

Occupational Exposure Limits for Nanomaterials

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Regulations, Challenges, and Outlook

Summary

The market for engineered nanomaterials (ENMs) – nanomaterials purposely manufactured for their specific properties – is growing rapidly, leading to an increasing number of workers being exposed at their workplace. These materials are present in many products, including pharmaceuticals, cosmetics, electronics, and food.

While consumers are mainly exposed to engineered nanomaterials through skin contact or ingestion, their exposure tends to be shorter and less intense compared to workers who regularly handle these materials. Workers are not only exposed to the final product, but also to intermediate components released during the manufacturing process through milling, manipulation of dry powders, or the release of fibres and particles in suspension. Inhalation of nanoparticles and fibres constitutes the most common route of occupational exposure. Due to their minuscule size, nanomaterials can penetrate deeply into the lungs, triggering inflammation and increasing the risks of cancer, lung fibrosis, and cardiovascular diseases. They can further translocate into the circulatory system and other organs.

The wide variety of engineered nanomaterials – varying in size, shape, chemical composition, and surface functionalisation – makes defining occupational exposure limits a particularly challenging and resource-intensive task. This complexity demands a thorough toxicological assessment for each material. Regulatory efforts must ensure worker protection while fostering innovation in the development of new nanomaterials.

This NanoTrust Dossier provides an overview of occupational exposure limits for ENMs in Europe. It highlights the challenges in establishing these limits and effectively safeguarding workers in a rapidly evolving field, and presents initiatives to accelerate the toxicity assessment of nanomaterials.

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Introduction

Nanomaterials are increasingly used across a wide range of industries due to their unique properties, such as enhanced mechanical resistance, optical properties, and improved electrical conductivity. Key sectors benefiting from these properties include cosmetics, healthcare, textiles, and electronics. The global nanomaterials market, valued at approximately €9 billion in 2020, is projected to exceed €30 billion by 2029.¹ According to the French nanomaterials register R-nano², some of the most widely used nanomaterials are silicon dioxide, carbon black, titanium dioxide, calcium carbonate, and aluminium oxide.

Although data on the number of exposed workers are scarce, the rapid expansion of the market suggests a growing number of workers exposed to ENMs at their workplaces, raising questions about their protection against adverse health impacts. Occupational exposure is typically higher than public exposure, as nanomaterials are often handled during product manufacturing processes (e.g., coating, painting, embedding nanomaterials in a matrix), even if the final consumer product does not contain them in the free form. The most common exposure pathways are inhalation, dermal exposure, ocular contact, and ingestion. This dossier will focus on inhalation, which is the most common exposure route and the primary source of potential adverse health outcomes.

The terms *engineered nanomaterials (ENMs)* and *nanomaterials* will be used interchangeably in this dossier to refer to materials “with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale” (according to ISO/TS 80004). Nanoscale refers to dimensions between 1 and 100 nm. The qualifier *engineered* stresses that the materials are intentionally manufactured for their properties, rather than *naturally occurring* nanomaterials, or *incidental* nanomaterials (also referred to as *process-generated*), typically resulting from processes such as combustion (e.g., ultrafine particles emitted by internal combustion engines).

Nanoparticles penetrate deep into the lungs

Airborne particles smaller than 1 µm are generally considered fully inhalable, whereas the inhalability of larger particles decreases with increasing diameter. Nanoparticles (1-100 nm) tend to form agglomerates larger than the particle's primary diameter. Once inhaled, particles and agglomerates follow the airflow through the respiratory tract and reach the alveolar region. A fraction of inhaled particles is exhaled again without depositing. The remainder is deposited at various sites along the respiratory system, including the nasal cavity, trachea, bronchi, and alveoli, following a size-dependent deposition pattern (see Figure 1). The size of the agglomerate predicts the pulmonary deposition. Although all nanoparticles are inhalable, only a fraction, up to 40% of the inhaled dose, will deposit in the alveoli (green line in Figure 1), where they cause adverse health impacts. This is particularly important in the establishment of Occupational Exposure Limits (OELs), which take into consideration respiratory deposition patterns and risks associated with alveolar exposure.

