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Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 2:
Use of the control banding approach

Nanotechnologies — Gestion du risque professionnel appliquée aux nanomatériaux manufacturés —

Partie 2: Utilisation de l'approche par bandes de dangers

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Foreword

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The committee responsible for this document is ISO/TC 229, *Nanotechnologies*.

ISO/TS 12901 consists of the following parts, under the general title *Nanotechnologies — Occupational risk management applied to engineered nanomaterials*:

— *Part 1: Principles and approaches*

— *Part 2: Use of the control banding approach*

Introduction

According to the current state of knowledge, nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAA) can exhibit properties, including toxicological properties, which are different from those of non-nanoscale (bulk) material. Therefore, current occupational exposure limits (OELs), which are mostly established for bulk materials might not be appropriate for NOAA. In the absence of relevant regulatory specifications for NOAA, the control banding approach can be used as a first approach to controlling workplace exposure to NOAA.

NOTE 1 Aggregates and agglomerates smaller than 100 nm are to be considered as nano-objects.

Control banding is a pragmatic approach which can be used for the control of workplace exposure to possibly hazardous agents with unknown or uncertain toxicological properties and for which quantitative exposure estimations are lacking. It may complement the traditional quantitative methods based on air sampling and analysis with reference to OELs when they exist. It can provide an alternative risk assessment and risk management process, by grouping occupational settings in categories presenting similarities of hazards and/or exposure, while incorporating professional judgment and monitoring. This process applies a range of control techniques (such as general ventilation or containment) to a specific chemical, considering its range (or band) of hazard and the range (or band) of exposure.

In general, control banding is based on the idea that while workers can be exposed to a diversity of chemicals, implying a diversity in risks, the number of common approaches to risk control is limited. These approaches are grouped into levels based on how much protection the approach offers (with “stringent” controls being the most protective). The greater the potential for harm, the greater the levels of protection needed for exposure control.

Control banding was originally developed by the pharmaceutical industry as a way to safely work with new chemicals that had little or no toxicity information. These new chemicals were classified into “bands” based on the toxicity of analogous and better known chemicals and were linked to anticipated safe work practices, taking into consideration exposure assessments. Each band was then aligned with a control scheme.[1] Following this concept, the Health and Safety Executive (HSE) in the UK has developed a user-friendly scheme called COSHH Essentials,[2][3][4] primarily for the benefit of small- and medium-sized enterprises that might not benefit from the expertise of a resident occupational hygienist. Similar schemes are used in the practical guidance given by the German Federal Institute for Occupational Safety and Health.[5] The Stoffenmanager Tool[6] represents a further development, combining a hazard banding scheme similar to that of COSHH Essentials and an exposure banding scheme based on an exposure process model, which was customized in order to allow non-expert users to understand and use the model.

Control banding can be particularly useful for the risk assessment and management of nanomaterials, given the level of uncertainty in work-related potential health risks from NOAA. It may be used for risk management in a proactive manner and in a retroactive manner. In the proactive manner existing control measures, if any, are not used as input variables in the potential exposure banding while in a retroactive manner existing control measures are used as input variables. Both approaches are described in this part of ISO/TS 12901. While control banding appears, in theory, to be appropriate for nanoscale materials exposure control, very few comprehensive tools are currently available for ongoing nanotechnology operations. A conceptual control banding model was presented by Maynard[7] offering the same four control approaches as COSHH. A slightly different approach, called “Control Banding Nanotool”, was presented by Paik et al.[8][9] This approach takes into account existing knowledge of NOAA toxicology and uses the control banding framework proposed in earlier publications. However, the ranges of values used in the “Control Banding Nanotool” correspond to those ranges that one would expect in small-scale research type operations (less than one gram) and might not seem appropriate for larger scale uses. In the meantime several other specific control banding tools have been published to control inhalation exposure to engineered nanomaterials for larger scale uses.[10][11][12][13][14] All these tools define hazard bands and exposure bands for inhalatory exposure and combine these in a two-dimensional matrix, resulting in a score for risk control (proactive approach).

Schneider et al.[15] have developed a conceptual model for assessment of inhalation exposure to engineered nanomaterials, suggesting a general framework for future exposure models. This framework follows the same structure as the conceptual model for inhalation exposure used in the Stoffenmanager Tool and the Advanced REACH Tool (ART).[6][16][17] Based on this conceptual framework, a control banding tool called “Stoffenmanager Nano” has been developed,[18] encompassing both proactive approach and retroactive (risk banding) approach.

In addition, the French agency for food, environmental and occupational health and safety (ANSES) have developed a control banding tool specifically for nanomaterials which is described in the report “Development of a specific control banding tool for nanomaterials” [31].

The biggest challenge in developing any control banding approach for NOAA is to decide which parameters are to be considered and what criteria are relevant to assign a nano-object to a control band, and what operational control strategies ought to be implemented at different operational levels.

This part of ISO/TS 12901 proposes guidelines for controlling and managing occupational risk based on a control banding approach specifically designed for NOAA. It is the responsibility of manufacturers and importers to determine whether a material of concern contains NOAA, and to provide relevant information in safety data sheets (SDS) and labels, in compliance with any national or international existing regulation. Employers can use this information to identify hazards and implement appropriate controls. This part of ISO/TS 12901 does not intend to give recommendations on this decision-making process. It cannot replace regulation and employers are expected to comply with the existing regulations.

It is emphasized that the control banding method applied to manufactured NOAA requires assumptions to be formulated on information that is desirable but unavailable. Thus the user of the control banding tool needs to have proven skills in chemical risk prevention and more specifically in risk issues known to be related to that type of material. The successful implementation of this approach requires a solid expertise combined with a capacity for critical evaluation of potential occupational exposures and training to use control banding tools to ensure appropriate control measures and an adequately conservative approach.

In parallel to the approach described in this part of ISO/TS 12901, a full hazard assessment is advisable to consider all substance-related hazards, including explosive risk (see NOTE 2), and environmental hazards.

NOTE 2 Explosive dust clouds can be generated from most organic materials, many metals and even some non-metallic inorganic materials. The primary factor influencing the ignition sensitivity and explosive violence of a dust cloud is the particle size or specific surface area (i.e. the total surface area per unit volume or unit mass of the dust) and the particle composition. As the particle size decreases the specific surface area increases. The general trend is for the violence of the dust explosion and the ease of ignition to increase as the particle size decreases, though for many dusts this trend begins to level out at particle sizes of the order of tens of micrometres (μm). However, no lower particle size limit has been established below which dust explosions cannot occur and it has to be considered that many nanoparticle types have the potential to cause explosions.

Nanotechnologies — Occupational risk management applied to engineered nanomaterials —

Part 2: Use of the control banding approach

1 Scope

The purpose of this part of ISO/TS 12901 is to describe the use of a control banding approach for controlling the risks associated with occupational exposures to nano-objects, and their aggregates and agglomerates greater than 100 nm (NOAA), even if knowledge regarding their toxicity and quantitative exposure estimations is limited or lacking.

The ultimate purpose of control banding is to control exposure in order to prevent any possible adverse effects on workers' health. The control banding tool described here is specifically designed for inhalation control. Some guidance for skin and eye protection is given in ISO/TS 12901-1.[19]

This part of ISO/TS 12901 is focused on intentionally produced NOAA that consist of nano-objects such as nanoparticles, nanopowders, nanofibres, nanotubes, nanowires, as well as of aggregates and agglomerates of the same. As used in this part of ISO/TS 12901, the term "NOAA" applies to such components, whether in their original form or incorporated in materials or preparations from which they could be released during their lifecycle. However, as for many other industrial processes, nanotechnological processes can generate by-products in the form of unintentionally produced NOAA which might be linked to health and safety issues that need to be addressed as well.

This part of ISO/TS 12901 is intended to help businesses and others, including research organizations engaged in the manufacturing, processing or handling of NOAA, by providing an easy-to-understand, pragmatic approach for the control of occupational exposures.

Control banding applies to issues related to occupational health in the development, manufacturing and use of NOAA under normal or reasonably predictable conditions, including maintenance and cleaning operations but excluding incidental or accidental situations.

Control banding is not intended to apply to the fields of safety management, environment or transportation; it is considered as only one part of a comprehensive risk management process.

Materials of biological origin are outside the scope of this part of ISO/TS 12901.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 27687, *Nanotechnologies — Terminology and definitions for nano-objects — Nanoparticle, nanofibre and nanoplate*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/TS 27687 and the following apply.

3.1
agglomerate
collection of weakly bound particles or aggregates or mixtures of the two where the resulting external surface area is similar to the sum of the surface areas of the individual components

Note 1 to entry: The forces holding an agglomerate together are weak forces, for example van der Waals forces, or simple physical entanglement.

Note 2 to entry: Agglomerates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO/TS 27687:2008, definition 3.2]

3.2
aggregate
particle comprising strongly bonded or fused particles where the resulting external surface area may be significantly smaller than the sum of calculated surface areas of the individual components

Note 1 to entry: The forces holding an aggregate together are strong forces, for example covalent bonds, or those resulting from sintering or complex physical entanglement.

Note 2 to entry: Aggregates are also termed secondary particles and the original source particles are termed primary particles.

