



*Safe production and  
use of nanomaterials*

***Do current regulations apply to  
engineered nanomaterials?***

***Standards – Why standardisation  
and standards are important?***

*Dissemination report  
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*Dissemination reports from Nanosafe2 project are designed to highlight and present in a simplified way the main results obtained in the studies carried out during this project. These reports mainly deal with one question which is of general concern for whom is interested by the safe production and use of nanomaterials. The full results are summarized in the corresponding Technical reports.*

**All the Dissemination reports and Technical reports are publicly available from Nanosafe2 project website: <http://www.nanosafe.org>**

## **Refer to:**

*D412: Report on Impacts of Nanotechnology on EU standards and Regulations.*

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### *Disclaimer*

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## ***I. Regulations – Do current regulations apply to engineered nanomaterials?***

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

- Directive 67/548 – 1999/45: Classification, packaging and labelling of Dangerous substances.
- Directive 98/24/EC 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).

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



Testing of protecting clothing  
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Testing of explosive materials  
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Air supplied hood  
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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 parental route.

The Directive 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 by 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).



***Lesson 1: National and European regulations are applicable to nanomaterials***

Element of the precautionary principle exist in different regulatory approaches. 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.

A number of voluntary measures in the management of engineered nanomaterials such as codes of conduct or voluntary schemes have been published.



Powered blouse respirator  
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The 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)

The voluntary schemes, where organisations and industries are encouraged to submit data on engineered nanomaterials including data on toxicity or exposure levels, include:

- Voluntary reporting scheme for engineered nanomaterials (DEFRA, UK)
- Nanoinventory (Switzerland)
- Voluntary Nanoscale Materials Stewardship Program (EPA, USA)

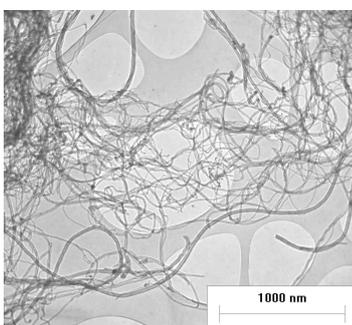


***Lesson 2: Element of the precautionary principle exists in different regulatory approaches.***

## **Standards – Why standardisation and standards are important?**

Standardisation and standards provide an important mechanism to support both innovation and the application of regulations. 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 from the production and use of chemicals and consumer products, containing nanomaterials. These organisations have also established specific committees on nanotechnology. These include:

- CEN/TC 352 "Nanotechnologies" established by the European Committee for Standardization. The website can be found at the following address: <http://www.cen.eu/CENORM/Sectors/TechnicalCommitteesWorkshops/CENTechnicalCommittees/CENTechnicalCommittees.asp?param=508478&title=CEN%2FTC+352>
- ISO TC229 "Nanotechnologies". The website can be found at the following address: [http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_tc\\_browse.htm?comid=381983](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?comid=381983)
- IEC/TC 113 "Nanotechnology standardization for electrical and electronic products and systems"
- The Organisation for Economic Co-operation and Development Working Party on Manufactured Nanomaterials (OECD WPMN) and a Working Party on Nanotechnology (OECD WPN). The website can be found at the following address: [www.oecd.org/sti/nano](http://www.oecd.org/sti/nano)



Carbon nanotubes imaged by transmission electron microscopy  
HSL photograph – Crown copyright



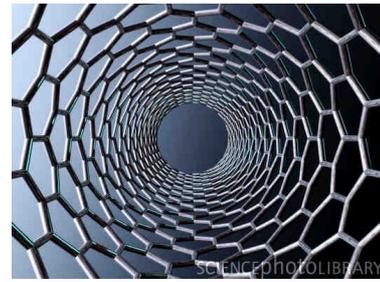
Setup for penetration tests of RPE against salt aerosol  
BGIA DGUV photograph

A number of organisations including CEN, ISO or OECD 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:

- Instruments and test methods for measurement and identification of airborne nanoparticle in the workplace and the environment;
- Test methods to characterize nanomaterials;
- 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 measures;
- Occupational health protocols relevant to nanotechnologies.

The first ISO standard for nanotechnology terminology has been published in 2008 as outcome of ISO TC 229 Nanotechnology: ISO/TS 27687 "Nanotechnologies - Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate". 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".

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



Nanotube technology  
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A workplace scenario - BGIA DGUV photograph



