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Current Standardisation for Nanotechnology

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Abstract. Standardisation and standards provide an important mechanism to support both innovation and the application of regulations. There is currently no specific regulation for any nanomaterials. Health, safety and environmental protection aspects associated with nanomaterials are however in principle covered to different levels by current EU regulatory framework. There are a number of national, European and international organisations developing standards associated with the development, description and use of nanomaterials as well as the protection of human health and the environment from the production and use of chemicals and consumer products, including nanomaterials. These organisations have also established specific committees on nanotechnology. This paper outlines the different relevant regulations and standards. This paper will mainly be focused on a European health and safety perspective.

1. European Union regulations
There is no specific regulation for any nanomaterials. However, national and European regulations are applicable to nanomaterials. The main European Union health and safety regulations for the protection of workers include:

- General Directive 89/391/EEC from 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work.
- Directive 98/24/EC from 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth Directive within the meaning of Article 16(1) of Directive 89/391/EEC).
- Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance)
- Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work (second individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
- Directive 1999/92/EC of the European parliament and of the council of 16 December 1999 on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres (15th individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)
Directive 67/548/EEC (substances) – 1999/45/EC (preparations): Classification, packaging and labelling of Dangerous substances/preparations. 7th amendment as Directive 92/32/EEC

Under this directive, an evaluation must be made for any substance or preparation manufactured within or imported into the EU and placed on the EU market and results in classification of the substance/preparation as dangerous for one or several end-points concerning physical-chemical properties, health or environmental effects. Classification and labelling is therefore a useful tool for risk management of chemicals. All marketed substances and preparations must be classified and labelled, irrespective of the quantity placed on the market. The labelling is the first and often the only information on the hazards of a chemical that reaches the user, which could be a consumer or a worker. In addition the classification has a large number of downstream consequences within EU legislation.

Annex V of the 67/548/EEC directive is divided in three parts that contain testing methods for chemicals that address all areas of concern.

Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances (Existing Substances Regulation (ESR)).

Health, safety and environmental protection aspects associated with nanomaterials are in principle covered to different levels by current EU regulatory framework.

The risks to be assessed under the Directive 98/24/EC due to the presence of hazardous chemical agents may be one or more of the following:

- Risk of fire and/or explosion.
- Risk generated due to hazardous chemical reactions, which may affect the health and safety of workers.
- Risk due to inhalation.
- Risk due to absorption through the skin.
- Risk due to contact with the skin or eyes.
- Risk due to ingestion.
- Risk due to penetration through the parenteral route.

The Directive 98/24/EC lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

In carrying out the obligations concerning risk assessment laid down in Articles 6(3) and 9(1) of Directive 89/391/EEC, the employer shall first determine whether any hazardous chemical agents are present at the workplace. If so, then the employer shall assess any risk to the safety and health of workers arising from the presence of those chemical agents, taking into consideration the following:

- their hazardous properties,
- information on safety and health that shall be provided by the supplier, (e.g. the relevant safety data sheet in accordance with the provisions of Directive 67/548/EEC or Directive 88/379/EEC),
- the level, type and duration of exposure,
- the circumstances of work involving such agents, including their amount,
- any occupational exposure limit values or biological limit values established on the territory of the Member State in question,
- the effect of preventive measures taken or to be taken,
- where available, the conclusions to be drawn from any health surveillance already undertaken.

The Directive 98/24/EC requires that the risk to the health and safety of workers using or handling hazardous chemical agents shall be eliminated or reduced to a minimum. The hierarchy of control measures, which should be applied to all hazards, consists of:

- Eliminate the use of the hazardous substance.
• Substitute the use of the hazardous substance a less hazardous substance.
• Enclose the process to reduce the potential for exposure to the hazardous substance.
• Control the exposure of the substance at source using engineering means.
• Provide adequate protective equipment (such as Respiratory Protective Equipment - RPE).

