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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

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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.

