

# **Nanomaterials and workplace health & safety What are the issues for workers?**

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## Preface

*Nanotechnologies have been variously seen as the great white hope of the 21<sup>st</sup> century economy. It is an agenda made up of the heady brew of research and knowledge, the dread of what human enhancement may hold, the cold language of the moneymen and the belief that a faster use of what the infinitely small has to offer could deliver environmentally-neutral growth.*

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Although invisible to the naked eye, nanomaterials are produced and used in real-life workplaces. The industries concerned are not the stuff of sci-fi, and the unquestionable beauty of the images yielded by electron microscopy reflect nothing of a work organization far removed from the clean-room lab environment. Nanomaterials are found in industries where risks abound, preventive measures are often disregarded and workers have little control over their working conditions.

This is largely glossed over by the scientific literature and public debate. There is nothing new there. In the late 19<sup>th</sup> century, asbestos was described as the “magic fibre” for being a cheap raw material in plentiful supply and adaptable to many uses. Even early warning signals of a looming health disaster failed to stem its unhindered massive spread throughout the first three quarters of the 20th century. An indiscriminate use that would cause millions of preventable deaths.

So that nanotechnologies do not become “the new asbestos”, the European Trade Union Institute has been putting out information on them over the years. This booklet on the working conditions involved in the production and use of nanomaterials is a new addition. There is no scaremongering here, but the sobering observation that nanomaterials are coming onto the market in a widening range of uses at a dizzying pace, but the impact on society is going largely undiscussed.

Occupational health is a specific aspect of that impact. The current data are scant and very patchy. The research that is sounding alarm bells about the toxicity of some nanomaterials should be prompting all stakeholders to implement the precautionary principle without more ado.

Current EU law does not address the specific properties of nanomaterials. Workers’ and consumers’ health will go unprotected unless EU law is adapted to

take into account the specific requirements of these new risk factors. And that means production and marketing rules as much as the Directives on the protection of workers' health.

This book sets out to do three things: give a better understanding of how nanomaterials impact on workers' health; identify improvements needed to the legislative framework; and suggest practical ways for trade unions and occupational health professionals to ensure better prevention right now and implement the necessary health surveillance for exposed workers.

— *Laurent Vogel*  
ETUI

## Part 1

# Why does it matter to workers?

When we talk about “nanotechnologies”, we are really talking about diverse technology platforms applied across many sectors and industries. Nanotechnology is all about manipulating matter at nanometric levels – a nanometre is one billionth part of a metre – enabling materials and structures to be created with properties very different from larger structures with the same composition. Working with such materials on a scale smaller than the human eye can see brings hazards and risks that may not be fully identified and yet there is no consensus on techniques for measuring nanoparticles in the workplace. But health and safety programmes need to be fully developed and implemented.

The market in products incorporating nanotechnologies stood at 200 billion dollars worldwide in 2008 and is constantly expanding as more products and more nano-enabled technologies come onto it – applications promising to help improve access to water, medicine, energy efficiency, and more. All in all, nanotechnology promises huge life-enhancing potential, but it would be a tragedy were the health of workers, who are in the front line, to pay the price for it.

Nanotechnology is a big issue for the European labour market because of its cross-sectoral penetration of traditional and emerging industries. The “nanotech revolution” is driving the emergence of new businesses, spin-off companies and small and medium-sized firms, and impacting on working conditions. Workers have been dealing with nanomaterials in sectors like construction, chemicals, electronics, car making, energy, etc. as they work with new materials, applications, machinery, industrial processes and products. Products are being brought to market with too little scrutiny by the authorities who therefore have little idea of what is being marketed.

Working with nanotechnologies brings unknowns for health and safety into the workplace, so extreme precaution is required in working conditions. The effects

on human health and the environment could be disastrous – think only of asbestos and other ultrafine particles in the past. Recent surveys (Conti 2008, INRS 2010b, Engeman 2012) in the United States and France reveal that companies are unsure about how best to go about protecting health and safety or what to do in case of contamination. Worryingly, they report that the number of workers potentially exposed to nanoparticles is not known.

If companies are having difficulties getting to grips with health and safety and their programmes do not include specific practices, workers are at even greater risk. Employees have no idea whether they are handling nanomaterials or what if any risks may be involved, and even highly qualified laboratory staff may be uncertain about how safe materials are to handle.

This publication aims to raise awareness among all those involved with nanotechnology at any stage of manufacture and production, right up to waste disposal. It tries to bring answers to key questions such as: What are nanomaterials? Where can they be found? How can workers be exposed? What is the essential information they need to know? How important is health surveillance? It also looks at some regulatory action taken by the European Union to provide a framework to the debate.

## Nanomaterials

The key characteristic of a nanomaterial is that it presents properties that would not be found in the same materials at its normal scale. The International Organization for Standardization (ISO) defines a nanomaterial as a material with any external dimension in the nanoscale or having internal or surface structure in the nanoscale. The nanoscale is the size range from approximately 1 to 100nm, where an nm (nanometre) is a billionth of a metre, or in scientific terms, about  $10$  to the power of  $-9$ .

The ISO classifies nanomaterials into 2 categories: nano-objects and nano-structured materials. Nano-objects are materials with any external dimension in the nanoscale. A nano-structured material is a material with internal or surface structure in the nanoscale. Nano-objects are nanoparticles, which have 3 external dimensions at the nanoscale; nano-fibres with 2 external dimensions at the nanoscale and nanoplates with only one external dimension at the nanoscale.

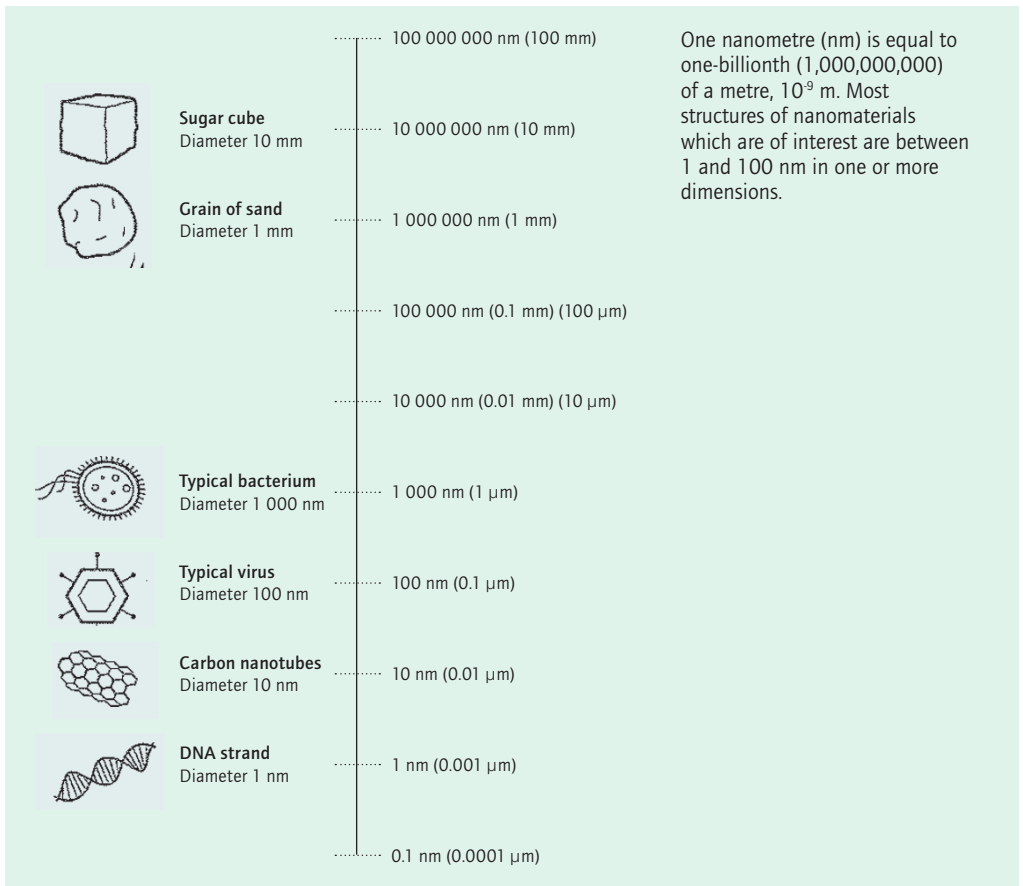
The problem with a technical definition is that it cannot be applied to all regulations that deal with nanotechnology. This is why the debate on a regulatory definition of what constitutes a “nanomaterial” has been exercising the minds of scientists, manufacturers, policy makers, Member States and different stakeholders in Europe since 2009.

A crucial part of the process was to have a science-based definition that could be accommodated within the legal system. Where nanotechnology is concerned, reliance on the current scientific data would have been on shifting sands because the science is not yet settled; knowledge is constantly emerging in those areas of nanotechnology that are yet uncharted territory. A regulatory definition cannot just be science-based because other factors are also in play; ethical, political and societal aspects have to be factored in to facilitate governance.

