

## Concerns related to Safety Management of Engineered Nanomaterials in research environment

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**Abstract.** Since the rise of occupational safety and health research on nanomaterials a lot of progress has been made in generating health effects and exposure data. However, when detailed quantitative risk analysis is in question, more research is needed, especially quantitative measures of workers exposure and standards to categorize toxicity/hazardousness data. In the absence of dose-response relationships and quantitative exposure measurements, control banding (CB) has been widely adopted by OHS community as a pragmatic tool in implementing a risk management strategy based on a precautionary approach. Being in charge of health and safety in a Swiss university, where nanomaterials are largely used and produced, we are also faced with the challenge related to nanomaterials' occupational safety. In this work, we discuss the field application of an in-house risk management methodology similar to CB as well as some other methodologies. The challenges and issues related to the process will be discussed. Since exact data on nanomaterials hazardousness are missing for most of the situations, we deduce that the outcome of the analysis for a particular process is essentially the same with a simple methodology that determines only exposure potential and the one taking into account the hazardousness of ENPs. It is evident that when reliable data on hazardousness factors (as surface chemistry, solubility, carcinogenicity, toxicity etc.) will be available, more differentiation will be possible in determining the risk for different materials. On the protective measures side, all CB methodologies are inclined to overprotection side, only that some of them suggest comprehensive protective/preventive measures and others remain with basic advices. The implementation and control of protective measures in research environment will also be discussed.

### 1. Introduction

The increasing production and use of engineered nanomaterials (ENMs) contributed to an evolving concern in occupational risk assessment and management of exposure to these materials. Currently, the assessment of possible health risks as a result of exposure ENMs is associated with significant

uncertainties [1]. This situation has given rise to initiatives of governmental authorities, policy makers, industrial organizations, and civil society organizations to advocate the application of the precautionary principle for risk management. Recommendations on working safely with nanomaterials have been developed in the past decade by government agencies and occupational health organizations [2-5]. Diverse good laboratory practices are proposed on the universities' side as well [6-8].

Control banding (CB) was developed in the pharmaceutical industry as a pragmatic tool to manage risks resulting from exposure to a wide variety of potentially hazardous substances in the absence of firm toxicological and exposure data [9]. In control banding approach Hazard and Exposure bands are estimated and combined into broad risk classes. Different levels of protection are suggested consequently to control the risk. In the context of uncertainty in the production and use of manufactured nanomaterials, CB approach can be very helpful in implementing a risk management strategy according to a precautionary approach [10]. In recent years a few teams published works [11-15] on qualitative risk estimate of ENPs based on this approach and it seems to be, at the moment, a largely accepted strategy to handle 'unknowns' in management of Nanomaterials safety.

However, the extent to which safety guidances are followed and recommended methodologies applied is not well known. The validation of the effectiveness of the exposure controls and measurements methods remain a key research needed [1].

Regarding universities' laboratories, Jesus Santamaria and his team [16] have conducted in 2010 an online survey to identify which safety practices researchers are following. The responses of the 240 participants shed some light on what was going on. The questions covered: details of the materials and processing methods used; safety measures; waste disposal procedure, and knowledge of legislation for handling nanomaterials. One of the most surprising results [17] is that nearly three quarters of respondents reported not having internal rules to follow regarding the handling of nanomaterials (approximately half of them didn't have rules and over a quarter were not aware of any internal regulations).

In this work we analyze our experience in implementing risk assessment and management of nanomaterials safety at EPFL in Switzerland.

## **2. EPFL method for Nanolaboratory classification**

In collaboration with accidents insurance and State Secretariat for Economic Affairs, as well as nanomaterials users and producers, the occupational safety and health team at the Ecole Polytechnique Fédérale de Lausanne (EPFL) developed a procedure for managing the OHS risks relevant to research laboratories producing and using nanomaterials [18]. The methodology (will be called EPFL method here in) is similar to control banding approaches. It consists of a schematic decision tree allowing classifying laboratories handling or producing ENPs into three exposure potential classes (from Nano 3 - highest exposure potential to Nano 1 - lowest exposure potential). The laboratories are classified by taking into account physical state of the substances, quantities of substances as well as agglomeration state (see figure 2 in reference [18]). The idea behind making the methodology simple is to allow a rapid determination of the precautionary exposure potential class by users of nanomaterials themselves.