[SOURCE: ISO/TS 27687:2008, definition 3.3]

3.3
analogous material
material of the same chemical category, with a similar composition and/or crystalline phase and documented similar physicochemical properties (metal oxides, graphite, ceramics, etc.)

3.4
bulk material
material of the same chemical composition as the NOAA, at a scale greater than the nanoscale

3.5
classification and labelling
system to communicate hazard information about a specific substance based on the principles of the GHS (Globally Harmonized System of classification and labelling of chemicals), or equivalent, and GHS' transposition into national legislation (e.g.: Regulation (EC) No 1272/2008 for the European Union)

3.6
chemical category
group of chemicals whose physicochemical and human health and/or ecotoxicological properties and/or environmental fate properties are likely to be similar or follow a regular pattern, usually as a result of structural similarity

3.7
dustiness
tendency of particles to separate from the main bulk of powder and then to be dispersed into the atmosphere

3.8
exposure
contact with a chemical, physical or biological agent by swallowing, breathing, or touching the skin or eyes

Note 1 to entry: Exposure can be short-term (acute exposure), of intermediate duration, or long term (chronic).

3.9
health hazard
potential source of harm to health

[SOURCE: ISO 10993-17:2002, definition 3.7]

3.10
health risk
combination of the likelihood of occurrence of harm to health and the severity of that harm

[SOURCE: ISO 10993-17:2002, definition 3.8]

3.11
nanofibre
nano-object with two similar external dimensions in the nanoscale and the third dimension being significantly larger

Note 1 to entry: A nanofibre can be flexible or rigid.

Note 2 to entry: The two similar external dimensions are considered to differ in size by less than three times and the significantly larger external dimension is considered to differ from the other two by more than three times.

Note 3 to entry: The largest external dimension is not necessarily in the nanoscale.

[SOURCE: ISO/TS 27687:2008, definition 4.3]

3.12
nano-object
material with one, two or three external dimensions in the nanoscale

Note 1 to entry: Generic term for all discrete nanoscale objects.

[SOURCE: ISO/TS 27687:2008, definition 2.2]

3.13
nanoparticle
nano-object with all three dimensions in the nanoscale

Note 1 to entry: If the lengths of the longest to the shortest axes of the nano-object differ significantly (typically by more than three times), the terms nanorod or nanoplate are intended to be used instead of the term nanoparticle.

[SOURCE: ISO/TS 27687:2008, definition 4.1]

3.14
nanoplate
nano-object with one external dimension in the nanoscale and the two other external dimensions significantly larger

Note 1 to entry: The smallest external dimension is the thickness of the nanoplate.

Note 2 to entry: The two significantly larger dimensions are considered to differ from the nanoscale dimension by more than three times.

Note 3 to entry: The larger external dimensions are not necessarily in the nanoscale.

[SOURCE: ISO/TS 27687:2008, definition 4.2]

3.15
nanoscale
size range from approximately 1 nm to 100 nm

Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate.

Note 2 to entry: The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit.

[SOURCE: ISO/TS 27687:2008, definition 2.1]

3.16
particle
minute piece of matter with defined physical boundaries

Note 1 to entry: A physical boundary can also be described as an interface.

Note 2 to entry: A particle can move as a unit.

Note 3 to entry: This general particle definition applies to nano-objects.

[SOURCE: ISO/TS 27687:2008, definition 3.1]

3.17
solubility
maximum mass of a nanomaterial that is soluble in a given volume of a particular solvent under specified conditions

Note 1 to entry: Solubility is expressed in grams per litre of solvent.

[SOURCE: ISO/TR 13014, definition 2.27]

4 Symbols and abbreviated terms

CMRS carcinogenicity, mutagenicity, reprotoxicity or sensitization

COSHH control of substances hazardous to health

GHS Globally Harmonized System of classification and labelling of chemicals

SDS safety data sheet

NOAA nano-objects, and their aggregates and agglomerates greater than 100 nm

OEL occupational exposure limit

PPE personal protective equipment

STOP substitution, technical measures, organizational measures, personal protective equipment

TEM transmission electron microscopy

5 General framework for control banding applied to NOAA

5.1 General

The control banding tool described in this part of ISO/TS 12901 applies to NOAA and materials containing NOAA. It is important to note that this control banding tool can only be considered as one part, though an integral part, of an overall system for health and safety risk management. It requires input data, irrespective of the phase of the NOAA life cycle, such as information collected at the place of work through observation of actual work by an occupational hygienist with a solid expertise and training to use control banding tools as well as the enunciation of hazards and the best toxicology data available.

The foundations of this approach are the hazard identification process, which is based on the current knowledge of the specific NOAA (toxicology or health effect data; physical and chemical properties) and the assessment of potential worker exposure. The hazard and exposure information is combined to determine an appropriate level of control (such as general ventilation, local exhaust, or containment).

This approach is based on the opinion of experts developing this part of ISO/TS 12901 that the engineering control techniques for nanoparticle exposure can build on the knowledge and experience from current exposure control to aerosols. This knowledge and control has already been applied to aerosols containing ultrafine particles (e.g. welding fumes, carbon black or viruses). Effective techniques can be obtained by adapting and redesigning current technology. This applies to techniques for general ventilation, local and process ventilation, containments, enclosures and filtration.

The control banding approach allows shifting from exposure assessment to exposure control and vice versa. Thus it can be performed either in a proactive way, based on anticipated exposures and using basic factors mitigating exposure potential, or in a retroactive way (or risk banding approach), based on a risk assessment that will take more exposure mitigating factors into account including control measures actually implemented or to be implemented. In both cases, hazard banding is a common step. The general structure of the process is presented in Figure 1 and includes the following elements:

— information gathering;

— assignment of the NOAA to a hazard band: hazard banding;

— description of potential exposure characteristics: exposure banding;

— definition of recommended work environments and handling practices: control banding;

— evaluation of the control strategy or risk banding.

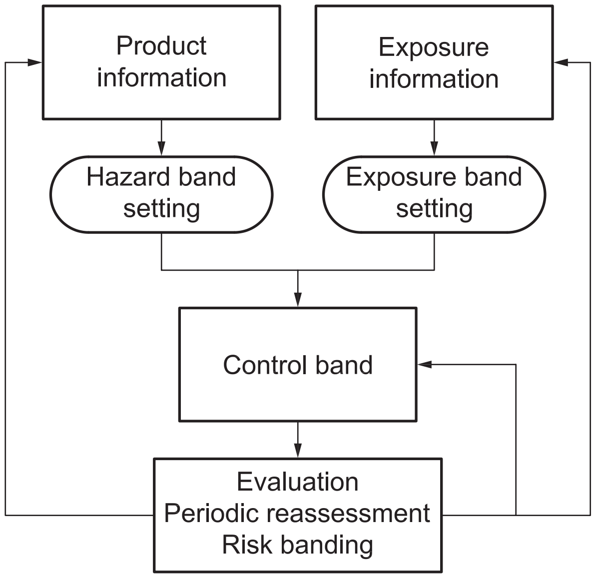

Figure 1 — Control banding process

5.2 Information gathering and data recording

The methodology presented in this part of ISO/TS 12901 is information driven; it does not implicitly assume the presence of risk or hazard in any material. Where there is little or no information to guide decisions on the potential for a particular hazard or exposure, “reasonable worst-case assumptions” should be used along with management practices appropriate for those options. The methodology is also designed to encourage replacing assumptions with real information and refining management practices accordingly.

Input data are pre-required in order to implement control banding. Especially considering NOAA for which no health-based limit values can be established, it is important to document substances being used, control measures taken, working conditions and possibly exposure measurements, given that these factors are not always easy to determine with complete certainty, and that they depend on the extent to which the hazard is known and on the accuracy of the methods used for exposure assessment.

All input data should be documented and be traceable through an appropriate documentation management system.

5.3 Hazard banding

Hazard banding consists in assigning a hazard band to NOAA on the basis of a comprehensive evaluation of all available data on this material, taking into account parameters such as toxicity, *in vivo* biopersistence and factors influencing the ability of particles to reach the respiratory tract, their ability to deposit in various regions of the respiratory tract, their ability to elicit biological responses. These factors can be related to physical and chemical properties such as surface area, surface chemistry, shape, particle size, etc.

5.4 Exposure banding

Exposure banding consists in assigning an exposure scenario (a set of conditions under which exposure may occur) at a workplace or a workstation to an exposure band on the basis of a comprehensive evaluation of all available data of the exposure scenario under consideration, e.g. physical form of NOAA, amount of NOAA, dust generation potential of processes and actual exposure measurement data.

5.5 Control banding

5.5.1 Proactive implementation of control banding

Control banding can be used for risk control management in a proactive manner. In that case, recommended work environments and handling practices may be defined on the basis of hazard banding as well as of fundamental factors mitigating anticipated exposure potential, e.g. propensity of the material to become airborne, the type of process and amounts of material being handled.

Such an approach is used to determine the control measures appropriate for the operation being assessed but not to determine an actual level of risk, as the existing control measures, if any, are not used as an input variable in the exposure banding process.

5.5.2 Retroactive implementation approach: evaluation of control banding and risk banding

In a retroactive approach, control banding may be used either to evaluate the controls recommended as outputs of the proactive approach, or for risk assessment on its own.

