Risk management tool

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1. Introduction

Within the realm of nanotechnology, Multi-Component Nanomaterials (MCNMs) and High Aspect Ratio Nanoparticles (HARNs) have become increasingly prevalent, presenting unique challenges in terms of safety and risk management. Recognizing the importance of addressing these challenges, a comprehensive effort is underway to define and characterize effective risk management approaches tailored specifically to MCNMs and HARNs.

The use of MCNMs and HARNs has expanded across various sectors including healthcare, pharmaceuticals, and defence, with further anticipated growth in the years ahead. Despite their advantageous properties, research on toxicity has underscored potential adverse health effects. Given the limited understanding of these risks, adherence to the precautionary principle is recommended, advocating for minimizing exposure these materials whenever feasible.

However, quantitative assessment of exposure to MCNMs and HARNs arise difficulties due to lack of adequate equipment for personal sampling, and the scarcity of toxicological and epidemiological studies to set limit values. Despite these limitations, there are other options to monitor the exposure as Control Banding tools, the establishment of internal limit values based on appropriate toxicological studies, or the use of toxicological information of similar substances. These qualitative methods play a crucial role in implementing safe by design strategies, enabling predictions of exposure based on material characteristics and exposure scenarios.

Control Banding tools offer a qualitative approach to assessing exposure to MCNMs and HARNs, facilitating decision-making regarding necessary control measures or the requirement for further risk assessment. These methods categorize situations into different bands, reflecting the likelihood of exposure and potential risks.

To this aim, within the scope of the DIAGONAL project [1], a risk assessment tool has been developed to broaden the application of such tools beyond research facilities to technicians of small and medium-sized enterprises (SMEs), assisting employers and employees in accurately assessing risks associated with exposure to MCNMs and HARNs. This facilitates the implementation of risk mitigation measures based on the priority determined by the risk bands. This interactive Risk Management Tool (RMT) play a key role supporting regulators, industries and other stakeholders on the selection of the best available approaches to reduce risk at source and mitigate the exposure at all stages of MCNMs and HARNs life cycle. .

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2. Applicability

The model and therefore the tool is used for conducting qualitative risk assessment of MCNMs and HARNs, with MCNMs defined as materials comprising multiple components at the nanoscale with a size range lower than 100 nm and HARNs as nanoparticles with a high aspect ratio, typically greater than 3:1. This tool is intended to examine production processes where MCNMs or HARNs are directly used as raw materials; processes where the resulting material intentionally falls within the nanoscale range or exhibits a high aspect ratio; and processes where nanoscale particulate material or high aspect ratio nanoparticles are obtained as by-products at various stages of the production line.

Exposure calculations are carried out based on in-situ data measured by industrial hygiene technicians through continuous monitoring equipment or based on concentration estimation from ITENE's own database, obtained from all nanoparticle exposure monitoring campaigns conducted by the technical staff of the environmental monitoring and safety department under various European projects.

3. The model

The developed risk assessment model implements the control banding qualitative methodology to estimate risk bands. To compute this risk level, the model estimates two different bands for hazard and exposure which result on five possible bands for risk when they are combined.

These bands classification is the outcome of the study of several commercial methods functionality and the experience of ITENE’s technical workers, identifying the best characteristics to give the user a better service, having the hazard bands scheme relying on the COSHH Essentials model widely known on the chemicals risk prevention area, while the exposure bands scheme is based on the combination of several models’ functionalities, such as Cherrie & Schneider model (1999) [2] and other already available platforms, for instance Stoffenmanager [3] nano 1.0 and Nanosafer.

To estimate the exposure band four different factors are considered: the emission source with information about the material and the process; the dispersion which takes into account the distance between the source and the worker; the inmission or personal protective equipment used by the workers; and the intensity, directly related to the task frequency and duration. The hazard band combines information about the material properties and its hazard statements or H-phrases to compute the hazard band.

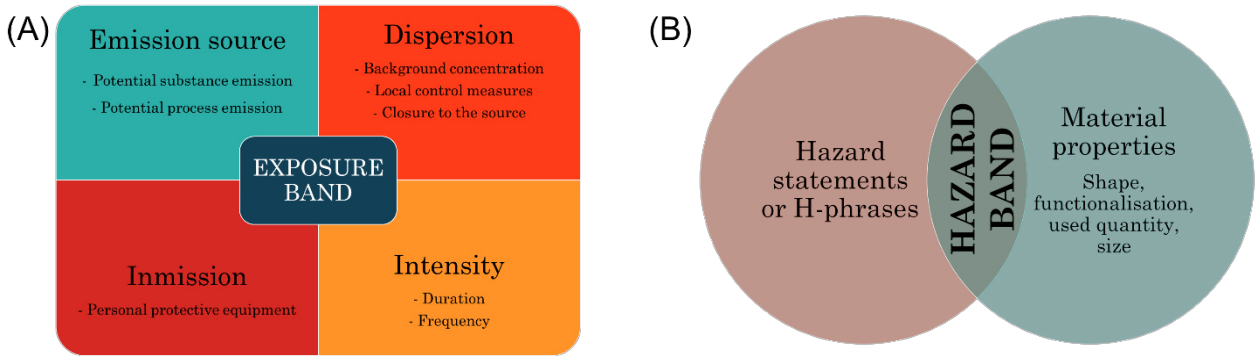

Figure 1: Factors involved in exposure band (A) and hazard band (B) estimation.

For most of the input parameters necessary to run the model, the work consisted of grouping by ranges, assigning a score to each range of the group. This score will be used by the model equations to calculate the respective bands. Once hazard and exposure bands have been set, they are combined to estimate the risk level. For each risk band a set of recommended preventive measures are shown in order to reduce the risk for the workers.

4. The tool

The model roughly described in the previous section has been implemented as a python script and will be included and integrated in the DIAGONAL cloud platform.

As the input parameters are grouped in ranges, the user interface is planned to be a simple form in which the user will select the most suitable option for each of the parameters the model needs. These input parameters will be grouped in three sections to better understanding for the users: working area to provide data about the conditions of the environment, task and the protective equipment used when it is performed, and material to define its specific properties. In this form will be also a question to complete and upload an excel file with the monitoring campaign measures.

Once the form is completed and the file uploaded, it will be shown to the user the computed risk band as well as the recommended preventive measures for that specific risk level.

5. Conclusions

The objective of this control-banding model and therefore of the risk assessment tool is to prioritize the risks related to exposure to nanomaterials, while providing preventive measures, establishing itself as an effective assessment method. Since not all information is currently available for MCNM and HARNs, the DIAGONAL risk assessment model has had to make several assumptions and simplifications. However as more studies are conducted and more information becomes available, both model and tool could be updated.

6. References

[1] Grant agreement No 953152

[2] Cherrie, John W., Schneider, Thomas (1999) *Validation of a new method for structured, subjective assessment of past concentrations*. Ann Occup Hyg 1999; 43: 235-245. https://doi.org/10.1093/annhyg/mer113

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