Health impacts of nanomaterials

The same characteristics that give nanomaterials their unique properties – such as extremely small size and high specific surface area – also drive their adverse health impacts. Smaller fibres and particles, also known as respirable dust, penetrate deeply into the lungs, reaching the alveolar region where they cause an inflammatory response proportional to their surface area: smaller particles trigger a stronger response than larger particles for a similar mass concentration. Particle-induced inflammation has been linked to lung cancer, fibrosis, and cardiovascular diseases.⁴

Depending on the particles' solubility in lung lining fluid, they can dissolve or accumulate in the lungs. Particle clearance (evacuation) is much slower in the alveolar region compared to the up-

per airways, which means that smaller insoluble particles stay longer in the lungs. From the airways, nanoparticles can translocate to the bloodstream and secondary organs such as the liver, brain, and kidneys and accumulate over time.^{5,6} Some nanoparticles have been reported to damage cells, increasing long-term cancer risks.⁷

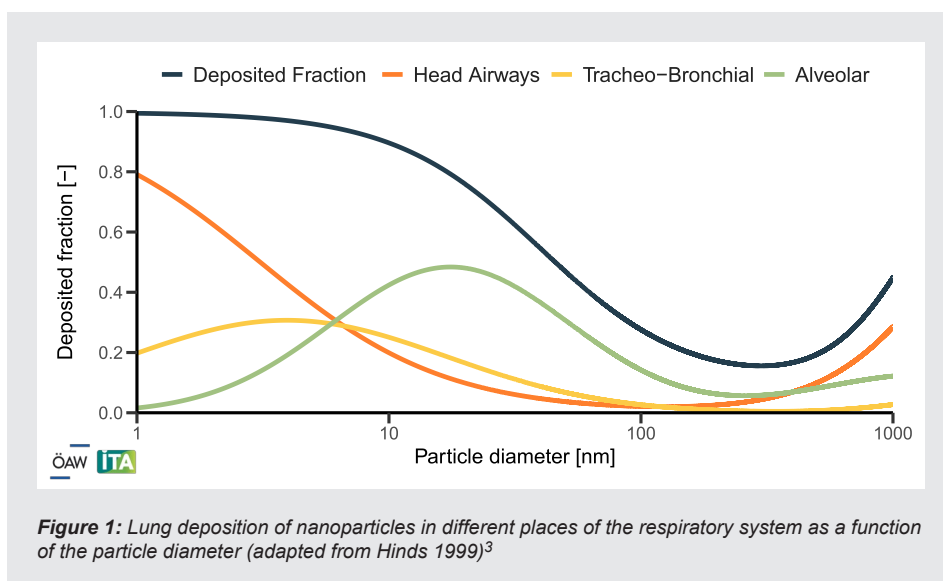
When a material is classified as toxic due to its chemical composition, its nanoform typically enters the body more quickly than the bulk form and stays there longer. Even materials considered non-toxic in bulk form may still cause lung inflammation or oxidative stress at the nanoscale due to their increased specific surface area, morphology, or surface reactivity. The toxicity of nanomaterials strongly depends on multiple physicochemical properties, including particle size distribution, shape, chemical composition, and surface modifications.

Although growing evidence shows adverse health outcomes associated with nanomaterials, the mechanisms underlying their toxicity remain poorly understood and are the subject of ongoing research.

The case of asbestos and its impact on workplace exposure regulation

Asbestos is a group of mineral fibres used in multiple applications for its thermal, electrical, and mechanical properties. The inhalation of asbestos fibres has severe impacts on the lungs, causing fibrosis (also known as asbestosis) and increasing the risk of lung cancer. Asbestos exposure represents the most well-documented example of severe health hazards resulting from occupational exposure to airborne fibres, responsible for more than 200 000 deaths per year worldwide in 2021 and accounting for 70 % of all work-related cancer fatalities.⁸ Although the health risks associated with asbestos exposure were documented as early as the 1930s, legally binding occupational exposure limits were only introduced four decades later, and the processing of the material into new products was banned in many countries only in the 1990s.⁹

The asbestos crisis played a central role in shaping modern occupational hygiene practices, including systematic exposure assessment, implementation of exposure-reduction measures, and the establishment of OELs. It highlighted the need for a proactive approach to regulating new materials through early toxicological assessment and structured risk management. It also highlighted the importance of coordinating among key stakeholders in occupational hygiene, scientists, manufacturers, and regulating authorities.