After a series of debates, analyses of scientific opinions submitted by the European Commission’s Joint Research Center (JRC) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the European Commission put a draft definition out to public consultation in late 2010. With the scientific opinions and consultation outcomes, the Commission was finally able to issue a recommendation on 18 October 2011 on an EU definition of the term “nanomaterial” to be applied by the European agencies, the Member States and companies operating in the EU.



**Figure 1 The nanoscale**



Source: *Novel Materials in the Environment: The case of Nanotechnology*, Royal Commission on Environmental Pollution, November 2008

The Commission's development of a benchmark definition for EU policy was mainly prompted by the European Parliament's call in its Resolution of 24 April 2009, coupled with the inclusion of specific provisions on nanomaterials in different pieces of legislation, like the requirements in the EU Regulation on cosmetic products (EC No. 1223/2009), and the fact that other non-identical definitions of nanomaterials were to be found.

The EC Recommendation on the definition has no regulatory impact "as is". To have any legislative effect it must be properly implemented in the relevant regulations. So far, it is already referenced in the EU Biocides and Ecolabel Directives. When used in biocides, nanomaterials will need a separate assessment; products containing nanomaterials will have to be clearly labelled, along with the specific risks of making available on the market.

The core terms of the definition are laid down in three different paragraphs. The first paragraph – the most technical part – refers to size rather than mass, reflecting assumptions about the risk of small particles. The definition specifies that the size rather than the mass of a particle is what determines what a nanomaterial is. According to the definition, a nanomaterial is "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 dimensions is in the size range 1 nm - 100 nm.”

It is the particle itself that is important: it may be unbound, aggregates or agglomerates, but 50% or more of the particles must be in the size distribution between 1 and 100 nm for the primary article to meet the definition. The 50% value was chosen over the 1% recommended by the SCENIHR scientists because a lower value would have brought too many materials within the scope of the definition. The definition does not mean that all nanomaterials will be subject to the specific requirements – incidental nanoparticles<sup>1</sup>, like those in volcano ashes or produced during milk homogenization, will escape it. And it does not supporting definitions of other term like “particles”, “agglomerates” and “aggregates”.

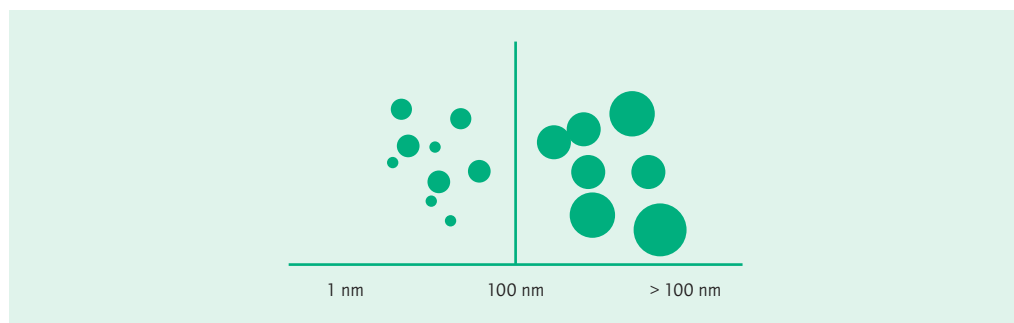
The second part of the recommendation is an exception that allows for a lower percentage. It says that where there are specific environmental, health, safety or competitiveness concerns, paragraph 1 may not apply and the number size can be between 1 and 50 percent.

The third and final part specifically says that fullerenes, graphene flakes and single wall carbon nanotubes are considered as nanomaterials, whether or not they are unbound or agglomerates.

The Commission set out to create a uniform definition, but the substantive debate was challenging in that different exposure risks had to be taken into account. Now that the definition has been published, the task ahead will be to update the accompanying Questions and Answers document.

Assuming that the Commission’s definition will be reviewed in 2014, care must be taken in using the Recommendation and appropriate guidance needs developing for its full implementation in REACH and other regulations. Even though REACH – the comprehensive regulation on chemical substances – was not designed to cover nanomaterials, the European Commission says that in principle it also applies to nanomaterials, notwithstanding that some gaps are currently under discussion, like the threshold for registration of chemical substances manufactured or imported in quantities less than 1 tonne per year, to which REACH does not apply.

**Figure 2 Counting nanoparticles**



Source: Author

1. “Incidental” nanoparticles are created during processes such as combustion and food milling, churning, freezing, and homogenization. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3060016/>

## Nanoproducts and applications in the market

Materials at the nanoscale present completely different properties to those at the macro-scale. This will undoubtedly put them at the centre of the next industrial revolution. Incidental nanomaterials exist in nature – sea breeze and volcanic ash are just two of many. This chapter will look at nanomaterials that are manufactured – generally in dry and soluble forms – to have specific properties or a specific composition for commercial purposes.

**Table 1 Selection of global market forecast for nanotech- products, billion USD**

	2005	2007	2008	2010	2011	2012	2014	2015
LuxResearch (2006, 2008)	30	147					2 600	3 100
Business Communication Company (2008)		12	13		27			
Cientifica (2008)			167			263		1 500
RNCOS Industry Research Solutions (2006)				1 000				
Wintergreen Research (2004)								750
Evolution Capital (2001)	105			700				
National Science Foundation (2001)	54							1 000

Source: Modified from Palmberg 2009

A 2010 report from the Organization for Economic Co-operation and Development (Palmberg 2009) details the investment trends and potential economic impacts of nanotechnologies. Its forecasts look at the full range of products along the value chain that are believed to be affected by nanotechnology. It foresees a host of products and applications, some possibly replacing or enhancing existing products, others completely new. The OECD suggests that even though these forecasts should be treated with caution, it is clear that nanotechnology is likely to have a big economic impact in the long term.

Too little can be found out about nanomaterial-containing products on the market; all that is available are figures from databases yielded by internet searches. According to a variety of internet databases like the Project on Emerging Technologies (PEN, [www.nanotechproject.org/](http://www.nanotechproject.org/)) or Nanowerk ([www.nanowerk.com](http://www.nanowerk.com)), nanotechnology-based products can be found in a wide range of sectors like the car making industry, space and aviation; electronics and communications, chemicals and novel materials; pharmaceuticals and medicine; cosmetics and healthcare and in energy technologies. The EU is investing 488 million euros in nanotechnology, concentrated in areas like factories of the future, green cars and energy-efficient buildings<sup>2</sup>.

Where the safety of these products is concerned, the European Parliament's 2009 Resolution claimed that there was a lack of information about the safety of nanomaterials already on the market. To get a better picture, Parliament asked the Commission to develop a public inventory of the different types and uses of nanomaterials on the market, respecting justified commercial secrets. While the discussions on the EU-wide inventory have been slow moving and the enforcement process can take years – while the products are being freely marketed internationally – some governments are pre-empting the European Commission by looking into the scope for developing national schemes for companies to report the use of nanomaterials in their products that would help authorities for better traceability. Moves towards developing such a national registry and making it compulsory are currently

2. *Funding boost of EUR 7 billion for Innovation Union.* European Commission, COMMUNITY RESEARCH AND DEVELOPMENT INFORMATION SERVICE (CORDIS). See <http://cordis.europa.eu/>

being taken by an informal coalition coordinated by the competent national authorities in Belgium, France, Italy, the Netherlands and Denmark.

France has taken the lead in Europe on tracing nanomaterials and nano-products by introducing regulations making it mandatory for manufacturers, national importers and distributors of nanomaterials in France to make an annual declaration of substances “with nanoparticle status”. Declarants must give information on the identity of the substance, quantities, uses and the identity of professional users.

However, in October 2012 the European Commission published its Communication on the Second Regulatory Review on Nanomaterials accompanied by a Commission Staff Working Paper on the types and uses of nanomaterials, including safety aspects. In this, the Commission argues that the currently available information generated by existing legislative tools like REACH constitute a good basis, so dismissing the idea of an EU-wide inventory called for by Member States.

### National initiatives on nano-registries in Europe

#### Nano-registry for a green transition in Denmark

An agreement between the Danish government and the Red-Green Alliance (*Enhedslisten*) to strengthen efforts on nanomaterials resulted in September 2012 in the publication of a draft amendment to the Danish Chemicals Act to create a national mandatory database of nanomaterial-containing products. The rules would require producers and importers to report to the government products or mixtures that contain or release nanomaterials.

The Danish Environmental Protection Agency will develop the database. The information collected will be used to assess whether the nanomaterial content of products on the Danish market poses a risk for consumers and the environment. The next step would be the enactment of a Ministerial Order containing the detailed rules, expected in 2013. The Ministry expects the first product reports to be available in early 2014.

#### Germany may have a statutory register of nano-products

Working to the precautionary principle of preventing hazards to the environment and to human health including in the workplace, German public authorities aim to authorize a product register covering as many as possible of the nanomaterials produced or placed on the market in Germany. The information gathered should help authorities to identify the manufacturers, producers, importers or distributors of the product.

