

TOOLS FOR THE MANAGEMENT OF NANOMATERIALS IN THE WORKPLACE AND PREVENTION MEASURES

This e-fact introduces a number of risk management tools that have been developed to aid in the election of appropriate workplace prevention measures and which could support companies in performing the workplace risk assessment with regard to nanomaterials.

1. Introduction

1.1 What are nanomaterials?

Nanomaterials are materials containing particles with one or more dimension between 1 and 100 nm⁽¹⁾, a scale comparable to atoms and molecules. They may be natural, such as from volcano ashes, or an unintended consequence of human activities, such as those contained in diesel exhaust fumes. However, a large number of nanomaterials are intentionally manufactured and placed on the market, and it is these that this e-fact focuses on.

Nanomaterials have specific properties - as a result mainly of their small size and large surface area, but also of their shape, chemical nature, surface functionalisation and surface treatment - that present many benefits for numerous applications. However, because of these characteristics nanomaterials may also have a wide range of potentially toxic effects, even if the same materials at macro scale do not [2, 3].

1.2 Health and safety hazards of nanomaterials and exposure routes

Under normal environmental conditions, nanomaterials may form agglomerates or aggregates larger than 100 nm, thereby changing (but not necessarily losing) their nano-specific properties. However, these nanomaterials may be released again from weakly bound agglomerates and, under certain conditions, even from more strongly bound aggregates. It is currently being investigated whether this could happen in lung fluid following inhalation of such agglomerates or aggregates [2, 3]. Agglomerates and aggregates containing nanomaterials should therefore also be taken into consideration in the workplace risk assessment.

The internal exposure mechanism, following the entry of nanomaterials into the body, could include further absorption, distribution and metabolism. Some nanomaterials have been found in, for example, the lungs, liver, kidneys, heart, reproductive organs, fetus, brain, spleen, skeleton and soft tissues [2]. Open questions remain concerning the bioaccumulation of nanomaterials and elimination mechanisms from cells and organs. An additional issue is that, while a nanomaterial itself may not be toxic, it could act as a Trojan horse, meaning that a more toxic material may attach itself to the nanomaterial and gain entry to the body, organs or cells [4].

⁽¹⁾ According to the European Commission's Recommendation [1]:

- 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. The number size distribution is expressed as number of objects within a given size range divided by the number of objects in total."
- "In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%."
- "By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials."

The most important effects of nanomaterials have been found in the lungs and include inflammation, tissue damage, oxidative stress, chronic toxicity, cytotoxicity, fibrosis and tumour generation. Some nanomaterials may also affect the cardiovascular system. The potentially hazardous properties of manufactured nanomaterials are a matter of ongoing research [2, 3].

There are three main possible routes of exposure to nanomaterials in the workplace [2, 4-8]:

- **Inhalation** is the most common route of exposure to airborne nanoparticles in the workplace. Inhaled nanoparticles can deposit in the respiratory tract and the lungs depending on their shape and size. Following inhalation, they may cross the pulmonary epithelium, enter the bloodstream and reach further organs and tissues. Some inhaled nanomaterials have also been found to reach the brain via the olfactory nerve.
- **Ingestion** can occur as a result of unintentional hand-to-mouth transfer from contaminated surfaces, or by ingestion of contaminated food or water. Ingestion may occur as a consequence of inhalation of nanomaterials, as inhaled particles that are cleared from the respiratory tract via the mucociliary escalator may be swallowed. Some ingested nanomaterials may cross the intestinal epithelium, enter the bloodstream and reach further organs and tissues.
- **Dermal** penetration is still being investigated [6, 8]. Intact skin seems to be a good barrier against the uptake of nanomaterials [9]. Damaged skin seems to be less effective, but the level of uptake is likely to be lower than that associated with inhalation [9]. However, notwithstanding this, dermal contact should also be prevented and controlled.

The potential for exposure therefore depends mainly on the likelihood of nanomaterials becoming airborne, with powder form or sprays presenting a greater risk potential than suspensions in liquid, pastes, granular materials or composites. In turn, nanomaterials in liquids present a greater risk potential than bound or fixed nanostructures, such as those in a polymer matrix [10].

Last but not least, safety hazards may also result from the high explosiveness, flammability and catalytic potential of some nanopowders (nanomaterials in powder form), in particular metal nanopowders.

1.3 Managing the risks of nanomaterials in the workplace

In the workplace, employers have a general duty to ensure the health and safety of workers in every aspect related to their work by conducting regular risk assessments - as specified in the 'Framework' Directive 89/391/EEC [11] - and these should also include possible risks from nanomaterials. In addition, Directive 98/24/EC on chemical agents at work [12] imposes more stringent provisions on the management of risks from substances at work - in particular, the hierarchy of prevention measures that strengthens elimination or substitution as priority measures - which also apply to nanomaterials, as these fall within the definition of 'substances'. If a nanomaterial, or the macro-scale material of the same composition, is carcinogenic or mutagenic, Directive 2004/37/EC on carcinogens and mutagens at work [13] must also be fulfilled. In any case, national legislation may have stricter provisions and should be consulted.

