Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE
MINISTÈRE DU TRAVAIL, DE L'EMPLOI ET DE LA SANTÉ

SPF Emploi, Travail et Concertation sociale

FOD Werkgelegenheid, Arbeid en Sociaal Overleg

Ministerie van Sociale Zaken en Werkgelegenheid

Working with nanomaterials

A seminar on policy, practice and the role of public authorities in dealing with uncertain risks

Brussels, 29 November 2011

Report

Table of contents

Acknowledgements

Speakers

Roel Gans (chair)

Director, Occupational Health and Safety, Ministry of social Affairs, The Netherlands

Christian Deneve

Director-General, Federal Public Service Employment, Labour and Social Dialogue, Belgium

Myriam Ricaud

Chemist Engineer, Institut National de Recherche et de Sécurité, France

Erik Tielemans

Research Manager, Netherlands Organisation for Applied Scientific Research, TNO

Rolf Packroff

Scientific Manager, Federal Institute for Occupational Safety and Health, BauA, Germany

Luc Maurer

Ministry for Ecology, Sustainable development, Transport and Housing, France

Juan Pineros Garçet

Federal Public Service Health, Food chain Safety and Environment, Belgium

Aida Ponce Del Castillo

European Trade Union Institute, ETUI

Kris de Meester

Chairman of the Health and Safety Working Group, Business Europe

Mireille Jarry

Deputy Director Ministry, Ministry of Labour, France

Organizers

Ilse van den Aker

Policy Advisor, Ministry of Social Affairs and Employment, The Netherlands

Linda Wouters

Attachée, Federal Public Service Employment, Labour and Social Dialogue, Belgium

Greet Van Meulder

Attachée, Federal Public Service Employment, Labour and Social Dialogue, Belgium

Matthieu Lassus

Prevention Engineer, Ministry of Labour, France

Brigitte Berlioz, documentalist, and **Myriam Ricaud**, Chemist Engineer, INRS, France, who had a major contribution to the writing of this report.

Logistics

Destrée Organisation

Foreword

This report with the annexed speeches and poster presentations provides an overview and lists the conclusions of the seminar "*Working with nanomaterials, a seminar on policy, practice and the role of public authorities in dealing with uncertain risks*", the aim of which was to stimulate awareness on the nanomaterials issue, promote activities to ensure the protection of workers and facilitate the exchange of information and collaboration between Member States. It contains information on individual Member State initiatives and Member State collaborations in this field, on relevant tools and instruments developed by OSH institutions, and on the views of workers' and employers' representatives. Therefore, it was considered appropriate to present it to the European Commission's DG Employment, Social Affairs and Inclusion, as an element to take into account while further shaping its nanopolicy.

Seminar program

Chair: Roel Gans (director Occupational Health and Safety, Ministry of Social Affairs, The Netherlands)

9.30 – 9.40 **Opening** by Mr. Christian Deneve (Director-General, Belgian Federal Public Service Employment, Labour and Social Dialogue)

9.40 – 9.45 **Remarks by the Chair**

9.45- 10.05 **Introductory statement by the European Commission** by Armindo Silva (Director Social Dialogue, Social Rights, Working Conditions and Adaption to Change, DG Employment)

key note lecture

10.05- 10.50 **On the hazard and exposure assessments of nanomaterials** by Myriam Ricaud (Chemical Engineer, INRS, France)

Coffee break 10.50 -11.20

Managing the risks: Experiences/initiatives in Member States (part I)

11.20 – 11.50 **Managing uncertain risks associated with nanotechnology** by Erik Tielemans (Research Manager Netherlands Organisation for Applied Scientific Research TNO)

11.50 – 12.10 **Risk assessment and dealing with hazard data gaps, the role of occupational exposure limits and alternatives** by Rolf Packroff (Scientific Manager, Federal Institute for Occupational Safety and Health, BAuA, Dortmund, Germany)

12.10 – 12.25 **Questions/discussion**

Lunch 12.25 – 13.25

Managing the risks: Experiences/initiatives in Member States (part II)

13.25- 13.50 **Traceability: the French Decree on the annual declaration of nanoparticle substances** by Luc Maurer (Ministère de l'Écologie, du Développement durable, des Transports et du Logement, France)

13.50- 14.15 **Towards a Regulatory Framework for Nanomaterials' Traceability** by Juan Pineros Garcet (Federal Public Service Health, Food Chain Safety and Environment, Belgium)

14.15 – 14.30 ***Questions/discussion***

Coffee break 14.30 -15.00

Viewpoint Stakeholders

15.00 - 15.20 ***Viewpoint from Workers' side***: by Aida Ponce del Castillo (European Trade Union Institute)

15.20 – 15.40 ***Viewpoint from Employers' side***: by Kris de Meester (Business Europe, Chairman of the Health and Safety Working Group)

15.40 - 16.00 ***Viewpoint from the Government side***: by Mireille Jarry (Deputy Director, Ministry of Labour, France)

Discussion and Conclusions

16.00- 16.45 ***Panel discussion***

16.45 – 17:00 ***Conclusions*** by the Chair
Cocktail 17:00 – 18.00

Introduction

Nanotechnology is already an economic reality. The diversity and complexity of manufactured nanomaterials are continuously increasing: we are facing a fast growing, very heterogeneous class of materials which demand attention. Their unique characteristics that are in the first place related to their small sizes lead to important scientific and technological innovations in various sectors, but there are legitimate concerns that the same characteristics may cause new risks, that cannot always be assessed by the classical tools.

Just as with other emerging technologies in the past, like for example genetic engineering, the development of the technological aspects is in this case much faster than the evaluation of the effects on human health and on the environment, and this in spite of the “no data, no market” principle of the EU’s new chemicals legislation.

In many cases, the lack of epidemiological and toxicological data, as well as the limited metrological means, do not allow the conduct of exhaustive quantitative assessments of potential risks. The fact that we are dealing with a very heterogeneous group of materials, for which it is not possible to make general statements about the risks, is complicating this problem even more.

Under these circumstances, it is a challenge to assure that society can benefit from the advantages of nanomaterials, while the protection of the environment and the health and safety of consumers and workers remain guaranteed.

Workers are the first in line to be exposed during the production and use of nanomaterials. Exposures in the working environment are more intense and more direct than the exposure of consumers who generally only come in contact with finished products.

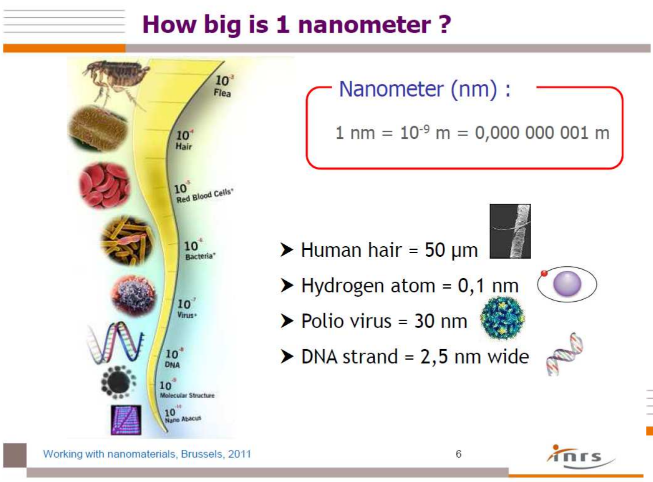
The protection of the growing number of workers that are exposed to nanomaterials was the central theme in the seminar, covered in this report. The worker protection legislation and the chemicals regulations form the basis for this protection. In principle, this legislation is generally applicable to nanomaterials. In practice, however, the specific characteristics of nanomaterials and a number of knowledge gaps impede the effectiveness of these legal instruments.

