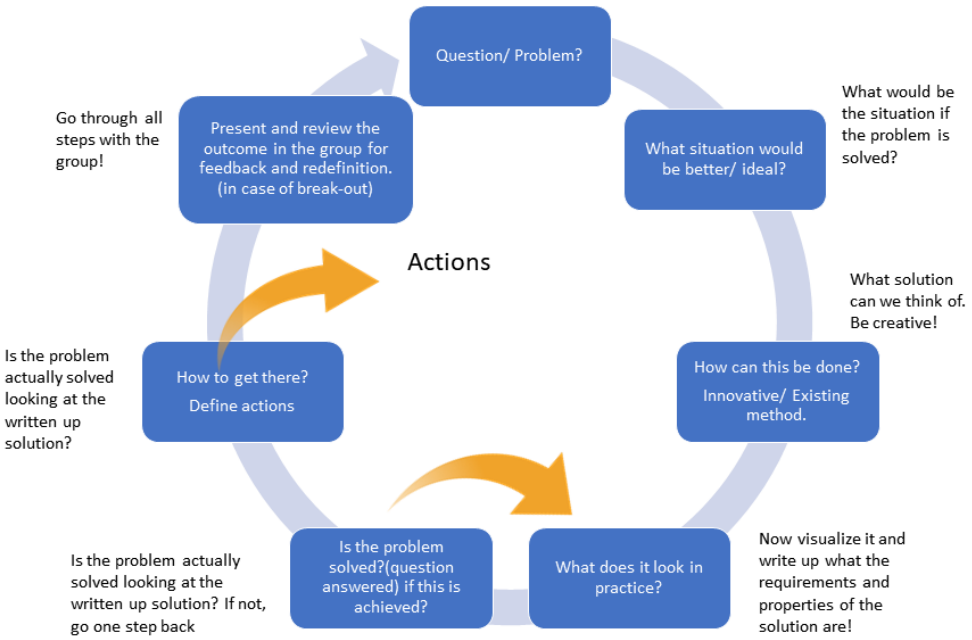
caLIBRAte
nano risk governance

Fact Sheet

Guidance for implementation of existing HRA models at appropriate stages in the production process

Based on the mismatches from the stakeholder assessment performed previously (See Fact sheet *Selecting environmental hazard, exposure and risk assessment*) an expert workshop was held to investigate mismatches between the top 5 tools (as a result from this stakeholder assessment). The workshop's goal was to identify mismatches, and provide innovative solutions which help model owners to overcome these mismatches and increase the applicability domain of their tool.

Expert workshop: Mismatch identification and solution



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Keld Alstrup Jensen
kaj@nfa.dk

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Guidance for implementation of existing HRA models

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For five HRA models (LICARA nanoSCAN, GUIDEnano tool, NanoSafer CB, Stoffenmanager Nano and RiskofDerm), the main mismatches address primarily data gaps or input requirements of which stakeholders indicated that the information is not present during a certain stage of innovation. Mismatches were identified in three domains, namely: characterization, hazard/risk and exposure.

Characterization outcomes

For characterization, main solutions were developed for the lack of characterization data such as dustiness and solubility. The main solutions were the use of existing data (read-across) or to predict e.g. dustiness based on standard physical parameters. Consequently, it was proposed that similarity tables with grouping and read-across approaches developed in other projects are constantly updated. This data can then be used in a funnel/filter function where relevant parameters can be searched to be used to fill in tool parameters which information is not known by the user.

Hazard outcomes

For hazard, predictive modelling was proposed as a solution for providing information (e.g. whether a metal-oxide induces oxidative stress) not available by model users. An overview of models/ methods was provided which are capable of predicting certain hazard information. Examples of such models/methods are Metal Oxide band gap QSAR, high- throughput screening (HTS), QSAR models and the Predictive Toxicogenomics Space (PTGS) tool.

Exposure outcomes

For exposure, an extensive list of default scenarios was developed which aid users to define their exposure situation. Typical workplace configuration, as well as typical control measures and concentration ranges were linked with very specific activities which help users to fill data gaps, especially when performing a risk assessment for end-users. Solutions were also provided for the improvement of release rates predominantly used in the GUIDEnano tool, as well as a refined read -across approach which assists users in filling possible data gaps.

This fact sheet is based on caLIBRAte Deliverable 2.3. 'Guidance for implementation of a set of existing HRA models at appropriate stages in production process' as a result of a collaboration between Nederlandse Organisatie voor toegepast-natuurwetenschappeljik (NL), National Institute for Public Health (NL), National Research Centre for the Working Environment (DK), Finnish Institute of Occupational Health (FI) and GAIKER (ES).

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Keld Alstrup Jensen
kaj@nfa.dk

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