Current initiatives aim to integrate these lessons, and more broadly, health, safety, and environmental considerations into the early stages of product development, particularly given the rapid pace of innovation in material science, which makes it impractical to conduct full toxicological assessments on each newly developed material. One example is the Safe-and-Sustainable-by-Design framework promoted by the EU Commission (see [NanoTrust Dossier Nr. 067](#)), which integrates safety and sustainability considerations throughout the product lifecycle.

Existing occupational exposure limits for nanomaterials

Currently, there are no explicit, legally binding OELs specifically defined for nanomaterials in the EU. Instead, exposure is regulated by generic threshold values such as dust limit values which apply broadly to airborne particulate matter – including both nano- and micro-sized particles and fibres capable of entering the respiratory system.

Nanomaterials fall under the general legal framework governing chemicals in the EU, structured around three major directives. The *Framework Directive 89/391/EEC* sets minimum requirements for health and safety at work, leaving it up to member states to adopt stricter regulations. The *Chemical Agent Directive 98/24/EC* sets minimum requirements for protecting workers against exposure to chemical agents (not specific to nanomaterials). Finally, the *Carcinogen and Mutagen Directive 2004/37/EC (CMD)* establishes rules to protect workers from occupational exposure to carcinogenic and mutagenic substances. The latter contains occupational exposure limits for inci-

dental nanomaterials, such as diesel engine exhaust ($50 \mu\text{g}/\text{m}^3$), chromium VI compounds ($5 \mu\text{g}/\text{m}^3$) or respirable crystalline silica dust ($100 \mu\text{g}/\text{m}^3$).

Employers have to perform a risk assessment for potentially hazardous materials not covered in the CMD, and indicative limits, such as the general dust limit, can be used instead. However, this limit is much less restrictive than specific exposure limits: in Austria, the general dust limit for long-term exposure is $10 \text{ mg}/\text{m}^3$ for the inhalable fraction, and $5 \text{ mg}/\text{m}^3$ for the alveolar fraction (the limits are doubled for a short-term exposure).¹⁰ Specific OELs provide clear targets to limit exposure.

The *European Agency for Safety and Health at Work (EU-OSHA)* plays a central role in promoting workplace health and safety by collecting and disseminating information, raising awareness, and supporting evidence-based policymaking.

Recognising the growing use of nanomaterials and the need for more targeted worker protection, the EU Commission published indicative values in 2014 in the *Guidance on the protection of the health and safety of workers from the potential risks related to nanomaterials at work*.¹¹ This document summarises provisional occupational exposure values for some of the most widely used nanomaterials in Europe (see Table 1).

Ongoing discussions at the European level¹² acknowledge the importance of intensifying research to generate robust toxicological and epidemiological data, which remain a prerequisite for establishing nanomaterial-specific health-based OELs. However, the diversity of nanomaterials and their physicochemical properties makes it difficult to define harmonised exposure limits.

How occupational exposure limits are defined

Setting OELs requires abundant scientific data to identify and quantify adverse health impacts. This process can be illustrated by the example of the limit developed by the *French Agency for Food, Environmental, and Occupational Health and Safety (ANSES)*¹³ for titanium dioxide nanoparticles (TiO₂-NP), specifically the P25 form, with a primary diameter (excluding agglomerates) of 20-25 nm. The derivation of an OEL generally follows several steps.

The process begins with a comprehensive review of the academic literature on potential toxicity mechanisms in humans and animals:

- *Toxicokinetics*, which describes how long particles remain in the lungs before being evacuated, and whether they translocate into the circulatory system and accumulate in secondary organs;
- *acute and chronic toxicity*, including short- and long-term effects on the respiratory, cardiovascular, immune, and nervous systems, as well as on organs where nanoparticles may accumulate;
- *reproductive toxicity, genotoxicity, and carcinogenicity*.