How can the health and safety of European workers be secured as efficiently as possible under these conditions, with the present knowledge and legislation? Which measures and instruments are already available? Do the Member States and the Commission have to promote these measures or make them mandatory? What are the priorities for the future? These issues were tackled during this seminar.

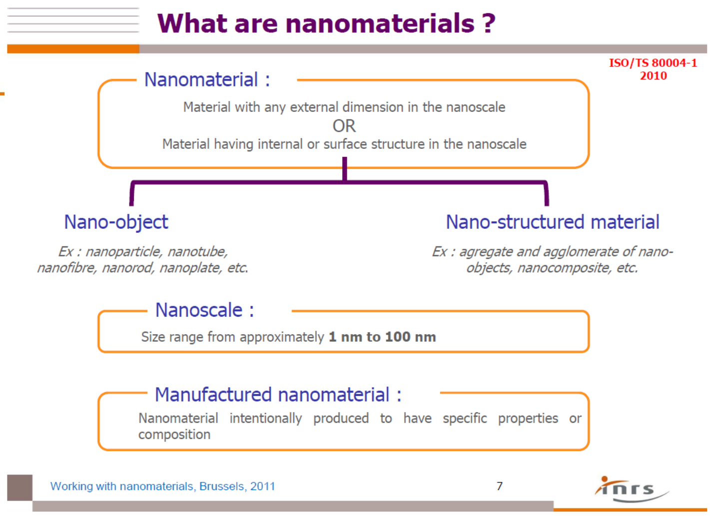
Synthesis of discussions

Nanomaterials

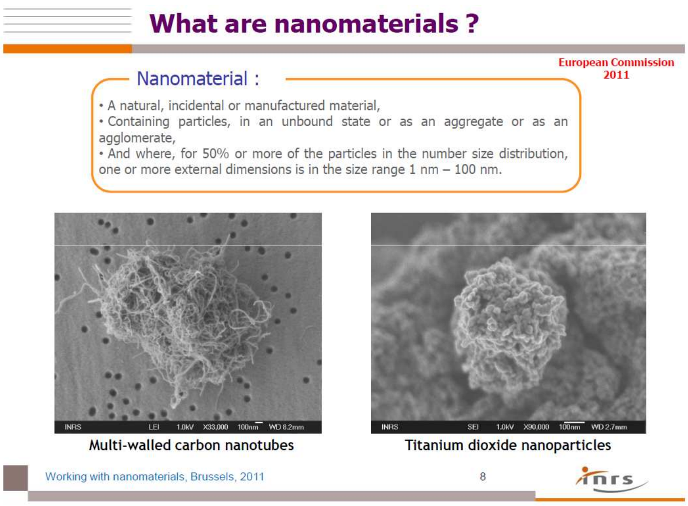
Definitions



The definition of the term "nanomaterial" was and is still the subject of many discussions and proposals at the European and international level.



In 2010, the standardization committee ISO TC 229 has defined nanomaterials as materials containing at least one dimension on the nanoscale (that is to say at least one dimension between approximately 1 nm and 100 nm) or with an internal or surface structure at the nanoscale (ISO TS 80004-1).



The European Commission has recently proposed a definition of the term **nanomaterial**[1] : 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimension is in the size range 1 nm-100 nm.

The EC recommendation also gives the following definitions:

particle : a minute piece of matter with defined physical boundaries;

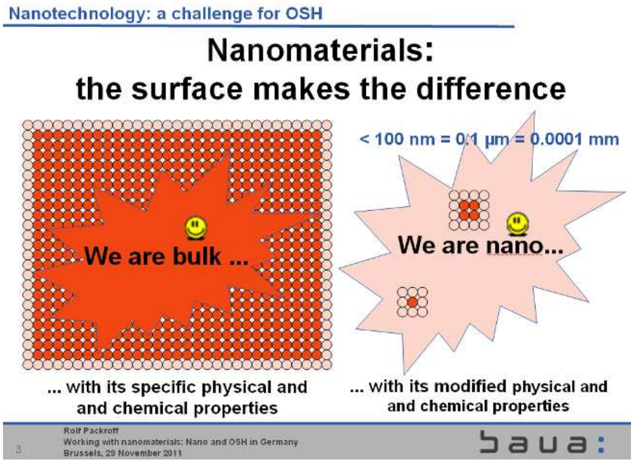
---

[1] Recommendation of the Commission of 18 October 2011 concerning the definition of nanomaterials. Official Journal of the European Union. October 20, 2011.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

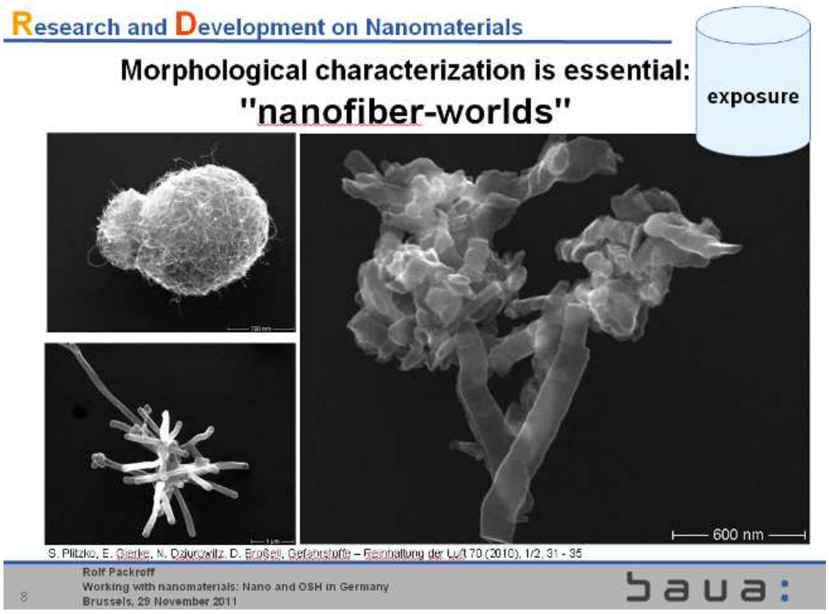
agglomerate : a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

aggregate : a particle comprising of strongly bound or fused particles.



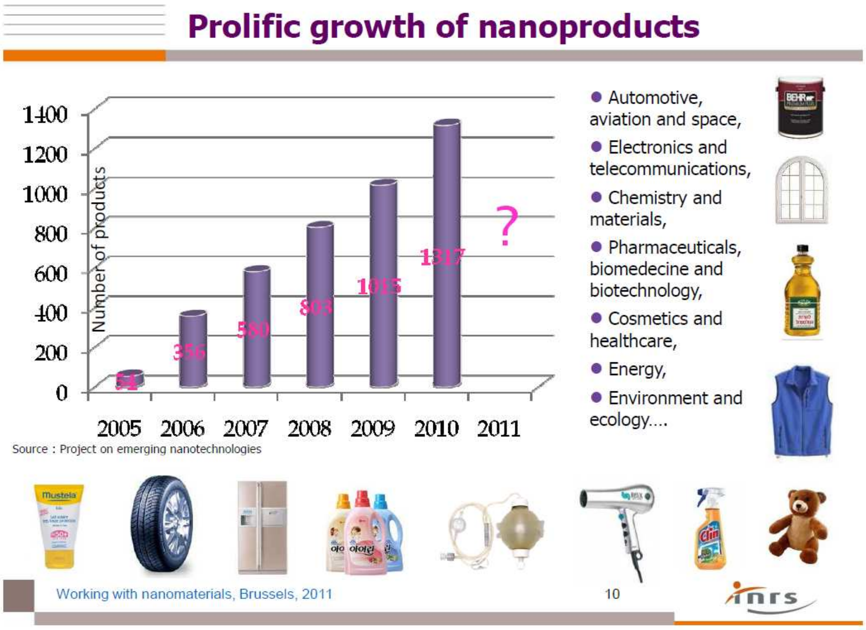
The occurence of matter in nano dimensions comes with properties (chemical, mechanical, optical, etc.) often unexpected and completely different from those of the same materials at the micro- or macro-scale.

