NATIONAL RESEARCH CENTRE FOR THE WORKING ENVIRONMENT

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NanoSafer vs. 1.1 Nanomaterial risk assessment using first order modeling

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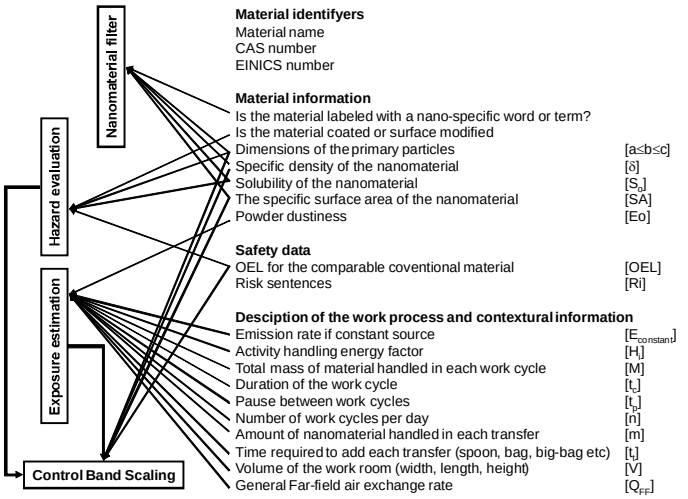
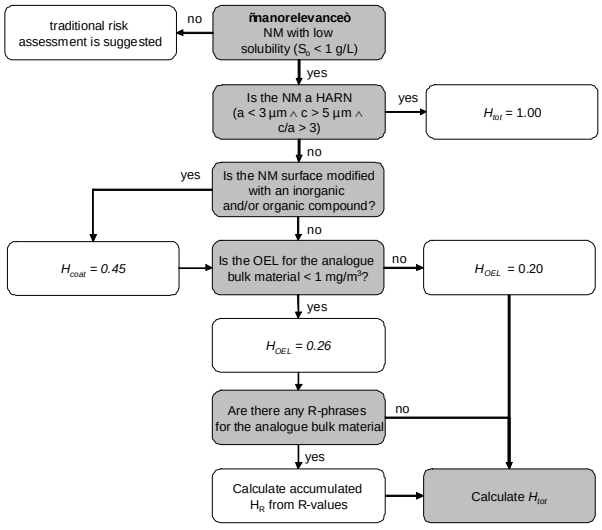
1. NanoSafer is an online control banding and risk management tool for Manufactured Nanomaterials (MNM). Hazard assessment and case-specific exposure potentials are currently combined into an integrated assessment of risk levels expressed in control bands with associated risk management recommendations and e-learning. The tool is currently intended for SME's. Further developments aims at more advanced applicability, including administrative and regulatory use.

2. Input data are typically available from the producers' technical information sheets. The hazard data are given in the SDS for the closest analogue bulk material for which the requested occupational exposure limit (OEL) is given as well. The emission potential is either given by a constant release rate or the dustiness level determined using the EN15051 rotating drum or similar.

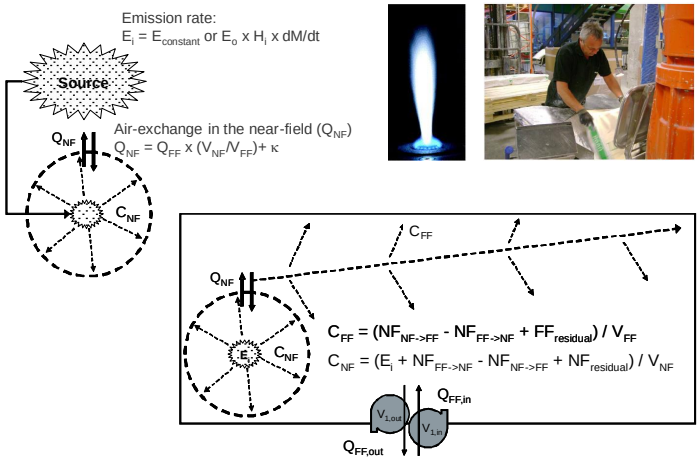


3. Hazard Evaluation is based on the physicochemical properties of the MN (water solubility, aspect ratio, presence of coatings), risk sentences of the nearest bulk analogue compound deemed relevant for the respiratory tract and the occupational exposure limit (OEL) of the nearest bulk analogue compound.



$$H_{carc} = \sum_{i=1}^{n} R_i \cdot \left(\prod_{j<i} (1 - R_j)\right) \qquad H_{tot} = \sum_{i=1}^{n} H_i \cdot \left(\prod_{j<i} (1 - H_j)\right)$$

4. Exposure Estimation is made using a two-box near-field (NF) and far-field (FF) source-to-recepter modelling assuming instant mixing. The emission potential is a constant emission rate (E_i, mg/min) or the powder dustiness levels (E_o, mg/kg) multiplied with a default activity energy factor (H_i) and the mass-flow (dM/dt) using either the total mass in the work cycle or the amount added in each transfer (e.g., bag) if the transfer takes longer than 1 minute. Powder dispersion and transfer between the NF and FF are calculated considering convection (κ) and ventilation rates (Q) between the NF and FF compartments, the general FF ventilation rate, and the volumes (V) of the NF and FF compartments.



5. Scaling is made to enable assessment of the risk level associated with the specific NM and work situation. The hazard scale for a NM is given by *Htot* calculated under bullet 2 and take values between 0.2 and 1. The exposure potential is scaled by normalizing the 15 min (*EXPAcute*) and daily (*EXP8-hour*) average exposure level (*EXPi*) calculated from first order modelling (bullet 4) with a theoretical NM occupational exposure limit (*OELnano*). *OELnano* is a first order approximation based on a volume specific surface area *(SSA)* paradigme (i.e. toxicity ∝ *f(SSA/δ)*). A VSSA of 30, corresponding to a 200 nm spherical particle with unit density, is used as the bulk reference. The exposure band take values between 0 and ∞, where 1 corresponds to *OELnano*.

$$OEL_{nano} = OEL \cdot \frac{30 \cdot \frac{1}{\delta}}{SSA_{nano}} \qquad EXP_{Acute} = \frac{C_{Acute}}{2 \cdot OEL_{nano}} \qquad EXP_{8-hour} = \frac{C_{8-hour}}{OEL_{nano}}$$

6. Control Banding and Risk Managemt. Four different control banding charts with indivdual assessment of the hazard potential and the potential to exceed acute and 8-hour *OELnano* in the NF and FF, respectively. The control band charts have 5 risk levels (RL), ranging from RL1 with low hazard and low exposure potential to RL5 with high hazard and or moderate to very high exposure potential. Each RL is associated with brief standard guidance on risk management and further information and advise on risk management is available as up-linked e-learning tools, pamphlets, and a background report..

Toxicity / Exposure	0.76-1.00	0.51-0.75	0.25-0.50	0.00-0.25
>1.00	RL5	RL5	RL5	RL5
0.51-1.00	RL5	RL5	RL4	RL4
0.26-0.50	RL5	RL4	RL4	RL3
0.11-0.25	RL4	RL4	RL3	RL2
< 0.11	RL4	RL3	RL2	RL1

http://nanosafer.i-bar.dk/

www.nanosikkerhed.nu