Since multiple mechanisms may contribute to toxicity, the mechanism leading to the most serious consequences at the lowest concentration is selected as the *critical effect*. The study most representative of real exposure conditions (e.g., concentration, duration) is then used to derive a *critical dose*, defined as the highest dose at which no significant adverse effects are observed.

For substances for which no safe level of exposure can be established (e.g., known carcinogens), a non-threshold exposure limit is defined, based on an acceptable level of risk. Asbestos, for example, is regulated under this approach. Risk management measures must then be applied to minimise exposure further. For substances without evidence of carcinogenic impacts at low doses, a threshold exposure limit is set, below which no adverse effects are expected.

Finally, correction factors are applied to adjust for uncertainties, such as differences between humans and test animals, variability within the

Table 1: Proposed OELs for commonly-used nanomaterials as of 2014¹¹

| Substance | Type of limit | Value |
|---------------------------------|---|---------------------------------------|
| Multi-walled carbon nanotubes | Long-term exposure | 50 µg/m ³ |
| Carbon nanotubes and nanofibers | 8-hour time-weighted average No indication | 1 µg/m ³ 0.01 fibres/mL |
| Fullerenes | Chronic inhalation | 270 µg/m ³ |
| Silver [18-19 nm] | Derived no-effect level | 98 µg/m ³ |
| Titanium dioxide [10-100 nm] | 10 hr/day – 40 hr/week | 300 µg/m ³ |

human population, or differences between the exposure scenarios in studies and those expected in occupational settings (e.g., an 8-hour workday). The resulting adjusted value constitutes the recommended OEL.

The challenge of developing new occupational exposure limits for nanomaterials

Establishing OELs for nanomaterials requires extensive toxicological evidence covering multiple potential routes of toxicity and material-specific properties. Generating such data is both time- and resource-intensive, particularly challenging because nanomaterials vary widely – not only in their chemical composition (e.g., carbon, silver, metal oxides), but also in morphology (e.g., multi-walled and single-walled carbon nanotubes, spherical particles), size distribution, aggregation potential (the tendency to form clusters, sometimes composed of different materials) and surface modifications (coating, functionalisation). Each of these factors strongly influences how nanomaterials interact with biological systems.

A pragmatic approach might be to prioritise the most widely used nanomaterials. However, this approach risks lagging behind scientific and industrial developments, since limits would only be defined once a material is already in widespread use. Moreover, information on the use of nanomaterials in Europe remains scarce, due to the absence of a unified reporting mechanism or registry, even though national initiatives exist. On the other hand, pre-emptively restricting or banning nanomaterials in the absence of sufficient data would hinder innovation and prevent society from benefiting from their positive aspects, many of which are expected to outweigh negative impacts.¹⁴

Current policy debates reflect these challenges, aiming to ensure worker protection while promoting innovation and technological progress. A precautionary approach is generally applied to minimise exposure to materials with unknown toxicity, while in parallel developing methods to accelerate the assessment of their health impacts. These efforts aim to accelerate the establishment of evidence-based OELs and ensure that regulation keeps pace with innovation in material science.^{15,16}

Ongoing efforts to develop occupational exposure limits for nanomaterials

Exposure limits are being developed for widely used nanomaterials, mostly at the national level, based on meta-analyses of the available scientific literature. According to a study from the *Health Council of the Netherlands*¹⁷, a long-term exposure to a concentration of 0.011 µg/m³ of elemental carbon, a marker of diesel exhaust particles, would result in an excess death rate from lung cancer of 4 in 100 000. The *Danish National Research Centre for the Working Environment* provides similar analyses for diesel exhaust¹⁸, TiO₂ nanoparticles¹⁹, carbon nanotubes²⁰, and carbon black²¹. In France, ANSES recommends long-term and short-term occupational exposure limits for P25 titanium dioxide nanoparticles¹³ of respectively 0.80 µg/m³ and 4 µg/m³, orders of magnitude lower than the 300 µg/m³ suggested in 2013 by the European Commission for titanium dioxide nanoparticles (see Table 1).