In addition, nanomaterials come in a wide variety of shapes : spherical particles, nanotubes, nanofibers, nanowires...



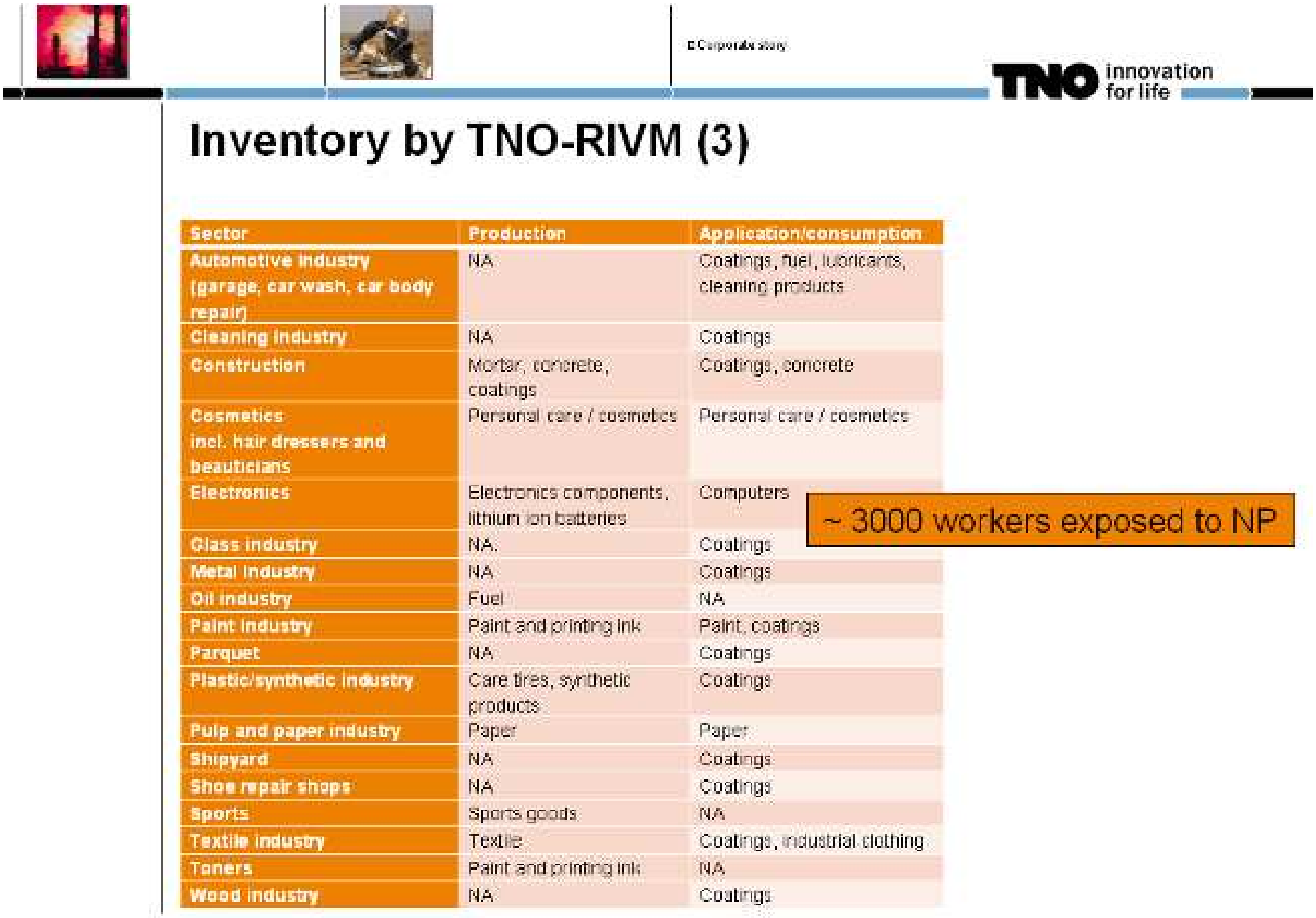
Industrial sectors

Nanomaterials are now a major economic and technological opportunity for companies in Europe and worldwide. The global market for nanomaterials was estimated still in its infancy in 2001 at 40 billion euros, and according to forecasts from the National Science Foundation it could reach 1000 billion euros by 2015.



Nanomaterials have an increasing impact in the new and emerging industries such as aerospace, computer, electronics and renewable energy, as well as in traditional industries such as food, cosmetics, automotive and construction. There are numerous applications: drug delivery, anti-scratch paint, transparent sunscreens, more durable tires, anti-bacterial clothes, self-cleaning concrete, etc.

A large number of employees is already being exposed to nanomaterials, both in research laboratories, production facilities or downstream user companies.



Inventory by TNO-RIVM (3)

Sector	Production	Application/consumption
Automotive industry (garage, car wash, car body repair)	NA	Coatings, fuel, lubricants, cleaning products
Cleaning industry	NA	Coatings
Construction	Mortar, concrete, coatings	Coatings, concrete
Cosmetics incl. hair dressers and beauticians	Personal care / cosmetics	Personal care / cosmetics
Electronics	Electronics components, lithium ion batteries	Computers
Glass industry	NA.	Coatings
Metal industry	NA	Coatings
Oil industry	Fuel	NA
Paint industry	Paint and printing ink	Paint, coatings
Parquet	NA	Coatings
Plastic/synthetic industry	Care tires, synthetic products	Coatings
Pulp and paper industry	Paper	Paper
Shipyard	NA	Coatings
Shoe repair shops	NA	Coatings
Sports	Sports goods	NA
Textile industry	Textile	Coatings, industrial clothing
Toners	Paint and printing ink	NA
Wood industry	NA	Coatings