They would have to report:

- The first manufacture, import or placing on the market of nanomaterials alone or in a mixture; and
- The first manufacture, placing on the market or import of semi-finished and finished products containing nanomaterials.

This would make it easier to keep track of the production, use and disposal of registered nanomaterials and products, and would also be helpful in estimating and assessing the potential contamination pathways for the environment and workers.

The OECD’s Working Party on Manufactured Nanomaterials (WPMN) is conducting the Sponsorship Programme on the testing of key manufactured nanomaterials to understand their intrinsic properties, toxicity and eco-toxicity that may be relevant for exposure and effects assessments. While this exercise may not produce conclusive results, it could serve as a baseline for more specific research on other nanomaterials and their characteristics and possible toxicity.

Nanomaterials that pose certain risks for manufacturing and production workers include carbon nanotubes, silicon dioxide, titanium dioxide and carbon black, and these will be part of the Commission’s inventory to be delivered in 2012.

**Table 2 Nano-products and applications by sector**

Automotive Space	<ul style="list-style-type: none"> <li>– Painting and coatings for cars and aeroplanes; reinforced car parts, fuel additives, batteries, durable and recyclable tyres</li> <li>– Radiation-tolerant electronics</li> <li>– Integrated nanosensor systems</li> <li>– Optical sensors</li> </ul>
Biomedicine, pharmaceuticals	<ul style="list-style-type: none"> <li>– Nanomaterials for drug delivery; remote laser light-induced opening of microcapsules</li> <li>– Coating of hospital textiles, masks, surgical gowns, catheters; wound dressings; molecular imaging</li> <li>– Additive in polymerizable dental materials, additive in bone cement; SiO<sub>2</sub> nano-composite resin filler. Coating of implant for joint replacement</li> </ul>
Chemistry and materials	<ul style="list-style-type: none"> <li>– Pigments, self-cleaning anti-scratch coatings, ceramic powders, corrosion inhibitors, anti-bacterial surfaces and textiles, thermal insulation, inks</li> </ul>
Cosmetics and Personal care	<ul style="list-style-type: none"> <li>– Sunscreens; facial moisturizers; toothpastes, lipsticks, acne treatments, baby care products</li> <li>– Shampoo, conditioner, hair driers, hair irons</li> </ul>
Defence	<ul style="list-style-type: none"> <li>– Battle suits for soldiers; health surveillance system and health healing</li> </ul>
Electronic and communications	<ul style="list-style-type: none"> <li>– Molecular electronics and photonics</li> <li>– Computer hardware, memories and information high density storage, multifunctional catalysts, micro-chips, sensors, flat screens, carbon nanotube transistors, light-weight display panels, corrosion inhibitors</li> <li>– Nanorobots, automatic operations at the nanoscale</li> <li>– Nanotube-based transparent conductive film for e-paper</li> </ul>
Energy	<ul style="list-style-type: none"> <li>– Photovoltaic cells, batteries, insulating materials</li> <li>– Storage of hydrogen in graphene</li> </ul>
Environment	<ul style="list-style-type: none"> <li>– Climate modelling</li> <li>– Pesticides and fertilizers</li> <li>– Water treatment and filters</li> <li>– Catalysts for better air quality</li> </ul>
Food	<ul style="list-style-type: none"> <li>– Plastic packaging to block UV rays and provide anti-bacterial protection</li> <li>– Bottles, cartons and films containing clay nanocomposite that act as a barrier to the passage of gasses or odours</li> <li>– Nanosensors are being developed that can detect bacteria and other contaminants like salmonella at a packaging plant</li> </ul>
Sports	<ul style="list-style-type: none"> <li>– Sports textiles</li> <li>– Coating for boats and kayaks</li> <li>– Fishing rods made with epoxy resin</li> <li>– Tennis rackets, golf clubs, baseball bats, ski equipment, bicycle frames and components</li> </ul>

Source: Author

## Common examples of nanomaterials at the workplace

### Silicon dioxide, SiO<sub>2</sub>

Nanomaterials like silicon dioxide or 'silica' are produced in high volumes and are extensively used in a variety of applications and products. Silica in bulk form has been widely used as a food additive for many years to clarify beverages, control viscosity and as an anti-foaming agent and dough modifier.

Silica can be also found in the nano form in some food products as an anti-caking agent (to prevent the formation of lumps), in the construction industry in high-performance concrete mixtures to increase concrete cohesion and reduce the tendency to particle segregation; and in paints and coatings. Nanosilica is being developed for biomedical applications such as cancer therapy, and drug delivery and in health care products.

Hydrophobic surfaces incorporating nano-silica. In nature, water is repelled by the rough surface of lotus leaves. The Lotus-effect™ has been patented by German scientist Dr Wilhelm Barthlott and refers to the idea of constructing surfaces with microscopic raised areas to make them self-cleaning; as a result, dirt and liquids cannot get into the surface and are repelled. Paints and coatings can incorporate silica particles making surfaces self-clean, anti-dirt, anti-graffiti or anti-fingerprint, with high durability. The same water-repellent, stay-clean property can be found in textiles, where fibres treated with the coating work in the same way to repel wet and dirt from the fabric.

## Nano-silver

Different silver compounds are known to have been used for many years: colloidal silver, for example, has been widely used for medicinal and hygienic purposes to treat bacterial infections (Nowack 2011).

Silver in the nano form is being manufactured and used in different products and applications to enhance efficiency. Nano-silver inhibits multiplication and growth of bacteria and fungi which cause infection, odour, itchiness and sores, and therefore has been used as an antibacterial, antifungal, anti-viral and anti-inflammatory agent. But it presents different toxicity to its bulk counterpart.

Nano-silver is currently found in different products: as a lining in plastic food containers, in underwear, sportswear or socks to kill bacteria, in toothbrushes, surface cleaners, lotions, toys; household appliances like dishwashers, vacuum cleaners and refrigerators. In electronics, nano-silver is mainly used in solder for circuit connections, while silver nano-wires are used as nanoconnectors and nanoelectrodes for nanoelectronic devices. It also has medical uses in wound dressings, medical textiles and sterilization materials. Also, at the nanoscale, silver has unique optical and physical properties of potential value in medical diagnostics, drug delivery and imaging.

Industry advocates in the United States argue that nanoscale silver has been widely used in the market for at least 12 decades as colloidal nano-silver algacides and composite materials. However silver formulations can vary in the size, solubility and aggregation of nanoparticles, meaning that there is no one single form of nano-silver (Wijnhoven 2009).

As far as human exposure goes, a Danish report (Hagen Mikkelsen 2011) has found no quantitative data on occupational and consumer dermal exposure. The report believes that consumers especially may be exposed to nano-silver due to its relatively widespread use in clothes, and exposure is also suspected to be highest in the working environment. The main exposure routes for occupational settings are inhalation and skin contact, but further data on exposure and human toxicity are needed. As regards the environment, there is scientific evidence that nano-silver is toxic to aquatic and terrestrial organisms (Wijnhoven 2009, EPA 2010). Certainly, more research is needed on the bonds between nano-silver and the product it is incorporated in, and whether changes occur in the chemical properties.

Nano-silver has latterly come under scrutiny from regulators, with the United States Environmental Protection Agency (EPA) deciding to look closely into it. In October 2011, the EPA published a notice that it was conditionally registering a pesticide product containing nano-silver as a new active ingredient. The product is used as a preservative for textiles. As a condition of registration, EPA is requiring additional data on the product that confirms that it will not cause unreasonable adverse effects on human health or the environment (EPA 2011).

In December 2011, the European Commission asked the SCENIHR<sup>3</sup> to prepare a scientific opinion for 2013 assessing whether the use of nano-silver, in particular in medical care and in consumer products, could result in additional risks compared to more traditional uses of silver, and to assess whether the use of nano-silver to control bacterial growth could result in resistance of micro-organisms.

## Multiwalled carbon nanotubes

Carbon nanotubes are a new form of carbon where nanotechnology development has brought a ferment of fabrication and commercialization activity since 1991. There are different types of nanotubes: single-walled (SWNTs) double-walled (DWCNTs) and multiwalled (MWNTs), differing in the arrangement of their graphene cylinders. SWNTs have only a single layer of graphene cylinders; DWCNTs have two layers, and MWNTs have many layers (Sinha and Yeow 2005). The ISO defines multiwalled carbon nanotubes (MWCNTs) as carbon nanotubes composed of nested, concentric or near-concentric graphene sheets with interlayer distances similar to those of graphite.

Their nano size, structure and topology give them unique mechanical properties like high stability, strength and stiffness, as well as special surface properties. In sum, they are stronger than steel but very light, offering much scope for practical applications, including the fabrication of reinforced fibres and nanocomposites, diverse uses for energy storage, spacecraft structures, and land and sea vehicles. They are also used in sports articles like tennis rackets, baseball bats, bicycle frames, skis and surfboards.