As nanomaterials are considered substances, the REACH (Registration, Evaluation and Authorisation of Chemicals) regulation [14] and the CLP (classification, labelling and packaging of substances and mixtures) regulation [15] are equally relevant.

Despite ongoing research, the field of nanotechnology is developing faster than the generation of knowledge of the health and safety aspects of nanomaterials. There are still knowledge gaps regarding the implications of nanomaterials on workers' health and safety and regarding risk assessment methods.

When undertaking a nanomaterial risk assessment in their workplace, employers may therefore encounter difficulties related to:

1. insufficient information on the hazardous properties of nanomaterials;
2. no consensus on the standardised methods and devices to be used for measuring exposure levels and for identifying nanomaterials and emission sources;
3. limited information on the effectiveness of risk reduction measures (filters, gloves, etc.); and

4. a lack of information on the presence of nanomaterials, in particular in mixtures or articles as well as down the user chain, when nanomaterials, or products containing nanomaterials, are used or processed.

Safety data sheets (SDSs) are an important information tool for the prevention of risks from hazardous substances in workplaces. However, they currently contain, in general, little or no information about the presence of nanomaterials and their characteristics, risks to workers and prevention measures [17–19]. Organisations are therefore advised to contact suppliers directly to request additional information. Changes in REACH Annex II [20], the legal framework for the SDSs, as well as the guidance from the European Chemicals Agency (ECHA) on the SDSs [21], which gives further advice on how to address characteristics of nanomaterials, are expected to improve the quality of the information contained in the SDSs.

Guidance from the Organisation for Economic Co-operation and Development (OECD) [22] provides support for identifying potential sources of emissions of airborne nanomaterials from various types of processes and work practices.

Preliminary indications suggest that the following workplace activities and practices involving nanomaterials require special attention when assessing exposures and should be prioritised for risk management:

- Activities in which nanomaterials with the following properties are used:
 - nanomaterials with known specific toxic effects (e.g. arsenic and cadmium and their compounds, or crystalline silica), or for which the same material at the macro scale is known to have specific toxic effects;
 - bio-persistent nanomaterials, both non-fibrous (such as titanium dioxide, aluminium oxide) and fibrous (such as carbon nanotubes); and
 - soluble materials for which health hazards have been identified or for which the absence of health hazards is not proven.
- Any situation in which nanomaterials may become airborne, such as the loading and unloading of nanomaterials or chemicals containing nanomaterials into/from milling or mixing equipment, filling of chemicals into containers, sampling of manufactured chemicals and opening of systems for product retrieval.
- Cleaning and maintenance of installations (including closed production systems) and of risk reduction equipment, such as filters in local exhaust ventilation systems.
- Research and development of nanomaterial-containing substances, such as composite materials.
- Handling powders and spraying mixtures containing nanomaterials. Powders are likely to have an increased risk of explosion, self-ignition and electrostatic charging, giving rise to safety concerns. In addition, they may form dust clouds, leading to inhalation exposure.
- Mechanical or thermal treatment of items containing nanomaterials which could be released because of these processes (e.g. laser treatment, grinding, cutting).
- Waste treatment operations involving items containing nanomaterials.

In principle, all activities involving nanomaterials that are conducted outside an enclosed installation can be regarded as critical because there is a risk of exposure to workers. However, even with enclosed installations exposures are still possible, for example in the case of leakages or during cleaning and maintenance activities, and this should also be considered in the risk assessment and implementation of prevention measures.

It is important that priorities in risk management processes are given not only to nanomaterials with known effects on health and safety, but also to those nanomaterials for which there is missing, incomplete or uncertain information regarding their hazards and exposures, in which case a precautionary approach to preventing exposure to nanomaterials in the workplace should be applied.

As traditional approaches for risk assessment of dangerous substances cannot always be applied to nanomaterials, because of the above-mentioned uncertainties, an alternative approach is to use control banding. This is a simplified method of evaluating the risks from activities, and the substances

they involve, and banding them according to their potential hazard and the potential for exposure in the workplace considered.

This e-fact introduces a number of such control banding risk management tools that have been developed to aid in the election of appropriate workplace prevention measures and which, in the context of the limitations mentioned above, could support companies with risk assessment procedures and guidance.

2 Guides and tools available for the management of nanomaterials in the workplace

In order to overcome the limitations already mentioned and to facilitate workplace risk assessment and management of nanomaterials, a number of helpful and informative guides and tools have been developed.

As with any other risk assessment, the complexity and detail needed is dependent on the hazardous substance involved and the activity being undertaken; therefore, in more complex situations it is recommended that expert assistance is sought to apply these tools.

In addition to the guides and tools described below, at the time of drafting this document the European Commission had commissioned Risk & Policy Analysts Ltd (<http://www.rpald.co.uk/>), together with IVAM UvA BV (<http://www.ivam.uva.nl/>), to prepare practical guidance on safe working with engineered nanomaterials and nanotechnology in the workplace, as part of a larger study aimed at establishing the potential impact of nanomaterials and nanotechnology in the workplace and evaluating the scope and requirements of possible modifications to relevant EU safety and health at work legislation. (See more information at:

<http://ec.europa.eu/social/main.jsp?catId=148&langId=en&callId=311&furtherCalls=yes>).