In that case, both hazard and actual exposure need to be characterized in order to define a risk level. The major difference with the proactive use of control banding is that exposure mitigating factors (such as implemented control measures) are taken into account using an exposure algorithm (see Annex A).

The approach then includes the following elements:

— assignment of the NOAA to a hazard band;

— exposure banding;

— overview of risks based on risk banding as a result of hazard and exposure banding;

— iterative examination of control measures until the risk is reduced to an acceptable level;

— design of an action plan based on the chosen specific control scenario.

Such an approach may be used to determine the actual risk level using the existing control measures as an input variable. In this respect, the retroactive approach can be considered as a means for periodic reevaluation of the proactive approach.

5.6 Review and data recording

In this "review and adapt" step, a system of periodic and as-needed reviews should be implemented to ensure that the information, evaluations, decisions and actions of the previous steps are kept up-to-date. Reviews should be performed when new information has been generated or has emerged. The adequacy of the risk management process for the material or the application at hand should be reassessed. It should be questioned whether the current risk evaluation needs to be revised in light of the new information and, if so, whether the current risk management practices need to be changed as well.

6 Information gathering

6.1 NOAA characterization

6.1.1 General

The lists of characteristics and end points given in 6.1.2 to 6.1.4 are to be taken into account when assessing human health hazards of NOAA. Addressing this data set should lead to the development of dossiers describing basic characterization parameters and available mammalian toxicity information. These end points are based upon the list proposed by the OECD testing program for a set of manufactured nanomaterials for human health and environmental safety.[22] It can be considered as a starting point when assessing human health hazards of NOAA. Epidemiological data, when available, should also be taken into account.

6.1.2 NOAA information and identification

— NOAA name

— CAS Number

— structural formula/molecular structure

— composition of NOAA being tested

— basic morphology

— description of surface chemistry

— method of production

6.1.3 Physicochemical properties and NOAA characterization

— agglomeration/aggregation

— solubility (e.g. in water or biologically relevant fluids)

— crystalline phase

— dustiness

— crystallite size

— representative TEM picture(s)

— particle size distribution

— specific surface area

— surface chemistry (where appropriate)

— catalytic or photocatalytic activity

— pour density

— porosity

— octanol-water partition coefficient, where relevant

— redox potential

— radical formation potential

— other relevant information (where available)

Although some of the above characteristics might not be available, and very few of these characteristics will actually be taken into account in the control banding process, NOAA's characteristics should be documented and recorded as accurately as possible (including reference to size and measurement conditions). This will be needed in the case of possible future medical issues. When utilizing characteristics relating to non-nanoscale materials, it should be taken into account that these characteristics can differ significantly from those for the material in the nanoscale.

6.1.4 NOAA toxicological data

— pharmacokinetics (absorption, distribution, metabolism, elimination)

— acute toxicity

— repeated dose toxicity

— chronic toxicity

— reproductive toxicity

— developmental toxicity

— genetic toxicity

— experience with human exposure

— epidemiological data

— other relevant test data

Although some of the above data might not be available, and some of these data might not be taken into account in the control banding process, NOAA's toxicological data should be documented and recorded as accurately as possible.

A list of hazard indications is presented in Annex B.

6.2 Exposure characterization

6.2.1 General exposure characterization elements

The main goal of exposure characterization is to provide a summary and a synthesis of available exposure information. General exposure characterization includes the following elements:

a) a statement of purpose, scope, level of detail, as well as the approach used in the exposure characterization;

b) estimates of exposure for each relevant pathway, both for individuals and populations (e.g. groups of workers);

c) an evaluation of the overall quality of the assessment and the degree of confidence in the exposure estimates and in the conclusions drawn, including sources and the extent of uncertainty (see ISO/TS 12901-1);

d) in this control banding approach, the critical elements of exposure characterization, which are necessary to determine exposure band and include:

— the physical form of NOAA,

— the amount of NOAA,

— the determination of dust generation potential during the processes,

— the actual exposure measurement data.

6.2.2 Physical form

The actual stage in the NOAA's life cycle is an important parameter to consider as it can influence the potential for worker exposure and thus the selection of risk control parameters.

NOAA can be in different forms, as produced (e.g. as a powder), or as used (e.g. embedded in a solid matrix or attached to a substrate), suspended in a gas or in a liquid; or as waste. Each of these different stages will have its own exposure pattern.

Thus, the NOAA's physical form (i.e. exposure availability) should be characterized throughout the product lifecycle. This information is critical for the appropriate and safe handling of the material.

6.2.3 Amount of NOAA

The amounts of nanomaterial processed or manufactured in the workplace is one of the most important determinants of exposure. The presence of large amounts of NOAA in the workplace increases the potential for the generation of a higher concentration in the air and, therefore, can lead to higher exposures.

6.2.4 Potential for dust generation

Workplace processes, such as spraying, packaging, maintenance activities and dumping can lead to generation of airborne particles. As a consequence, it is important to analyse the details of the operator's activities and process operations in order to estimate the potency of the process to release NOAA into the workplace air. This implies performing an inventory of operators' tasks, including start and stop operations, process steps, etc.

6.2.5 Quantitative exposure measurements

Actual exposure measurements, when feasible, represent the best information for the selection of the appropriate exposure band. Therefore they should be encouraged and when both personal sampling and area measurements are available, the preference should be given to individual exposure measurements. The results should be taken into account when determining the corresponding exposure band. ISO/TS 12901-1 provides information on available measurement equipment, possible measurement strategies and results interpretations.

6.3 Characterization of control measures

6.3.1 General

Exposure control measures implemented in the workplace should be characterized. They can lower exposures by reducing emission, transmission and immission.

6.3.2 Reduction of emission

The reduction of NOAA emission from the source can be achieved in several ways such as handling NOAA in suspension into a liquid or dispersed into a paste or a solid matrix rather than in the form of dry powders; avoiding high energy processes or any activity likely to release free NOAA in the workplaces.

6.3.3 Reduction of transmission

Reduction of transmission from the source towards the worker is possible in several ways. Two generic control measures are:

— local control, e.g. containment and/or local exhaust ventilation,

— general ventilation, e.g. natural or mechanical ventilation.

6.3.4 Reduction of immission

The reduction of immission has three generic control measures:

— personal enclosure/separating the worker from the source, e.g. a ventilated cabin,

— segregation of the source from the worker, i.e. isolation of sources from the work environment in a separate room without direct containment of the source itself,

— use of personal protective equipment.

6.3.5 Workplace area and personal exposure monitoring data

When feasible, actual exposure measurements provide important information on the effectiveness of controls and workers protection level.

7 Control banding implementation

7.1 Preliminary remarks

Whatever the approach, control banding implementation should be consistent with the hierarchy of controls (and the so-called STOP principle): substitution, technical measures, organizational measures and personal protective equipment (PPE) as the last resort when measures do not provide adequate control.

Control banding should incorporate general industrial hygiene good practices. In the case when control measures recommended by the nano-specific control banding differ from other industrial hygiene considerations, then the more stringent control measures should be applied.

As mentioned above, control banding can be used in two different ways, a proactive approach and a retroactive, evaluation or risk banding approach. Both approaches are described in this part of ISO/TS 12901. They present a first common step which is the hazard banding process.

7.2 Hazard band setting

7.2.1 Hazard categorization of chemicals and general hazard banding process for bulk materials

Hazard bands are defined, for a specific chemical, according to the severity level of the hazard resulting from the analysis of the available information as evaluated by knowledgeable and experienced professionals. This information can relate to various criteria for toxicity, described or suspected, in the literature or technical documentation (labelling, product classification).

NOTE A knowledgeable and experienced professional is an individual who will properly perform a specific job. This person utilizes a combination of knowledge, skills and behaviour to improve performance. More generally, competence is the state or quality of being adequately or well qualified, having the ability to perform a specific role.

The approach presented in the International Labour Organization Control Banding Toolkit[23] is to group chemicals into one of five inhalation hazard groups (A to E) and the Skin (S) group according to the increasing severity described in GHS hazard classification applicable to the chemical (see in Table 1 and Annex B). The dose ranges given in this table correspond to the criteria set for classification under GHS. Hazard band allocation can vary depending on national statutory provisions.

Hazard group allocation table according to the GHS Health classes are listed in Table 1.