Some types of MWCNT present great mechanical strength and heat-dissipation properties, conducting electricity much better than copper, and so are finding extensive applications in the electronics and computer industries. In the biomedical sector they have applications in radiotherapy, for sensors, as carriers for drug delivery and for implantable nanosensors and nanorobots.

Probably the most on-trend and most marketed nanotechnology products are the MWCNTs. These are long, straight, multi-walled structures and regarded as “the most perfect fibre that has ever been fabricated” (Ajayan and Zhou 2001). Nevertheless, they have also shown adverse effects in animals, causing inflammation when deposited in the lungs and inducing asbestos-like effects. Scientists have, for example, reported that laboratory rodents when exposed to MWCNT develop mesothelioma (Poland 2008, Sakamoto 2009, Tagaki 2008).

According to Ken Donaldson, a toxicologist at the University of Edinburgh specialized in workplace health, long fibres compared to short fibres have greater potency of pro-inflammatory and genotoxicity activity (Schinwald 2012). Since CNTs have specific properties related to strength and durability, they can be translated into biopersistence in the human body. The retention of long fibres in the parietal pleura initiates inflammation. Since fibres cannot be removed from the lung, the lesion aggravates and may give rise to mesothelioma.

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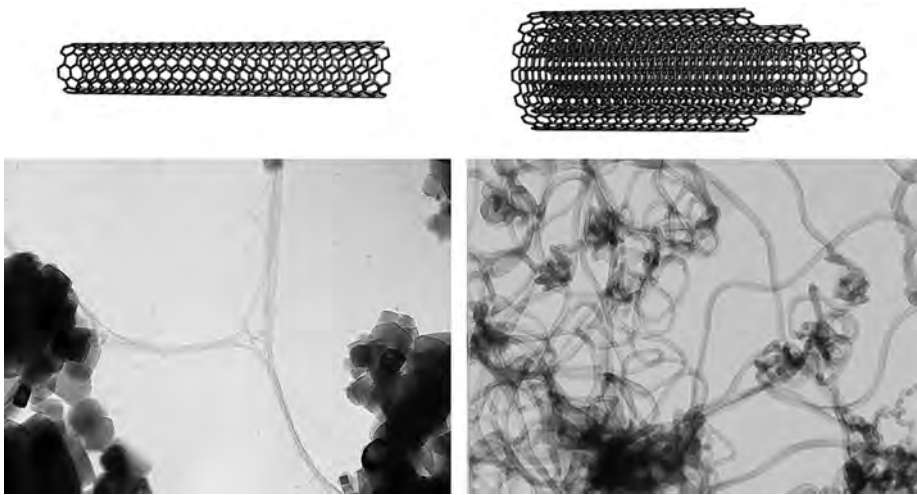
3. *Request for a scientific opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance*, Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). [http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_q\\_027.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_027.pdf)

MWCNTs may be pathogenic because they are (Donaldson 2006):

- Thin enough to get past the upper airways and into the areas of the lungs where oxygen diffuses into the bloodstream;
- Long enough to start harming the lungs because they break down natural defences found in the lungs;
- Durable in that they stick around for a long time without dissolving or being broken down by the body (biopersistence).

Those characteristics – length, diameter, biopersistence - are known as the fibre paradigm.

**Figure 3 Single-Walled and Multi-Walled Carbon Nanotubes**



Sources: Petrica Cristea 2013, Donaldson 2006

MWCNT can be fabricated by different methods and processing conditions, so special care must be taken at the workplace. The US National Institute of Occupational Health and Safety has determined that workers may be at risk of developing adverse respiratory health effects if exposed for a working lifetime at upper limits according to their own methods for measurement of airborne CNTs (NIOSH 2010).

Workers' safety and protection must have top priority when dealing with this material. It is crucial for workers to be given sufficient enough information on the main processes they might possibly be exposed to (synthesis, collection, handling, purification and packing). While there is yet no scientific consensus on the dose and time needed to cause adverse health effects, workers should not be exposed to airborne MWCNT in any circumstances.

## Routes of human exposure to nanoparticles

Particles in the nano form have various shapes – spheres, fibres, tubes, rings and planes – and are very small and highly active. These are key parameters in determining biological impacts. Nanoparticles may enter the human body by inhalation, through the skin, by injection or ingestion. Inhalation is the main route of exposure to nanoparticles. Once inhaled, a substantial proportion of nanoparticles are likely to deposit uniformly in the respiratory tract; the smaller the particles, the further down the respiratory tract they go. They can be



deposited in the nasopharyngeal compartment, in the tracheobronchial region and further in the alveolar region (or air sac), and may persist for a long time in the human body.

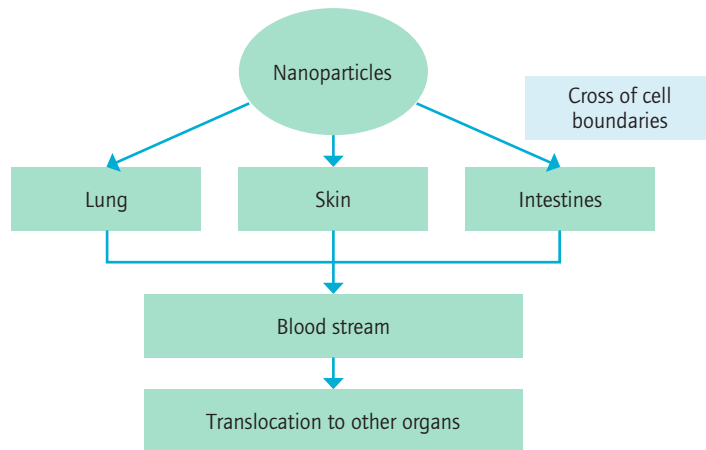
Once in the body, nanoparticles can be translocated elsewhere by different routes. Because shape and size play an important role, they may enter the blood stream, and can be distributed throughout other organs. For example, close contact between the alveoli and the circulatory system means that nanoparticles can displace easily to other organs, like the liver, kidney, heart or spleen. Scientific evidence demonstrates that nanoparticles can also travel to the nervous system via the olfactory nerves and they may reach deeper brain structures affecting cardiac and nervous system functions (Oberdörster 2004, 2005).

When particles enter inside cells they may interfere with normal functions, and may trigger inflammatory or immunological responses. This is an extremely important discovery to have made and occupational toxicologists are now beginning to understand the physicochemical nature of inhaled particles and its potential to show unrecognized biological effects (Maynard 2010).

Ingestion is the second main route of exposure. Nanoparticles can enter the digestive tract through the mouth (including by hand to mouth). Swallowed particles can move through the digestive tract and intestines, and enter the bloodstream.

A third possible route of exposure is absorption through the skin; the scientific literature is still divided on this, so materials should be handled to avoid skin contact. In a workplace setting, dermal exposure can come about through handling nanomaterials and contact with contaminated surfaces. Transdermal exposure may also occur where biomedical applications for diagnostic and therapeutic purposes require intravenous, subcutaneous, or intramuscular administration (Oberdörster 2005).

**Figure 4** Movement of nanoparticles in the human body



Source: Author



## Part 2

# Working with nanoparticles

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### How can workers identify nanomaterials?

The European Framework Directive on the safety and health of workers at work (89/391/EC, the so-called 1989 Framework Directive) is the legal framework for protecting workers at the workplace. Although it contains no specific provisions on nanomaterials, it does specify that the responsibility for workers' safety and health lies on the employer. Generally, occupational health and safety has to be continuously improved and it is a worker's right to be involved in it.

On 3 October 2012 the European Commission issued its Second Regulatory Review on Nanomaterials to assess the implementation of EU legislation for nanomaterials and respond to issues raised by the European Parliament, the Council and the European Economic and Social Committee. The Communication touches on some occupational health and safety aspects but fails to propose a consistent strategy for guaranteeing the protection of workers handling or in contact with nanomaterials. A final assessment on a review of occupational health and safety legislation will be made by the European Commission by 2014.

At present, nanomaterials and nanoproducts cannot be easily identified as there is no obligation to label them, despite the "no data, no market" principle that underpins the REACH Regulation. The European Commission is discussing the classification, labelling and packaging of chemicals and nanomaterials under the REACH and CLP (1272/2008/EC) regulations which set the general framework to see how they might apply to nanomaterials.

A European Parliament Resolution has called for consumer products to be labelled, and the nano-label was recently introduced in the Cosmetics Regulation (1223/2009/EC) published in the Official Journal of the European Union on

22 December 2009, and in the new EU Regulation on the provision of food information to consumers (1169/2011) published in the Official Journal of the European Union on 25 October 2011. Both regulations state that product ingredients in the form of nanomaterials must be indicated in the list of ingredients followed by the word “nano” in brackets.

The situation becomes even more complex when it comes to the workplace. Nanotechnology workplaces may be either big or multinational companies, spin-off businesses from academia or any number of small and medium-sized companies, including retailers, where there is a flow of raw materials, unfinished products and end products in all directions. This mixed bag of situations makes it hard to identify which and how many jobs are nano-related and their working conditions, and so information does not flow easily along the value chain. Just as manufacturers and processors need to know what they are working with, retailers need to know what they are selling and workers need to know what they are handling.