2.1 Web-based interactive control banding tools

Control banding is a qualitative or semi-quantitative risk assessment and management approach to promoting occupational safety and health (OSH). It is intended to minimise the exposure of workers to hazardous chemicals and other risk factors in the workplace, particularly in work situations in which information on hazards, exposure levels and risks are limited. These tools deal with hazard uncertainties in a given work setting or activity by estimating the potential risk at hand in a pragmatic and precautionary way. In other words, in the absence of a full set of data, a precautionary approach is taken.

They are intended to help organisations by providing an easy-to-understand, practical approach to assess the risks of nanomaterials in their workplaces, help them select appropriate prevention measures and assist in raising awareness on the risks associated with the use and handling of nanomaterials. They may therefore be particularly useful for small and medium-sized enterprises (SMEs), and especially micro enterprises, which may encounter the added difficulty of having fewer resources or no in-house expertise in this area.

Most of these tools are under continuous development so that they can be kept up to date with new knowledge on the health and safety aspects of nanomaterials, methods to measure exposure levels, and prevention measures. However, because of the current limitation in information in this area, control banding relies on a number of hazards and exposure assumptions, and some limitations in their use exist.

2.1.1 Stoffenmanager Nano (available in Dutch, English and Finnish)

Available at: <http://nano.stoffenmanager.nl/Default.aspx>

Stoffenmanager Nano Module 1.0 (version 1.0) is a control banding tool, designed by the Dutch Ministry of Social Affairs and Employment together with TNO (the Netherlands Organisation for Applied Scientific Research) and Arbo Unie, for the qualitative assessment and management of

occupational health risks from exposure to nanomaterials via inhalation [23]. Stoffenmanager Nano has been developed to help employers and workers to prioritise the exposure situations involving the handling of nanomaterials and to help in the selection of adequate measures to control the risks. The tool is web based and free (registration required).

It is suitable for all types of insoluble manufactured nanomaterials, for example carbon, insoluble metal and metal oxide nanoparticles, and persistent nanofibres. In the case of soluble nanoparticles, the user is redirected to the generic Stoffenmanager tool for the management of occupational risk associated with dangerous substances. Stoffenmanager Nano can be used when the size of the primary nanoparticles is less than 100 nm or the specific surface area of the nanopowder is greater than 60 m²/g. The tool applies to single particles as well as agglomerates or aggregates. It is based on the determination of hazard and exposure bands through various attributes, with each attribute being allocated a score. All these scores result in a particular hazard band (low, average, high, very high or extreme) and exposure band (low, average, high or very high). The combination of these bands determines the overall risk priority (low, middle or high).

The attributes used to classify nanomaterials into these *hazard* bands relates to the nanomaterials' properties and toxicological data, together with the properties of the same material in its coarse form. All insoluble nanofibres are classified in the most hazardous band because of concerns over their asbestos-like effects after inhalation.

The potential *exposure* is assessed stepwise, taking various aspects into account from the source of the nanomaterial to the breathing zone of the worker. The factors that are used to determine the exposure band are as follows:

- the potential of the nanomaterial to become airborne (dustiness);
- handling process of nanomaterials;
- control measures in use;
- dilution/dispersion potential of the nanomaterial;
- separation of the worker;
- surface contamination;
- respiratory protective equipment in use;
- frequency of the task; and
- duration of the task.

The Stoffenmanager Nano tool finally creates three risk (or priority) bands by combining the results from the exposure and hazard banding steps. A risk reduction plan can then be designed. Stoffenmanager Nano provides a list of possible control measures for each risk band that can be implemented to lower the potential exposure and thus reduce the risk. Subsequently, the risk assessment process is performed again automatically. This allows the user to check the effectiveness of the control measures that have been chosen.

Stoffenmanager Nano gives the option of generating and printing a report with the results of the risk assessment. In addition, it allows the user to create a list/library of the nanoproducts used in the workplace/company and offers educational factsheets with examples of good practice as well as PIMEX movies (²).

2.1.2 CB Nanotool 2.0 (available in English)

Available at: <http://controlbanding.net/Services.html>

CB Nanotool 2.0 is an interactive control-banding-based toolkit for nanomaterials. The toolkit was developed at the US Lawrence Livermore National Laboratory in order to perform a risk assessment and to protect researchers in the laboratory [24–26].