~ 3000 workers exposed to NP

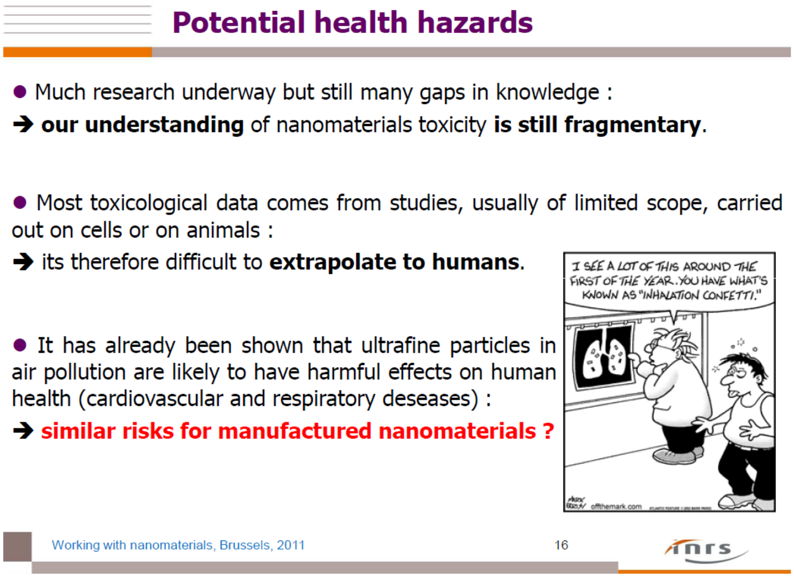
Health Hazards

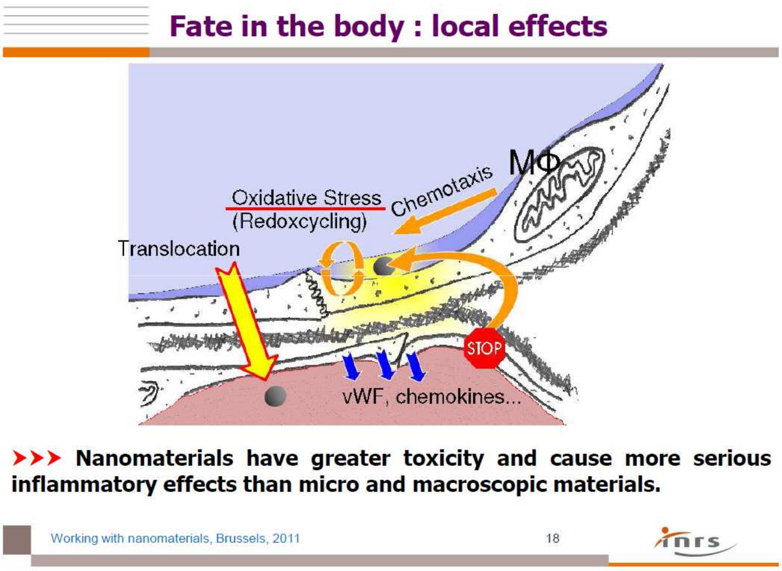
Most of the toxicological data on nanomaterials are derived from studies of limited scope, performed on cells or animals, and are therefore difficult to extrapolate to humans.

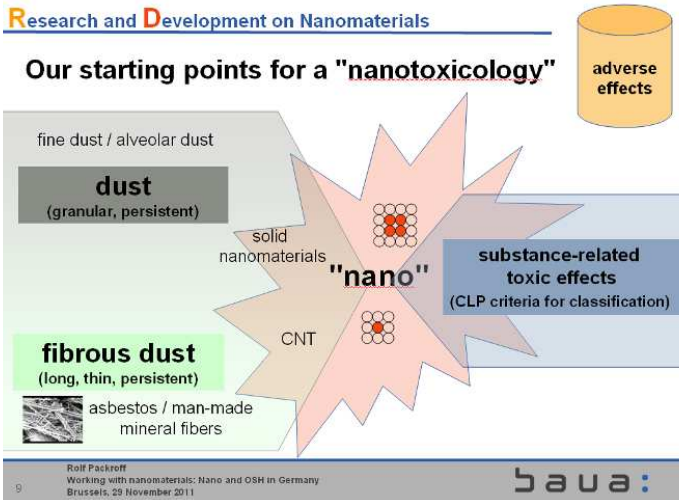
However, they indicate that:

- given their size, inhaled or ingested nanomaterials are able to cross biological barriers (nasal, bronchial, alveolar ...) to reach the blood and lymph and migrate to various organs, notably the most perfused as the heart or liver (translocation process).

- nanomaterials' toxicity and potency of causing inflammatory effects outweigh those of micro- and macroscopic materials of the same chemical nature- each nanomaterial has a toxic potential of its own that depends on its chemical composition and its physicochemical properties: size, surface area, particle size distribution, morphology, solubility, state of aggregation and agglomeration, and so on.

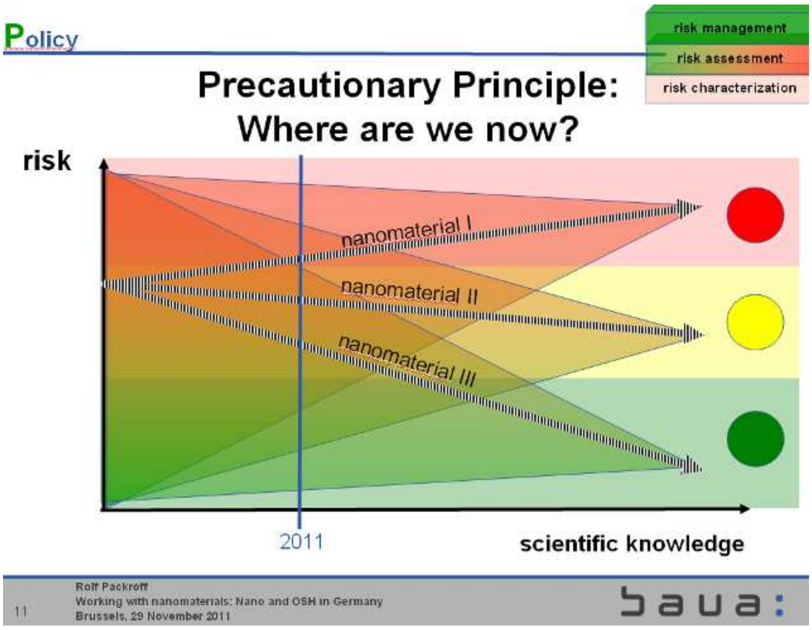






The main objective of the NANOGENOTOX project, initiated by the European Commission is to establish, by inter-laboratory studies, assessments of the genotoxic potential of various manufactured nanomaterials : silica, titanium dioxide and carbon nanotubes. Seventeen European research institutes are involved in this project[2].

Even though hazard data are for the moment inadequate, worker protection has to be assured. To do so, it is essential to perform a "good enough" risk assessment where the substances or preparations, in the absence of reliable data or with information gaps on toxic effects, shall be treated as hazardous to not be lowered in the priority scheme of the risk assessment (p. 20).



2 ANSES (Agence Nationale de Sécurité Sanitaire, France) ; BfR (Federal Institute for Risk Assessment, Germany) ; CEA (Commissariat à l'Energie Atomique, France) ; CLMC (Central Laboratory of Mineralogy and Crystallography, Bulgaria) ; FIOH (Finnish Institute of Occupational Health, Finland) ; IMB-BAS (Institute of Molecular Biology "Roumen Tsanev" - Bulgarian Academy of Sciences, Bulgaria) ; INRS (Institut National de Recherche et de Sécurité, France) ; INSA (Instituto Nacional de Saude Dr. Ricardo Jorge, IP, Portugal) ; IPH (Scientific Institute of Public Health, Belgium) ; IPL (Institute Pasteur de Lille, France) ; ISS (Istituto Superiore de Sanità, Italy) ; National Research Centre for the Working Environment, Denmark) ; NIOM (Nofer Institute of Occupational Medicine, Poland) ; RIVM (Rijksinstituut voor Volksgezondheid en Milieu, The Netherlands) ; UAB (Universitat Autonoma de Barcelona, Spain)

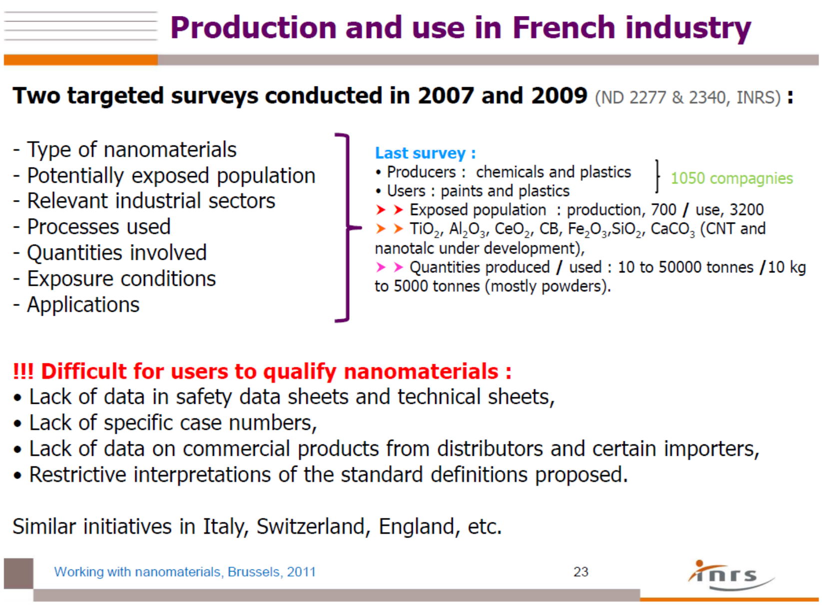
Occupational exposure

Field studies

Many studies were and are being conducted in Europe (Italy, Switzerland, The Netherlands, France, Great Britain, etc.), with the aim to provide an overview of nanomaterials that are produced and used (chemical nature and quantity), industrial sectors associated and to estimate the population of potentially exposed employees.