Table 2: Classification of nanomaterials and corresponding proposed OELs according to the “Dutch National Institute for Public Health and the Environment”

| Category | Description | Material Density | Proposed value |
|----------|--|---------------------------|---|
| 1 | Rigid, biopersistent nanofibers for which asbestos-like effects cannot be excluded | – | 0.01 fibres/cm ³ [10 000 fibres/m ³] |
| 2a | Biopersistent, granular nanomaterials in the range 1-100 nm | > 6 000 kg/m ³ | 20 000 particles/cm ³ |
| 2b | Biopersistent, granular and fibrous nanomaterials in the range 1-100 nm | < 6 000 kg/m ³ | 40 000 particles/cm ³ |
| 3 | Non-biopersistent, granular nanomaterials in the range 1-100 nm | – | Current limit value [of the bulk material] |

Rather than assessing each material individually, nanomaterials can be classified based on key properties that influence health impacts, such as fibre-like morphology, density, and biopersistence (i.e., dissolution time in the lungs). The *Dutch National Institute for Public Health and the Environment* proposes such a classification to derive OELs, shown in Table 2.

Building on this approach, an expert group further refined the methodology for deriving OELs for engineered nanomaterials.²² They aimed to identify the main drivers of toxicity, whether related to morphology (the *particle-effect*) or the inherent toxicity of the bulk material. They proposed six categories based on the bulk material's toxicology, the solubility in the lungs, and the shape. These categories can be broadly grouped into fibre-like materials, soluble spheroidal materials, and non-soluble (biopersistent) spheroidal materials.

The **first** group comprises rigid, fibre-like and biopersistent materials that pose health risks similar to those of asbestos, for which asbestos exposure limits apply.

The **second** group contains other fibre-like materials not included in the first group (e.g., flexible carbon nanotubes and fibres), which require more toxicological data to derive OELs.

The **third** group contains soluble spheroidal nanomaterials whose toxicity comes from their chemical composition. OELs should be based on the bulk or ionic form.

The **fourth** group contains biopersistent spherical particles with unknown substance-specific

toxicity. Further testing is required to determine whether toxicity is driven by chemical composition (classification into the **fifth** group) or by the particle-effect (classification into the **sixth** group).

The **fifth** group contains biopersistent spherical particles with identified substance-specific toxicity. Experts recommend applying a scaling factor to the bulk material OEL to account for particle effects and ensure the resulting exposure limit is more restrictive than the limit for materials in the **sixth** group.

Finally, the **sixth** group contains biopersistent spherical particles with relatively low substance-specific toxicity, where toxicity is primarily particle-driven. OELs can be derived from benchmark materials and applied to future materials falling into this category.

In addition to these categories, modifications such as coating, surface functionalisation, and the presence of reactive groups should be assessed separately on a case-by-case basis, as they can substantially alter nanoparticle properties and, in turn, their health impacts.

At the European level, research programs such as *Horizon 2020* and *Horizon Europe*²³, coordinated by the EU Commission, fund projects aimed at managing nanomaterial-related health risks along two main axes: (1) accelerating toxicological assessment of new materials, including the development of in-silico methods supported by machine learning, with projects such as *Comp-SafeNano*, *nanoPASS*, *EU-ToxRisk*, *SmartNanoTox*, *MACRAMÉ* or *iCare*; (2) integrating health and safety considerations as early as possible in

the development process of new materials, for example, in projects like *SUNSHINE*, *INTEGRANO*, or *ACCORDs*. These efforts do not focus exclusively on nanomaterials but potentially include all existing and future materials.

Because nanotoxicology studies often rely on animal testing, ongoing efforts also focus on developing animal-free testing methods, such as the *nanoPASS* or the *EU-ToxRisk* projects. Although not specific to occupational exposure, these methodologies are expected to facilitate the derivation of OELs for nanomaterials significantly.