²) PIMEX (Picture Mixed Exposure) are movies that can be used to give insight into the impact of control measures. The Dutch Ministry of Social Affairs and Employment has developed these movies as part of the enhancement of the Health and Safety Policy Substances Program. More information is available at: <https://www.stoffenmanager.nl/Public/Pimex.aspx>

The tool utilises a 4×4 risk matrix to determine the risk level, with the severity parameters on one axis and probability parameters on the other. The severity score is calculated using the following factors:

- nanomaterial properties:
 - surface chemistry;
 - particle shape;
 - particle diameter;
 - solubility;
 - carcinogenic, mutagenic and reprotoxic (CMR) properties (three factors);
 - dermal toxicity; and
 - asthma-inducing properties (asthmagen).
- parent material properties:
 - toxicity based on the occupational exposure limit (OEL) of the parent material;
 - CRM properties (three factors);
 - dermal hazard potential; and
 - asthma-inducing properties (asthmagen).

The probability score is based on the following factors that determine the extent of the potential exposure:

- amount of nanomaterial handled during the work operation;
- dustiness or mistiness level of the material;
- number of workers with similar exposure;
- frequency of operation; and
- duration of operation.

The tool provides indications on how to score each of these parameters and sets the maximum score that can be attributed to each.

The tool handles the health risk uncertainty of the nanomaterials by combining information on the nanomaterial and the same material at macro scale. If the information required in relation to a specific parameter is unknown, the input value of 75% of the maximum score defined for this parameter by the tool is assigned to the unknown parameter. This is said to be a balance between a precautionary principle (conservative approach) and a reasonable scientific estimate, enabling research to progress while still protecting the workers.

The risk level of the nanomaterial operation is ascertained by combining the severity and the probability scores. The method defines four possible risk levels, each with a corresponding control band:

- implementation of general ventilation (lowest risk level);
- fume hood or local exhaust ventilation;
- containment; and
- seek specialist advice (highest risk level).

2.1.3 NanoSafer (available in Danish)

Available at: <http://nanosafer.i-bar.dk/>

NanoSafer is a Danish control banding tool for managing nanomaterials in the workplace [27]. This control banding tool covers only nanomaterials in powder form. NanoSafer was developed by the Danish Technological Institute and National Research Center for the Working Environment. It is web based and free (registration required), but available only in Danish.

The first step is to identify the nanomaterial and its physical properties (particle size, density and surface area), its OEL (if available), its dustiness index (for respirable or mineral dust) and toxicological information from the SDS.

The second step is to define the process (powder handling or accidental release, such as spillage), the amount of nanomaterial used, the frequency of use and the working environment.

The method combines the data on the material (enabling assessment of the toxicity level) with the process data (enabling assessment of the exposure level). The risk level is assessed for acute exposure (15 minutes) and 8-hour exposure. This is carried out for workers who are both near to and far from the emission source (near-and far-field exposure, respectively). Furthermore, the tool recommends suitable control measures for each risk level, with educational videos about these measures.

2.2 Other control banding tools for nanomaterials

2.2.1 ANSES Control Banding tool for nanomaterials (available in French and English)

Available at: <http://www.afsset.fr/index.php?pageid=2820&parentid=805>

This control banding tool for nanomaterials was developed by experts from the Agence nationale de sécurité sanitaire, de l'alimentation, de l'environnement et du travail (ANSES, France) together with an expert panel from the National Research and Safety Institute (INRS, France), the Institut de Recherche Robert Sauvé en Santé et en Sécurité du Travail (IRSST, Canada), the Scientific Institute of Public Health (ISP-WIV, Belgium) and the Institute for Work and Health (IST, Switzerland). The ANSES Control Banding tool is available only as a paper version [28].

This tool can be used in any working environment where nanomaterials are manufactured or used, for example industrial workshops, research laboratories and pilot plants.

The authors point out that this method must be integrated into an overall system for OSH management as is, in fact, the case for all other tools described in this e-fact. Its use is, however, subject to some limitations:

- The method should be applied only to routine handling of materials in the workplace, as part of the company's normal operations.
- The nanomaterials should not be too diluted, nor in too great a volume.
- The method can be used to determine only the risks to health - not the risks to safety (i.e. not for fire/explosion risk) or the environment.

It is also recommended that the user should be adequately qualified in chemical risk prevention (e.g. chemistry and toxicology), as well as nanoscience and nanotechnology. Finally, it is noted that applying the method without expertise, critical outlook or support may lead to false assumptions, meaning that unsuitable prevention measures are taken, which increases the risk of exposure.

Hazard band allocation starts with preliminary questions to determine:

- whether the product or material used in the work process contains nanomaterials;
- whether the nanomaterial or product that contains nanomaterials is classified as a hazardous substance; or
- whether the product contains bio-persistent fibrous nanomaterials.

If the nanomaterial or the product in question is classified according to the chemical and labelling legislation, that classification information should be used for the hazard band allocation. If the toxicological information is incomplete or non-existent, a preliminary hazard band allocation is made based on the information available for the parent material or analogous material (i.e. a substance with similar composition and/or crystalline phase and from the same chemical category; with similar documented physicochemical properties to the substance in question). In cases for which toxicity information about a parent material or analogous material has been used, the tool describes increment factors that will address the uncertainty linked to the analogy made. When the bulk material exists, it takes precedence over the analogous material. Finally, if there are several choices for the same bulk (analogous) material, the most toxic one should be taken into account.

