8th US/EU joint Conference on OSH

Nanotechnology in the workplace
Principles for control for MNMs
EU guidance for assessing nanomaterials

Patrick Levy MD,
EU Employer
UIC – Medical Advisor
France

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC

Introduction

- **First EU simplified Guidance for performing risk assessment** for MNMs
- Purpose of the EU Guidance: **assisting employers, health and safety practitioners and workers** in fulfilling their regulatory obligations regarding risk assessment and control
- Guidance drafted by a consultant (Risk Policy Analysis (RPA - UK)) in the frame of a service contract launched by the EU Commission
- Modified by WPC for becoming a **Commission Guidance** after approval by the Advisory Committee on Health and Safety at work
- The guidance will be **translated into EU national languages**

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC

Introduction

- Based on the existing **EU definition of nanomaterials** (which is under review)
- Focused on **exposure by inhalation**
- Based on **control banding and categorisation** approaches taking limited number of PC criteria
- **The focus of this Guidance is on Manufactured NMs**, some of the risk management measures suggested could contribute to minimising exposure to **naturally occurring nanomaterials and incidental nanomaterials**

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC

Risk Assessment and Management Process

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC

Step 2 – Hazard assessment
Categorising level of concern
shape and solubility

A categorisation rating for the level of concern relating to the possible effects of MNMs on workers' health based on the **geometry/shape** and **persistence/water solubility** characteristics

Concern Category	Characteristics of the MNM
High Concern	**Poorly soluble or insoluble** (water solubility <100 mg/l) **WHO nanofibres**
Medium-High Concern	**Poorly soluble or insoluble** (water solubility <100 mg/l) **nanoparticles with specific toxicity and poorly soluble or insoluble HARNs** other than poorly soluble or insoluble WHO nanofibres
Medium-Low Concern	**Poorly soluble or insoluble nanomaterials with no specific toxicity**
Low Concern	**Soluble nanomaterials**

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

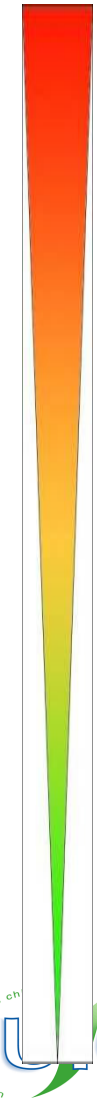
union des industries chimiques
UIC

Step 2 – Hazard assessment
Categorising level of concern dustiness and flammability

Band	Dustiness
High	Fine, light powders. When used, dust clouds can be seen to form and remain airborne for several minutes. For example: cement, titanium dioxide, photocopier toner
Medium	Crystalline, granular solids. When used, dust is seen, but it settles quickly. Dust is seen on the surface after use. For example: soap powder, sugar granules
Low	Pellet-like, non-friable solids. Little evidence of any dust observed during use. For example: PVC pellets, waxes

Step 3 – Exposure Assessment

Level of exposure	Description
High	Free/unbound MNMs, dustiness high band, likely emission of MNMs Tasks that are likely to produce airborne MNMs: • Manufacture of MNMs — e.g. synthesis, "top-down" process • MNM handling in dry state or powder form, e.g. sampling, weighing and measuring, scraping, packing and opening of bags • Spraying of a solution containing MNMs • Cleaning and maintenance of equipment
Medium High	Possible Emission of MNMs (friable or brittle matrix), dustiness medium band: • Dry blending of MNMs into a matrix (e.g. polymer) • Processing of solid substances in the nanoform or solid mixtures containing MNMs through, e.g. weave, knit, twist, cut, grind, scrape, etc. • Cutting/grinding a matrix containing MNMs if they can be released from the matrix
Medium Low	Emission of MNMs anticipated as very low, dustiness low band: • Extruding and manipulating matrixes containing MNMs (e.g. paints or polymers) • Processing, shaping, moulding of matrixes containing MNMs • Cutting/grinding a matrix containing MNMs if release is unlikely • Solutions containing MNMs are mixed or agitated • MNMs in articles or in fully cured coating on surfaces of articles
Low	Unlikely emission of MNMs: • Painting, coating (excluding spraying) or packaging of extruded product • MNMs are embedded in a matrix and no machining