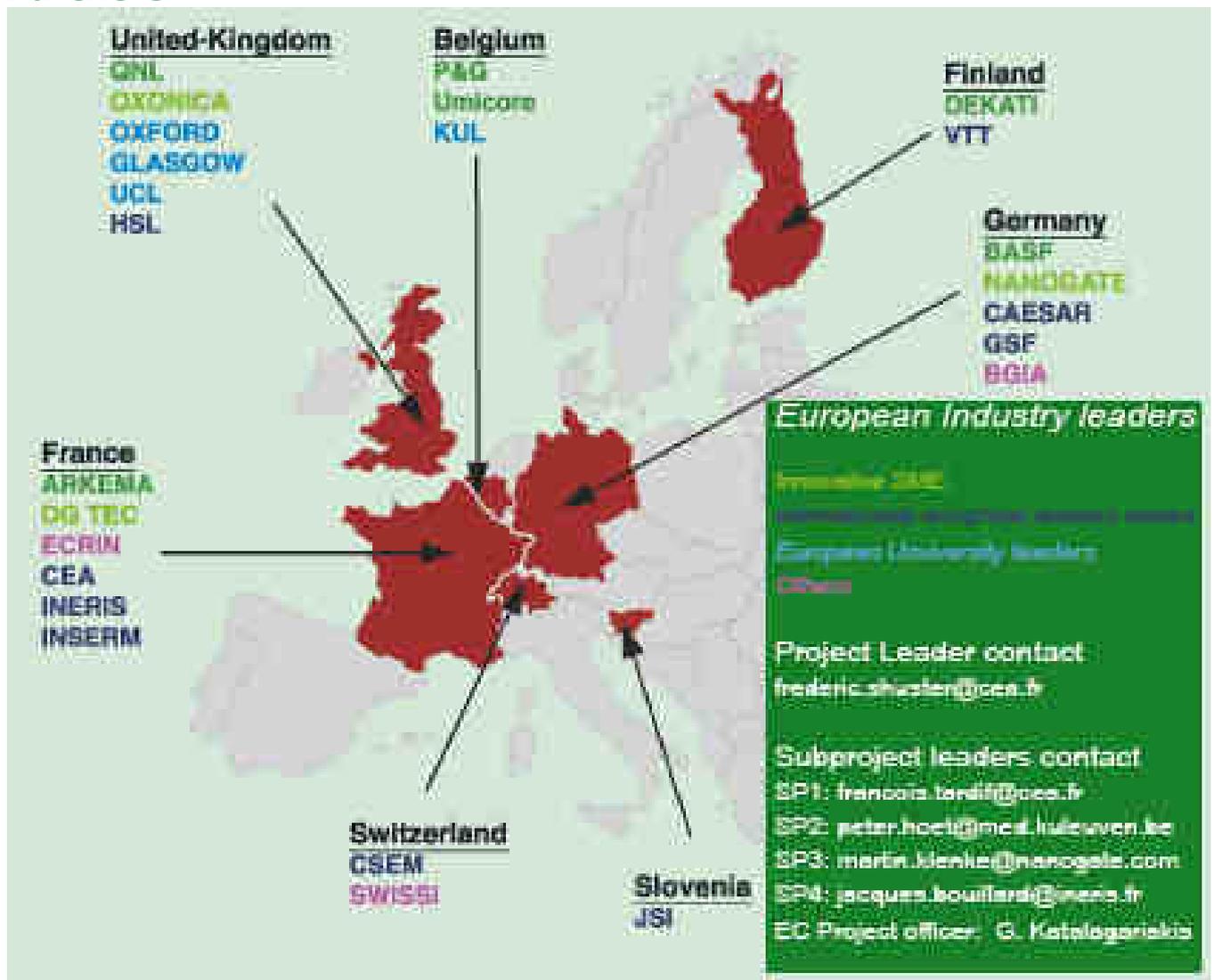
***Lesson 3: Standardisation and standards provide an important mechanism to support both innovation and the application of regulations.***



Nanosafe2 brings together twenty five partners from seven different countries of the European Union, mainly small, medium and large enterprises and public research laboratories. The project is supported through the Sixth Framework Programme for Research and technological Development and addresses the thematic priority 3.4.3.2-1: Hazard reduction in production plant and storage sites. The project has started in April 2005 and will end in March 2009.

Nanosafe2 main objective is to develop risk assessment and management for secure industrial production of nanoparticles. It focuses on four areas: detection and characterisation techniques, Health hazard assessment, Development of secure industrial production systems and safe applications, Societal and environmental aspects.

## Partners



<http://www.nanosafe.org>

How to characterise nanoparticles for safety issues?  
 DR-???? -2008 12-7, Nanosafe-December 2008

# **Do current regulations apply to engineered nanomaterials?**

## **Standards – Why standardisation and standards are important?**

December 2008

### **European Regulations**



- Health, safety and environmental protection aspects associated with nanomaterials are in principle covered to different levels by current EU regulatory framework.
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
- No specific regulations on nanomaterials.

### **Element of the precautionary principle exists in different regulatory approaches**



- REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) explicitly mentions the precautionary approach.
- A number of voluntary measures in the management of engineered nanomaterials such as codes of conduct or voluntary schemes have been published.

### **Standardisation and standards are important.**



- They provide an important mechanism to support innovation, the application of regulations and economic development.
- A number of organisations including CEN, ISO or OECD are working to develop and standardise instruments and test methods for the support of appropriate health, safety and environment legislation and regulations of nanomaterials.
- ISO/TC 229 "Nanotechnologies", CEN/TC 352 "Nanotechnologies", national standardisation bodies and the OECD are major actors.
- IEC/TC 113 "Nanotechnology standardization for electrical and electronic products and systems"



- Current fields for developing standards are
  - Terminology and nomenclature
  - Measurement and characterization
  - Health, Safety and Environmental Aspects of Nanotechnologies
  - Material specifications

**Regulations and standardisation**

**<http://www.nanosafe.org>**