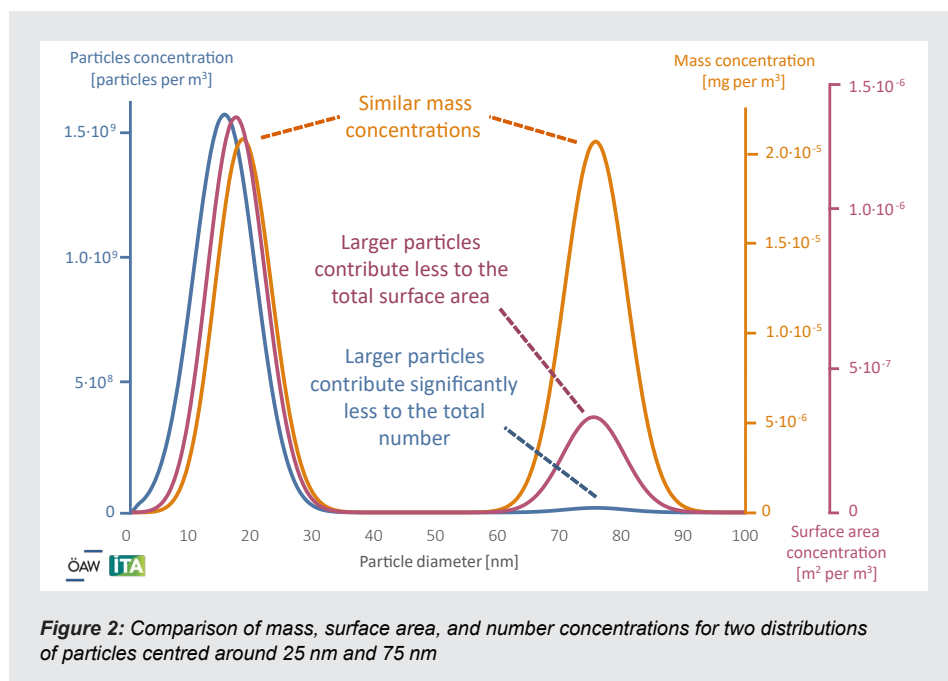
The importance of choosing the right metric

Occupational exposure limits are traditionally expressed in units of mass per volume of air (typically in $\mu\text{g}/\text{m}^3$ or mg/m^3). This metric is well-suited for conventional chemicals, where health impacts are largely proportional to the inhaled mass. However, for nanomaterials, this approach is increasingly challenged, particularly when toxicity is driven by specific surface area, particle morphology or surface modifications rather than by the bulk chemical composition.

Alternative exposure metrics, such as particle number concentration (particles per m^3) or surface area concentration (m^2 of particle surface area per m^3 of air), may better correlate with observed health effects. However, no single metric is universally applicable across all categories of nanomaterials, and the choice of the metric remains a matter of scientific and regulatory debate.²⁴

The relation between mass, surface area, and particle number concentrations for two size distributions of particles, centred around 25 nm and 75 nm, is illustrated in Figure 2. While both distributions have similar mass concentrations, the corresponding surface area and particle number are substantially lower for the larger particles. If adverse health effects correlate more closely with surface area or particle number rather than mass, mass-based OELs may fail to capture the true risk.

In addition to toxicological relevance, the choice of the exposure metric is constrained by the availability and practicality of monitoring instruments, which should be adapted to detect particles below the exposure limit reliably. Mass-based concentrations are typically easier to measure with current instruments. Instruments should also be able to distinguish ENMs from background particles (e.g., pollen, road traffic emissions, dust), remain affordable and easy to operate for workplace monitoring.



Risk management

Existing chemical safety regulations, such as those applying to carcinogenic or genotoxic materials, also apply to engineered nanomaterials. In the EU, the *Council Directive 89/391/EEC* established employers' obligations to protect workers' health and safety, which fully apply to nanomaterials. However, their health impacts are amplified by their large specific surface area compared to the bulk form of the same material.²⁵ There are still many major knowledge gaps over the potential adverse effects of titanium dioxide nanoparticles (TiO₂-NPs). Therefore, risk management strategies in the absence of occupational exposure limits need to take into account the specific risks linked to exposure to nanomaterials.