Table 1 — Hazard group allocation

	Category A **No significant risk to health**	**Category B** **Slight hazard – Slightly toxic**	**Category C** **Moderate hazard**	**Category D** **Serious hazard**	**Category E** **Severe hazard**
OEL dust mg/m^3 (8-h time weighted average)	1–10	0,1–1	0,01 – 0,1	< 0,01	
Acute toxicity	Low	Acute tox 4	Acute tox 3	Acute tox 1–2	
LD50 oral route mg/kg	> 2 000	300 - 2 000	50 - 300	< 50	
LD50 dermal route mg/kg	> 2 000	1 000 - 2 000	200 – 1 000	< 200	
LC50 inhalation 4H (mg/l) Aerosols/particles	> 5	1 - 5	0,5 - 1	< 0,5	-
Severity of acute (life-threatening) effects		STOT SE 2–3; Asp. Tox 1	STOT SE 1	-	-
Adverse effects per oral route (mg/kg) (single exposure)[a]	-	Adverse effects seen ≤ 2 000	Adverse effects seen ≤ 300		-
Adverse effects per dermal route (mg/kg) (single exposure) [a]	-	Adverse effects seen ≤ 2 000	Adverse effects seen ≤ 1 000	-	-
Sensitization	Negative	Slight cutaneous allergic reactions*	Moderate/strong cutaneous allergic reactions Skin sens.1*	-	Prevalent moderate to strong respiratory allergic reactions Resp. sens. 1
Mutagenicity/genotoxicity	Negative	Negative	Negative	Negative	Mutagenic in most relevant *in vivo* and *in vitro* assays. Muta 2 Muta 1A – 1B

Table 1 *(continued)*

	Category A No significant risk to health	Category B Slight hazard – Slightly toxic	Category C Moderate hazard	Category D Serious hazard	Category E Severe hazard
Irritant/corrosiveness[a]	None to Irritant Eye Irrit.2; skin Irrit. 2 EUH 066	-	Severe irritant skin/eyes Irritant to respiratory tract STOT SE 3; Eye Dam. 1 Corrosive Skin Cor. 1A – 1B	-	-
Carcinogenicity	Negative	Negative	Some evidence in animals Carc. 2	-	Confirmed in animals or humans. Carc. 1A – 1B
Developmental/reproductive toxicity	Negative	Negative	Negative	Reprotoxic defects in animals and / or suspected or proved in humans Repr. 1A, 1B, 2	
Likelihood of chronic effects (e.g. Systemic)	Unlikely	Unlikely	Possible STOT RE 2	Probable STOT RE 2	
Adverse effects per oral route (mg/kg-day) (90 chronic study) [a]			Adverse effects seen ≤ 100	Adverse effects seen ≤ 10	
Adverse effects per dermal route (mg/kg-day) (90 day chronic study) [a]			Adverse effects seen ≤ 200	Adverse effects seen ≤ 20	
IH/Occupational health experience	No evidence of adverse health effects	Low evidence of adverse health effects	Probable evidence of adverse health effects	High evidence of adverse health effects	High evidence of severe adverse health effects

[a] Informative only as this part of ISO/TS 12901 focuses only on inhalation control.

7.2.2 Allocation of a NOAA to a hazard band

The hazard banding process follows a tiered approach which is summarized in Figure 2.

a) Question 1: Has the NOAA already been classified and labelled according to national or regional legislation or GHS?

The completeness of the data set used for the classification and labelling should be evaluated and if classification and labelling is based on the lack of information, the “NO” option described below should be applied.

If “YES”, then the identified human health hazards of the material should be used to assign the NOAA to the corresponding Hazard Band.

If "NO" then proceed to Question 2.

b) Question 2: Is the NOAA solubility in water higher than 0,1 g/l?

The solubility refers to the degree to which a material can be dissolved in another material so that a single, homogenous, temporally stable phase results. Solubility occurs when the material is surrounded by solvent at the molecular level.

It is important not to confuse solubility and dispersibility, as we are interested in the potential of a material to lose its particulate character and to change its form to a smaller molecular or ionic form. This is to be stressed as the distinction can be difficult in the case of colloidal suspensions of nanomaterials.

The measurand for solubility is the maximum mass or concentration of the solute that can be dissolved in a unit mass or volume of the solvent at a specified (or standard) temperature and pressure; unit: [kg/kg] or [kg/(m)^3], or g/l or [mole/mole]). A possible method to assess the solubility of a NOAA can be derived from the OECD test guidelines TG 105.[24]

In the context of this part of ISO/TS 12901, the solubility of a NOAA is taken into consideration to assess its potential hazard. The rationale for choosing solubility as one of the factors for allocating a NOAA to a hazard band is related to peculiarities of the toxicology of particulate matters. If a NOAA is highly soluble, then its potential hazard should be addressed with regard to its solutes toxicity, without any consideration on a nano-specific toxicity. Therefore, the hazard banding process should apply only to low solubility NOAA.

Although it is acknowledged that solubility in biologically relevant media such as simulated lung lining fluid or human serum would be a more appropriate parameter, in the absence of standard methods to date, it is proposed to use, as a surrogate, the water solubility. Based on expert judgment[25] and as a pragmatic approach, the threshold value of 0,1 g/l is proposed to distinguish between high and low water soluble materials.

— If the water solubility is more than 0,1 g/l, then the material's hazard should be considered as a classical chemical hazard and the risk should be addressed using either an appropriate control banding method currently applied in some industries in the chemical sector or any other appropriate risk assessment and control tool.

— A water solubility of less than 0,1 g/l leads to Question 3.

c) Question 3: does the NOAA contain biopersistent fibres or fibre–like structures? Is it appropriate to apply the fibre toxicity paradigm to the NOAA?

NOTE Biopersistence of fibres is defined as the ability of a fibre to remain in the lung in spite of the lung's physiological clearance mechanisms. These defence mechanisms are:

— transportation of entire particles by the mucociliary escalator and by alveolar macrophages,

— dissolution of fibres, and

— disintegration, where the fibre breaks into smaller particles that can be cleared.

For the purpose of this part of ISO/TS 12901, the definition of a long biopersistent fibre relates to the fact that some respirable, biopersistent, long and rigid fibres can penetrate mesothelium such as the pleura, induce a sustainable inflammatory response as a consequence of macrophage mediated frustrated phagocytosis, which can ultimately result in mesotheliomas. This physio-pathological mechanism is commonly named as the fibre paradigm.[26] As a consequence, any NOAA that falls within the definition of a rigid fibre (a free standing fibre in collected samples would appear in electron-microscopic images as a straight fibre with length > 5 μm, diameter < 3 μm, Length/diameter ratio > 3) should be considered as a material whose toxicity is driven by the fibre paradigm and should be allocated to the highest hazard band, unless toxicological data provide evidence that it is not the case.

In some situations, NOAA can exist in structures which are not fibre-like (e.g. globular structures), but which can potentially release fibres after inhalation. Limited work has been undertaken to date in relation to the potential release of fibres from these structures. Therefore as a default, such structures should be allocated to the highest hazard band. However, if toxicological data provide evidence that these structures toxicity is not driven by the fibre paradigm, it should then be allocated to a hazard band corresponding to its toxicity.

d) Question 4: are there hazard indications for the NOAA?

Although in most cases, a full hazard characterization for a NOAA is unavailable, a limited set of screening tests could allow for assignment to a lower hazard band provided that screening tests for toxicity end-points describing higher hazard bands returned negative results. In this approach existing hazard categorization ranging from A (practically non-hazardous) to E (non-threshold effects such as carcinogenicity or sensitization) can still be used. For example, if screening tests showed that a nanomaterial does not have carcinogenicity, mutagenicity, toxic to reproduction or sensitization by inhalation (CMRS) properties, then it can be assigned to the hazard band D. Correlation between toxicity end-points and hazard bands is given in Table 1, while a preliminary review of the applicability of testing guidelines to nanomaterials has been published elsewhere.[27]

Considering the situation in which comprehensive hazard data are available, hazard bands are allocated to NOAA following the same rationale as for bulk materials, according to Table 1. For example, NOAA with carcinogenicity and mutagenicity/respiratory sensitization properties are assigned to category E. NOAA with pronounced toxicological profiles or associated reprotoxic properties are placed in the second highest hazard band D. Currently, hazard of most NOAA are (at least partly) unknown. For the most widely used NOAA, the hazard category is based on the limited information available on the NOAA as such and the hazardous properties of the bulk or any analogous material.

If only limited toxicological data are available for a specific NOAA, and in particular in the case of negative results for specific toxicity end-points, these data should be evaluated to assign a hazard band. One way to do this is to use a tiered approach. For example, CMRS properties of the NOAA might be first assessed: if screening tests show that a NOAA does not have CMRS properties, then it can be assigned to the hazard band D. Information on possible approaches to determining hazard profiles of NOAA can be found in ISO/TR 13121.

e) Question 5: is there a hazard band for the bulk material or an analogous material?

If toxicological information on the NOAA is very limited or non-existent, the hazardous properties of the bulk material or an analogous material (an analogous material can be a NOAA) provide a basis for hazard categorization of NOAA and should be considered. If there are several choices for analogous materials, the most toxic one should be taken into account.

However, it has to be stressed that it is not yet known to which extent the toxicity of NOAA is influenced by the toxicity of the corresponding bulk or analogous material and this uncertainty should be taken into account when allocating the NOAA to a hazard band.

Therefore, if a corresponding bulk material or analogous material is used, it is recommended to increment by one the known hazard band of the bulk material or the analogous material defined according to the GHS (see Table 1). An exception is possible when the bulk material or the analogous material used belongs to the lowest hazard band A. In this case and in the absence of specific toxicological information, as a precautionary approach, the corresponding NOAA should be allocated to hazard band C.

In case there is no indication of a bulk or analogous material, the NOAA should either be assigned to the maximum hazard band (E), or a comprehensive toxicological hazard assessment be performed by a toxicologist and a hazard band determined according to the toxicological data.