Elements of the precautionary principle exist in different regulation approaches and REACH (Registration, Evaluation, Authorization and Restriction of Chemicals), which came into effect on the 1st of July 2007, explicitly mentions the precautionary approach. Chemicals notified under REACH should include hazard data for nano-sized materials where these are supplied. The threshold value for the registration of a new chemical substance is 1 ton.

In 2008, the Commission and EU agencies will start to review existing documents that support implementation of the various directives with regard to their applicability and appropriateness to nanomaterials.

2. Voluntary codes and voluntary schemes
To address the growing concerns about nanomaterials a number of organisations or industries have released and or adopted voluntary measures in the management of engineered nanomaterials such as codes of conduct or voluntary schemes.

These voluntary codes of conduct include:
• Code of conduct for responsible nanotechnology (European Commission)
• Responsible nanocode for businesses (Royal Society, UK)
• Code of conduct for nanotechnology in consumer products (Switzerland)
• Code of conduct for the protection of employees, customers and the environment (established by several manufacturers of nanomaterials)
• Guideline for operations with nanomaterials at workplaces (VCI, BAuA, Germany)

There are also voluntary schemes set up at national levels, where organisations and industries are encouraged to submit data on engineered nanomaterials including data on toxicity or exposure levels. These schemes include:
• Voluntary reporting scheme for engineered nanomaterials (DEFRA, UK)
• Nanoinventory (Switzerland)
• Voluntary Nanoscale Materials Stewardship Program (EPA, USA)

3. Standards
Pre-normative and co-normative research may also be required before certain projects may commence or be completed. It is foreseen that standards may be required to support legislation, particularly in the areas of health, safety and the environment, and so the work programme will be influenced by what these requirements are, and when they will be needed.

There are many national, European and international organisations developing standards associated with the development, description and use of nanomaterials as well as the protection of human health and the environment from the production and use of chemicals and consumer products, including nanomaterials. These organisations have also established specific committees on nanotechnology. The European Committee for Standardization CEN established CEN/TC 352 “Nanotechnologies”; the ISO established ISO/TC 229 "Nanotechnologies”; the IEC founded TC 113 “Nanotechnology standardization for electrical and electronic products and systems". According to the Vienna agreement most of the new normative projects are carried out in conjunction with and under lead of ISO/TC 229 “Nanotechnologies". The Organisation for Economic Co-operation and Development (OECD) also established a Working Party on Manufactured Nanomaterials and a Working Party on Nanotechnology. In parallel different national “mirror” groups are working meanwhile on this subject.

These organisations are working to develop and standardise instruments and test methods for the support of appropriate health, safety and environment legislation and regulations of nanomaterials. It includes work on the development and standardisation of:
Nomenclature and definitions of terms in nanotechnology;
Test methods to characterise nanomaterials;
Instruments and test methods for measurement of airborne nanoparticles in the workplace;
Test methods to detect and identify nanoparticles in the workplace and in the environment;
Protocols for toxicity and eco toxicity testing;
Protocols for whole life cycle assessment of nanomaterials, devices and products;
Risk assessment tools relevant to the field of nanotechnologies;
Test methods to assess the performance efficiency of engineered and personal control;
Occupational health protocols relevant to nanotechnologies;
Materials performance.

In the context of the NANOSAFE 2 project (EU FP6 project; contract number NMP2-CT-2005-515843) the following areas are of interest:
• exposure measurement and characterisation;
• exposure control;
• toxicity;
• fire and Explosions;
• life cycle analysis;
• risk assessment.

Experience gained in these fields through the NANOSAFE project will lead to interactions with CEN/TC 352 for the development of future standards.

4. European standards
The first CEN standard for nanotechnology terminology was published in 2008: CEN ISO/TS 27687:2008 Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate.

A number of work items are also under development including:
• prCEN ISO/TR 11808 Guide to nanoparticle measurement methods and their limitations.
• Guide to labelling of manufactured nanoparticles and products containing manufactured nanoparticles.