The tool cannot be applied if the toxicity of the nanomaterial is unknown or cannot be associated with any parent material or analogous material.

In order to allocate nanomaterial operations into exposure bands, the emission potential of the operation must be estimated. A key parameter in this estimation is the physical form of the nanomaterial processed. Four physical categories are considered: solid, liquid, powder and aerosol. In certain cases, the emission potential of the physical form is modified to take account of the natural tendency of the material to become airborne [e.g. friable solids (solids that can be crumbled, pulverised or reduced to powder by the pressure of an ordinary human hand), highly volatile liquids, or powders with high or moderate dustiness] and certain process operations (e.g. melting and spraying).

The risk control band is determined by combining the hazard and emission potential bands. Technical solutions are recommended for each of the five risk control bands (CLs) defined in the tool:

- natural or mechanical general ventilation (CL1);
- local ventilation (CL2);
- enclosed ventilation (CL3);
- full containment (CL4); and
- full containment and review by a specialist (CL5).

2.2.2 Guidance on working safely with nanomaterials and nanoproducts - guide for employers and employees (available in English)

Available at:

<http://www.industox.nl/Guidance%20on%20safe%20handling%20nanomats&products.pdf>

This control banding guidance has been developed in a joint effort among Dutch employers and workers and the social partners FNV, VNO-NCV and CNV, and is financed by the Dutch Ministry of Social Affairs and Employment. The guidance is especially aimed at employers and employees so that they can organise a safe workplace for working with nanomaterials and products containing nanomaterials and to support them in designing suitable control measures and in implementing good work practices. It is available only as a paper version [29].

This guidance consists of eight different steps and provides the appropriate forms for collecting the required information:

- making an inventory of nanomaterials produced or used;
- establishing the potential health hazards associated with nanomaterials produced or used (three categories);
- making an inventory of activities performed with nanomaterials;
- scoring the possibility that workers are exposed to nanoparticles through the activities performed (three categories);
- obtaining the resulting control approach band for each activity (three categories);
- drawing up an action plan with risk control measures;
- making a register for all workers dealing with nanomaterials with hazard category 2 or 3; and
- investigating whether preventive medical surveillance is possible and acting accordingly.

This control banding guidance is simple and easy to use, and it gives recommendations for risk management measures to improve safety when working with engineered nanomaterials. It is emphasised that existing legislation for working with hazardous substances does apply; if the corresponding coarse material of the nanomaterial has been classified as a CMR substance, or if the nanomaterial itself shows CMR characteristics, the appropriate legislation should be followed. The guidance does not support risk management of unintentionally generated nanomaterials, such as diesel or welding fumes.

2.2.3 Workplace Health and Safety Queensland: nanomaterial control banding tool worksheet (available in English)

Available at: <http://www.deir.qld.gov.au/workplace/subjects/nanotechnology/controlbanding/index.htm>

The control banding section of this worksheet is similar to CB Nanotool 2.0. It also considers the flammability of nanomaterials, but does not cover all the information needed to evaluate the fire and explosion risks of nanomaterials.

This nanotool is particularly relevant to research facilities, where small quantities of nanomaterials are likely to be used. However, it can also be applied generally to all workplaces where nanomaterials are present. This tool is likely to improve as more information on the hazards and risks of nanomaterials becomes available.

2.3 Other tools

2.3.1 GoodNanoGuide (GNG) (available in English)

Available at: <http://www.goodnanoguide.org>

The GoodNanoGuide (GNG) is a web-based interactive collaboration platform developed by the International Council on Nanotechnology at Rice University in the USA. The website serves as a platform for exchanging ideas on handling nanomaterials in the workplace. It also provides guidance on how best to handle nanomaterials in an occupational setting for basic, intermediate and advanced users [30].

In **the basic section** there is only a brief explanation of nanomaterials, nanotechnology and nanotechnology safety, with links to other Internet resources.

In **the intermediate section**, it is assumed that the user is already familiar with nanotechnologies and nanomaterials and is looking for guidelines or protocols for working with specific types of engineered nanomaterials. This section proposes three different ways in which to categorise nanomaterials. Users decide which approach they consider the best for the situation at their workplace:

- The first approach is a simplified control banding approach, in which nanomaterials are classified according to the level of knowledge on the hazards of the nanomaterial (known to be inert/reactive/unknown). It also gives guidance on how the exposure can be controlled based on the exposure duration (short/medium/long) and the potential of the nanomaterial to become airborne (bound materials/potential release/free or unbound).
- The second proposed approach is taken from the British Standards Institution (BSI), according to which nanomaterials are categorised by type of hazard (fibrous/Carcinogenic, Mutagenic, Asthmagenic or Reprotoxic/insoluble/soluble) [31]. It is considered as a starting point for hazard assessment. No guidance is specified here for exposure assessment/control.
- The third approach is based on the chemical structure of the nanomaterial (fullerenes/ carbon nanotubes (CNTs) / metals / oxides / quantum dots / semiconductor nanomaterials). Information on specific risks and safe-handling protocols are given.

