A common European approach to the regulatory testing of nanomaterials

Improved and validated occupational exposure models of release, exposure, dispersion and transfer Deliverable 3.8

Introduction

First tier risk assessment of manufactured nanomaterial often uses control banding tools like the CB NanoTool Nanosafer, Stoffenmanager-NANO for occupational exposures and ConsExpo-nano for consumer exposure. The input for such tools is information provided by the user on the hazard of the nanomaterials, and the exposure conditions (emission potential, duration and frequency of exposure). Based on this input these tools make an estimation of hazard and exposure level (usually a category) and combine them into a risk score. A number of these tools also recommend control measures -if necessary- for the scenario being considered. These tools do not provide quantitative estimates of exposure.

Task 3.4 of the NANoREG project evaluated the scientific basis for such tools with a focus on reliability of the results and validation with high quality measurement results. Partners involved in this task also developed a quantitative inhalation exposure model for nanoparticles and implemented into a tool: the I-Nano tool.

Description of Work

Four models have been evaluated with respect to their applicability domain, assumptions made, inputs required and outputs as well as performance. For two of the most common used tools, the Advance Reach Tool (ART) and Stoffenmanager-NANO, a comparison was made between the outputs and measurement data. For five different tools an inter-user study has been performed to evaluate the potential variability in the answers obtained from different users of the tools.

Furthermore this task developed a quantitative inhalation exposure model for nanoparticles and demonstrated it making use of measurements taken in a large exposure chamber reported in deliverable 3.4.

Main results and evaluation

Scientific Basis

The table below summarizes some characteristics of the tools that have been evaluated.

	Source Domain						Control banding (CB)/ Risk Level (RL) and number of bands
CB tool	Synthesis	Powder handling	Ready to use product	Abra-sion	Emission potential	Exposure potential	
ANSES	Y	Y	Y	Y	Y	N	CB (5)
Precautionary Matrix	Y	Y	Y	Y	Y	N	CB (2)
CB NanoTool	Y	Y	N	N	Y	N	CB (4)
Stoffenmanager-NANO	Y	Y	Y	N	N	Y	RL (3)

The search for peer reviewed (English) literature on the performance of these tools, did not result in any publication for the ANSES tool or the Precautionary Matrix that met the selection criteria. Four studies were retrieved, where the CB NanoTool was studied. For the Stoffenmanager-NANO two studies provided relevant information.

In general the CB NanoTool was found to be conservative compared to the exposure controls that were advised by the occupational hygienists (no such data for the Stoffenmanager-NANO). For both tools, the studies including measurement results did not show good agreement with the output of the models.

Category	Spearman correlation	P-value	Spearman correlation	P-value
	ART		**Stoffenmanager - NANO**	
Transfer	0.464	**0.017**	0.195	0.340
Coating	0.515	**0.000**	0.590	**0.000**
Spraying	-0.596	0.001	-0.177	0.377
Welding	0.075	0.680	-0.148	0.413
hot process	-0.473	0.088	0.244	0.401
Impaction	0.476	**0.016**	0.651	**0.000**

Table: Correlations between particle number concentrations and scores

The comparison between 24 field measurements provided by the Swiss Accident Insurance Fund and the results of Stoffenmanager-NANO and ART (not specifically designed for nanomaterials) show little correlation with the particle number concentration. In the case of ART, the tool is not calibrated for MNMs, so this is perhaps not unexpected but in the case of Stoffenmanager-NANO a better correlation was expected.

The potential variability in outcome of exposure assessment tools when applied by different users was investigated for CB NanoTool, Stoffenmanager-NANO Nanosafer, ConsExpo-nano and ART tool; although, the latter has not been calibrated for MNMs. Only the exposure assessment module of the tool was studied -and not the hazard assessment.

Five exposure scenarios were applied by 28 people with different areas of expertise. For the same tool and the same scenario all data points should be aligned along the same exposure score. However for all the tools a high inter-user variability was observed. Nanosafer showed the largest variability; Stoffenmanager-NANO resulted in less inter-user variability. The scores obtained by the different tools also show large variability.

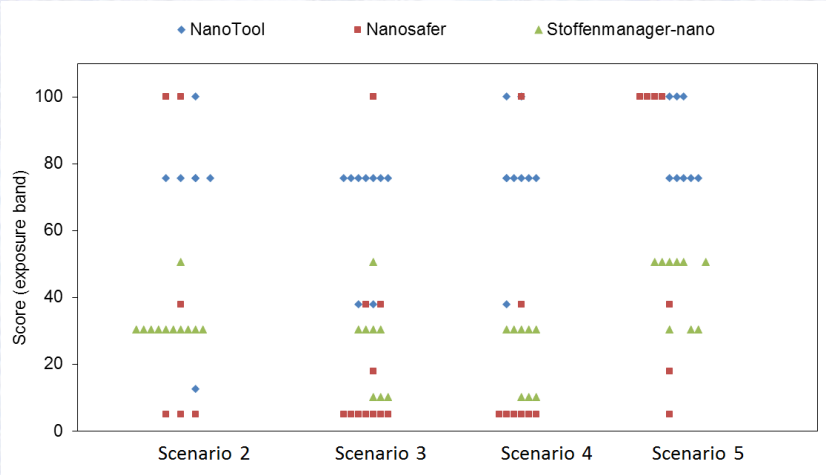


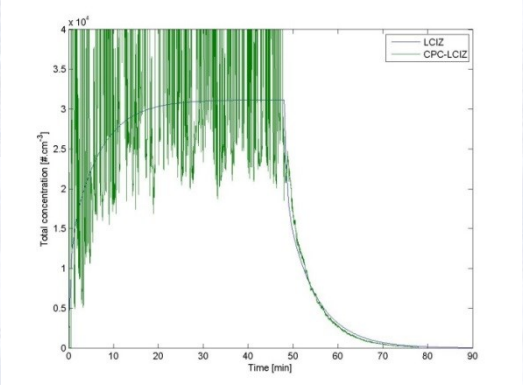
Figure Tools' scores for each scenario: normalised to a scale of 1-100

The results make clear that user variation in interpretation of exposure scenario information and converting these into the input variables is an important source of uncertainty. It can lead to completely different conclusions based on exactly the same set of information. This uncertainty needs to be taken into account during the development of the tools and its supporting guidance documentation and also by users of the tools.

Generally speaking, the conclusion is that that the tools can lead to misclassification of the risks.

Quantitative models

Apart from the inter-user variability study of ART and ConsExponano and the comparison of ART outputs with measurement data, the deliverable also presents the I-Nano tool developed under the umbrella of NANoREG and the demonstration of this model with the results of data measured in a large exposure chamber reported in deliverable 3.04.



The predictions from the I-Nano tool compared well with the measured data collected in the 'purpose build' simulation study. Concentrations in some locations were overestimated for some scenarios but overall the model appeared to be reliable at least within this experimental set-up.

Unfortunately the concentrations achieved where not sufficiently high to cause coagulation between the released nanoparticles. Therefore, the model could not be tested for its sensitivity to pick up changes in the particle size distribution over time.

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