According to the survey of TNO in 2011 about 3000 employees in The Netherlands would be potentially exposed to nanomaterials in products (so, by working with nanomaterials or products containing them). Branches where workers may be exposed are for example manufacture of tires, concrete repair, production of coatings, shoe repair, etc. Besides, also at least 400 employees may be exposed by working in production of nanomaterials, or by working in research and development.

In The Netherlands, a first targeted inspection project on nanomaterials was launched in 2010 by the Labour Inspectorate. 43 companies where employees were working with nanomaterials were inspected. It included mainly research institutions, companies producing coatings, chemicals industry and « downstream users » like car repair shops. Starting points were the need to minimize the exposure as long as there are uncertainties about the health risks of nanomaterials, and the need to address the issue in the risk inventory and evaluation. The inspected companies all had measures in place to reduce exposure to (normal) chemicals, but few did specifically address the risks of nanomaterials.



In France, the latest study focused on the production and use of nanomaterials in the chemical industry (plastics, paints and chemicals) This survey, conducted among 1050 companies showed that the most frequently used nanomaterials are titanium dioxide, alumina, carbon black, calcium carbonate, amorphous silica, cerium oxide and iron oxide. Quantities may reach several thousand tonnes. About 700 workers were exposed in production companies and 3200 in companies using nanomaterials[3]

These surveys highlight trends similar to those encountered in The Netherlands, namely that:

- The majority of producers do not inform their customers about the possible presence of nanomaterials in their products. Data sheets and safety data sheets are often incomplete and do not relate specifically to nanomaterials. The provided information (toxicological data, prevention, etc.) is not appropriate.

- Downstream user companies thus do not generally consider the "nano" risk in their risk assessment.

---

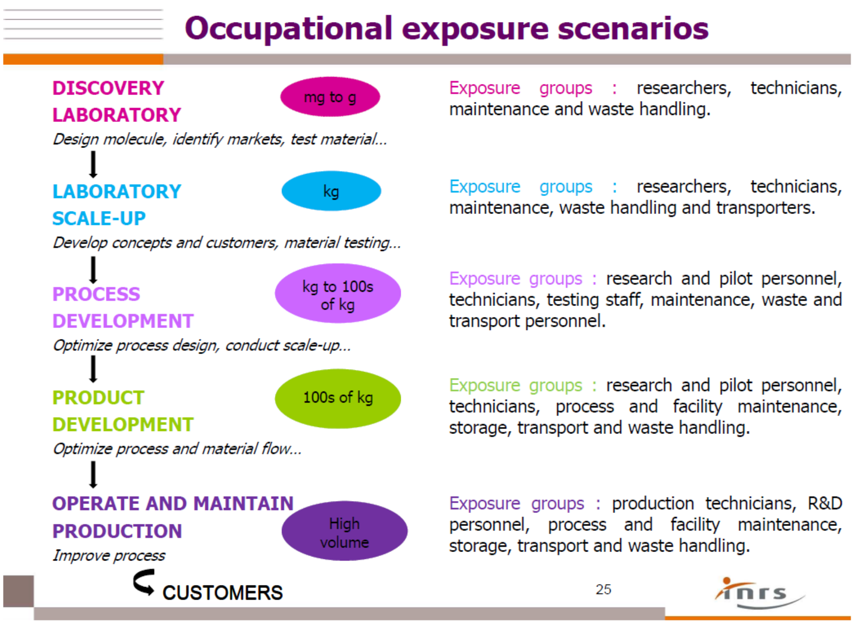
[3] Survey on the industrial use of nano-objects. Difficulty of establishement-based identification. INRS, Note Documentaire. ND 2340, 2011

http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=ND%202340

Occupational exposure situations

There are many work situations in numerous sectors during which employees may be exposed to nanomaterials:

- Transfer, sampling, weighing, suspension and incorporation of nanopowders in a mineral or organic matrix,
- Pouring, agitation, mixing and drying liquid suspensions containing nanomaterials,
- Machining of nanocomposites: cutting, polishing, sanding,
- Packaging, storage and transportation of products,
- Cleaning, servicing and maintenance of equipment and facilities: cleaning of work surfaces, changing used filters, ...
- Collection, packaging, storage and transport of waste,
- Degraded operation or incidents: a reactor leak or a closed system leak.



Several lectures revealed that there is a general need for exhaustive exposure databases, with input from all Member States.

Traceability of nanomaterials

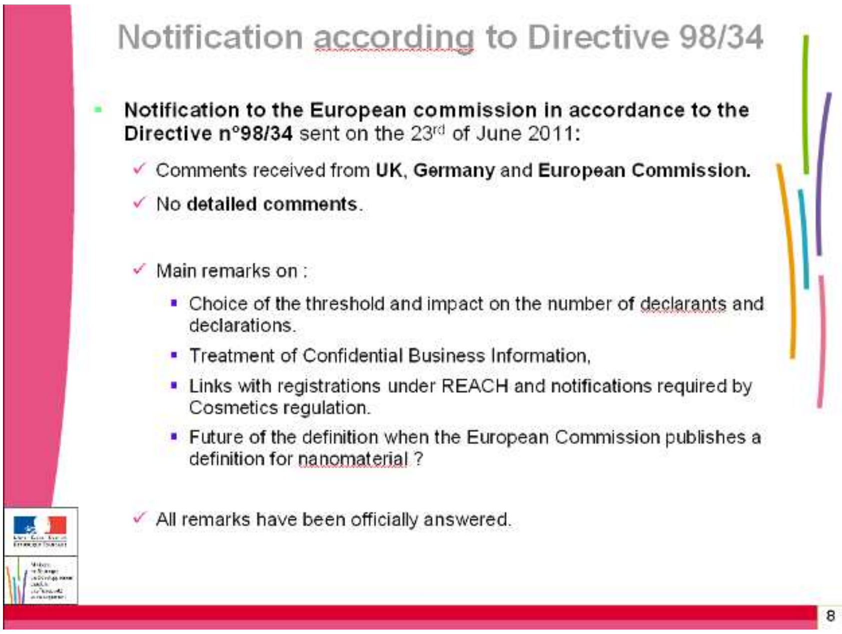
In spite of several studies aiming to get a view on the production and use of nanomaterials, no Member State succeeded in getting a real comprehensive overview on these aspects yet. The data obtained from REACH are considered to be insufficient by many, due to, for instance, tonnage requirements that are not adapted to the specific case of nanomaterials. Many participants are of the opinion that a better market knowledge and traceability of nanomaterials on the EU market is needed.

Regulations to set up a notification system for nanomaterial providers to national authorities are currently in preparation in France, Belgium and Italy.

In France, following the Grenelle Environment Forum 1 and 2, a new law which seeks to impose on any manufacturer, importer or distributor of substances at the nanoscale (on their own or contained in a mixture), or articles with intended release of nanomaterials, to make an annual declaration, was recorded in the Environmental Code on July 12th, 2010.

The conditions for execution of this law have to be specified in a decree[4] in which the term "substance at the nanoscale" is defined, the threshold for declaration is set and provisions for research and development are listed.

The draft decree has already been notified to the European Commission and is about to be officially published early 2012.