The advanced section provides environmental, health and safety protocols for safe handling of nanomaterials. It features a matrix of activities that pose potential handling hazards combined with various physical forms of nanomaterials (dry powder, liquid dispersion, solid polymer matrix and non-polymer matrix).

- The process starts with identifying the **potential hazards**. The indicators for potential hazards that should be considered are the physicochemical, toxicological and ecotoxicological characteristics (e.g. particle size, surface area, surface chemistry, reactivity, morphology, bio-persistence, interactions with bio-molecules and anti-microbial effects, as well as possible modifications due to, for example, ageing of the nanomaterial or interactions with other molecules). The BSI classification scheme is also recommended [31].

- The second step is estimating the **exposure potential**. Information on exposure during different phases of nanomaterial handling is given by the tool.
- The third step in the process is the choice of appropriate **controls**. Information on the recommended controls for different tasks in which nanomaterials are handled is given by the tool.

The advanced knowledge section also includes an editable OSH Reference Manual to guide the user in investigating and mitigating the risks posed by nanomaterials.

2.4. Comparative overview of the tools described

Table 1: Overview of the risk management tools available and their characteristics

Risk management tool	Risk management approach	Application area	Limitations
Stoffenmanager Nano (Dutch, English, Finnish)	<ol style="list-style-type: none"> (1) Identification of the nanomaterial and listing of the properties of the nanomaterials (2) Description of processes (3) Description of working area (4) Description of control measures already in place (5) Resulting risk assessment (6) Creating action plan with risk control measures 	Insoluble (in water) manufactured nanomaterials with a size smaller than 100 nm and a specific surface area larger than 60 m ² /g. It covers primary nanoparticles, agglomerates and aggregates	<ol style="list-style-type: none"> (a) If nanomaterial belongs to the most hazardous class (E), it will be a high-priority risk regardless of the exposure, because the tool is based on a precautionary approach with regards to the most hazardous materials (b) All the fibres are placed in the most hazardous class (E) (c) Control measures selected for use seldom decrease the actual risk level within the tool
CB Nanotool 2.0 (English)	Typical control banding scheme with estimation of hazard band (severity score) and exposure band (probability score) of the activity used to determine the overall risk level (four levels). Severity score is calculated based on the characteristics of the nanomaterial and macro-scale material. A recommended control approach is given for each risk level	Laboratory-scale work; situations involving only small amounts of nanomaterials	Toxicological endpoints covered by the tool have seldom been studied; exposure band covers only a few determinants

Risk management tool	Risk management approach	Application area	Limitations
NanoSafer (Danish)	<ol style="list-style-type: none"> (1) Identification of the nanomaterial and macro-scale material properties (particle size, density and surface area), OELs available for respirable or mineral dust, dustiness index and toxicological information from SDS (2) Identification of the process (powder handling or accidental release) (3) Determination of the assessment score (4) Provision of guidance for control measures 	Workplaces in which nanomaterials are handled in powder form, as well as accidental releases of nanomaterials	The hazard assessment is based on physical parameters and SDSs, which seldom have any toxicological information for nanomaterials; the tool covers nanomaterials only in powder form; available only in Danish
ANSES Control Banding (French, English)	<p>Control banding integrated to OHSAS 18001 (standard for OSH management systems) scheme:</p> <ol style="list-style-type: none"> (1) Analysis of available information (product and workplace) (2) Hazard band allocation (3) Emission potential allocation (4) Action plan definition (5) Implementation of action plan (6) Routine monitoring (7) Periodical risk review (8) Scientific and technology survey for updating knowledge (9) Data recording 	All working environments	Information necessary for hazard band allocation (e.g. reactive oxygen species activity) might be difficult to gather. Available as only a paper version
Guidance on working safely with nanomaterials and nanoproducts (English)	<ol style="list-style-type: none"> (1) Making an inventory of nanomaterials produced or used (2) Classifying the potential health hazards of nanomaterials produced or used (3) Making an inventory of activities performed with nanomaterials (4) Classifying the possibility of exposure of workers 	For employers and workers working with nanomaterials	Available as only a paper version

Risk management tool	Risk management approach	Application area	Limitations
	(5) Obtaining the resulting control approach band for each activity involving nanomaterials (6) Drawing up an action plan (7) Keeping a register of workers dealing with nanomaterials (8) Investigating whether preventative medical surveillance is possible		
Queensland control banding worksheet (English)	Control banding part similar to CB Nanotool, but also includes aspects of flammability	As for CB Nanotool; considers flammability	As for CB Nanotool. Fire and explosion risk is not fully identified. Available only as a paper version
GoodNanoGuide (English)	Guidance is provided based on the knowledge level of the user: basic, intermediate and advanced. In the advanced option, the risk management approach is to (1) identify hazard potential, (2) estimate exposure and (3) recommend controls	Approach is very general and applicable to many situations in which nanomaterials are handled	Many web pages of the tool still incomplete. Guidance is based on US regulations (e.g. for personal protective equipment)

3. Prevention measures

Having made an assessment of the risk from exposure to nanomaterials, employers must ensure that such exposure is either prevented or adequately controlled.