If the result of this hazard banding process is considered to be overly conservative, it is suggested to ask for expert advice, considering the possibility to allocate the material to a lower hazard band. This decision should then be justified and the necessary documentation be recorded.

In line with the STOP principle, after working through the decision tree (Figure 2), if it is determined that the hazard band is D or E, then it is should be considered whether the NOAA can be modified or replaced by a potentially less hazardous material which maintains the required properties.

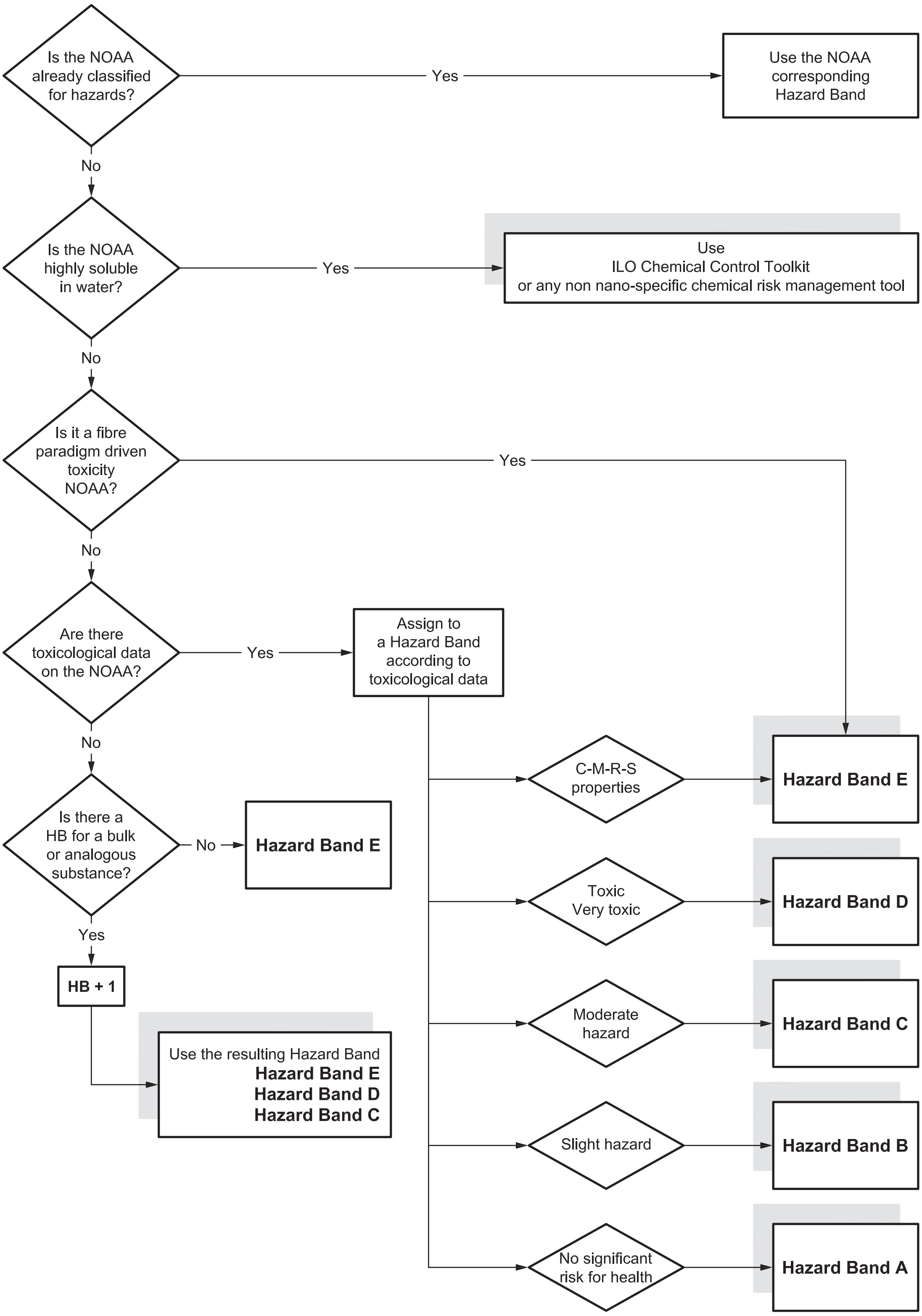

Figure 2 — Decision tree for hazard banding

7.3 Exposure band setting

7.3.1 Preliminary remarks

In the proactive use of control banding, following the hazard banding process, the second step is intended to determine an expected level of workers exposure which is designated as an exposure band (EB, ranging from EB 1 the lowest exposure to EB 4 the highest exposure).

Matching the hazard band and the exposure band through a control banding matrix determines the appropriate level of control i.e. the control band.

The exposure bands characterize the potential for NOAA to become airborne under normal conditions of the process or the operation, regardless of any control measures that could already be implemented and therefore should not be considered as an actual assessment of workers exposure.

The exposure bands are defined according to the emission potential of a specific NOAA, whether free, or dispersed into a liquid or solid matrix. They take into account the physical form in which it is produced or used and, where applicable, the state of the matrix incorporating the NOAA. The physical form is a key parameter to consider, in order to assess the NOAA's emissivity from the product and hence the potential operator exposure level when it is handled.

Before any allocation to an exposure band, it is necessary to identify and characterize each work station in regard to its exposure potential related to the processes or handling operations performed by the workers.

The physical form to be considered is that of the material at the beginning of the process at the work station being evaluated. Three categories of physical forms have been identified according to their increased emission potential (NOAA dispersed in a matrix, in suspension or in the form of powder).

In addition, the type of process or handling operation is also of utmost importance for determining the likelihood of workers' exposure. Whatever the physical form of the material, in order to set an appropriate exposure band, it is necessary to make some assumptions on certain characteristics of the material like friability, viscosity, volatility and on the process or handling operation and its ability to release NOAA aerosols or dust in the workplaces. All these parameters contribute to the likelihood for a specific NOAA to be released in the workplace. As the responses will ultimately determine the exposure band, issues such as deciding whether NOAA are strongly or weakly bound to a matrix, or whether a process has a high or low potential of aerosol generation should be addressed by the organization's health and safety officer or any other staff member well informed about materials' characteristics, nature of the processes of interest and health and safety related issues.

7.3.2 Synthesis, production and manufacturing of NOAA

The likelihood of exposure to NOAA during synthesis, production and manufacturing processes is highly dependent upon the type of process and the type of equipment involved in the process. In some cases, due to physico-chemical or technical reasons, the process needs to be enclosed (e.g. in gas when an extremely low pressure or an inert atmosphere is required). Thus, the presence of an intrinsic barrier being part of the equipment might lead to allocate the workstation to a low exposure band. However, in order to avoid underestimating a possible risk of leaks of NOAA during the process, it is recommended not taking into account these intrinsic barriers during the exposure banding process. Evidently, these barriers should be taken into account as protective measures during the final control banding process.

The exposure band setting according to most types of processes is presented in Figure 3.

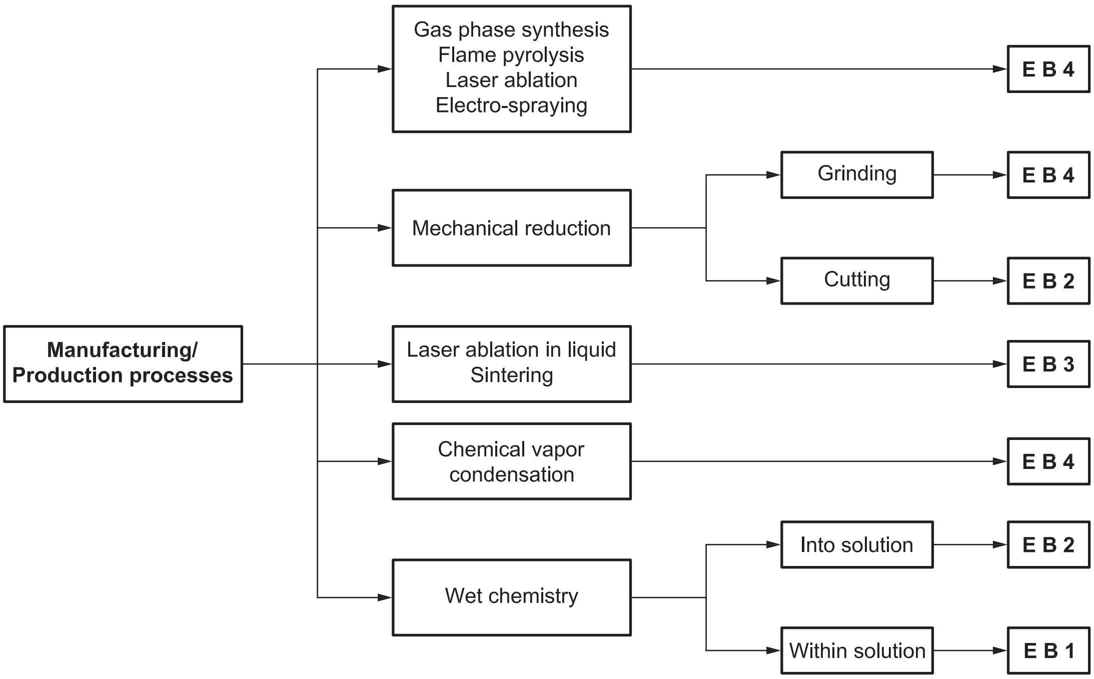

Figure 3 — Exposure banding process: Synthesis, production, manufacturing

7.3.3 Material dispersed in a solid matrix

In this case, the solid material being used contains NOAA or has a surface covered with NOAA.

