Banding approach for engineered nanomaterial risk assessment and control

Nausikaä Van Hoornick¹, Dimitar Prodanov¹, Alain Pardon¹

¹Imec, Kapeldreef 75, 3001 Heverlee, Belgium
Email: nausikaavanhornick@imec.be

Abstract. Since there is a lack of sufficient toxicological information about engineered nanomaterials, and since within the semiconductor research and manufacturing use is already made of these materials, an alternative for the classical quantitative risk assessment was sought. Within the research facilities of imec use is made of a banding technique to determine the risks associated with the nanomaterial research. The method and the measures that are taken are discussed in the paper. The method has been benchmarked with other available techniques.

1. Introduction

In contrast to the quantitative risk assessment approach based on sufficient toxicological data, which is used into risk assessments of bulk materials, engineered nanomaterials (ENM) represent a challenge because their effects on the human health and environment are poorly understood. Despite the fact that the effects of these materials are scarcely known, novel ENMs are designed, synthesized and used on a regular basis.

One way to deal with this would be to look at the properties of the bulk materials and base the risk assessment of the ENMs on this. However it is known that the properties and thus the effects of the ENM’s are quite different than the properties of their parent bulk materials.

Obtaining all necessary data to do a quantitative risk assessment requires considerable resources. Moreover, health effects of nanomaterials are still generally uncertain because of the lack of standardization in testing protocols and in most of the cases there are no established reference values. Since even a best case scenario introduces a considerable time lag between the actual work and the availability of the input information for a quantitative risk assessment other techniques of risk assessment should be used.

2. Risk and Control Banding approaches

In order to manage the environment, health and safety (EHS) risks in circumstances where information is missing various risk and control banding tools have been developed by a variety of academic and industrial groups [1]. 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 other more-studied materials' toxicity and anticipated safe work practices, taking into consideration exposure assessments. Each band was then aligned with a control scheme. At present, the concept is used in the ISO Standard ISO/TS 12901-2:2014 Nanotechnologies - Occupational risk management applied to engineered nanomaterials [3]. ISO/TS 12901-2:2014 is focused on intentionally produced nano-objects such as nanoparticles, nanosheets, nanofibres, nanotubes, nanowires, as well as of aggregates and agglomerates of the same. Currently, the risk and
control banding approach is applied for emerging risks such as nano-objects (e.g. nanoparticles), by the development of various control banding approach tools, for example ISO/TS 12901-2, ANSES, Stoffenmanager Nano, NanoSafer etc.

The EHS team of Imec – a large research center for semiconductor nanotechnology – uses a banding approach to deal with risk assessments of ENMs. The risk control approach is based on the one proposed originally in Stoffenmanager[4], but has been geared for application within the semiconductor research and development. Our approach parallels the accepted practices in life sciences (e.g. biosafety) where the intrinsic hazard of the biological entity is difficult to quantify precisely.

Within the risk control approach we look at the hazard potential of the ENM and to the exposure potential during specific activities. Both aspects are divided into three groups: low, moderate and high. By classifying the ENM and the exposure to the ENM the appropriate risk control bands can be defined, as is shown in figure 1. Based on these risk control bands measures are proposed in order to work safely during the activity at hand.

![Figure 1: Risk banding approach based on hazard potential of the ENM and exposure potential of the activity as adapted from Stoffenmanager.](image)

### 2.1 Hazard potential

A number of different characteristics of the ENM are taken into account in order to determine the hazard potential of the material. The most important properties taken into consideration for this classification are:

- size and shape
- water solubility
- dispersion capacity
- toxicity of parent material
- toxicity of the chemical functionalization.

The hazard is considered high when the particle size is less than 10 nm, the particles have high aspect ratio and the ENM is dispersed and hydrophobic.

The intrinsic hazard is considered moderate if the particle size is in the range of 10 nm - 100 nm, the ENM aggregates or agglomerates or it has irregular shape.

The intrinsic hazard is considered low if the parent material is water soluble or dispersed in liquid, if it is embedded in solid matrix or has a low dispersion capacity.

### 2.2 Exposure potential

The probability of exposure (e.g. the potential of a process step to generate airborne ENM) is banded in three categories. Banding is based on the assumption that the greatest health hazard comes from airborne particles. The most important properties taken into consideration for this classification are:
• quantity of ENM
• proximity of the activity (near breathing zone or not)
• duration of the activity
• kind of activity (grinding, milling, polishing, ...)

A high exposure potential is introduced by manipulations that mechanically disrupt a surface functionalized with ENM, manipulations done within the breathing zone (i.e. less than half a meter away), involving large amount (area factor) of ENM, steps producing aerosols or mechanical cleaning of process chambers and HVAC systems.

The moderate exposure potential is used when manipulations are done in the near field (in between half and one meter from the breathing zone), when the duration of the activity is taking less than 4 hours a day, 3 days a week or when cleaning of process chambers is done with wet tissues.

A low exposure potential is met when the manipulations are taking place more than 1 meter from the breathing zone and when less than 1 g ENM is used.

2.3 Risk control band
Finally, the activities involving ENM are grouped in three risk bands of unlikely, potential and likely risk (see Figure 1). The classification is realized by a combination of structured questionnaires, sample characterization and workplace assessments where the presence of risky operations are identified.