The objectives of this mandatory electronic reporting scheme are to:

- collect available information on nanomaterials,
- have a better knowledge of the market,
- have traceability in the user chains,
- acquire this information from 100 g of produced material (while the reporting threshold in REACH is > 1 t). This threshold will allow to cover small businesses,
- acquire market information fast (no delays of several years as for REACH),
-provide easy access in a standard format (IUCLID, suitable for nanomaterials).
- have some specific provisions that do not obstruct research and development activities.

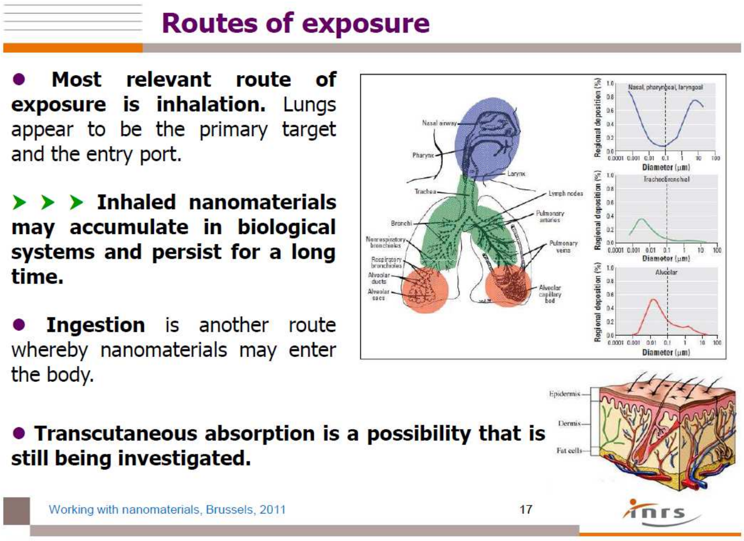
Next to these efforts of individual Member States, Belgium, France and Italy started an initiative to harmonize national databases for nanomaterials on the market. A modular approach is envisaged, with on the one hand core information that all the participating Member States agreed on, and on the other hand additional information that may be asked by some Member States. The format will be compatible with ECHA's IUCLID and with OECD harmonized templates.

[4] The draft decree on the annual reporting nanoparticle substances placed on the market is available at: http://www.developpement-durable.gouv.fr

Exposure analysis

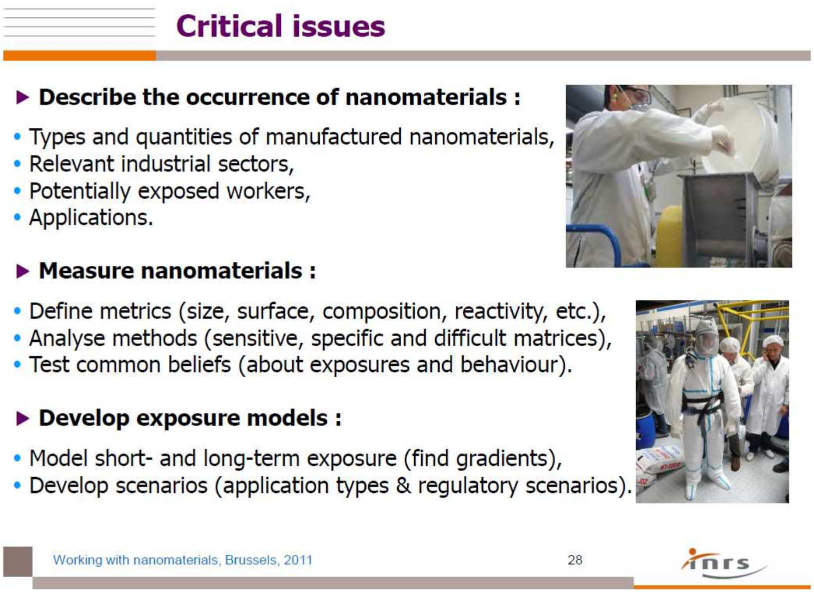
The main route of entry of nanomaterials in the body is through the respiratory system.

While assessing the occupational exposure by inhalation, it is essential to focus on the characterization of materials dispersed in the air, thus in the aerosol phase (referred to as nano-aerosols).



The current approach for assessing occupational exposure to larger-sized aerosols does not seem to be adapted to the case of nano-aerosols. Indeed, in view of the first toxicological data, in addition to the mass and chemical composition of the nanoparticles, two other indicators of exposure should be measured: surface area and number. From a practical point of view, the surface area, number and mass concentration of nano-aerosols should be determined, but if possible also the size distribution, chemical composition, crystalline structure.

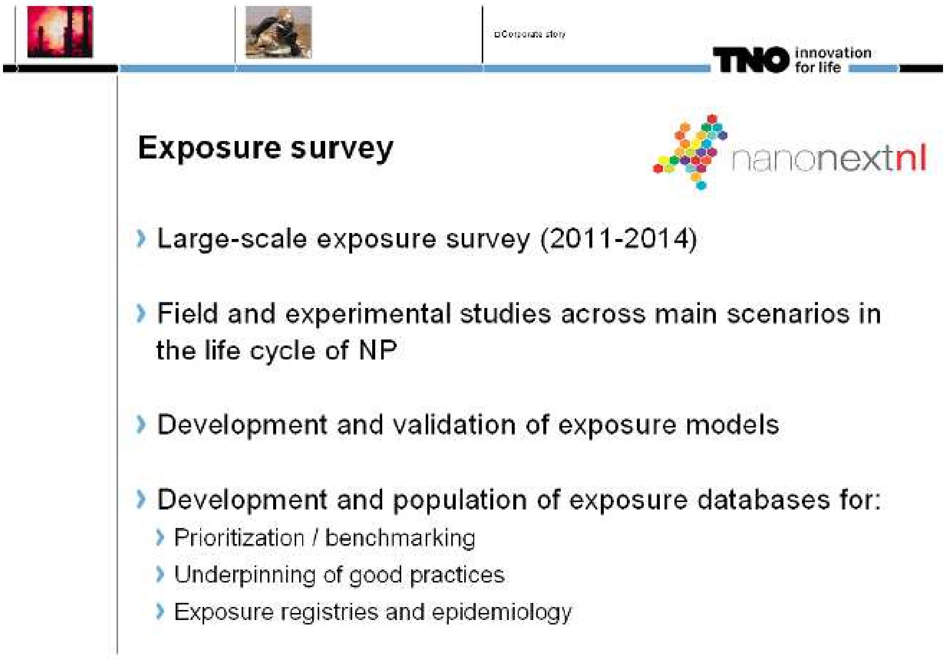
At present, there is no straightforward single analysis method to measure occupational exposure to nanomaterials. However, there are now a number of instruments to characterize nano-aerosols, most of them being relatively complex, bulky and expensive.



A database of portable instruments, easy to use for air analyses of nanomaterials is available: Nanodevice[5].

[5] http://www.nano-device.eu/

In France and The Netherlands, measurement campaigns are underway to model the occupational exposures throughout the life cycle of nanomaterials. The data collected will allow to prioritize prevention efforts, develop good practices and may be used for epidemiological investigations. In the Netherlands, this will be part of a large research project carried out by a consortium of more than 100 companies and research institutions called Nanoextnl,[6] in France the program is called Exponano[7]



[6] http://www.nanonextnl.nl/

[7] http://www.inrs.fr/accueil/recherche/etudes-publications-communications/doc/etude.html?refINRS=B.1%2F2.040

Risk assessment

Given the knowledge gaps that remain concerning the of nanomaterials' health hazards, uses and occupational exposure levels, a quantitative risk assessment is difficult, if not impossible, in most cases.