Furthermore, there are many other European standards associated with the protection of human health and the environment from the production and use of chemicals and consumer products, which may be of relevance to nanomaterials. Nevertheless these standards must be assessed whether they will apply to nanomaterials or amendments are required. For example in the workplace, the standard method of assessing worker exposure to airborne particles currently involves measuring the mass concentration and chemical composition of health-related aerosol fractions (inhalable or respirable) in the breathing zone. The exceptions are for fibres (e.g. asbestos), where the number concentration is determined by microscopy, and for micro-organisms, that are collected on a growth medium, where the number of colony forming units is counted. For the ambient atmosphere, particulate pollution is measured currently according to the PM 10 fraction and the finer PM 2.5 fraction to be introduced soon. A few protocols for measurement of submicrometer particles in environmental air exist and research is currently being carried out in a number of EU states to investigate particle number concentrations and particle number size distributions, prior to the possible introduction of number-based limits for ambient particles.

These other standards include:
EN 14530: 2004, „Workplace atmospheres - Determination of diesel particulate matter - General requirements” specifies a method for the determination of diesel particulate matter in the workplace atmosphere by collecting the particles on a filter and determining the elemental and organic carbon component by successive heating of the sample and measuring the carbon dioxide emitted at two different temperatures.
EN 14175-3:2003, “Fume cupboards – Part 3: Type test methods”, is part of a series of standards on assessing the performance of fume cupboards.

EN 12469: 2000, “Biotechnology - Performance criteria for Microbiological Safety Cabinets”, gives test methods for assessing the performance of microbiological safety cabinets in preventing the release of micro-organisms into laboratory air.

EN 60335-2-69:1999, “Safety of household and similar electrical appliances – Part 2: Particular requirements for wet and dry vacuum cleaners, including power brush, for industrial and commercial use”, provides performance standards for industrial vacuum cleaners. Part 2 of the standard specifies performance of vacuum cleaners in 3 hazard classes according to particle penetration at the most penetrating particle size (MPPS).

In EN 1882: 1993, “Standard for testing and categorising HEPA and ULPA filtration systems”, test aerosols of solid sodium chloride particles or liquid di-octyl phthalate (DOP) are used to test the filtration efficiency of filters used in ventilation and air cleaning systems.

For personal protective equipment, EN 143: 2000, “Filters – particles”, and EN 13274-7: 2002, “Respiratory protective devices. Methods of test. Determination of particle filter penetration”, two protocols are given for testing the particle penetration efficiency of the filter material used in the respirator or dust mask. These do not include particle penetration through face seals or valve seals.

EN 943-1:2002, “Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles – Part 1: Performance requirements for ventilated and non-ventilated “gas tight” (Type 1) and “non gas tight” (Type 2) chemical protective suits”.

EN 13982-2:2005, “Protective clothing for use against solid particulate chemicals. Part 2: Test methods for chemical protective clothing providing protection to the full body against solid particulate chemicals (type 5 clothing)”.

These two standards use a similar methodology to that used for assessing inward leakage of respirators – solid sodium chloride test aerosol with monitoring inside and outside the suit worn by live subjects following a prescribed exercise routine.

The following four standards describe different test methods for the determination of explosion and combustion characteristics of dusts. Special adaptations for the testing of nanomaterials have to be taken into account and were tested in the NANOSAFE 2 project (for example, a system that employs powder confinement is recommended for these tests). This will facilitate control over the atmosphere within the test chamber such that, for example, the powder can be protected from oxidation until the point of ignition.

EN 1127-1: 1998, “Explosive atmospheres – Explosion prevention and protection Part 1. Basic concepts and methodology”.

The occurrence of an explosive atmosphere depends on the presence of a flammable material, the degree of dispersion of the material and the concentration of the material in air within the explosibility range.

EN 13821: 2002, “Potentially explosive atmospheres — Explosion prevention and protection — Determination of minimum ignition energy of dust/air mixtures”.