The likelihood for those materials to release free single NOAA in the workplace during the process or activity depends upon two parameters:

a) the strength of the bonding between the NOAA and the solid matrix; and

b) the degree of energy involved during the process or the activity.

A material composed of NOAA that are unbounded or weakly bounded to the matrix is more likely to release free airborne primary NOAA when it is subjected to a low or high energy process activity.

A material composed of NOAA that are strongly bonded to the matrix is less likely to release free airborne NOAA but can release nanocomposite particles comprising primary NOAA engulfed in matrix components when it is subjected to high energy process or activity.

Processes such as grinding, milling and cutting with band saws or discs saws can be considered as high energy activities while manual cutting or moulding can be considered as low energy processes.

The exposure banding process is described in Figure 4.

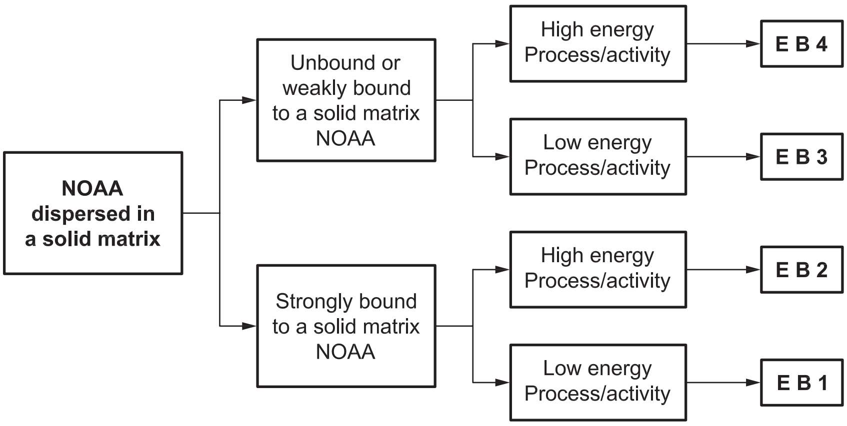

Figure 4 — Exposure banding process: NOAA dispersed in solid materials

7.3.4 Material in suspension in a liquid

The likelihood for NOAA in solutions to become airborne under normal working conditions depends mostly on the amount of material being handled, on the nature of the liquid and more specifically its viscosity and volatility, and on the type of process.

In processes where deliberate aerosolization takes place, whatever the amount of NOAA handled, the exposure band should be set at the maximum level 4.

In manufacturing, use and handling operations, the potential for workers exposure depends upon the amount of NOAA being handled by a worker and per task (less or more than a 1 g of NOAA), and on the risk of aerosol or dust generation according to the characteristics of the liquid and the type of process.

The exposure banding scheme is described in Figure 5.

7.3.5 Material in powder form

When NOAA are handled as powders, workers' exposure depends upon the amount being handled, on the propensity of this specific NOAA to become airborne, this being related to dustiness, moisture content and the type of process.

The exposure banding process is described in Figure 6.

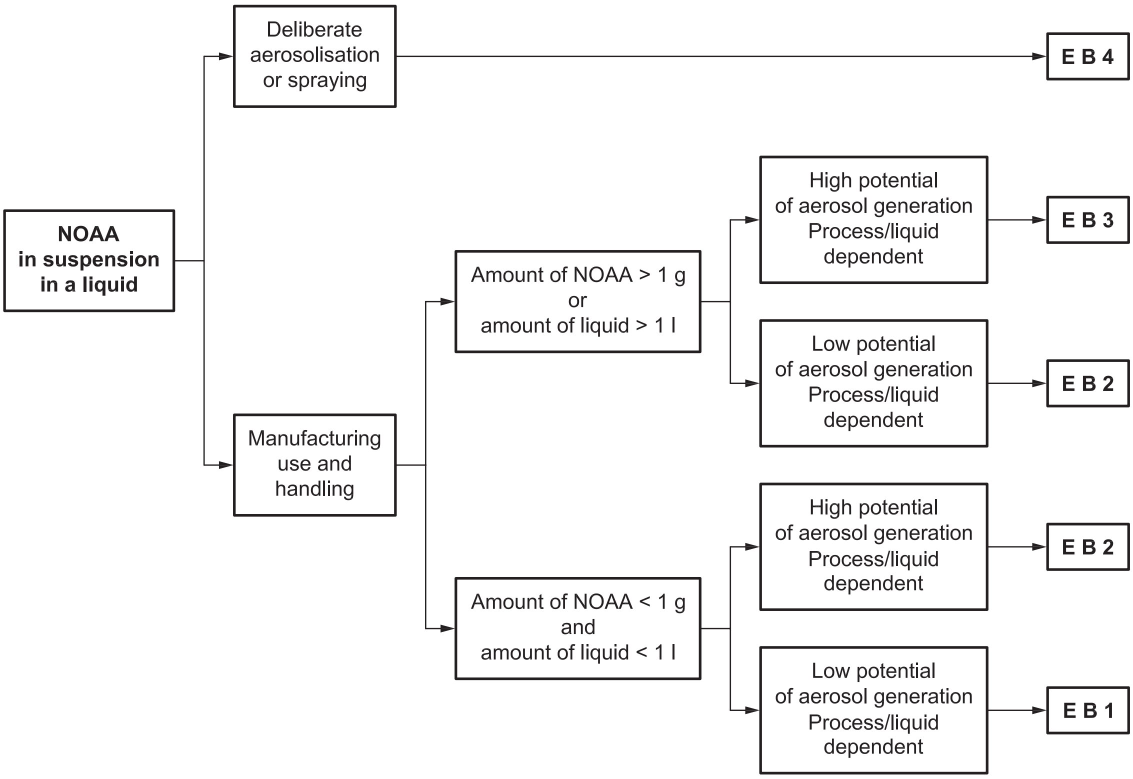

Figure 5 — Exposure banding process: NOAA in suspension in a liquid

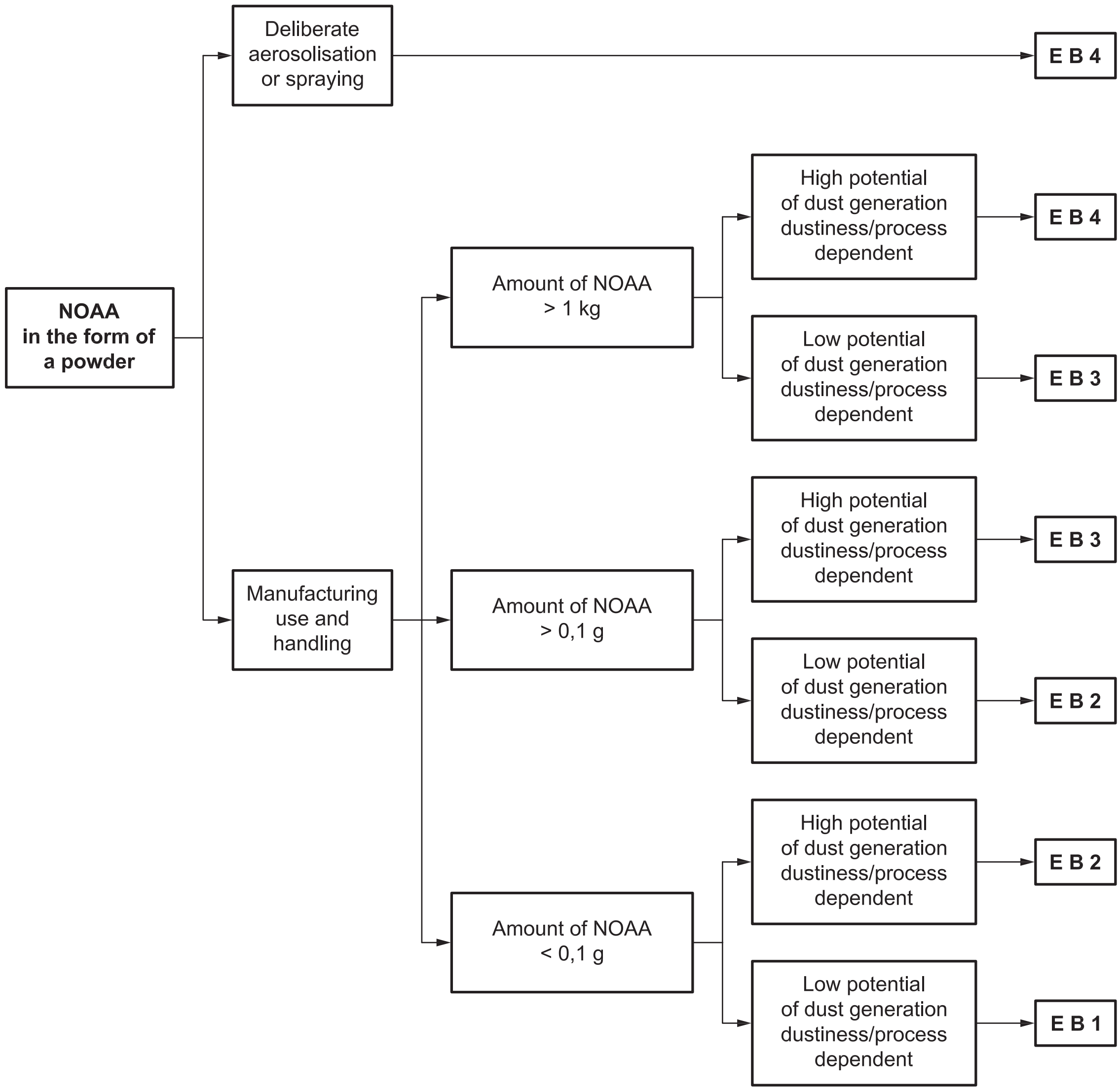

Figure 6 — Exposure banding process: NOAA in powder form

7.3.6 Option for modifying the process to reduce exposure levels

In line with the STOP principle, after the level of exposure is determined, if the exposure band is set to 4, then it should be considered whether the process can be modified in order to reduce exposure levels.

