

Current hazard, exposure and (integrated) HRA models considered for input requirements and applicability at the Cooper innovation stage-gates defined

caLIBRAte has focused on the identification and categorization of suitable existing Human Risk Assessment (HRA) models along the stages in a Cooper Stage-Gate® Idea to Market model as defined by stakeholders (SHs). Within the project,

this knowledge will create the basis of a gap analysis to further refine the existing HRA models.

Four assessment steps

- 1) Inventory and selection of appropriate HRA tools based on previous experience and expert knowledge, and agreement
- 2) Assessment of each model for the stakeholders, stage-gate specific parameters and matching of the models against stage-gate specific requirements, using a numerical scoring system
- 3) Selection of models that matched best with stakeholder input
- 4) Further discussion and assessment of the best matching models and consequent conclusions on their applicability (or not) in the Risk Governance Portal

Parameters for model assessment

The models were assessed on two sets of parameters. For this, a scoring system was developed:

- a good match between model parameter and criteria gave a +1
- a full mismatch resulted in a score of -1
- everything unclear or in between resulted in a score of 0

Matching was carried out separately for each stage-gate.

1) Models were assessed for the same parameters, divided into 3 thematic groups:

- 1) Input requirements such as information on characterization, hazard and exposure needed to run the models
- 2) Overall criteria on the properties of the

models (e.g. cost to run model, expertise needed)

- 3) Output criteria of the models (divided into hazard, exposure and risk).

Assessment was also undertaken with regard to each stage-gate, again with parameters divided into 3 thematic groups:

- 1) Available information on characterization, hazard and exposure was available at different stages of innovation
- 2) Overall criteria for risk assessment models at different stage-gates (e.g. cost to run model, expertise needed)
- 3) Output criteria the SHs needed to be able to get from a model.

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Selection of models per stage gate of innovation: The starting point for discussion

Tool Ranking	Stage 1 IDEA	Stage 2 SCOPING	Stage 3 BUSINESS CASE	Stage 4 R&D	Stage 5 VALIDATION	Stage 6 LAUNCH	Stage 7 MONITORING
1	n/a	NanoSafer CB	NanoSafer CB	Guidenano	GUIDEnano	GUIDEnano	GUIDEnano
2	n/a	LICARA nanoSCAN	LICARA nanoSCAN	Nanosafer CB	NanoSafer CB	NanoSafer CB	Nanosafer CB
3	n/a	GUIDEnano	GUIDEnano	RiskofDerm	Stoffenmanager	RiskofDerm	ECETOC TRA
4	n/a	RiskofDerm	ECETOC TRA	LICARA nanoSCAN	ECETOC TRA	ECETOC TRA	Stoffenmanager
5	n/a	Stoffenmanager nano	EGRET	ECETOC TRA	RiskofDerm	Stoffenmanager	ART

The EGRET and ART models will not be used in the system-of-systems of the caLIBRAte project.

n/a: not applicable

A total of 29 models were selected for assessment in the caLIBRAte project. Of these, 9 were ranked in the “top 5” final model ranking based on output and overall tool criteria.

When selecting the models that best matched each stage gate with the stakeholder input, it became clear that the stakeholders do not intend to use models for risk assessment in the idea phase (the first stage gate) of development, and no are models are therefore shown for stage 1.

With increasing stage gate points, the ranking of NanoSafer CB and LICARA nanoSCAN decreased, with NanoSafer CB moving from rank 1 at stages 2 and 3 to rank 2 at stages 4 through 7. LICARA nanoSCAN decreased from rank 2 at stages 2 and 3, to rank 4 at stage 4 and then

disappearing from the top 5 altogether.

In contrast to this, the ranking of GUIDEnano increases with increasing stage gate, from rank 3 at stages 2 and 3 to ending up as the highest ranked for stages 4 through 7.

RiskofDerm holds a median score of 3,5 with an end score of 3 at stage 6 and ECETOC TRA holds a median score of 4 with an end score of 3 at stage 7.

Further development and calibration/validation of existing risk assessment tools, as well as development of default scenarios and linking of tools to standard exposure scenarios and defaults for input values, can overcome many mismatches.

caLIBRAte will continue to undertake this work and support model development.

This fact sheet is based on caLIBRAte D2.2: *Review of current hazard, exposure and (integrated) HRA models considering their input requirements and applicability at the Cooper innovation stage-gates defined* as the result of a collaboration between Netherlands Organisation for Applied Scientific Research (NL), Finnish Institute of Occupational Health, Tampere University of Technology (FI) and the National Research Centre for the Working Environment (DK)

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