

CONTROL BANDING, NANOMATERIALS MANUFACTURING, AND OCCUPATIONAL HEALTH AND SAFETY—A REVIEW

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1. Introduction and Problem Statement

- ▶ Health risk assessment (HRA) was first proposed by the National Research Council (NRC) in (1983). HRA follows 4 steps.
- ▶ In the case of ENMs, a quantitative health risk assessment (QHRA) is difficult, given an important uncertainties regarding the toxicity of nanomaterials.
- ▶ *A risk assessment method for controlling nanoparticle exposures remains mainly qualitative or semi-quantitative in nature. This method is known as “control banding (CB),” an alternative approach to QHRA.*

2. Objectives of the Research

- ▶ A brief literature review over the past 20 years that focuses on the CB approach and comparison of the main CB tools specifically developed for nanomaterials.
- ▶ Development of an original risk assessment method combining QHRA and CB based on characterization of physico-chemical and biological properties of nanomaterials.

3. Methodology: Literature Review

- ▶ In the 1980s, the pharmaceutical industry developed the CB approach for new products without toxicological data or occupational exposure limits (OELs).
- ▶ CB is a qualitative or semi-quantitative approach to risk assessment and risk management. CB consists of grouping the health hazards (risk bands), grouping the exposure potential (exposure bands), and then combining these elements to generate a set of controls (control bands).

3. Methodology: CB Example (Cornelissen R., IVAM Uva bv, nl)

Description of the hazard category for NMP				
Possibility of exposure to nanoparticles during a certain activity with NMP		<i>Hazard category 1:</i> (water) soluble nanoparticles	<i>Hazard category 2:</i> Synthetic, persistent nanomaterials (non-fibrous)	<i>Hazard category 3:</i> Fibrous, non soluble nanomaterials for which asbestos like properties can not be ruled out
	<i>Exposure category I:</i> Emission of free nanoparticles minimized due to working in full containment	A	A	B
	<i>Exposure category II:</i> Emission of nanoparticles (1-100 nm) embedded in a larger solid or liquid matrix (100 nm - 100 µm) is possible	A	B	C
	<i>Exposure category III:</i> Emission of primary nanoparticles (1-100 nm) is possible	A	C	C

Control level	Advised control measures
A : Low	Apply sufficient (room) ventilation, if needed local exhaust ventilation and/or containment of the emission source and use appropriate personal protective equipment.
B : Uncertain	According to the hierarchic Occupational Hygienic Strategy, the technical and organizational feasible protective measures are evaluated on their economical feasibility. Control measures will be based on this evaluation
C : High	The hierarchic Occupational Hygienic Strategy will be strictly applied and all protective measures that are both technically and organizationally feasible will be implemented.

3. Methodology: Literature Review (contd.)

- ▶ The approach was adapted by organizations, in particular, for small and medium-sized enterprises (SMEs) that may not have the benefit of a full-time occupational hygienist's expertise.
- ▶ The process is now used in many industries and in diverse applications around the globe and more recently, ENMs.
- ▶ Several CB-type tools have already been developed for nanomaterials.

3. Methodology: Literature Review (contd.)

CB is

- A system that makes use of previous knowledge
- Task-based advice
- Useful to SMEs
- Focused on controls

3. Methodology: Literature Review (contd.)

CB is not

- A replacement for professionals (i.e., Industrial Hygienists)
- A replacement for health surveillance or environmental samples
- The only and last step; additional follow up must be performed

4. Result: Literature Review Summary

- ❑ **The CB Nanotool (Paik et al. [2008) Lawrence Livermore National Laboratory USA**
 - <http://controlbanding.net/Services.html>
- ❑ **The Swiss Precautionary Matrix (Höck et al., 2008) Switzerland**
 - <http://www.bag.admin.ch/nanotechnologie/12171/12174/14653/index.html?lang=en>
- ❑ **ANSES CB Nanotool (2010) Anses France**
 - <http://www.anses.fr/>
- ❑ **The NanoSafer CB tool (Jensen et al.; Kristensen et al., 2010), Danish**
 - <http://nanosafer.i-bar.dk/>
- ❑ **The IVAM Guidance (Cornelissen et al., 2011), Dutch Social Partners**
 - [http://www.industox.nl/Guidance on safe handling nanomats&products.pdf](http://www.industox.nl/Guidance%20on%20safe%20handling%20nanomats&products.pdf)
- ❑ **Stoffenmanager Nano (Van Duuren-Stuurman et al., 2012), TNO and ArboUnie, Holland**
 - <https://nano.stoffenmanager.nl/>

4. Results (contd.)

These CB-type tools for nanomaterials that were developed between 2008 and 2012 have already been reviewed for a comparative analysis:

- ✓ **Brouwer, 2012;**
- ✓ **Ligouri et al., 2016;**
- ✓ **Jiménez et al., 2016;**
- ✓ **Eastlake et al., 2016.**

4. Results (contd.)

- ❑ It is evident from the scope of each of the tools that they were developed for different purposes such as the following:
 - ❑ **CB Nanotool** was created to protect nanotechnology researchers.
 - ❑ **IVAM Guidance** was developed to support employers and employees in identifying the risks associated with different work situations.
 - ❑ **Stoffenmanager Nano, NanoSafer, and the ANSES tool** were developed for occupational risk assessment and management during synthesis and downstream use of nanomaterials, but also for laboratory work.
 - ❑ **Precautionary Matrix** was created for risk identification and prioritization, taking into consideration the workplace, consumers, and the environment from a life-cycle perspective.

4. Results (contd.)

- ▶ The first phase of this work was to develop an assessment tool of ENMs, based on the NRC's approach. (2015)
- ▶ *“ Integrated Approach to Design and Safe Handling of Nanomaterials - A Program based on a Dialogue Between Industry and Evaluators of Health Risks ”* (published on IRSST's website).

4. Results (contd.)

- ▶ This work, based on physico-chemical and biological characteristics, represents the second phase of this project.
- ▶ This phase is needed in order to select appropriate chemical and biological characterization tests in order to standardize the assessment tools developed.
- ▶ The most relevant parameters for the physico-chemical and biological characterizations of nanomaterials are selected.

4. Results: Assessment Tool of Nanomaterials Based on Physico-Chemical and Biological Characteristics (contd.)

Physicochemical Biological	TEST 1	TEST 2	TEST 3	TEST 4	TEST 5	TEST 6
TEST 1	Green	Green	Yellow	Yellow	Orange	Orange
TEST 2	Green	Green	Yellow	Yellow	Orange	Orange
TEST 3	Yellow	Yellow	Yellow	Orange	Orange	Orange
TEST 4	Yellow	Yellow	Orange	Orange	Orange	Orange
TEST 5	Orange	Orange	Orange	Red	Red	Red
TEST 6	Orange	Orange	Orange	Red	Red	Red

4. Results: Step Forward CB-MC Here as an Example (contd.)

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CB NanoTool
Control Banding Deterministic Model

Scenario Description: aaa
Name or description of nanomaterial: aaa
CAS #: aaa
Current Engineering Control: General ventilation
Activity classification: Working with nanomaterials in liquid media

A) Severity score

1- Surface reactivity	Unknown	7,5
2- Particle Shape	Unknown	7,5
3- Particle diameter	> 41-100 nm	0
4- Solubility	Soluble	5
5- Cancerogenicity	Yes	6
6- Reproductive toxicity	Yes	6
7- Mutagenicity	Yes	6
8- Dermal toxicity	No	0
9- Asthmagen	No	0
10- Toxicity of parent material	< 10 µg/m³	10
11- Carcinogenicity of parent material	No	0
12- Reproductive toxicity of parent material	No	0
13- Mutagenicity of parent material	Yes	4
14- Dermal toxicity of parent material	No	0
15- Asthmagen of parent material	Yes	4

B) Probability score

1- Estimated amount of chemical used during task	> 100 mg	25
2- Dustiness / mistiness	High	30
3- Number of employees with similar exposure	1 - 5	0
4- Frequency of operation	Less than monthly	0
5- Operation duration	Less than 30 min	0

Result

Severity: 56
Probability: 55

RL 3

RL 3 : Containment
Upgrade ? Yes

1 novembre 2016

(Daniel Drolet retired from IRSST as a collaborator for this portion of project)

5. Discussion

- ▶ The characterization of nanomaterials is a crucial step
- ▶ In this study, we were mainly interested in the characterization of ENMs to analyze this reactivity with biological materials.
- ▶ This method will contribute to a better understanding of nanomaterials to anticipate their potential effects on humans.

5. Discussion (contd.)

- ▶ This approach is different from that developed by other agencies that assess and characterize the risk for workers and the population.
- ▶ It was important to identify a minimum number of tests that could generate a maximum amount of information.
- ▶ The toxicology and physico-chemical tests that were selected are the most commonly used in the nanotechnology field.

6. Conclusions

- ▶ The proposed method of CB is original because it is dependent upon the structure of nanomaterials, but is not based on the exposure on the first intention.
- ▶ This CB, based on characterizations of the potential hazards posed by nanomaterials for a better guideline of the health implications and safe handling. From this independent hazardous assessment, it is possible to combine this assessment and the exposure assessment.

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