7.4 Control band setting and control strategies

To achieve a balance of simplicity and effectiveness, five control categories (or bands) are proposed, to assist in preventing exposure to NOAA.

Conceptually, the five control approaches consist of:

— CB 1: Natural or mechanical general ventilation

— CB 2: Local ventilation: extractor hood, slot hood, arm hood, table hood, etc.

— CB 3: Enclosed ventilation: ventilated booth, fume hood, closed reactor with regular opening

— CB 4: Full containment: glove box/bags, continuously closed systems

— CB 5: Full containment and review by a specialist: seek expert advice

Control bands are obtained by matching the hazard band and the exposure potential band according to the matrix given in Table 2.

Table 2 — Control band matrix as a result of hazard band and exposure potential band

Hazard band	Exposure potential band			
	EB 1	**EB 2**	**EB 3**	**EB 4**
A	CB 1	CB 1	CB 1	CB 2
B	CB 1	CB 1	CB 2	CB 3
C	CB 2	CB 3	CB 3	CB 4
D	CB 3	CB 4	CB 4	CB 5
E	CB 4	CB 5	CB 5	CB 5

Exposure should be minimized following the hierarchy of control (STOP principle): substitution, technical measures, organizational measures, personal protective equipment (PPE) as the last resort when measures do not provide adequate control.

As seen previously, in line with the STOP principle and after working through the decision tree (Figure 2), if it is determined that the hazard band is D or E, then it should be considered whether the nanomaterial can be modified or substituted for a potentially less hazardous alternative which maintains the required properties. As well, after determining the level of exposure (Figure 3, 4, 5 or 6), if it is determined that the exposure band is 4, then it should be considered if the process itself can be modified to reduce exposure levels.

In the case where the material under consideration comprises different NOAA, the control banding process should be performed for each NOAA, and the most stringent control band be applied.

If the result of the control banding process is considered to be overly conservative, it is suggested to ask for an expert industrial hygienist advice, considering the possibility to apply a lower control band. This decision should then be justified and the necessary documentation be recorded.

7.5 Evaluation of controls

The severity of the NOAA hazard and the potential for emission are the factors which determine the recommended controls in the proactive approach to control banding. The outputs of the proactive approach are recommended controls to reduce emission, transmission and immission and hence to mitigate exposure, illustrated in Figure 7.[29,30]

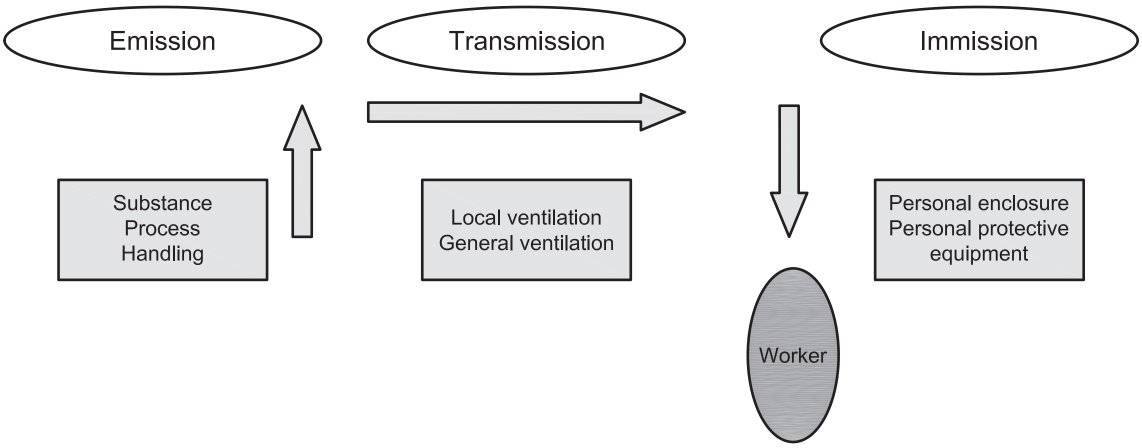

Figure 7 — Exposure mitigating factors

There are a number of ways whereby the effectiveness of the controls can be evaluated and validated:

— measurement of exposure levels and comparison with published NOAA exposure standards – noting that there are few currently;

— determination of the hazard band for the NOAA (Figure 2). Comparison of mass concentration measured exposure levels with the OEL ranges for the nanomaterial's hazard band in Table 1 (7.2.1);

— characterization of work places aerosols based on number concentrations. Information on evaluating exposure control approaches can be found in ISO/TS 12901-1.

— evaluation of controls in place using a risk banding approach (7.6).

This evaluation should be performed periodically, and control measures improved whenever needed.

7.6 Retroactive approach — Risk banding

In a retroactive approach, control banding may be used:

a) to evaluate the controls recommended as outputs of the proactive approach, or

b) for risk assessment on its own.

The risk banding process is shown in Figure 8. In a risk banding strategy, emission, transmission and immission controls are taken into account to calculate the exposure band. This means that control measures which have already been implemented or might be implemented in a new process design, are being used as a variable input of the model. The hazard banding is the same as in the proactive approach.

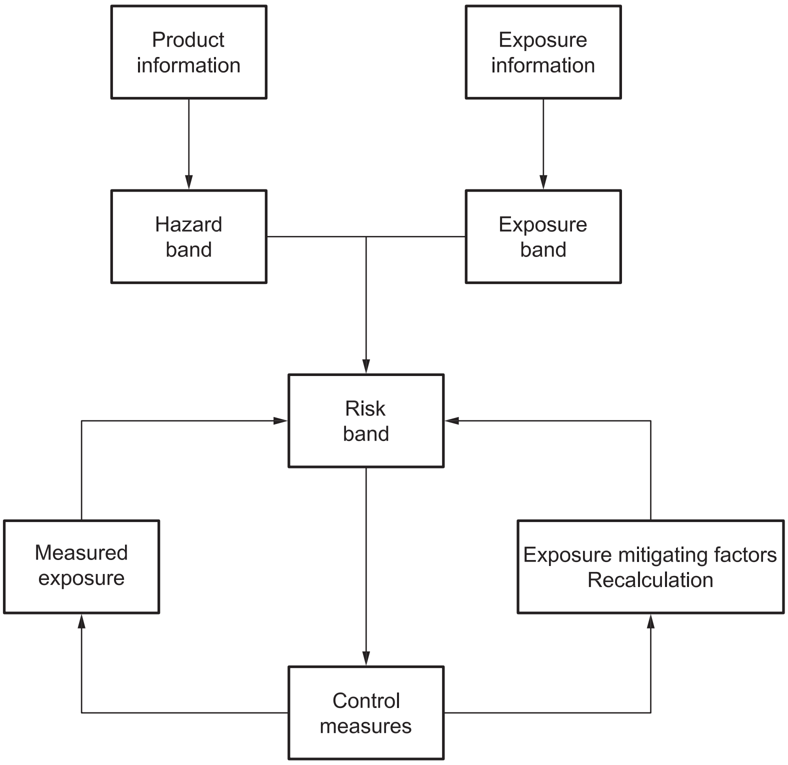

Figure 8 — Evaluation and risk banding process

After assignment of a hazard band to NOAA and a subsequent exposure banding is performed, a risk band is derived. A generic example is shown in Table 3. The resulting risk bands provide a relative ranking of risks from activities for individual workers. At this point in the risk banding process, no quantitative evaluation of exposure levels and hazard levels can be made because both exposure and hazards bands are based on qualitative considerations. The result of the risk banding should therefore be considered as a “priority band”. An example of such a risk banding process is given in Annex A.

Table 3 — Risk or priority bands

Hazard band	Exposure band			
	1	2	3	4
A	Low	Low	Low	Medium
B	Low	Low	Medium	High
C	Low	Medium	Medium	High
D	Medium	Medium	High	High
E	Medium	High	High	High

The need to implement further control measures is determined by the priority band, high being highest priority. In addition to the risk banding process, there are two possible feedback loops:

— a loop for an iterative examination of control measures using an exposure algorithm (see Annex A) if the situation is not under control;

— after implementing controls, a loop for evaluating the controls is done by using exposure measurements.

