

Identification of data sets for risk governance tool performance testing

Data available for performance testing

For performance testing of models and tools for human and environmental risk assessment of nanomaterials selected in the caLIBRAte project, appropriate data sets are needed.

Several European and national projects have produced an enormous amount of data on hazard, release and exposure of nanomaterials, including EU-projects NANoREG, NANOSOLUTIONS, MARINA and NANOGENOTOX, that may be of significant use for assessment.

A thorough analysis, comparing the available information on 34 reference nanomaterials with the input parameters required by the models, was completed within caLIBRAte. Complete datasets were identified, as were data gaps. The latter were identified with the goal to generate new data within the project to fill these gaps.

A detailed gap analysis on information for physico-chemical characteristics, human toxicity and ecotoxicity for different nanoforms of specific referencenanomaterials was carried out using the data from the caLIBRAte database (data from projects MARINA, NANoREG, NANOGENOTOX, NanoTest) plus additional data from projects EnvNano, nanoFATE, NanoMILE and the NanoE-Tox dataset, plus data available from OECD.

The information on nanomaterials from within those data sets was matched to the identified input parameters of the selected models for human and environmental risk assessments along the different stages of the Cooper Stage-Gate model: Guidenano, NanoSafer, LICARA, SUNDS, Swiss Precautionary Matrix (SPM), SimpleBox4Nano, Mend2Nano, NanoQSAR and SSWD.

caLIBRAte data findings from data sets accessed

- Data on environmental hazard (acute and chronic) are missing for most of the nanomaterials.
- For the human risk assessment (HRA) models data on carcinogenicity, sensitization, dermal toxicity, corrosivity, irritation potential (skin/eye) and reproductive toxicity are scarce.
- Complete datasets for performance testing have been found for the NanoSafer tool (for four silicon dioxide (SiO₂) and four titanium dioxide (TiO₂) nanomaterials plus one zinc oxide nanomaterial (ZnO)) and the SUNDS tool (four TiO₂ nanomaterials).
- For various representative materials, many of the data gaps are for a number of physico-chemical parameters, which can be relatively easily measured.
- The available information (physico-chemical characteristics/toxicity assays performed including innovative technologies) and the location where this information is stored (data collections, datasets, projects) have been identified. The next step is to assess whether this available information is sufficient to obtain the input parameters required by the selected tools

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Table: NMs selected for each model based on the number of gaps in toxicity and ecotoxicity. Green squares indicate that the NM has been selected for the model.

	Ag	Au	SiO ₂				TiO ₂				ZnO	CeO ₂	MWCNT						SWCNT	Dendrimers	Bentonite	Cellulose												
	NM-300 NM-300K	NM-330	NM-200	NM-201	NM-202	NM-203	NM-204	NM-100	NM-101	NM-102	NM-103	NM-104	NM-105	NM-110	NM-111	NM-211	NM-212	NM-213	Nikkiso	Mitsui-7	NM-400	NM-401	NM-402	NM-403	NRCWE-006	NRCWE-007	Nikkiso	Super Growth	G3-PAMAM-(NH ₂) ₃₂	G4-PAMAM-(NH ₂) ₆₄	NM-600	Nanofibrillar cellulose 2-15nm NFC Fine	Nanofibrillar cellulose 2-10nm UPM Biofibrils	
Guidenano																																		
Licara																																		
Nanosafer (case1)																																		
Nanosafer (case2)																																		
SPM																																		
SUNDS																																		
SSWD																																		
SB4N																																		
Mend2Nano																																		

MWCNT Nikkiso and Mitsui and SWCNT Nikkiso and Super Growth are two NMs used in the OECD testing Programme on Manufacturing Nanomaterials.

Nanosafer (case 1). No OEL is available for the NM so only physico chemical parameters are needed (toxicology being that of the bulk material)

Nanosafer (case 2) OEL for NMs is available so toxicological parameters are needed for the NM.

Conclusion

caLIBRAte ensured that localization of the characterisation of reference Nanomaterials is given and gaps in information are identified within existing datasets from a broad range of sources.

This is potentially of value for different stakeholders: e.g. industry and scientific community intending to develop or apply nanomaterials. The origin of the data included in the final caLIBRAte database should be easily tracked if any clarification/additional information is needed.

This fact sheet is based on caLIBRAte Deliverable 5.4: *Results of gap analysis* as a result of a collaboration between National Research Centre for the Working Environment (DK), Karolinska Institutet (SE), Misvik (FI), GAIKER (ES), National Institute for Public Health and the Environment (NL), Danmarks Tekniske Universitet (DK), Finnish Institute of Occupational Health (FI), Nederlands Organisatie voor toegepast-natuurwetenschappelijk (NL), Leitat (ES), Institut national de l'environnement industriel et des risques (FR), Swiss Federal Institute of Aquatic Science and Technology (SW) and University of Helsinki (FI).

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