## **What activities involve working with nanomaterials?**

Occupational exposure to nanoparticles can occur in laboratories where nanomaterials are being produced and handled, and at workplaces where nanomaterials or nanoproducts are being produced, manufactured or processed.

Workers are mainly exposed to nanoparticles in production processes at different stages – filling, sampling, cleaning and maintenance work – or in disruptions of normal operations. Where activities involve liquid media (e.g., precipitation reactions, dispersion in the liquid phase), ingestion by inhalation is usually precluded by avoiding aerosol formation.

The *Guidance on Safe Handling of Nanomaterials and Nanoproduct* published by the Dutch Trade Union Confederation FNV (FNV 2010) recommends assessing the life cycle starting at the moment the materials or products enter the company and ending when those materials or products leave the company again as “ready-for-use product” or waste material. If those materials are modified or incorporated into another product, workers will also be exposed when handling, transporting, disposing of and recycling them.

Activities at the workplace that may involve exposure to nanoparticles may include:

- Laboratory handling of nanopowders;
- Transfer, sampling and incorporation (into a mineral or organic matrix of nanopowders);
- Working in liquid media;
- Product recovery from reactors or filters;
- Direct leakage from reactors;
- Cleaning and maintenance of equipment or rooms (including reactor evacuation and filters);
- Processing and packaging of dry powder;
- Welding processes;
- Painting and sanding;
- Collection, transport and disposal of waste.

The hierarchy of exposure controls – elimination, substitution, engineering controls, work practice/administrative procedures, and personal protective equipment – should be followed.

Exposure to nanoparticles should be prevented, preferably by keeping the number of potentially exposed workers as low as possible. Furthermore, hazardous substances should be also avoided, but if that is not feasible, substances or processes should be substituted.

## What type of health and safety information do workers need to know?

Workers who are working with nanomaterials have to be fully involved and properly trained. The 1989 Framework Directive makes appropriate training for workers part of the employer's obligations on information and training, and these should apply to nanotechnology. Employers must ensure that each worker receives adequate and periodically-repeated health and safety information and training, and instructions specific to his job. The European Parliament has also emphasized these obligations in its Resolution mentioned earlier.

Employees need to know what is necessary for their protection at all stages of manufacturing to the end of the production process. Through this document, workers can find out what type of information should be provided to them, and the key issues involved in working with nanomaterials.

Even though the REACH Regulation does not specifically cover nanomaterials, it interacts closely with Framework Directive 89/391/EEC and Chemicals Agent Directive 98/24/EC to protect workers' health and safety.

REACH aims for transparency of information. If applied to nanomaterials, this can effectively help to protect workers where there is insufficient scientific information available on the possible hazards of nanomaterials by generating specific information. Nevertheless, the existing rules need to be further developed to specifically address the potential risks from nanomaterials.

### REACH limitations for nanomaterials

- REACH does not define nanomaterials, nor are there any substance identity rules for nanomaterials under it.
- Nanomaterials cannot be properly distinguished as phase-in (already on the market) or non-phase-in (new) substances.
- There are no tonnage thresholds for substances within the scope of the EC definition of "nanomaterial"; REACH registration requirements apply only for production volumes of one tonne or more per year per manufacturer or importer.
- There is no requirement for registration dossiers for nanomaterials to include a Chemical Safety Assessment.
- Current test guidelines are not specific to nanomaterials. There is a need to adapt them and the risk assessment procedures that apply to nanomaterials.

Source: Center for International Environmental Law (CIEL 2011)

## Information on nanomaterials

Safety Data Sheets (SDS) are key documents that enable workers to handle substances safely at the workplace and be informed of hazards that might be present. They are tools for communicating comprehensive safety information down the supply chain of substances and mixtures. SDS were introduced by Directive 91/55, replaced by REACH's Annex II and the adapted classification criteria and labelling rules of the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Safety Data Sheets tend to consist of large amounts of technical information and are rarely used by non-experts because of their complexity. SDS for nanomaterials should contain concrete, usable information. The employer has a duty to make them comprehensible, keep them up to date and instruct workers in their content from the beginning of the manufacturing process. The information in the SDS enables the employer to develop programmes of worker protection measures, including training, and to consider any measures that may be necessary to protect the environment.

The Australian health and safety agency did a review to get a snapshot of SDS and labels available for nanomaterials. Its report concluded that overall, only 18% of SDS provide a description adequate and sufficient to support an occupational risk assessment. But most SDS do not provide nano-specific descriptions and data (Safe Work Australia 2010). This conclusion chimes with the findings of other reports done by the US National Institute for Occupational Safety and Health (NIOSH) and the Nordic Council of Ministries<sup>4</sup>.

It is clear, then, that the traditional data sources – SDS – are unlikely to provide information on nanomaterials. The answer would therefore be to provide guidance on appropriate statements for use on SDS in the absence of data, and specific recommendations for control measures – particularly engineering controls and personal protective equipment – for nano-sized particulates.

SDS should contain information on the specific physical properties of the substance, detail the form of the nanomaterial and the type of container, describe its storage, and give hazard information. The Swiss Secretariat of Economic Affairs recommends that Safety Data Sheets should be available for nanomaterials and should contain nano-specific data.

To ensure that nanomaterials are handled safely in the workplace, and because the risk to health and the environment from nanomaterial-containing products cannot be excluded, the Swiss guidelines call for recommend that safety information to be passed on down the production chain (SECO 2010).

The Guidelines recommend that nanomaterials Safety Data Sheets should contain the following key things:

- Identification of the substance/mixture and of the company/undertaking;
- Composition/information on ingredients;
- Physical and chemical properties;
- Stability & reactivity;
- Fire-fighting measures;
- Handling and storage;
- Exposure controls/personal protection;
- Toxicological information;
- Ecological considerations;
- Transport information;
- Disposal considerations;
- Other information.

Without these data it is not possible to evaluate protective measures. If there is no information available, this should also be stated in the SDS.

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4. The Nordic Council is a geo-political, inter-parliamentary forum for co-operation between the Nordic countries. It was established after World War II and its first concrete achievement was the introduction in 1952 of a common labour market and free movement across borders without passports for the countries' citizens.

Workers and their representatives should bear in mind that Safety Data Sheets have to contain appropriate, useful and comprehensive information to be used in the risk assessment, and tell workers how to protect their health and stay safe.

## Information on the technical and organizational measures

A diverse mix of companies may be producing or working with nanomaterials. They need to make adaptations for different working environments and different product conditions. The production of nanomaterials takes place predominantly in closed systems. Working in closed systems means that nanoparticles are inside a sealed container, closed pipes, or equipment without exposure to the open air or circulation of air to other rooms<sup>5</sup>. Since working with closed systems might not be enough, the employer must take complementary control measures.

Workers may chiefly be exposed at interface points in the production process (BAuA 2007), so engineering controls should be available in the handling area (e.g., laminar flow hoods, chemical fume hoods, glove boxes, and other local exhaust ventilation capability).

The employer is required to take measures to prevent industrial accidents and illnesses. Workers must be given training in the type of processes that the company uses to control exposure, enclosure processes, extraction or other types of exhaust ventilation. They must be provided with clear, relevant information on the operating instructions of such systems.

Regular cleaning of workplaces and work wear has to be ensured. Work wear and private clothing must be stored separately. The BAuA guidance says that the only way to remove deposits or spilled substances is with a suction device or by wiping them up with a moist cloth, and not by blowing them away (BAuA 2007).

## Information on protective clothing and equipment

In addition to control processes, the employer must ensure that Personal Protective Equipment (PPE) is adequate to prevent exposure. Proper equipment and adequate maintenance are key to minimizing the risk.

Protective clothing must be suitable for the worker, not be burdensome to wear, meet the requirements for maximum wearing time and permeation (break-through time depending on glove material and material strength) in actual conditions and avoid particle penetration.

The European Commission has mandated the European Committee for Standardisation (CEN) to give its opinion on new standardisation requirements for different PPE – gloves, overshoes, filters and masks, non-woven suits – against nanosize solid particles. CEN's TC 162 WG3 is currently revising the work item “Protective clothing against Chemicals, Infective agents and Radioactive contamination”, which ties in to protection against particles in nanoform, as well as the work item on “Air filters for general air cleaning”.

Closed-toed shoes, for example, must be made of low permeability material; protective suits or long trousers without turn-ups and a long-sleeved shirt must be made out of a non-woven membrane material. Protective goggles need to have side protection. Double

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5. Factsheet Stoffenmanager Nano-Closed systems [http://nano.stoffenmanager.nl/public/factsheets/FactsheetStoffenmanagerNano-GeslotenSysteem\\_en.pdf](http://nano.stoffenmanager.nl/public/factsheets/FactsheetStoffenmanagerNano-GeslotenSysteem_en.pdf)

layer gloves of a material chosen based on the chemicals involved or Nitrile gloves are recommended for most dry and liquid applications. This means that the gloves should be resistant to chemical attack by the nanomaterial or nanomaterials suspended in a liquid, and should be disposed of in the appropriate waste container after use.