The first differentiation in the decision tree for exposure potential class determination regards the environment, whether the process is carried out in a closed (complete process confinement) or open system. In case the process is not fully enclosed (glove box or completely sealed environment), different types of activities with nanomaterials are correspondingly discussed:

- Activity with nanofibers
- Activity with nanoobjects in powder
- Activity with nanoobjects in suspension
- Activity with nanoobjects in solid matrix.

Inside these categories, hazard potential classification is based on the quantity of nanomaterial as well as on the aggregation/agglomeration state (for activities with nanopowders).

For nanopowders we also distinguish *production* and *handling*. Very often, particles are supplied by other laboratories or external suppliers, where occupational safety and health team cannot control the process as well as for home-made particles. Furthermore, users manipulate such particles more often in confined spaces. Limits for exposure potential classes' in case of *handling* are therefore lower than those for *production*.

The hazards related to nanomaterials suspension are not only influenced by the nature of particles but also by the dispersant. The decision tree is organized accordingly: For manipulated quantities superior to 1 liter the nature of the used dispersant (flammable, toxic etc.) is considered.

The preparation of composites is either treated as "Activity with nanoobjects in suspension" or "Activity with nanoobjects in powder" when performed in solution or in dry conditions, respectively. The laboratory is treated as Nano 1 if material characterization and post-preparation processing activities do not include any mechanical or thermal treatment. If dust can be released during the manipulation or if composites are friable, laboratory is treated as "Activity with nanoobjects in powder".

Protective measures are subsequently recommended for each of three exposure potential classes, and they are divided in technical, organizational and personal, as custom in health and safety/occupational hygiene practice when managing the risks. For example, laboratories with exposure potential Nano 3 will require rather extensive technical measures with capture at source, exiting air filtering with at least a F7 filter [EN 779 - European Standard for ventilation filters. F7 has 80-90 % average efficiency for 0.4  $\mu\text{m}$  particles], and access restrictions using a security vestibule (double door). Examples of organizational protective measures are the following:

- Each laboratory must have a responsible person (nano-officer).
- An ordering/receiving procedure must be established with identified collecting points.
- Pregnant women are allowed to work with nanomaterials only with a special work authorization issued by an occupational physician.
- Lab safety audits are performed by occupational health and safety specialists.
- Permanent laboratory staff working in Nano 2 lab and every person working in Nano 3 are subject to medical surveillance.

As illustrated, the set of measures is quite extensive and gives detailed information on all elements when handling/producing nanomaterials, including delivery, storage, cleaning, medical surveillance etc. [18].

### **3. Implementation of the management of the nanomaterials safety in practice**

The presented approach for management of nanomaterials is currently being implemented at EPFL for research and teaching labs dealing with nanomaterials. Using above mentioned decision tree, the researchers themselves determine preliminary exposure potential level for each process involving nanomaterials.

The results of inquiry (see table 1 for part of results) tell us that: there are about 30 processes that classify laboratory to Nano 3 type (more than 70 in Nano 1 type). The main types of activities are: use of different types of nanopowders for producing new materials, production and use of nanofibers and a multitude of processes including nanomaterials in suspensions. The most frequently used types of particles are:  $\text{TiO}_2$ , Au,  $\text{SiO}_2$ , Carbon nanotubes, C black,  $\text{Fe}_2\text{O}_3$ , Ag,  $\text{RuO}_2$ ,  $\text{Fe}_3\text{O}_4$ , ZnO etc.