3.1 Elimination and substitution

As with all other dangerous substances, elimination and substitution should be given priority over other prevention measures. The aim is to prevent all workers from exposure to nanomaterials. However, in the case manufactured nanomaterials are used or produced for specific properties that may not be exhibited by other less hazardous materials, elimination or substitution of the may not be an option. However, the balance between the desired properties and effects, on the one hand, and health risks, on the other hand, should always be borne in mind and elimination and substitution given thorough consideration.

In any case, using or producing nanomaterials in a form that may become airborne (such as powders) should be avoided. These should be substituted by a less hazardous form, such as solubilised or liquid forms, granulates or pastes, or nanomaterials bounded into solids.

In addition, it may be possible to reduce the hazard potential of a nanomaterial by coating it, that is modifying its surface.

3.2 Technical measures

Technical prevention measures should be implemented at the source of emission. The most effective technical preventive measure is containment at source through the use of closed systems and enclosed machines and processes, that is enclosures and isolations that create a physical barrier between a person and the nanomaterial. However, even with such measures, it is important to stress that the risk of leakages would still need to be considered. Local exhaust ventilation systems equipped with particle filters, such as high-efficiency particulate air (HEPA) or ultra-low penetration air filters, incorporated in fume hoods or downflow booths, are other standard measures for processes that cannot be fully contained.

Specific provisions other than engineering controls will be required if contained processes are opened, for example for loading/unloading, sampling, cleaning or maintenance. In these situations the use of respiratory protective equipment is considered a valid control strategy (see section 3.4.1).

3.3 Organisational measures

The most important organisational measure that will help to minimise the potential exposure of workers is the segregation of work areas, in other words minimising the number of people potentially exposed. Specific areas where nanomaterials are manufactured or used, and could therefore be released, should be designated and isolated or separated by, for example, walls from other workplaces. These areas should be clearly marked with appropriate signs that indicate that access is permitted only to authorised and trained personnel.

It is important to note that currently there is no standardised approach for the use of safety signs or for the labelling of workplaces or containers with nanomaterials. It is recommended that a diligent approach is taken using existing risk and safety phrases (European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixture [15]) and warning signs to provide adequate, relevant and specific information on any actual or potential health and safety risks from the use and handling of nanomaterials.

In addition to reducing the number of workers exposed to nanomaterials, it is also important that the following organisational measures are implemented:

- Minimise the potential exposure time of workers.
- Minimise the quantity of particulate nanomaterial in use at any one time.
- Monitor air concentration levels.
- Clean (wet wiping) work areas regularly.
- Workers handling potentially hazardous nanomaterials should be included in health surveillance programmes, with the exposure situation documented in detail.

In addition, all workers who may be exposed to nanomaterials in their workplace should receive sufficient instructions, information and training to understand the risks to their safety and health caused by potential exposure to nanomaterials and the precautions that should be taken to avoid or minimise such exposure. If there are uncertainties about the health and safety impact of these nanomaterials, workers should be equally informed about this, and the precautionary principle should be implemented.

3.4 Personal protective equipment

According to the hierarchy of control measures, personal protective equipment (PPE) should be used as a last resort. If PPE⁽³⁾ is determined to be necessary in the risk assessment, a PPE programme should be designed [32]. A good PPE programme will consist of the following elements: selection of appropriate PPE, fitting, training and maintenance of PPE.

⁽³⁾ The European Directive 89/686/EEC [32] regulates the design and use of PPE and ensures it fulfills its intended function of protecting workers from specific risks.

The additional physical demand of wearing any PPE needs to be assessed to ensure that the user is sufficiently fit to wear the equipment. Trials could be carried out to ensure that the PPE does not impede the worker from carrying out his or her work safely and from using other necessary equipment and tools, for example spectacles. It should be borne in mind that the level of protection of a PPE may be reduced when several types of PPE are used simultaneously. Additional hazards, such as solvent vapours, may also reduce the effectiveness of the PPE. Therefore, all hazards in addition to nanomaterials must be considered during the risk assessment process and when selecting the PPE. All PPE must have a CE marking, and be used in accordance with the manufacturer's instructions, without modification.

3.4.1 Respiratory protection

If the measures previously mentioned are not adequate to control exposure to airborne nanomaterials (e.g. nanopowders or aerosols containing nanomaterials), or do not sufficiently reduce this exposure, it is recommended that appropriate respiratory protective devices (RPDs) for such exposures are used. This should for example be the case when the control measures themselves are being maintained or repaired.

The choice of RPD will depend on the:

- type, size and concentration of the airborne nanomaterial;
- assigned protective factor for the RPD (which integrates filtering effectiveness and face–seal fit); and
- working conditions.

The RPDs selected could be half-face masks or full-face masks with P3/FFP3 or P2/FFP2 filters, particle-filtering devices with air blower and helmet (TH2P or MH3P) or particle-filtering devices with air blower and full or half-face masks (TM2P and TM3P) ⁽⁴⁾. Full-face masks in combination with airlines and powered filtering devices usually have higher protection factors.