EN 14034-1:2004, “Determination of explosion characteristics of dust clouds – Part 1: determination of the maximum explosion pressure Pmax of dust clouds”.

EN 14034-2:2006, “Determination of explosion characteristics of dust clouds – Part 2: determination of the maximum rate of pressure rise (dp/dt) max of dust clouds”.

5. ISO standards

The first ISO standard for nanotechnology terminology was published in 2008 as an outcome of ISO/TC 229 Nanotechnologies: ISO/TS 27687 “Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate”, also adopted by CEN. Nano-objects are considered to have at least one dimension below 100 nm. In advance of this, ASTM International had published a similar terminology standard: ASTM E2456 - 06 “Standard terminology relating to Nanotechnology”.

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Concerning the health and safety aspects of nanotechnologies, ISO/TR 12885 “Health and safety practices in occupational settings relevant to nanotechnologies”, published in September 2008, describes current procedures applied in manufacture and processing of nanomaterials.

Further project groups in ISO TC 229 are busy working on following topics:

- ISO/CD 29701 – “Nanotechnologies – Endotoxin test on nanomaterial samples for in-vitro systems”.
- ISO/CD 10801 “Nanotechnologies – Generation of silver nanoparticles for inhalation toxicity testing”.
- ISO/CD 10808 “Nanotechnologies – Monitoring silver nanoparticles in inhalation exposure chambers for inhalation toxicity testing”.
- ISO/TR 13014 “Nanotechnologies – Guidance on physico-chemical characterisation of engineered nanoscale materials for toxicological assessment”.

Other existing international standards to be considered when working with nanomaterials, are the following:

- ISO/TR 27628: 2007, “Workplace Atmospheres – Ultrafine, nanoparticle and nano-structured aerosols – Exposure characterization and assessment”, gives guidance on the current methods of assessing human exposure to ultrafine, nanoparticle and nano-structured aerosols in workplace atmospheres.
- ISO 10882-1:2001, “Health and safety in welding and allied processes - Sampling of airborne particles and gases in the operator's breathing zone - Part 1: Sampling of airborne particles”, gives guidance of how to measure exposure to welding fume in the workplace.
- ISO 8672: 1993, “Air quality - Determination of the number concentration of airborne inorganic fibres by phase contrast optical microscopy - Membrane filter method”.
- ISO 10312: 1995, “Ambient air - Determination of asbestos fibres - Direct transfer transmission electron microscopy method”
- ISO 13794: 1999, “Ambient air - Determination of asbestos fibres - indirect transfer transmission electron microscopy method”
- ISO 14966:2002, “Ambient air - Determination of numerical concentration of inorganic fibrous particles - Scanning electron microscopy method”
- ISO 14644, “Clean rooms and associated controlled environments”, is a suite of 8 standards with the main aim of protecting components (especially semiconductors, computer chips, etc.) from damage by airborne particles. There are 9 classes of air cleanliness assessed by monitoring particle number size distributions using Optical Particle Counters (OPCs).

6. Conclusions:

There is currently no regulation specific to nanomaterials. Health, safety and environmental protection aspects associated with nanomaterials are however in principle covered to different levels by current EU regulatory framework. In 2008, the EU Commission and Agencies will start to review existing documents that support implementation of the various directives with regard to their applicability and appropriateness to nanomaterials.

A number of national, European and international organisations are developing standards that either focus on or have sections dealing with the protection of human health and the environment against the production and use of chemicals and consumer products containing nanomaterials. ISO/TC229 has recently published ISO/TR 12885 “Health and safety practices in occupational settings relevant to nanotechnologies” (September 2008), which describes current procedures applied in manufacture and processing of nanomaterials. Much work is still to be carried out and multiple co-operations are required. Furthermore, there are knowledge gaps in toxicological and exposure data. Such additional knowledge is necessary for a full risk assessment on the manufacture, handling or use of nanomaterials. In the meantime the precautionary principle should be followed to minimise possible risks.