Woven fabrics have proved to be efficient against nanoparticle penetration; cotton fabrics are not recommended. Clothing contaminated with nanoparticles must be removed immediately and treated as hazardous waste. Personal hygiene (washing, showering) is essential after removing protective clothing.

NANOSAFE2 is an FP6 project that studied different conventional individual protection devices well-qualified for micron size particles such as fibrous filters, respirator cartridges, protective clothing and gloves, which were tested with graphite nanoparticles ranging from 10 to 150 nm. The report found fibrous High-Efficiency Particulate Air (HEPA) filters, respirator cartridges and masks made with fibrous filters to be much more efficient for nanoparticles (NANOSAFE2 2008).

## Nanowaste – exposure to nanomaterials in waste

Nanotechnology not only generates new products and enables technologies, it also creates new forms of waste from laboratories, industries, and end-of-life products containing nanomaterials that can challenge current waste management, re-use and recycling. What happens to nanomaterials at the end of their life-cycle is an issue that has not yet been addressed. The working conditions of workers who are dealing with nanowaste are still an unknown.

Some key considerations relating to the end-life of nanomaterials can be mentioned. The first thing to say is that there is no single specific definition of nanowaste. Generally speaking, it can be said to refer to waste streams containing engineered nanomaterials. While there is as yet no internationally agreed classification, the BSI<sup>6</sup> British Standards Guide (BSI 2007) on disposal and handling of nanomaterials classifies waste into 4 categories:

1. Pure nanomaterials generated in manufacture and production;
2. Items, materials and surfaces contaminated with nanomaterials, such as containers, wipes and disposable PPE;
3. Liquid suspensions containing nanomaterials;
4. Solid matrices with nanomaterials that are friable or have a nanostructure loosely attached to the surface such that they can reasonably be expected to break free or leach out when in contact with air or water, or when subjected to reasonably foreseeable mechanical forces.

In addition, the key issues for waste management are knowing when the life of a nanomaterial ends, what the mobility of nanomaterials is in the different waste streams, and which nanomaterials may be potential hazards.

Firstly, there is great uncertainty about the end-of-life of a nanomaterial. Existing scientific knowledge limits our understanding of the fate of nanomaterials and nanoproducts in the different waste streams, including waste incineration, wastewater treatment and recycling.

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6. British Standards Institution (or BSI), is a multinational business services provider whose principal activity is the production of standards and the supply of standards-related services.



Nanomaterials in unknown quantities could potentially escape into the air, leach into soil, end up in landfill, sewage, incinerator residues, underground water and be dispersed in the environment, where it would be difficult to identify and clean them up. Also, knowing the potential release by weathering, decomposition or reaction with other materials may be equally essential (Musee 2011, Walser 2012, Health Council of the Netherlands, 2011).

Secondly, there is no description of suitable collection and disposal techniques for nanomaterial-containing products, or the processes that might release nanomaterials into waste streams. Their mobility is not easy to track and control.

Thirdly, there is not yet any way of assessing the toxicity of nanomaterials and nanomaterial-containing products through their life cycle to determine when it ends. There still remains a knowledge gap and a crucial need for research on all these issues (Tellenbach-Sommer, 2012).

#### **Waste containing unbound carbon nanotubes**

The United Kingdom's Environment Agency's advice is that for classification and handling of waste containing unbound carbon nanotubes – waste where the nanotubes are not fixed within a matrix and are capable of being inhaled – the precautionary approach should prevail. Carbon nanotubes should be treated as inorganic waste containing dangerous substances, classified as hazardous waste.

To ensure that waste is rendered safe, the Agency is taking a precautionary approach to the protection of people and the environment, and considers high temperature incineration at a hazardous waste incinerator as the preferred disposal method for carbon nanotubes, although other technologies may be suitable if it can be demonstrated that they render the wastes safe.

Source: <http://www.nerc.ac.uk/research/programmes/nanoscience/events/waste.asp>

Coupled with this are various considerations concerning the safety of workers who handle or are exposed to nanomaterials in waste.

Ideally, they should have the same level of safety protection as in a manufacturing environment without exposure. In principle, the exposure of workers handling nanowaste with the potential to cause harm or of unknown effects should be reduced to a minimum (Article 5 Directive 98/24/EC).

It is equally important for workers to be aware that their potential exposure to nanomaterials or products containing them in the disposal stage is influenced by a variety of factors like whether a product has a nanomaterial coating, the possible disposal pathways for specific nanowaste (waste water, landfill, incineration, or recycling), the bioavailability and persistence of the nanomaterial, the effect of the disposal media (air, soil, water) and the potential release of nanomaterials from the product (like cerium oxide particles contained in some fuel additives or titanium dioxide in some cosmetics).

Since the mobility of different types of nanomaterials in waste is hard to predict, workers should be informed about how to protect themselves in the different phases of waste management.

Where collection, disposal, disassembly or separating-out of parts containing nanomaterials are concerned, this means how to handle them for long-term storage and how to handle waste when working with incinerators and their residues, as hazardous materials that require to be handled in a specific way may be involved. The safest option is therefore to consider all nanowaste streams as potentially hazardous.

This, however, requires urgent research because the few studies in this field investigate only the potential environmental impact of nanomaterial waste<sup>7</sup>. There is no study inquiring into the working conditions and health risks when working with nanomaterials in waste.

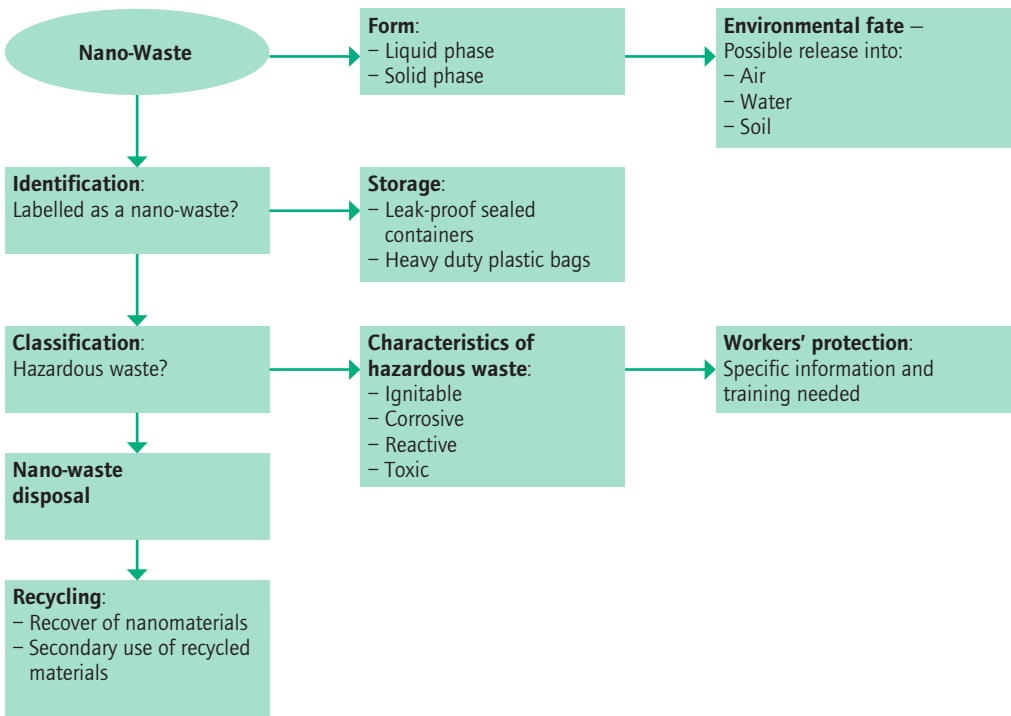
Ideally, nanomaterials and products should be designed as safe throughout and until the end of their life. As a precautionary approach, it is key to anticipate growth of nano-waste; the earlier in the chain action is taken, the smaller the ultimate problem (Health Council of the Netherlands 2011).

An additional issue is the lack of current regulatory provisions to address nanowaste specifically. There is no legislative provision for nanomaterials in waste, although the European Commission believes that the current regulatory framework does in principle apply to the management of nanomaterials in waste.

The Commission has been asked by Parliament to review the waste legislation – including on landfill and incineration – so the challenge will be to see whether current regulations can deal with nanowaste and how they can provide specific guidance on ways of managing it that avoid health and environmental consequences.

The Basel Convention on the control of transboundary movements of hazardous wastes and their disposal is a global treaty whose regime could be extended to nanowaste and entrenched it in international law. This needs to be explored in more detail.