The effectiveness of filters in RPDs for a specific nanomaterial under specific conditions should be checked with the PPE producer, as test results may not be generalised for all nanomaterials. It should be noted that HEPA filters, respiratory cartridges and masks with fibrous filtering materials are effective for nanomaterials (even more effective than for larger particles [34]).

Other factors, such as face-fit, proper RPD maintenance and the length of time worn, can also influence exposure mitigation. For face masks, the main risks stem from insufficient tightness between the mask and the face [34]. Regular testing for the fit of masks should be arranged for all users to ensure they are leak tight, and users should be trained in the use of RPDs. Exposure reduction should always be regarded as a combination of the filter effectiveness and the usage characteristics of the respirator, which is expressed by so-called respiratory factors in some EU countries.

In cases in which the RPDs do not cover the eyes, eye protection should also be used (tight-fitting safety goggles).

3.4.2 Gloves

Gloves need to have a high mechanical durability, and only gloves that fulfil the requirements of the standard series EN 374 should be used to protect against chemical hazards in general. When handling nanomaterials, gloves made from latex, nitrile or neoprene have been found to be effective [33]. The effectiveness of gloves for a specific nanomaterial will depend on the physical form of the nanomaterial that is present in the workplace (dusts, liquids, etc.) - this should be checked and confirmed by the glove suppliers. The thickness of the glove material is a major factor in determining the diffusion rate of the nanomaterial; therefore it is also recommended that two pairs of gloves are used at the same time to provide appropriate protection [34].

⁽⁴⁾ See [33]: The penetration of P2 filters is 0.2% and of P3 filters is 0.011% of the particles for nanoparticles of potassium chloride. Tests with different sizes of graphite particle showed penetration of maximum 8%. This indicates a higher protection from P3 filters, but the results cannot be generalised to all nanoparticles.

3.4.3 Protective clothing

Protective clothing should be selected according to the risk assessment. Non-woven textiles (air-tight materials) such as high-density polyethylene (low-dust-retention and low-dust-release fabrics) should be preferred over woven ones. It is recommended that the use of protective clothing made with cotton fabric is avoided [34].

If re-usable protective clothing such as overalls is used, provision should be made for regular laundry and the prevention of secondary exposure [35]. Provision must be made to allow clean overalls and protective clothing coats to be put on and dirty ones removed in a manner that does not contaminate the individuals or the general workplace.

3.5 Prevention of explosion and/or fire

As a result of their small size and large surface area, particulate nanomaterials in powder form may present risks of explosion, whereas their respective coarse materials may not ⁽⁵⁾ [36]. Care should be taken when nanopowders are handled or generated, including when grinding, sanding or polishing materials containing nanomaterials.

Preventive measures for nanomaterials in powder form are essentially the same as for any other explosive and flammable coarse material and explosive dust clouds, and should follow the requirements in Directive 99/92/EC on minimum requirements for improving the safety and health protection of workers potentially at risk from explosive atmospheres. These include:

- Handling should, when possible, be limited to specific Ex-zones, and carried out in inert atmospheres.
- Materials should be solubilised by wetting the workplace (prevention of dusts).
- Low-spark equipment and other ignition sources or conditions facilitating electrostatic charging should be removed from the workplace; instead intrinsically safe equipment (signal and control circuits operating with low currents and voltages) should be used, when possible.
- Dust layers should be removed by wet mopping up.
- Storage of explosive or flammable materials at workplaces should be minimised. Anti-static bags may be used.

If nanomaterials are used, as opposed to generated, during work activities, the manufacturer's recommendations in the SDS should be considered. However, the general remarks mentioned previously regarding the quality of SDSs in relation to nanomaterials should be borne in mind.

3.6 Checking the effectiveness of prevention measures

The risk assessment should be regularly revised and the choice and implementation of risk management measures regularly controlled and checked with regards to their effectiveness. This means ensuring the proper functioning of all protective equipment, such as clean benches or laminar flow booths, and regular inspection of all ventilation equipment and their respective filtering systems. Furthermore, the suitability of PPE should be checked and updated, if necessary.

The effectiveness of a risk reduction measure can be assessed by analysing the concentration of nanomaterials in the air before and after the prevention measure. The exposure levels measured when risk management measures are applied should not significantly differ from background concentrations, when there is no source of manufactured nanomaterials. Other indirect measurements for the effectiveness of technical preventive measures can also be applied, such as smoke tests and/or control velocity measurements.

⁽⁵⁾ The explosiveness of most organic and many metal dusts increases with decreasing particle size. 500 µm appears to be the upper particle size limit of an explosive dust cloud. Currently, no size limit has been determined below which dust explosions can be excluded.

OEL values may be developed in the future; however, exposure minimisation should be the primary goal of workplace risk management, so meeting OELs is not sufficient. At present there are several approaches for developing benchmark levels for nanomaterial [37, 38].

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