caLIBRAte
nano risk governance

Fact Sheet

Quality criteria for data within nanomaterials safety assessment

Curated high quality data is essential to understanding and predicting behaviour of manufactured nanomaterials (MNM). This is important in order to reliably use existing data within various risk assessment approaches, such as grouping and read-across.

Assessing data quality within the nanosafety field is challenged by its multidisciplinary nature, where highly diverse fields of research have traditionally handled, stored and annotated their data in widely different ways.

Topics such as uncertainty, reproducibility and interoperability are now being tackled within the nano-community to address viable solutions for complex data quality assessment.

The proposed caLIBRAte quality assessment method involves scoring of relevance, reliability and completeness of data, including the possibility of addressing the entities in flexible order and related to a developing and increasingly precise nanomaterials ontology.

The caLIBRAte data quality assessment methodology

Information on previous initiatives for data quality assessment were collected within an inventory.

Data requirements for selected human and environmental risk assessment (RA) models were analysed, with compulsory model parameters, i.e. the parameters that are required in an experimental dataset in order to be useful for model testing.

Compulsory model input parameters were further linked to assays deemed adequate for retrieving the necessary data.

Work mapped of RA model parameters, minimum information checklists and relevant assays to IDs in the eNanoMapper ontology through the Bioportal repository interface.

Evaluation of the previous initiatives was performed and a caLIBRAte-specific quality assessment method was developed based on the most relevant previous initiatives.

Elements from the most commonly used and widely accepted methods were adopted and integrated to be suitable for the specific purpose of the caLIBRAte project, taking into account the recent advances and ongoing discussions within the field.

Data quality assessment learnings

caLIBRAte listed eleven different approaches, ranging from general toxicity to nano-specific needs, such as the Klimisch scoring system and the nano-refined version by Card & Magnuson (2010), plus EU and national initiatives e.g. GUIDEnano and the DaNa Literature Criteria Checklist and community-wide efforts, e.g. the Nanomaterial Registry MIAN-based numerical scoring method.

Based on the definitions of quality in Klimisch et al. (1997) and the review by Marchese Robinson et al. (2016) caLIBRAte determined that data relevance, reliability and completeness should be assessed separately in caLIBRAte.

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The caLIBRAte three step approach

A 3-step strategy was established to assess data relevance, reliability and completeness

Relevance of data is assessed on the basis of whether the compulsory parameters, needed for the RA models to give relevant output, have been measured.

Reliability of data is assessed based on the original ToxRTool criteria.

Completeness of data is assessed based on whether the NM tested has been characterized adequately and confers to a list of 11 physicochemical characterization criteria.

QUALITY

1.Relevance

- Relevance for Calibrate (**output: R0-Rx**, x depends on the RA tool)
- Assess the relevance of a dataset by comparing the data with the list of model parameters for each tool

2.Reliability

- Reliability of a study (Using the ToxRTool and Klimisch categories)
- Based on yes/no answers to a number questions related to study design, test article, test organism, and results documentation ("red criteria" must be met)
- A study is assigned a calculated score of 1 (reliable without restrictions), 2 (reliable with restrictions) or 3 (unreliable). (**output: K1-K3**)

3.Completeness

- Completeness of assessing the physicochemical parameters of the NM
- Based on whether information related to 11 parameters was reported, a given study can be assigned a ''Nanomaterial score'' (**output: N1-N11**)

Creating a pathway for data use within nanomaterials innovation

Work within caLIBRAte sets the basis for further development and particularly for implementation of well-defined curation workflows.

Experimentalist-driven curation of data into common databases, through use of harmonized/ standardised ontology implementing data templates, will allow for automated quality labelling and eventually efficient re-use of data for the development of novel risk predictive models.

This fact sheet is based on caLIBRAte Deliverable 5.3: Document on quality criteria for data as the result of a collaboration between Karolinska Institute (SE), RIVM (NL), Finnish Institute of Occupational Health (FI), GAIKER (ES), Technical University of Denmark (DK), TNO (NL), LEITAT (ES) and National Research Centre for the Working Environment (DK).

www.nanocalibrate.eu

Keld Alstrup Jensen
kaj@nfa.dk

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