**Figure 5 Nano-waste disposal pathways at the workplace**



Source: Author

7. Nanoparticles of titanium dioxide have so far been detected in the water running down outside walls coated with paint containing this substance (Kaegi 2008). Another study reports nano silver sulphide particles detected in sewage sludge (Kim 2010).

## Safety control tools at the workplace

Participation by workers in setting the appropriate prevention measures is a key factor. The absolute priority is to eliminate or reduce nanoparticle exposure as far as is technically possible. The whole workforce must be involved in the company's risk assessment programme and be certain that the information supplied by the company is sound.

Because these are key actions that workers must take, Safe Work Australia, an independent statutory agency responsible for improving occupational health and safety across Australia, has designed an assessment tool which covers information about the work or research on nanotechnologies and allows the user to identify and record information. It can be easily used to help workers in a wide number of industries to identify safe ways of working with nanomaterials.

The key thing is to know or identify what sorts of control the workplace uses or has previously used in setting up these kinds of processes, such as:

- Equipment design;
- Nanoparticle modification/substitution;
- Closed system working;
- Local exhaust ventilation;
- High Efficiency Particulate Air (HEPA) filters.

Personal protective equipment that may be identified includes accessories such as gloves, clothing, respirators, masks and safety glasses.

Procedures can also be identified, including limiting access to work areas, developing specific training in nanomaterials for equipment maintenance, cleaning-up spills or material disposal for nanoparticle hazards, or training on fit-checking and fit-testing of personal protective equipment.



## Part 3

# Health surveillance during and after exposure

Periodic health checks for exposed workers are an essential component of occupational health. NIOSH scientist Paul A. Schulte defines occupational health surveillance as the ongoing systematic collection, analysis, and dissemination of exposure and health data on groups of workers for the purpose of early detection of disease and injury as well as trends or patterns of occurrence presumably leading to prevention of subsequent disease (Schulte 2008). In general, health surveillance leads to preventive actions.

The 1989 Framework Directive on safety and health at work aims to ensure that essential preventive measures are taken, like the surveillance of workers' health for risks incurred at work<sup>8</sup>, while article 10 of Chemicals Directive 98/24/EC lays down a more detailed framework for health surveillance, including requirements for individual health and exposure records to be introduced at national level.

A guidance document issued by the International Labour Organisation (ILO) points out that there is a clear linkage between workers' health surveillance and workplace control measures, and that a medical approach is needed (ILO 1998). Health surveillance programmes should be used for prevention purposes; the scope and purposes should be broad enough to elicit and address new problems and take place under controlled conditions, ensuring:

- Professional independence and impartiality of the relevant health professionals;
- Workers' privacy and the confidentiality of individual health information.

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8. Directive 89/391/EC, Article 14 - Health surveillance.

Working with nanomaterials may pose work-related hazards and safety risks. A scientific review by the NIOSH agency in the United States reveals that studies of workers exposed to ultrafine particles like diesel exhaust and welding fumes have reported elevated lung cancer risks (NIOSH 2009). Results from some animal studies have shown that many types of poorly soluble ultrafine particles can produce a greater pulmonary inflammatory response than larger particles of the same composition. The publication had previously reported that various studies had demonstrated that nanoparticles may enter the bloodstream from the lungs and translocate to other organs; that nanoparticles between 35-37 nm can deposit in the nasal region and may be able to enter the brain by translocation along the olfactory nerve; and that inhalation of certain types of SWCNT causes interstitial fibrosis.

Yet much uncertainty surrounds work with nanomaterials, and health effects may take many years to present. This means that workers' health surveillance must extend over the long term, including when they have stopped being exposed to nanomaterials or stopped working for the company. This is the case for chronic effects – like pulmonary and circulatory diseases – that may take decades to assess and diagnose. Long-term medical surveillance may therefore serve as an early warning system for possible health effects linked to exposure.

This means that medical surveillance is assuming growing importance and a better understanding of work-related nano hazards is vital. There is a consensus in the scientific literature on setting up non-specific medical examinations for workers exposed to nanoparticles, and arrangements need to be made to help assess whether control measures are working and apt to identify new or unrecognized problems and health effects<sup>9</sup>.

**French proposal on medical surveillance at the workplace**

France has specific provisions on workplace health arrangements – all workers must have occupational medical surveillance. However, risk assessment and consistent risk management measures suffer badly from the lack of epidemiological and biomedical data on the potential human health risks from exposure to engineered nanomaterials. The Institute for Public Health Surveillance (INVS) is responsible for designing an epidemiological surveillance system for workers occupationally exposed to engineered nanomaterials for approval by the French ministries.

Two engineered nanomaterials – carbon nanotubes and nano-titanium dioxide – were chosen as a priority for the

registry. Workers will be identified using a three level approach:

1. Identification and selection of companies concerned by engineered nanomaterials exposure, based on the mandatory declaration;
2. On-site exposure assessment and identification of the jobs and tasks involving engineered nanomaterials exposure;
3. Identification of the workers concerned.

The workers identified will be included in a registry and a prospective cohort study will be worked up from it. This kind of exposure registry is necessary to conduct specific epidemiological studies and national and international OSH research.

Source: Malard and Radauceanu (2010)

The most common means of health surveillance is medical examinations. They may be of limited usefulness at the present time because the health endpoints that may be linked to engineered nanoparticles are not well known. But they will certainly be helpful in the

9. Schulte (2010), Malard and Radauceanu (2010), NIOSH (2009), ISO/TR 12885 Nanotechnologies –Health and safety practices in occupational settings relevant to nanotechnologies.

future for observing health parameters and setting up epidemiological studies. For instance, health testing of the pulmonary system of workers exposed to nanoparticles is to be recommended because toxicology literature reviews bear out assumptions about the behaviour of long fibres in the pleura, pinpointing carbon nanotubes as a new potential pleural hazard (Donaldson 2010).

In addition to medical surveillance, hazard surveillance involves identifying potentially hazardous practices, tasks or exposures in the workplace and assessing the extent to which they can be linked to workers, the effectiveness of controls, and the reliability of exposure measures.

It comprises the following practices (NIOSH 2009):

1. An initial medical examination and collection of information on medical and occupational histories, such as:
  - Medical history
  - Respiratory status
  - Allergies
  - Chest X-ray (CXR), spirometry.
2. Periodic medical examinations at regularly scheduled intervals, including specific medical screening tests when warranted. Some examinations recommended by Professor Dominique Lison<sup>10</sup> are:
  - Skin
  - Lung function
  - Chest imaging
  - Allergies
  - Nature-specific, such as when working with metals.
3. Frequent and detailed medical examinations on the basis of findings from the previous examinations.
4. Post-incident examinations and medical screening following uncontrolled or non-routine increases in exposures such as spills.
5. Providing worker training to recognize symptoms of exposure to a given hazard.
6. Production of a written report on medical findings.
7. Implementation of employer's actions in response to identification of potential hazards.

The results of the medical surveillance can be used to track and trace the exposure, and this information can be provided to workers' safety reps. It is recommended that workers who have been exposed are able to keep track of their exposures and the results of the checks in their medical dossier.

The medical surveillance records must be kept long-term by the company, and should to be linked to the exposure registry so that both tools can be used for future epidemiological studies.

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**10.** Paper on *Nanomatériaux, risques toxicologiques et surveillance médicale* given by Pr Lison to an event hosted by the Belgian trade union confederation FGTB in Brussels on 21 November 2012.





## Part 4

# Exposure registries as tools for medical surveillance

The number of nanotechnology jobs is undetermined. One projection forecasts 6 million new nanotechnology workers required by 2020 worldwide (Roco 2011), but the claim is unsupported by explanations as to how this figure was reached, and so where these jobs will be is not readily identifiable.

One factor in the exponential growth of jobs over time may be upcoming products and processes using second- and third-generation nanomaterials that are expected to come onto the market in the years ahead. Jobs are predicted to multiply in small and medium-sized firms, making them even harder to identify.

For all the estimates, no-one has been able to put firm figures on nanotechnology related employment, or specify the sectors from which demand will come.

Workers are potentially exposed to nanomaterials, but the practical circumstances of the exposure, dose, number of workers and activities, and the hazards of exposing workers to these new nanomaterials, are unknown. Surveys sent to nanotechnology companies to enquire about their nanotech processes and the number of workers concerned return poor quality results (Conti 2008, Engeman 2012). The vagueness and lack of information means that no figures can be put on the number of workers, which is unfortunate.

Likewise, national bodies in different countries have reported difficulties in obtaining data. The United States' National Institute for Occupational Safety and Health (NIOSH) has stated that it is unaware of any comprehensive statistics on the number of people employed in all occupations or industries in which they might be exposed to engineered nanoparticles in the production or use of nanomaterials<sup>11</sup>.