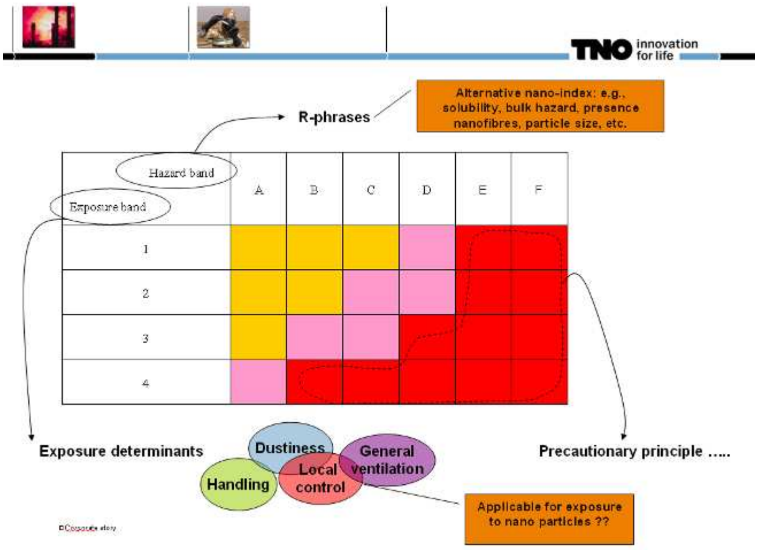
Recently, alternative qualitative or semi-quantitative methods of risk assessment and management are developed such as "Control Banding".

Discussions are also taking place on the desirability of nano-specific occupational exposure limit values.

Control Banding

The "control banding" tool is an instrument incorporating risk assessment and management, originally developed by the International Labour Organisation (ILO)[8].

Based on the information collected on toxicity, a hazard band is assigned to each nanomaterial handled. A band of potential exposure is also determined. By crossing the previously defined hazard band and the exposure band, a risk control band is obtained. The risk control band corresponds to minimum prevention measures to be put in place, consistent with the estimated risk level .

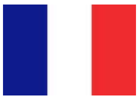


This instrument takes into account existing information, technical and scientific data, and also makes a number of reasonably conservative assumptions, on required but unavailable information, to produce a risk assessment despite incomplete input data. This is an adaptive approach, as the instrument can be refined as new data emerge. Given the need to make assumptions about unavailable information, it is essential that the user has a specific expertise in the areas of chemical safety and nanomaterials.

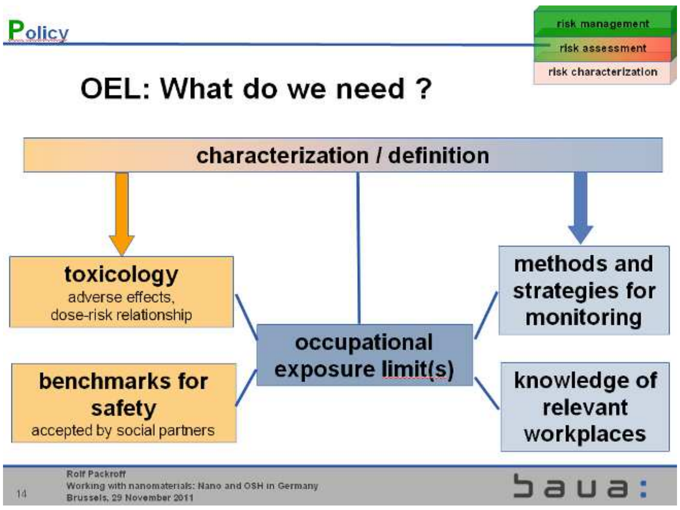
---

[8] http://www.ilo.org/legacy/english/protection/safework/ctrl_banding/index.htm

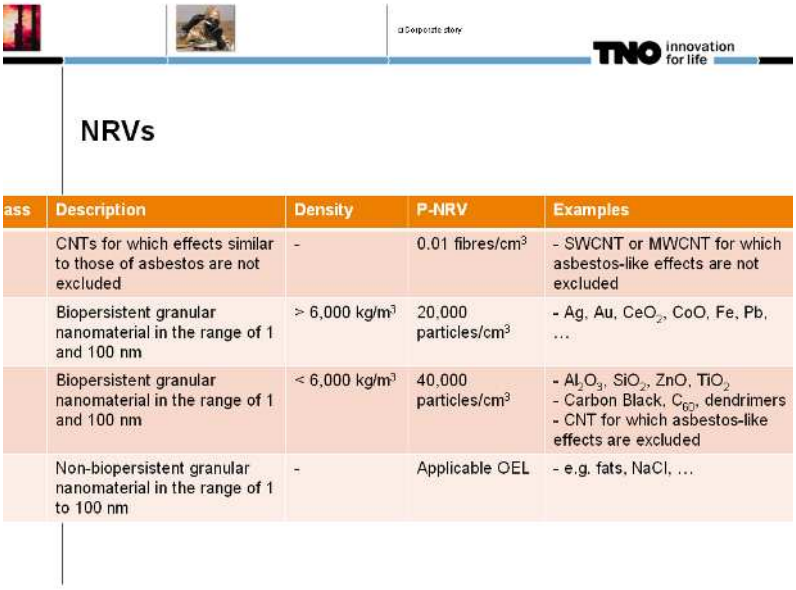
Several countries have developed nano-specific Control Banding instruments. As these methods don't always seem to arrive at the same answers, there is an obvious need for harmonisation. Furthermore, harmonisation of present knowledge and of knowledge that will be acquired in the future will contribute to the improvement of these instruments, leading towards a more and more (semi-) quantitative assessment.

	Precautionary matrix	Web-available spreadsheet www.nanotechnologie.admin.ch
	NanoCB tool (Palk & Zalk 2009)	Table/publisher paper
	ANSES Nano CB tool	(Web-available) Report www.anses.fr
	Stoffenmanager Nano 1.0	Web-based tool www.nano.stoffenmanager.nl/
	Guideline safe handling of nanomaterials	(Web-available) Report www.ivam.uva.nl
	Nanosafer	Web-based tool http://nanosafer.i-bar.dk/

Occupational Exposure Limits



There are no occupational exposure limits (OELs) specific for nanomaterials in the European and international regulations. Although OELs on dust levels are in principle applicable to nanoparticules, discussions are still ongoing in several Member States, as well as outside the EU. NIOSH proposes benchmark exposure limit values (weighted average concentration for a period of 40 working hours per week) of 2.4 mg/m^3 for fine titanium dioxide and of 0.3 mg/m^3 for ultrafine titanium dioxide (particles smaller than 100 nm). For carbon nanotubes, it proposes a value of 7 µg/m^3.



ass	Description	Density	P-NRV	Examples
	CNTs for which effects similar to those of asbestos are not excluded	-	0.01 fibres/cm³	- SWCNT or MWCNT for which asbestos-like effects are not excluded
	Biopersistent granular nanomaterial in the range of 1 and 100 nm	> 6,000 kg/m³	20,000 particles/cm³	- Ag, Au, CeO_2, CoO, Fe, Pb, …
	Biopersistent granular nanomaterial in the range of 1 and 100 nm	< 6,000 kg/m³	40,000 particles/cm³	- Al_2O_3, SiO_2, ZnO, TiO_2 - Carbon Black, C_{60}, dendrimers - CNT for which asbestos-like effects are excluded
	Non-biopersistent granular nanomaterial in the range of 1 to 100 nm	-	Applicable OEL	- e.g. fats, NaCl, …

According to some organisations, the limit values for nanomaterials (as they are nanoparticles) should not be expressed in a mass per volume ratio, but e.g. in a number of particles per volume ratio. Also the use of benchmark limit values is discussed. For example the Dutch RIVM proposed reference values: NRV's (Nano Reference Values)[9] with a provisional character, based on a proposal by the German IFA[10].

