts is available from HSE books[5]. This explains that there are relatively simple tests available that can determine if a dust is combustible and what its explosion characteristics are. It also outlines some, mitigation measures that will reduce the effects of an event, e.g. explosion relief panels.

MANAGEMENT ARRANGEMENTS

22. Whatever controls are used to provide health and safety in the workplace, they must be supported by suitable management arrangements[9] including working procedures, training to ensure competence, adequate supervision and an appropriate maintenance regime. In particular effective arrangements should be made for informing workers about the risks and for involving them in the design and implementation of control measures.

Future HSE Guidance

23. This document is not formal guidance and is a result of HSE's initial examination of the health and safety issues of nanotechnology. HSE is undertaking further work to review the health and safety implications of nanotechnology and will evaluate the need for guidance after this review.

FURTHER INFORMATION

Below is a list of guidance that may be helpful on general principles but they do not specifically mention nanoparticles.

General Guidance

Formula for Health & Safety: Guidance for Small and Medium Sized Firms in the Chemical Industry. HSG166.
Health Risk Management: A Practical Guide for Managers in SMEs. HSG137.

Risk Assessment

[1] Risk assessment website www.hse.gov.uk/risk/index.htm
5 steps to risk assessment INDG163(rev1)

Human Health

[2] Control of substances hazardous to health 2002 Regulations(4th ed) ACOP L5
[3] A step by step guide to COSHH assessment HSG97
COSHH Essentials www.coshh-essentials.org.uk
EH40/2003 Occupational Exposure limits
www.hse.gov.uk/coshh/index.htm

Fire and Explosion

[4] Dangerous Substances and Explosive Atmosphere Regulations ACOP L138
[5] www.hse.gov.uk/fireandexplosion/index.htm
Safe handling of combustible dusts: precautions against explosions. HSG103.

PPE/RPE

[6] www.hse.gov.uk/pubns/ppeindex.htm
Personal protective equipment at work. Guidance on Regulations 1992. L25.
[7] The Selection, Use and Maintenance of Respiratory Protective Equipment. HSG53.

Health Monitoring

[8] Health surveillance at work. HSG61 (second edition).

Management of Health and Safety

[9] The Management of health and safety at work Regulations 1999. Approved Code or Practice and Guidance. L21.

For information about health and safety ring HSE's InfoLine Tel: 08701 545500 Fax: 02920 859260 e-mail: hseinformationservices@natbrit.com or write to HSE Information Services, Caerphilly Business Park, Caerphilly CF83 3GG. You can also visit HSE's website: www.hse.gov.uk