Employers must implement risk management strategies to identify, quantify, and reduce risks, including measures to substitute hazardous substances with safer alternatives, reduce emissions, lower exposure by providing adequate ventilation

and air filtration, train employees, and provide protective equipment such as facemasks or protective clothing.

Organisations such as the EU Commission^{11,26,27}, the World Health Organization²⁸, and national authorities^{29,30} provide risk management guidance documents for ENMs, which typically follow similar structures: identifying the nanomaterials (source, form – e.g., bound in a matrix or dissolved in a liquid), assessing the hazard (physico-chemical properties of the nanomaterial) and the exposure of the employees (exposure route and duration), characterising the risk (quantification of the risk based on the hazard and exposure), and managing the risk (substituting the nanomaterial, enclosing critical processes, providing protective equipment).

This structured approach ensures that, even in the absence of material-specific OELs, employers remain responsible for minimising worker risks associated with engineered nanomaterials.

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All URLs have been checked on Jan. 22, 2026.

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Conclusion

Nanomaterials pose significant health risks to workers manipulating them without adequate protection. The ongoing efforts to establish health-based occupational limits for widely used nanomaterials and incidental nanomaterials highlight increased risks of lung cancer and other adverse health effects at concentrations well below the limit for respirable dust. Employers need to minimise workers' exposure by identifying potential sources of airborne nanoparticles, reducing the use of hazardous substances, and implementing protection measures such as appropriate ventilation and air filtration, as well as the use of personal protective equipment.

Nanomaterials act as catalysts for scientific progress, not only by enabling the design of materials with novel properties, but also by driving necessary advances in health, safety, and environmental assessment to ensure their safe and responsible use. Emerging tools such as artificial intelligence can support existing in-silico methods in predicting the toxicity of nanomaterials based on their physicochemical properties³², thereby supporting safer innovation while reducing reliance on animal testing. Nevertheless, nanomaterials pose new challenges for worker protection due to the difficulty of detecting and identifying them, and the large diversity of materials involved.

Regulators are working to standardise nanomaterial classification, detection, and characterisation methods to enable reliable measurement and support the implementation of evidence-based OELs. These initiatives take place across multiple levels, including ISO^{33,34} and CEN standards³⁵ and the activities of the OECD Working Party on Manufactured Nanomaterials.³⁶

Policy-makers are advised to foster continuous dialogue among all stakeholders (researchers, regulators, workers, and employers) to ensure the efficient translation of new scientific findings into coherent regulation and to accelerate the adoption of protection measures and OELs. Strengthening data collection on the industrial use of nanomaterials is particularly important for assessing workers' exposure, thus effectively guiding risk assessment and protection strategies for workers. Finally, it is crucial to dedicate resources to educate and inform employers and workers about the risks associated with nanomaterials, and to support employers, particularly small and medium-sized enterprises, in identifying hazards and implementing appropriate monitoring and protection measures.

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Acknowledgement

The authors would like to thank Ulla Birgitte Vogel from the Danish National Research Centre for the Working Environment and Sabine Lehr from the Austrian Labour Inspectorate for reviewing this Dossier and providing insightful comments and suggestions.

MASTHEAD

Owner: Austrian Academy of Sciences; legal person under public law (BGBl 569/1921 idF BGBl I 31/2018); Dr. Ignaz Seipel-Platz 2, A-1010 Vienna

Editor: Institute of Technology Assessment (ITA); Bäckerstraße 13, A-1010 Vienna; www.oew.ac.at/ita

Mode of publication: The NanoTrust Dossiers are published irregularly and contain the research results of the Institute of Technology Assessment as well as its cooperation partners in the framework of its research project NanoTrust. The Dossiers are made available to the public exclusively via the Internet portal "epub.oew": epub.oew.ac.at/ita/nanotrust-dossiers/

NanoTrust-Dossier Nr. 69en, January 2026:
epub.oew.ac.at/ita/nanotrust-dossiers/dossier069en.pdf

ISSN: 1998-7293

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