The following (generic) control measures can be distinguished.

1) Measures that have impact at the source:

  — removal of the hazardous product from the task,

  — removal of the task from the process,

  — modification of the product form,

  — modification of the task, e.g. instead of ‘frequent handling’ the task can be modified to ‘handling in closed systems’,

  — replacement of the product by another product with a different composition, changing the hazard and possibly also the exposure,

  — automation of the process, leading to a whole new exposure assessment,

  — changing the order of tasks, e.g. adding powder to liquid instead of the other way around;

2) Measures in an area directly around the source:

  — glove box/bags,

  — enclosure of the source in combination with local exhaust ventilation (e.g. fume cupboard),

  — enclosure of the source,

  — local exhaust ventilation,

  — limiting the emission of a product (e.g. wetting powder);

3) Measures affecting the worker’s wide surroundings:

  — creating and ensuring natural ventilation,

  — installing mechanical general ventilation,

  — use of a spray cabin;

4) Adaptation of the workers situation:

- — use of work cabins with clean air supply,
- — use of work cabins without clean air supply;

5) Personal protective equipment:

- — use of respiratory protective equipment.

In comparison to the proactive approach, a retroactive approach presents a complete control strategy according to the STOP principle. This guides a user to start minimizing exposure at the first order of control, i.e. measures that have impact at the source.

8 Performance, review and continual improvement

8.1 General

In order to perpetuate the benefits of control banding and to justify decisions related to the levels of control that have been chosen, it is highly recommended to base the management on a continual improvement approach. Such an approach is based on the belief that our knowledge and skills are limited, but improving. Especially at the start of a project, key information might be lacking; feedback allows justifying hypotheses and increasing knowledge.

Indeed, it is necessary to check the efficiency of the control banding implementation and be able to react as soon as a new data about the risk become available. Airborne exposure measurements should be performed to determine whether controls are reducing exposure concentrations to the desired performance levels.

If exposure limits were to be promulgated for NOAA, these limits should be used for assessing the effectiveness of existing controls and for determining what additional control measures might be needed to reduce exposures.

Three points should be considered to ensure the method dynamics and to ensure the traceability of data and decisions. Control banding is not a static method and improvements should be done continuously.

8.2 Objectives and performance

The objectives to be attained by implementing a control banding method must be clearly identified. They will constitute the base of the continual improvement of the risk management process. They will allow the development of prevention actions and must be updated periodically or when major changes occur.

One of these objectives should in particular concern the literature review which constitutes the major source of information to identify knowledge progress for NOAA justifying the updating of the control banding operation.

8.3 Data recording

The data used for conducting the assessment and the conclusions of these studies should be recorded in a file for a certain period of time, which needs to be defined with regard, in particular, to legal issues. The results of all studies, regardless of their conclusions, should be included in the report with all assumptions clearly articulated. The advantages and limitations of each test, measurement, model, or estimate employed should be identified and residual uncertainty caused by the nature or source of the data — as well as data gaps and potential biases — noted.

The exact method used for archiving these documents needs to be specified clearly. It should be possible to retrieve key data relating to the assessment, such as type of activities, substances used, relevant data related to risk assessment, conclusions, actions to be put in place and follow-up.

Data storage should be clear, easily accessible and understandable by anyone who needs to access the data.

8.4 Management review

Management review allows the improvement of the system by elaborating new action programs and leading corrective actions in response to potential malfunctions in the risk control system. This periodic evaluation is also essential to identify and to respond to the difficulties of the organization's general activity which could hinder the efficiency of the control banding process, or to consider the evolution of scientific knowledge and risk control technology in the field of NOAA.

Annex A
(informative)

Exposure algorithm in the Stoffenmanager risk banding approach

The underlying model of Stoffenmanager Nano, the conceptual model described by Schneider et al. (2011),[15] is based on the same source-receptor model as described in Figure 7; the relative exposure score underlying the exposure bands are derived by multiplication of relative multipliers (on a logarithmic scale) for the various modifying factors using the same exposure algorithm as used for the generic Stoffenmanager.[6]

$$B = \left[\left(C_{nf} \right) + \left(C_{ff} \right) + \left(C_{ds} \right) \right] \cdot \eta_{imm} \cdot \eta_{ppe} \cdot t_h \cdot f_h$$

and

$$C_{nf} = E \cdot H \cdot \eta_{lc\_nf} \cdot \eta_{gv\_nf}$$

$$C_{ff} = E \cdot H \cdot \eta_{lc\_ff} \cdot \eta_{gv\_ff}$$

$$C_{ds} = E \cdot a$$

where

B	is the exposure score (arbitrary units);
t_h	is the multiplier for duration of the handling;
f_n	is the multiplier for frequency of the handling;
C_{ds}	is the background concentration (score) due to diffusive sources;
C_{nf}	is the concentration (score) due to near-field sources;
C_{ff}	is the concentration (score) due to far-field sources;
η_{imm}	is the multiplier for the reduction of exposure due to control measures at the worker;
η_{ppe}	is the multiplier for the reduction of exposure due to use of personal protective equipment;
E	is the intrinsic emission multiplier;
a	is the multiplier for the relative influence of background sources;
H	is the handling (or task) multiplier;
η_{lc}	is the multiplier for the effect of local control measures;
η_{gv_nf}	is the multiplier for the effect of general ventilation in relation to the room size on the exposure due to near field sources;
η_{gv_ff}	is the multiplier for the effect of general ventilation in relation to the room size on the exposure due to far field sources.

Details of the exposure algorithm calculations including a worked example are described in Van Duuren-Stuurman et al.[18] The exposure algorithm gives two separate prioritizations for personal exposure to offer insight in the risk prioritization between different tasks within a company:

— an event-based risk prioritization based on the exposure during an event;

— a yearly-based risk prioritization, where weighing for exposure intensity, duration and frequency/occurrence of a task is included in the prioritization. This results in a risk prioritization for working 40 hours a week on a yearly basis.

To clarify the algorithm and the multipliers in the mechanistic model, we present a worked example, ‘bagging of iron powder’ with average particle size of 25 nm. There is one operator active at the bagging station, the task being carried out in the breathing zone. Demonstrable and effective housekeeping practices are in place. No information on dustiness and moisture content is stated on the SDS. The product is described as being irritating to the eyes and the respiratory system (R36/37). The duration of the task is 0,5 to 2 hours per day with a frequency of 4 to 5 days per week. The work is performed indoors (room size 100 m^3 by 1 000 m^3) with mechanical ventilation in the work room and local exhaust ventilation at the source being present. No respiratory protective equipment is used. Table A.1 below shows the relevant parameters for each of the modifying factors in the mechanistic model and the accompanying multipliers.

Table A.1 — Relevant factors for modifying parameters

Modifying factor	Relevant parameter	Description	Multiplier
Activity emission potential	Source domain: Handling of bulk aggregated/ agglomerated nanopowders	Activity: Handling of products with a relatively high speed/force which leads to dispersion of dust	30
Substance emission potential	Dustiness	Unknown	1
	Moisture content	Unknown	1
	Weight fraction	Pure product	1
Localized controls		Local exhaust ventilation	0,3
Dilution/dispersion		Room volume 100 m^3 by 1 000 m^3	
		Mechanical ventilation	
Separation		The worker does not work in a cabin	1
Surface contamination		Demonstrable and effective housekeeping practices	0,01
Personal protective equipment		None	1
Frequency of the task		4 to 5 days/week	1
Duration of the task		0,5 to 2 hours/day	0,25

Applying the equations of the model results in an exposure score of 9,01 during the task and 2,2525 as time and frequency weighted score. Based on these scores exposure band ‘3’ is assigned.

$$B = \left[\left(C_{nf}\right) + \left(C_{ff}\right) + \left(C_{ds}\right)\right] \cdot \eta_{imm} \cdot \eta_{ppe} \cdot t_h \cdot f_h$$

B = [(9) + (0) + (0,01)] 1·1·0,25·1 = 2,2525 and

$$C_{nf} = E \cdot H \cdot \eta_{lc\_nf} \cdot \eta_{gv\_nf}$$

C_{nf} =(1·1·1) ·30·0,3·1

$$C_{ff} = E \cdot H \cdot \eta_{lc\_ff} \cdot \eta_{gv\_ff}$$

C_{ff} = 0 (no far field exposure)

$$C_{ds} = E \cdot a$$

C_{ds}=(1.1.1) · 0,01

E = weight fraction·dustiness·moisture content.

Annex B
(informative)

Health hazard class according to GHS

Criteria for classifying chemicals have been developed for the following health hazard classes:

— acute toxicity (acute tox.);

— skin irritation/corrosion (Skin Irrit./Skin Corr.);

— serious eye damage/eye irritation (Eye Dam./Eye Irrit.);

— respiratory or skin sensitization (Resp. or skin sens.);

— mutations in germ cells (Muta.);

— cancer (Carc.);

— reproductive toxicity (Repr.);

— target organ systemic toxicity - single exposure (STOT-SE);

— target organ systemic toxicity - repeated exposure (STOT-RE);

— aspiration hazard (Asp. Tox).

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