**Table 1.** Excerpt from the results of inquiry on production/use of nanomaterials at the EPFL.

Process	Number of labs concerned	Lab classification according to EPFL methodology
Manipulating nanoparticles in suspension, less than 1 litre	28	Nano 1
Production of nanopowders, less than 100 mg per batch. Particles agglomerate.	10	Nano 1
Use of more than 10 mg of nanoparticles in powder per experience. Particles agglomerate.	6	Nano 2
Use of more than 1 mg and less than 10 mg of nanoparticles in powder. Unknown agglomeration.	7	Nano 2
Manipulation of dry nanofibers.	15	Nano 3
Use of more than 10 mg of nanopowders per experience. Particles do not agglomerate.	5	Nano 3
Production of more than 100 mg of nanopowders per batch. Unknown agglomeration properties.	5	Nano 3

As an illustration of methodology use, we will discuss a simple process of manipulation of C black nanoparticles. These particles (commercial name FW200) with average diameter of 13 nm and specific surface area of 550 m<sup>2</sup>/g are received in 500 grams containers and first weighted in order to distribute the powder into smaller containers. Then 30 grams of carbon black is weighted from a small container and added to the previously prepared liquid polymer. The working surface is cleaned using tissue and a solvent. The approximate time needed for operation of weighting/cleaning is about 30 minutes. The prepared mixture is then stirred in magnetic stirrer in order to obtain paste for further studies. This process is done with 2-3 times per week frequency. Work is performed under a fume hood and with a FFP3 respiratory mask.

If a part of process in which powder is used is analyzed using EPFL methodology to obtain exposure potential, decision tree will rapidly give: Activity with powder form, Use of nanomaterial, Quantity more than 100 mg per experiment, unknown particles agglomeration state. This will lead to *Nano 3* as safety classification, requiring the most extensive risk mitigation measures; the process should be done in the restricted access room, under a fume hood and using overall with hood-Tyvek® style, overshoes, close fitting safety goggles, 2 pairs of gloves and FFP 3 mask. The contaminated material tissue used for wet cleaning etc. is disposed in a special bin dedicated to toxic waste.

After laboratories' nano levels are determined, a workplace visit for each process classified as Nano 2 or Nano 3 are performed in order to validate/complete the analysis by occupational safety and health specialists. For the above-mentioned process, as an example, we have applied three other CB methods in order to check which risk band they recommend. Summary of the analysis is given below.

ANSES CB method [11]: In order to determine hazard band, this method suggests using classification of the nano substance by authorized authority if the former exists. C black is classified as

carcinogenic of category 2 by EU-GHS/CLP [19]; According to ANSES CB this corresponds to hazard band 4 (HB4). To determine Emission potential band (EP) we have considered that C black has high or moderate dustiness powder, giving final emission potential band EP4. Final risk control level (CL), obtained by combining HB4 and EP4 is CL5. For the case of CL5, the ANSES CB method advises full containment and review by a specialist required: seek expert advice.

Another method used is Control Banding Nanotool [20]. Based on the knowledge of the nanomaterial characteristics and review of the operation in the field, the CB Nanotool gave value 51.25 for severity (High severity) and 80 (Probable) for probability score (see table 2). As it can be seen in table, 5 out of 13 factors contributing to severity are unknown contributing largely to the high severity score.

**Table 2.** Results of risk evaluation using CB Nanotool

Severity factor	Points	Probability of exposure	Points
Surface chemistry, reactivity and capacity to induce free radicals	10	Quantity of NP used during the task	25
Particle shape	0	Dust making capacity	30
Particle diameter of NP	5	Number of employees occupying similar working place	5
Solubility of NP	10	Operation frequency	15
Carcinogenicity of NP	5.625	Time for procedure	5
Reproductive toxicity of NP	5.625		
Mutagenicity of NP	5.625		
Dermal toxicity of NP	5.625		
Toxicity of parent material	0		
Carcinogenicity of PM	3.75		
Reproductive toxicity of PM	0		
Mutagenicity of PM	0		
Dermal hazard of PM	0		
Total severity	51.25	Total probability of exposure	80

Combination of obtained severity and probability values for the analyzed activity indicated that the overall risk level (RL) is 4 (the highest risk level). As risk mitigation measure for RL4, the CB Nanotool suggests consulting an expert (general ventilation is proposed for RL 1, Fume hoods or local exhaust for RL 2 and containment for RL 3).