11. See <http://www.cdc.gov/niosh/topics/nanotech/faq.html>

**Table 3 Main types of manufactured nanomaterials in France**

Nanoparticles	Number of workers involved in production
Amorphous silica	1 300
Alumina	1 000
Rare earths	330
Carbon black	380
Titanium dioxide	270
Nanoclay	50
Carbon nanotubes	10
<b>Total</b>	<b>3 340</b>

Source: Honnert and Vincent 2007

Various studies have been done in France by the INRS in collaboration with the Centre interservices du santé du travail en entreprise (CISME), the Agence française de sécurité sanitaire de l'environnement du travail (CISME) and Institut de veille sanitaire (InVS), but they give only an approximation of the number of employees working with some nanomaterials (Honnert and Vincent 2007, INRS 2010, Honnert and Grzebyk 2011).

Among these efforts was a 2-year, 2-phase national survey started in 2010 to identify the type of nanomaterials in the French market (Jacquet 2012), the hazard situations to which workers are exposed, protective methods and the number of workers potentially exposed. The final phase reported 288 workers potentially exposed to nanoparticles, some of whom are exposed to different types of nanomaterials.

These results reflect a very poor level of industry concern, with some companies refusing to answer various questions, resulting in poor quality data and revealing that information at the workplace is not sufficient.

An examination of the French studies reveals that the preliminary studies and the national survey faced the same problem: an information gap about the industry sectors where nanomaterials are used. The poor responses yielded by approaches to companies merely compound the difficulties.

**Table 4 Approximations of the nano-workforce in different sectors in France**

Nanoparticles	Number of workers
Titanium dioxide (powder)	48
Titanium dioxide (suspension)	30
Zinc oxide (suspension)	30
Zinc oxide (powder)	10
Nano silver	28
Silicium oxide (suspension)	7
Amorphous silica	
Silicium dioxide	
Zinc oxide	25
Carbon black	79
Aluminium oxide	19
Cerium oxide	10
Barium titanate	2
<b>Total</b>	<b>288</b>

Source: Jacquet 2012

The results therefore point up the extreme difficulty of quantifying the number of potentially exposed workers, leaving a huge information gap about their working conditions and risks. This is reason enough to insist on exposure traceability and mandatory preventive measures.

For public health purposes, the prevention of occupational diseases requires information on the occurrence of exposures. An exposure registry collects particular exposure information, following-up individuals' histories from a period of exposure to determine whether one or more adverse health outcomes develop (Schultz 2010).

Exposure registries are useful for the collection, storage, retrieval, analysis, and dissemination of information on individuals with a particular disease, condition or risk factor that predisposes them to the occurrence of a health-related event, or prior exposure to substances or circumstances known or suspected to cause adverse health effects.

Exposure registries already exist and work well for carcinogens. The CAREX (carcinogen exposure) database, for example, contains documented estimates of the numbers of workers occupationally exposed to carcinogens broken down by agent and industry in several countries of the European Union. A similar model with a long-term time frame could possibly be developed for nanotechnologies.

The aim of an occupational exposure registry for nanomaterials is to provide selected exposure data and documented estimates of the number of workers exposed to specific substances.

## **Register who? Doing what? Identifying workers and their activities**

There is support in the scientific literature for establishing a nanotechnology worker registry (Boutou-Kempf 2011, Schulte 2009, Schultz 2010). Exposure registries for recording who is working with which materials, when, and where in the facility are tools for monitoring the emergence of new or perceived hazards.

As the data registered may be limited, it is vital to get workers to collaborate in collecting information through exposure surveys, especially where the risks of nanomaterials are not well-defined. What constitutes adequate exposure measurement and how to adequately distinguish exposed from non-exposed workers are questions not readily answered where nanomaterials are concerned. As the epidemiologist Myron G. Schultz has argued, accurate exposure assessment is a key issue in the utility of any exposure registry and is critical in establishing an association for health outcomes (Schultz 2010).

When should a registry be established? There are already a large number of products and processes derived from or incorporating nanomaterials, and it is projected that these will continue to grow. The lack of certainty about occupational hazards, the current population of exposed workers, and the types of diseases or health conditions possibly associated with nanomaterial exposures dictate that exposure registries should be established without delay.

Who should be registered? First and foremost, workers who actually handle most of the nanomaterials at any stage of the process life cycle. But as NIOSH's Paul Schulte argues, there is a need to define what is meant by a "nanotechnology worker" (Schulte 2010).

The National Institute for Occupational Safety and Health (NIOSH 2009<sup>12</sup>) summarizes the purposes and functions of exposure registries for workers exposed to nanomaterials as follows:

1. Delineate a population at risk;
2. Follow cohort to ascertain exposure-disease associations;
3. Follow cohort to ensure the institution of appropriate primary and secondary prevention and medical surveillance;
4. Follow cohort to allow for appropriate social, legal, and economic support;
5. Demonstrate societal concern for the cohort and provide a base for political action relevant to the exposure;
6. Notify a cohort of an exposure, preventive measures, or therapeutic advances that were not understood or known at the time the registry was established.

What information should it contain? The exposure registry should hold the name of the nanomaterial, the type of activity, the duration and intensity of exposure and the frequency of exposure. It is important to register the level of exposures by jobs and processes in order to pursue further effective epidemiological studies.

<b>Tracking nano-exposure at the workplace</b>
Date
Workplace
<b>Type of activity/process</b>
Description
Duration
Intensity of exposure
<b>Identification of nanomaterials or nano-product</b>
Name
Composition of particles
Size distribution of particles in the inhalable size range
<b>Identification of the worker</b>
Name
Age
PPE used
Other risk factors
Duration of the employment

Source: Author

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12. See Annex F: Exposure registry.

Who should keep it? The exposure registry could be kept by the company, which would provide the data to the public authorities subject to proper arrangements for ensuring business confidentiality and avoiding misuse of information. As this is a long-term process, it is important that the data received be consolidated so that worker exposure can be followed up and action taken if issues arise. The architecture of the exposure registry process needs to be further developed taking national regulations into account. France and the United States have already shown signs of such an approach.



## Conclusion

*Nanotechnology is a fast-growing industry. New nanotechnologies are gradually becoming embedded across a wide range of industry sectors. Even in the current global economic crisis, levels of public and private investment in nanotechnologies remain high, supported by national initiatives to promote and sponsor them around the world.*

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Although actual figures are hard to come by, employment growth is projected to be high. New jobs will be created and some existing ones will need to adapt. Both traditional and cutting-edge sectors will need new skills and workers to fill the jobs created globally.

Improvements in working conditions in those jobs where employees are exposed to nanoparticles at different stages of the production chain are unlikely to keep pace with growth in the nanosector. A number of occupational health and safety challenges therefore stand to be addressed.

The real number of workers potentially exposed to nanomaterials remains unclear. Because of the vast range of nanotechnology-related industries, figures on the workforce and the nanomaterials they work with are of uncertain reliability. Additionally, industry is struggling with transparency as to the type and quantity of nanomaterials they work with, pleading trade secrecy and business competition. More and better data are needed in order to properly identify workers who may be exposed to nanomaterials.

While not all nanomaterials are hazardous, there is scientific evidence that certain nanomaterials do pose potential risks to human health. This is reason enough to make the health and safety of potentially exposed workers the top priority, and to opt for a resolutely precautionary approach.

Workers themselves have a clear interest in preventing risks. They need to be properly informed about potential hazards that may arise, about which activities - at every stage of the production and disposal process - may expose them to nanomaterials, and about how they can be protected. They must be given understandable information and all necessary precautions must be taken to protect their health.

Along with that, workers' exposure needs to be documented. Workers must be aware that continued expansion in the sector brings with it an increasing number of scientific unknowns about the risks, and therefore health and safety. Yet there are no epidemiological studies evaluating the impact on human health of engineered nanomaterials, nor are any likely to become available for many years. For this reason alone workers must be given comprehensive information about the most common exposure pathways at the workplace. This could be achieved by establishing an exposure registry of tasks and processes at the workplace. The participation of workers in this initiative is key.

In addition, long term-medical surveillance and monitoring of health parameters are of huge importance. Since there are yet no formal medical surveillance programmes for workers exposed to nanomaterials, a baseline medical screening including specific tests should be set up to collect specific information about health history when nanomaterials are being worked with.

Furthermore, the political context is not conducive to improving working conditions and worker protection. Policy decisions on nanotechnologies have been completely politicized, which has hobbled safety regulation.

So far, the Commission has shown no intention of developing specific provisions for nanomaterials, claiming that they are not a special case, while MEPs, various Member States, consumer organisations, environmental groups and trade unions have long been arguing otherwise.

Where the political situation in the EU is concerned, the key thing is to shift the current policy agenda: existing EU and national regulations can be used but there is a clear and urgent need for the European Commission to take and implement coherent legal provisions for nanomaterials.

At the workplace, health cannot be sidelined. Specific programmes involving workers have to be established and the precautionary principle has to be part of these, so as to protect them from any risks, avoid occupational diseases and ensure their health over the long-term.

The wider interests of society must prevail, and it is to society that the greatest benefits of nanotechnologies should accrue. It is important to create stronger synergies with different government bodies, industry and stakeholders in a sustainable, long-term approach in order for those benefits to be secured.



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