3. Safety measures
Different safety measures are prescribed based on the assigned risk control band. The measures are about:
• work practices in storage and shipment
• proper labelling and signposting
• primary containment
• use of appropriate personal protective equipment (PPE)

Table 1 gives an overview of the prescribed measures depending on the risk control band.

| Risk control band | Measures |
|-------------------|----------|
| Unlikely          | • Signposting on receptacles  
                    • Signposting on doors and labs  
                    • Storage of materials in closed receptacles  
                    • Use of appropriate PPE (lab coats, chemical resistant gloves, safety goggles)  
                    • All personnel involved with working with nanomaterials should be properly trained  
                    • Practices of good housekeeping |
| Potential         | • All of the above +  
                    • Workplace assessment to be conducted  
                    • Air sampling to identify possible routes of exposure |
| Likely            | • All of the above +  
                    • Working in closed environments (i.e. containment of manipulations)  
                    • Working with breathing apparatus |
When the risk control band is defined as being likely, this means there either is a high or potential hazard associated with the ENM or there is a high possibility of exposure to the product. This means protecting yourself against the material is of the utmost importance.

Looking into working in closed environments means as such that it is recommended to use for example glove boxes to do the activity. If this is not possible – and only then – ventilated and closed environments, like biosafety cabinets are allowed. If this is not possible either, use can be made of semi-closed environments with ventilation, like fume hoods and wet benches. If course in the latter cases additionally use has to be made of the appropriate personal protective equipment.

In some cases – i.e. when cleaning process chambers – use has to be made of self-contained breathing apparatus to do the job. In case of doing experiments in labs use is made of FPP3 masks.

4. Discussion and Conclusions

Several types of control banding tools are in use at present. In order to determine the hazard and exposure bands, two major systems are used:

i. A decision tree or a binary system that utilizes decision criteria to allocate specific nanomaterial or workplace condition into certain hazard categories or exposure categories.

ii. A scoring system that evaluates the toxicity data or workplace conditions. The hazard band and the exposure band are then determined according to the obtained score.

Afterwards, the risk band and corresponding control band can be determined by a matrix.

Typical representatives of decision tree and scoring system are the ISO approach and the CB NanoTool [4] respectively. However, the used type of decision systems varies. Some are a mixture of a binary decision system and a scoring system such as Stoffenmanager. Some are solely decision trees, such as the NanoValid approach [6].

The ways of dealing with unknown toxicity data are also different. For instance, the ISO approach allocates an unknown toxicity parameter to the most hazardous category while CB NanoTool presumes an unknown hazard property between medium and high.

As Table 2 indicates our approach compares with several other approaches. The imec approach uses a binary system to determine the hazard and exposure bands. Imec decided to work with 3 distinct risk bands making it clear and easy for researcher to determine the measures that need to be taken. The method has proven to be very effective within the imec organization to reduce the risks associated with the research on nanomaterials.

Acknowledgements

The authors wish to thank Ms Yange Liu who helped with the literature search and comparison. Publication has been supported in part by NanoStreeM (Horizon 2020 grant agreement No 688194).
Table 2: Comparison of different banding approaches.

| Name                     | Hazard band and exposure band determination | Number of hazard bands | Number of exposure bands | Risk band/control band determination | Number of risk/control bands | Method for dealing with unknown information                                                                 | Ref |
|--------------------------|---------------------------------------------|------------------------|--------------------------|---------------------------------------|------------------------------|-----------------------------------------------------------------------------------------------------------------|-----|
| imec approach            | Binary system                               | 3                      | 3                        | Matrix                                | 3                            | Allocating an unknown toxicity parameter to the most hazardous category                                        |     |
| ISO approach             | Decision tree                               | 5                      | 4                        | Matrix                                | 5                            | Assigning score to an unknown hazard property between medium and high. e.g. score for carcinogenicity- Yes: 6 pts, No: 0 pts, Unknown: 4.5 pts. | [3] |
| CB NanoTool              | Scoring system                              | 4                      | 4                        | Matrix                                | 4                            | - Setting default choice if user selected ‘unknown’. - Importing data from OECD’s testing program for available nanomaterials. |     |
| Stoffenmanager Nano      | Binary system                               | 5                      | 4                        | Matrix                                | 3                            | Classifying nanomaterials into categories without knowing detailed properties.                                | [4][7] |
| NanoValid approach       | Decision tree                               |                         | 5 categories             |                                       |                              |                                                                                                                | [6] |

References
[1] Bhushan, D. (2014). Handbook of Nanomaterials Properties. Berlin: Springer Berlin Heidelberg.
[2] Brouwer D., Control Banding Approaches for Nanomaterials, Ann. Occup. Hyg. 2012, 56 (5), p506–514.
[3] ISO Standard ISO/TS 12901-2:2014 ; http://www.iso.org/iso/catalogue_detail.htm?csnumber=53375
[4] Cosanta, B. Stoffenmanager Nano module 1.0. Retrieved from stoffenmanager 6®:
https://nano.stoffenmanager.nl/

[5] Zalk, D. M., & Paik, S. Y., Summary instructions for CB NanoTool 2.0. retrieved from http://controlbanding.net/Services.html

[6] NanoValid. (2015). Safe handling of nanomaterials and other advanced materials at workplace. Dortmund: Federal Institute for Occupational Safety and Health

[7] Duuren-Stuurman, B. V., Vink, S. R., Verbist, K. J., Heussen, H. G., Brouwer, D. H., Kroese, D. E., Van Niftrik, M. F., Tielemans, E. and Fransman, W. (2012). Stoffenmanager Nano Version 1.0: A Web-Based Tool for Risk Prioritization of Airborne Manufactured Nano Objects. The annuals of occupational hygiene, July 2012, 56(5), p525-541. doi:10.1093/annhyg/mer113