

Stoffenmanager nano 1.0 & RISKOFDERM

Performance test

Neeraj Shandilya, Remy Franken, Wouter Fransman
 TNO, Risk Assessment of Products in Development, Zeist, Netherlands

Introduction

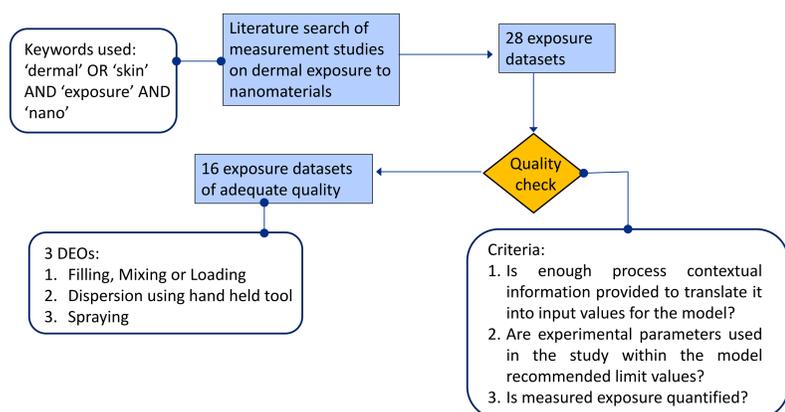
- Stoffenmanager nano is a modular web-based control banding tool which is used to qualitatively estimate worker inhalation exposure to manufactured nano-objects for risk assessment.
- On the other hand, RISKOFDERM is a quantitative modelling tool for estimating potential dermal exposure to general chemical substances. It includes six dermal exposure operation (DEO) units, where each unit is a cluster of exposure scenarios. In the context of nanomaterials, its applicability domain is not yet established.
- In the present study, the performance of these two tools is tested before including them in caLIBRAte system of tools by comparing their estimated outputs with experimentally measured exposure levels of nanomaterials.

Method

Selection of measured exposure data

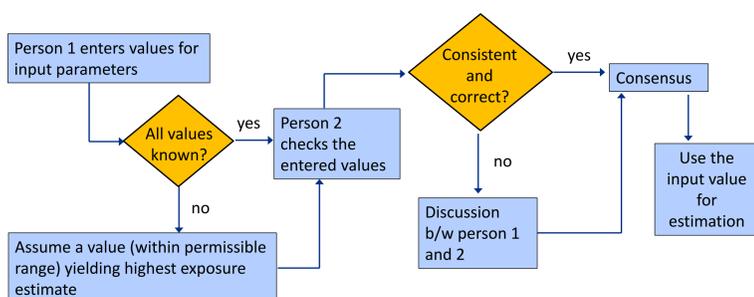
For Stoffenmanager nano, a literature search on the inhalation exposure measurements and their assessment for adequate data quality were carried out using the existing criteria in project deliverable 6.3. It resulted in 82 exposure measurements with adequate quality.

For RISKOFDERM, a different methodology was used as outlined below:

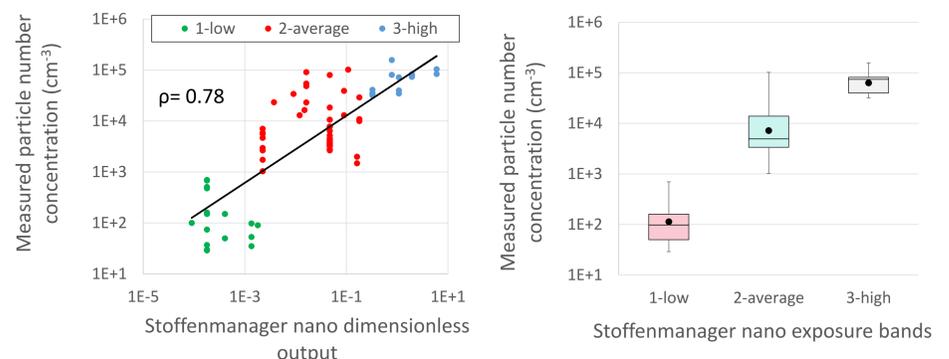


Model input parameters

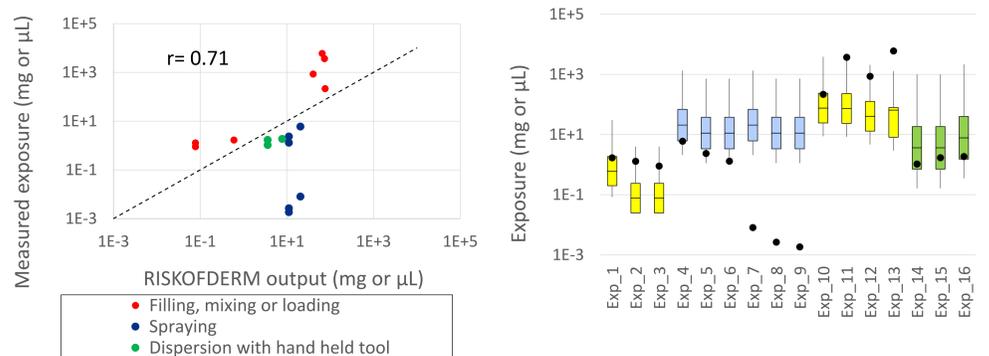
The available information in the adequate studies was translated into input values for both tools via an elicitation process.



Results



- For Stoffenmanager nano, better correlation with higher measured exposure concentrations.
- Overestimation at lower levels of exposure.
- No overlapping between respective interquartile ranges (IQR) of measured exposure concentrations lying in 1-low and 2-average exposure bands.
- Both median and GM exposure values of 3-high exposure band, however, overlap with the IQR of 2-average exposure band.



RISKOFDERM DEO	Measurement method	Estimated exposure
Filling, mixing or loading	Interception	Under-estimation by a factor of 28
Dispersion	Interception	Over-estimation by a factor of 3
Spraying	Interception	Over-estimation by a factor of 6
	Wiping	Over-estimation by a factor of 1.3×10^4

- Overall increasing exposure ranking of DEOs is consistent for both estimated median and measured exposure levels.
- For measurements #1, 4, 10, 14, 15 and 16, measured exposure is within estimated IQR.
- For measurements #2, 3, 5, 6, 11 and 12, measured exposure exceeds estimated IQR but lies within 10th and 99th percentiles.
- For measurements #7, 8, 9 and 13, measured exposure lies beyond the entire statistical dispersion of the estimated exposure.

Conclusion

- Overall estimated outputs of both tools **strongly correlate** with measured exposure concentrations.
- For **Stoffenmanager nano**, the **correlation improves** from poor to strong with higher exposure concentrations
- **RISKOFDERM underestimates** the exposure during filling, mixing or loading and **overestimates** it during spraying and dispersion by hand held tool.
- **Inherent bias** in RISKOFDERM: Severe overestimation of dermal exposure at low exposures → **care must be taken** when using the tool for nanomaterials at low concentration.
- The study concludes that while Stoffenmanager nano is **entirely suitable** to be included in the CaLIBRAte system, RISKOFDERM is (partly) suitable for its inclusion and that too for the **tested DEO units**.