Step 4 – Categorisation of Risk (Control Banding)

Table 4.7: Control Banding: Risk Level = Concern Category x Level of Exposure				
	Level of Exposure			
Concern Category	Low	Medium-low	Medium-high	High
Low	1	1	2	2
Medium-low	1	2	2	3
Medium-high	2	2	3	4
High	3	3	4	4

Step 5 – Detailed Risk Assessment

Substance		REL µg/m³	DNEL µg/m³	Reference
MWCNT	Long term exposure		50	Pauluhn, 2009 ;
CNT and CNF	8-hr TWA	1		NIOSH 2013
Fullerenes	Chronic inhalation		270	Stone et al 2009
Ag (18-19nm)	DNEL		98	Stone et al 2009
TiO_2 (10 -100nm) (REL)	10hr/day, 40hr/week	300		NIOSH 2011

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC

Step 6 – Risk Management

Risk level 1

- In general, in these situations, the risk to the health and safety of workers may be regarded as *slight* within the meaning of Article 5(4) of the CAD. In addition, if the application of the general principles for prevention is sufficient to reduce this risk, Article 5(4) of the Directive establishes that the provisions of Articles 6, 7 and 10 do not need to be applied. Normally, **such situations can be controlled through the use of general ventilation.**

Step 6 – Risk Management

Risk Level 2

- In the following situations, **specific prevention measures should be implemented, in addition to what is required for risk level 1 situations:**

- where the emission of medium-high concern MNMs is anticipated as very low or unlikely;

- where the emission of medium-low concern MNMs is probable or very low; or

- where low concern MNMs are likely to be emitted.

- For risk level 2, engineering control measures such as local extraction might suffice in minimising the exposure and associated risk.

- In situations leading to a risk level 2 according to table 4.7, **specific prevention measures should be implemented**, in addition to what is required for risk level 1 situations. Engineering control measures such as local exhaust ventilation might suffice in minimising the exposure and associated risk.

Step 6 – Risk Management

Risk Level 3

- In the following situations, **closed systems or containment must be used. A detailed Risk Assessment, informed by exposure measurements, should be carried out with the assistance of an expert:**

- where MNMs of high concern are used but their emission is expected to be very low;
- where the emission of MNMs of medium-high concern is probable due to their dustiness and the characteristics of the work activities; or

- where poorly soluble/insoluble nanomaterials with no specific toxicity are likely to be emitted.
- The optimum combination of engineering control measures, administrative control measures and the adoption of personal protective equipment by the workers potentially exposed to the MNMs should be selected and implemented for the minimisation of the exposure.

- In situations leading to a risk level 3 according to table 4.7, **closed systems or containment must be used** and their efficiency ensured by checking regularly their performance (this may be done by measuring key variables of the functioning of the control systems and/or by measuring airborne concentrations of the MNM).
- The optimum combination of engineering control measures, administrative control measures and the adoption of personal protective equipment by the workers potentially exposed to the MNMs should be selected and implemented to minimise exposure.

Step 6 – Risk Management

Risk Level 4

- In the following situations, **it is essential that measures specifically designed for the processes in question are adopted:**

- where MNMs have given rise to significant concerns over their potential impacts on human health on the basis of the evidence gathered by research (namely poorly soluble/insoluble WHO nanofibres) and where it is likely or probable that emissions will occur during the work activities resulting in a high level of exposure of the workers; and / or

- where MNMs have given rise to a medium-high concern (namely poorly soluble/insoluble nanoparticles with specific toxicity and poorly soluble/insoluble HARNs other than those encompassed in concern category 1) and the MNMs easily could be released into the atmosphere.

- In situations leading to a risk level 4 according to table 4.7, **it is essential that measures specifically designed for the processes are adopted.**

Concluding remarks

- **New simplified guidance at EU level based on control banding**
- **Approved by EU Governments, Employees and Employers**
- Next steps: **establishment of categorical OELs and substance specific OELs** to perform quantitative risk assessment activities for priority MNMs

Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

union des industries chimiques
UIC