All proposed recommended benchmark limit values should only be used temporarily, as long as health based exposure limits are unavailable, and should not be confused with health-based workplace limit values, as they do not offer the same safety. At the moment the social partners in The Netherlands are completing a project in which they tested the practical use of NRV's in companies.

Prevention

Given the many unknowns, it is important to establish in any professional environment where nanomaterials are used (factories, research laboratories, universities ...) throughout the entire product life cycle, specific procedures for risk prevention.

These measures aim to avoid, or at least to minimize, occupational exposures. They are not very different from those recommended for all activities involving exposure to hazardous chemical agents. But they are particularly important for nanomaterials because of their very high capacity to be distributed in the workplace atmosphere.

Nanomaterials being chemicals, the general rules of prevention of chemical risks apply (particularly in terms of substitution, collective protection, training and information of employees, appropriate health surveillance).

Some general prevention measures for working with nanomaterials are:

---

[9] http://www.rivm.nl/bibliotheek/rapporten/601044001.html

[10] http://www.dguv.de/ifa/en/fac/nanopartikel/beurteilungsmassstaebe/index.jsp

- handle them as a liquid suspension or gel rather than as a powder,

- define, indicate, and restrict the work area to only those employees directly involved in their handling,

- optimize the process to obtain a minimal dust concentration: focus on closed systems and automated techniques,

- capture pollutants at the source (laboratory fume hood, glove box, etc.) and filter the air before discharge outside of the workplace (use fiber filters with very high efficiency, class higher than H13)

- wear personal protective respiratory equipment (filter class 3) or isolating, disposable protective clothing against chemical risk (type 5), gloves and goggles,

- regularly and carefully clean floors and work surfaces with a vacuum cleaner equipped with fiber filters with very high efficiency or wet cloths,

- collect and treat waste.

Many guides offer preventive measures to limit exposure to nanomaterials, for example:

The brochure INRS "Nanomaterials. Definition, toxicological hazards, exposure characterization professional and preventive measures "(INRS ED 6050[11], 2009).

"Guidance for Handling and Use of Nanomaterials at the Workplace"[12], 2007, BAuA.

OSH Practical Guideline for handling of nanomaterials in a laboratory scale, ongoing study as part of 7th EU framework program NANOVALID for BAuA research.

INRS will shortly publish a guide specifically dedicated to the prevention of risks in laboratories referenced ED 6115 www.inrs.fr.

"Guidance Working Safely with Nanomaterials and Nanoproducts – guide for employers and employees"[13], by the Dutch Trade Unions FNV and CNV and the Confederation of Netherlands Industry. May 2011.

[11] http://www.inrs.fr/accueil/produits/mediatheque/doc/publications.html?refINRS=ED%206050

[12] http://www.baua.de/nn_49456/en/Topics-from-A-to-Z/Hazardous-Substances/Nanotechnology/pdf/guidance.pdf

[13] http://www.ivam.uva.nl/fileadmin/user_upload/PDF_documenten/Artikelen_en_Publicaties/NANO/Guidance%20on%20how%20to%20work%20safely%20with%20nanoparticles.pdf

Conclusions of the seminar

Nanotechnology has many benefits, but at this moment, in the absence of full data, a precautionary approach is important: a new asbestos scenario ("late lessons from early warnings") should be avoided. For this purpose, several initiatives are already taken in some of the Member States. These concern legislative issues, as well as initiatives on risk management.

There is a clear need for harmonisation of approaches in several fields, and most of the participants[14] are of the opinion that the Commission should take the lead in this:

Research - a lot of work in this field is undertaken and under way by the OECD and the EU Nanosafety Cluster. According to some participants, a safe-by-design approach should be an integral part of product development.

The development and use of (control banding) tools – Different tools are developed, and very welcomed by both employers', workers', and government's representatives, but without a coordinated harmonisation effort these tools will not be convergent and it will stay unclear which tools are good enough for proper risk management.

Legislation - According to most participants, a review of the existing legislation is needed. The employers' representative insisted that we take full account of all regulations already in force (imposing prevention principles, dust exposure control, etc.), and we develop guidance on how to comply with the existing regulations. Although REACH is applicable to nanomaterials, most of the participants agree that it does not seem to be sufficient to guarantee worker health if it is not adapted to the specific characteristics of nanomaterials. The workers' representative noted that ECHA[15] had identified only 3 nanomaterials among the thousands of registration dossiers in its possession by May 2011, and the representative of the French government highlighted that nearly 50% of the companies involved in nanomaterials production fall outside the scope of registration under REACH. Therefore, at this moment OSH regulations are very important as they provide the only safety net. Next to this, improving the implementation of existing legislation is needed.

[14] Viewpoints of participants and stakeholders can be found in the presentations and speeches in the Annex

[15] European CHemicals Agency : http://echa.europa.eu

Traceability (by notification schemes and/or product databases) – The need to get a comprehensive overview on the production and use of nanomaterials is shared by most participants. France already developed its own legal initiative on notification. A Member State initiative of Belgium, France and Italy aims to harmonise approaches on improving traceability. In the opinion of workers' and government's representatives, a mandatory scheme at EU level should serve for the protection of workers, as it will provide essential information to be passed along the supply chain. Furthermore, it will provide a more comprehensive overview on the field.

The way of dealing with exposure limits – Occupational exposure limits of "conventional" (non-nano) substances are not likely to protect the health of the nano-worker sufficiently. Alternatives at the moment are developing ultrafine dust exposure limits, or making use of Nano Reference Values (as are currently tested in the Netherlands).

An opinion shared by all the participants of seminar is that harmonisation in these fields requires coordination on a level higher than that of individual research consortia or Member States. Measures at the European level are preferred, because only in that way workers in the EU are uniformly protected, and a level playing field for companies is guaranteed.

Annex I : Presentations

Opening
by Christian Deneve (Director-General, Belgian Federal Public Service Employment, Labour and Social Dialogue)

On the hazard and exposure assessments of nanomaterials
by Myriam Ricaud (Chemical Engineer, INRS, France)

Managing uncertain risks associated with nanotechnology
by Erik Tielemans (Research Manager Netherlands Organisation for Applied Scientific Research TNO)

Risk assessment and dealing with hazard data gaps, the role of occupational exposure limits and alternatives
by Rolf Packroff (Scientific Manager, Federal Institute for Occupational Safety and Health, BAuA, Dortmund, Germany)

Traceability: the French Decree on the annual declaration of nanoparticle substances
by Luc Maurer (Ministère de l'Écologie, du Développement durable, des Transports et du Logement, France)

Towards a Regulatory Framework for Nanomaterials' Traceability
by Juan Pineros Garcet (Federal Public Service Health, Food Chain Safety and Environment, Belgium)

Viewpoint from Workers' side
by Aida Ponce del Castillo (European Trade Union Institute)

Viewpoint from Employers' side
by Kris de Meester (Business Europe, Chairman of the Health and Safety Working Group)

Viewpoint from the Government side
by Mireille Jarry (Deputy Director, Ministry of Labour, France)

Annex II : Posters

Development of a control banding tool adapted to nanomaterials
by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)

Nanosafety Research Centre
by the Finnish Institute of Occupational Health (FIOH)

Airborne nanoparticle exposures: Sampling strategy issues & example of a field study
by the French Institute for Health and safety at work (INRS)

Working with nanomaterials - Current development in Slovenia
by the Slovenian Ministry of Labour, Family and Social Affairs

Initiatives in the Netherlands : Nano Reference Values, practical tool and nanotechnology actionplan
by the Social Partners in the Dutch Social Economical Council and the Dutch Trade Unions

Sampling of nanoparticles on working places
by the Belgian Federal Public Service Employment, Labour and Social Dialogue

Nano Health and Environment Commented Database (NHECD)
supported by the Joint Research Centre of the European Commission