Application of Stoffenmanager Nano web tool [12, 21] for risk analysis of the same process gives Hazard band D (fourth on the scale of 5). When taken into account that the process is performed in a fume hood and with a FFP3 mask, one obtains exposure band 2 (on the scale of 4) so the obtained risk priority band is equal to II (medium risk priority). Since existing protection is already taken into account when doing risk analysis, different protective measures can be investigated when using the Stoffenmanager Nano tool and observe their effect on the risk priority band. For example, if it is assumed that the process is done with full containment, exposure band is reduced to 1 (lowest), but due to high hazard band (D), the risk priority band still remains the same (medium).

Summary of results of risk classification and control measures using different methods is given in table 3.

**Table 3.** Results of risk evaluation for the process of C black weighting, using four different tools

	EPFL	ANSES tool	CB Nanotool	Stoffenmanager
Risk classification of the process	Level 3 on the scale of 3	Level 5 on the scale of 5	Level 3 on the scale of 4	Level 2 on the scale of 3
Control measures	Technical, organizational and personal measures for Nano 3	Full containment and review by a specialist	Containment of the process	Measures included in the analysis process

In similar way, these risk analysis methods were applied to evaluate the process of dry cleaning of the quartz tube used for the synthesis of Multi Walled Carbon Nano tubes (MWCNT) by Chemical Vapor Deposition. MWCNT in question have 20 nm diameter and several microns length; 30 grams are synthesized per batch. After MWCNT synthesis, the tube is emptied into a beaker and then cleaned with a dry tissue for about 5-10 minutes (synthesis and cleaning are realized one time per week in average). FFP3 respiratory mask, lab coat and close fitting goggles are used for manipulation.

EPFL method gives the highest exposure potential classification (Nano 3). It is assumed that fibers in question are biopersistent; ANSES CB methodology therefore gives the highest risk band (full containment and review by specialist). The CB Nanotool gives RL3 risk level requiring containment of the process. Stoffenmanager gives hazard class E (highest) and time weighted exposure class 1 (lowest). The obtained risk score is the highest one on the scale of 3.

## 4. Discussion

### 4.1. Results of risk analysis using different tools

From the analysis described above as well as other analysis of processes involving nanomaterials in our research laboratories ( $\text{BiVO}_4$ ,  $\text{LiNbO}_3$  fibers,  $\text{Al}_2\text{O}_3$ ,  $\text{TiO}_2$  etc.), we could deduce that EPFL method is easy to use (very little information is required for doing analysis). Stoffenmanager Nano explicitly focuses on work environment. Its database contains certain number of particles type in a list, so the user is not asked to search for information on their properties for hazard band determination. This tool is mainly intended to be used by non-expert SME's employers and employees [10]. Among the CB tools, CB Nanotool requires the most extensive effort in information retrieval on nanoparticles properties (as surface chemistry, reactivity, toxicity etc.) This methodology was developed to support the front line occupational health and safety specialists in the first place [10] since nanomaterials users are less willing to do safety information search for the substances they are using if the former are not accessible in Material Safety Data Sheets (MSDS). In case of ANSES CB methodology, one of the key elements for its application is the use of MSDSs according to the GHS system. ANSES CB is intended to be used by persons adequately qualified in chemical risk prevention [10].

One of the main difficulties when using those tools remains the lack of nanomaterials' specific information and MSDSs in hazard band determination. Namely, the majority of MSDSs for ENMs, when available, provide most of their safety and health information based on the bulk parent material [15]. In a recent study [22] on 97 MSDSs of ENMs, it is found that most of the time, MSDS do not include sufficient information on safety of nanomaterials, such as their toxicity and physicochemical properties. As a consequence, severity factors often give value 'unknown' and the result of risk analysis for a particular process is essentially the same with a simplified methodology requiring very little input information (as EPFL methodology) and one that takes hazardousness/toxicity into account

(CB Nanotool and ANSES CB methodology). CB methodologies give the same or similar (high) hazard band resulting in high risk/ protection.

