caLIBRAte
nano risk governance

Human exposure and environmental release data for models performance testing

Evaluation of data availability

Value-chain case-studies (CS) with relevant exposure scenarios (ES) containing data on human exposure and environmental release along the life cycle stages of nanomaterials (NMs) and nano-enabled products (NEPs) are of great importance for performance testing of the models selected within caLIBRAte because they provide measured data to be compared with modelling results. Data from different CS and related ES have been inventoried from selected data sources, including:

i. Exposure databases (NECID, GUIDEnano library);

ii. Data generated in EU Projects

iii. Scientific literature.

The information and data contained in the CS and their relevant ES were collected and analyzed, identifying both emerging knowledge gaps and missing data on human exposure and environmental release and fate studies.

Evaluation of data quality

An evaluation of quality was undertaken within 70 occupational ES plus a selection of relevant, reliable and complete cases that can be used for model performance testing of occupational exposure models such as GUIDEnano, NanoSafer, Stoffenmanager Nano, and the Swiss Precautionary Matrix. The over-all criterion focused on the following three aspects:

Relevance
- Source domain
- NMs

Reliability
- Study design
- Substance information
- Activity information

Completeness
- Dustness
- Emission rate
- Room size
- Ventilation
- …

$$\text{Quality score (Q)} = \frac{\text{weighing factor}_1 R_1 + \text{weiging factor} R_2 + \cdots + \text{weighing factor}_n R_n}{\text{weighing factor}_1 + \text{weighing factor}_2 + \cdots + \text{weighing factor}_n}$$

50 studies were classified with rank > 0.7 [0 to 1]

These aspects contain information/parameters expected to have an impact on exposure and are therefore deemed relevant for the gathering and evaluation of the CS. However, some type of parameters were considered more relevant than others for evaluating occupational exposure by attributing different weighing factors in the quality rank equation.

The calculation of the quality score (Q) of the data and information contained in the CS consisted in an inclusion/exclusion criteria regarding the requirements (if present in study: $R_i=1$ and if not $R_i=0$). From the best ranked CS (Q≥0.7), parameterisations of each model/tool are available for testing and further model/tool refinement/development.

Moreover, missing parameters/data were identified, generated or assumed (e.g. dustness, size, release rate of nanomaterials from products).

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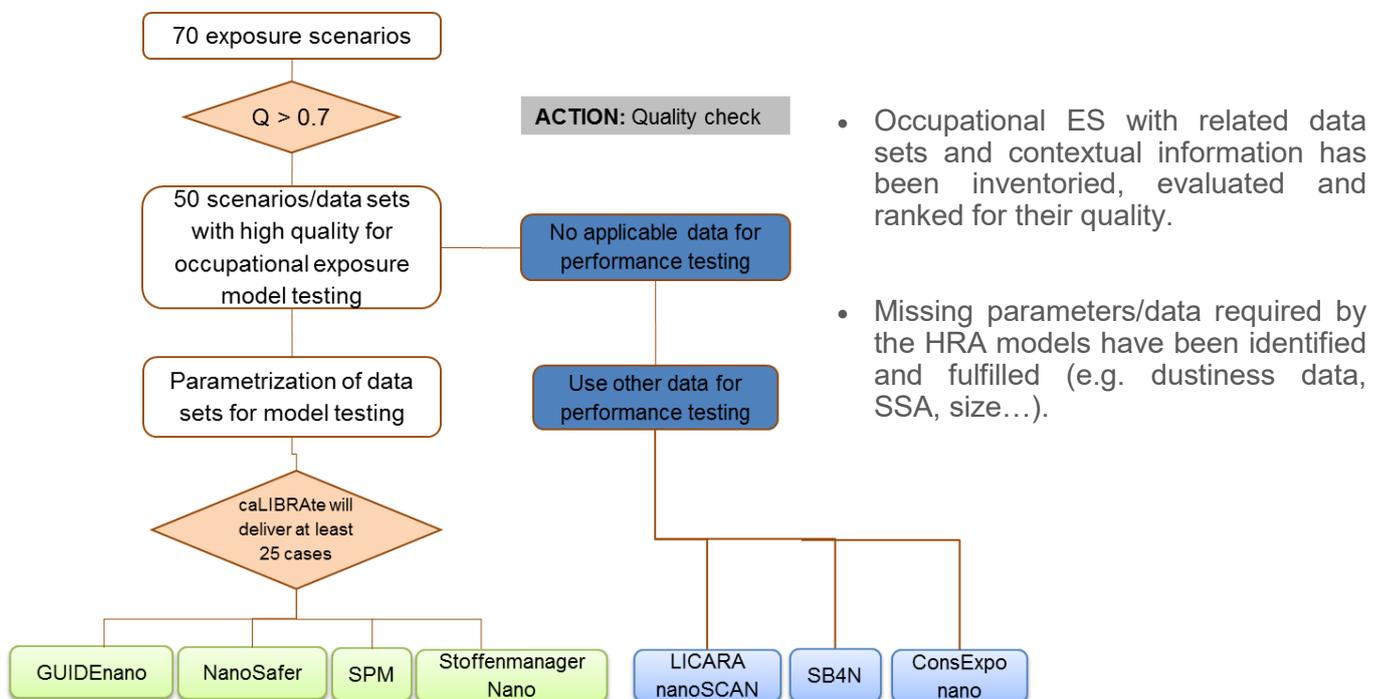
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Relevance for performance testing and calibration

Model INPUT Real Data → **Model OUTPUT** Predicted Data

Tested by comparing the modelling results with the observations (real data)

This work delivered several useful items for risk assessment modelers, such as a scientifically sound quality screening kit usable for new occupational exposure measurement studies, as well as an up-to date overview of available high quality exposure assessment studies. Parameters required by each model/tool can be easily collected from the caLIBRAte database, and used for tool testing and further tool refinement/development.

Summary

- 70 exposure scenarios
- Q > 0.7 — ACTION: Quality check
- 50 scenarios/data sets with high quality for occupational exposure model testing
- No applicable data for performance testing
- Parametrization of data sets for model testing
- Use other data for performance testing
- caLIBRAte will deliver at least 25 cases
- GUIDEnano | NanoSafer | SPM | Stoffenmanager Nano
- LICARA nanoSCAN | SB4N | ConsExpo nano

- Occupational ES with related data sets and contextual information has been inventoried, evaluated and ranked for their quality.

- Missing parameters/data required by the HRA models have been identified and fulfilled (e.g. dustiness data, SSA, size…).

- CS and relevant ES have been parameterized for the applicable model with data available in each case study, with assumption, default parameter and/or calculated values, which were properly indicated.
- Data/knowledge have been transferred for model testing and further model refinement and/or development.

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