Since new research initiatives arise, the CB tools will certainly evolve [10]. New information will also become available on toxicity and exposure. Indeed, taking into account, when available, information on surface chemistry, solubility, carcinogenicity, toxicity etc., instead of ‘unknowns’ is crucial when hazard band is determined; this will allow more sophisticated CB tools to give more precise results of analysis. To create a consistent standard for the information provided on safety, health, and environment matters for manufactured nanomaterials-containing products, guidance for the preparation of nanomaterials-specific MSDS, including both nanomaterials and mixtures of nanomaterials with conventional non nano scale materials was recently initiated by ISO TC 229 [22].

Regarding exposure band determination, in order to give dustiness level of the product, ideally dustiness tests should be made [23]. Furthermore, information on the agglomeration state of the particles is also necessary. Namely, it is suggested that for the same mass concentration, non-agglomerated dry nano - particles should be given a higher dustiness/mistiness rating than agglomerated or liquid-suspended nano-particles [14, 18]. Without detailed analysis, it is often difficult to know whether particles agglomerate. Even if the answer is known, the potential of deaggregation either in aerosols form or after absorption by body fluids will often be a key issue [24].

#### *4.2. Challenges in exposure studies (measurements) in research environment*

At the moment, quantitative and sensitive measurements of workers’ exposure to nanomaterials are difficult, requiring multitude of instruments for measuring different parameters (average concentration, particles size distribution, elemental analysis...), in process near and far field. At this stage, it would be interesting for OHS specialists in academia research environment to do at least survey measurement for sources of emission/ potential exposure for a particular processes using simple portable instruments as portable Condensation Particle Counter [25] or Miniature Diffusion size classifier [26]. According to our experience at the moment, due to small quantities of substances used and rapidity of the processes, emissions are difficult to detect.

#### *4.3. The implementation and control of protective measures*

As already discussed above, the applied qualitative methodologies to analyze the risk of different processes involving nanomaterials give in general high risk band demanding high protection. For the highest risk levels, consulting an expert/specialist is demanded in CB Nanotool and ANSES CB. According to ANSES CB, an expert in this context is person highly knowledgeable in toxicology and industrial hygiene [11]; this person or group of people has to make a full risk assessment which is not possible to do using CB methods. In practice, finding adequate expert to complete risk analysis might be difficult. The other difficulty is related to process containment that is suggested but often not possible to implement due to the size of equipment for example. One should not forget that taking materials out of contained equipment might also represent a risk.

A technical measure generally suggested is the use of enclosed ventilation, as ventilated booth, fume hood and similar. An important point recommended by EPFL method is filtering (HEPA F12 filter) of all extraction air (therefore from enclosed ventilation) coming from the labs Nano 3 before this air reaches the ventilation system of the building. Air contamination outside the research labs should be avoided in this way.

As far as organizational measures are concerned, EPFL method recommended restricted access to the labs; only authorized personnel can access the Nano 3 laboratories. Lab personnel also do cleaning. All nanomaterials contaminated waste is treated as toxic waste.

Regarding medical surveillance, the reports [4] indicate that level of knowledge today doesn’t allow advising a specific medical survey, or indicators of exposure or effects. Still, certain consensus is obtained at international level [27] to recommend that potentially exposed workers should have periodical medical survey with ‘conventional’ exams, specific for potential target organ. On Swiss national accident insurance company’s (SUVA) initiative, the potentially exposed workers (exposures

30 days or 200 hours per year) at the EPFL are subject to rather extensive medical tests comprising: lungs radiogram, blood and urine test, spirometry and ECG with 2 years frequency. The idea is to use results of these examinations as input for database to make epidemiological studies; although the data might be limited due to high turn-over of the staff and constantly changing processes in academia research [28].

## 5. Conclusions

Making rules and policies is one aspects but it is even more important to implement control, continuous improvement and adaptation of the mitigation measures. Monitoring, adaptation, control and review of measures in place have high importance. As research' processes and equipment evolve very fast, the use of simplified methods with dedicated correctives measures and actions is essential. Due to lack of knowledge/ application of precautionary approach in all methodologies used at the moment, protective measures have an 'over-protection' tendency; there is high chance that these measures will be reduced as knowledge will increase. As far as academia research is concerned, being on 'over-protective' side is far better than having insufficient protection; one should not forget that this environment has an important role in educating people who will work in industry afterwards.

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