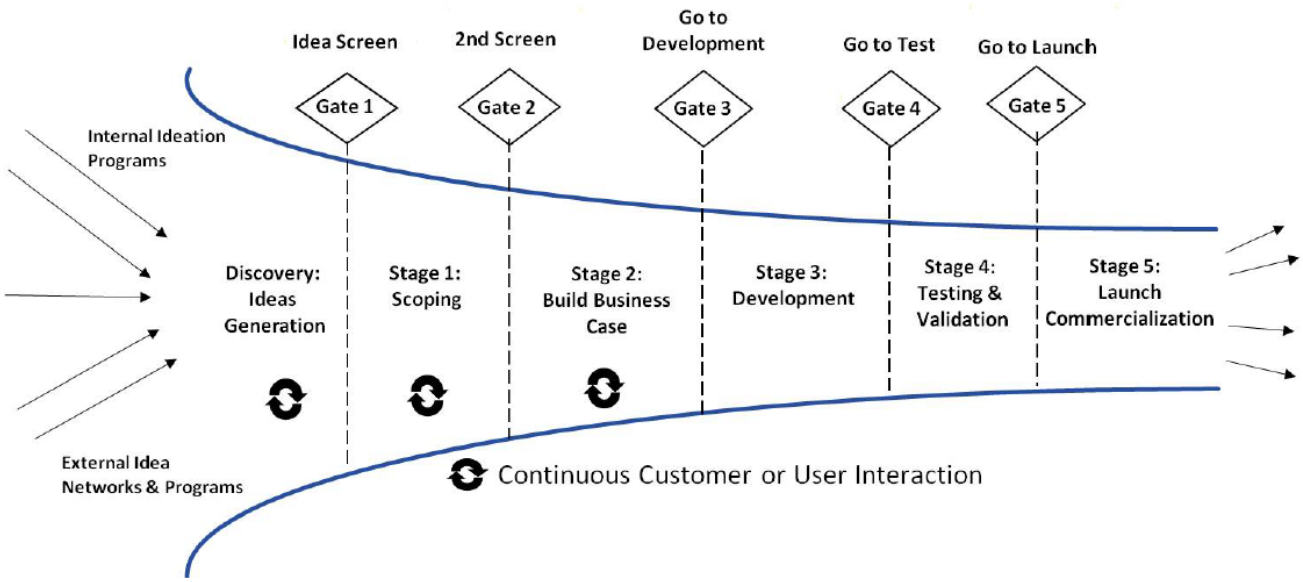
caLIBRAte
nano risk governance

Fact Sheet

Criteria for human exposure, hazard, risk assessment models

The EU H2020 caLIBRAte project aims to design, calibrate and implement a next generation systems-of-systems (SoS) risk governance framework for manufactured nanomaterials (NM), suited for the "Cooper Stage-Gate®" product innovation model. In order to optimally design this SoS along the innovation chain, this factsheet is concerned with the identification of requirements and objective performance criteria, specifically for human risk assessment, to accommodate different stage gates, exposure scenarios and stakeholder needs. It also lists the criteria for environmental risk assessment (ERA) models/tools along the product innovation stage-gates for NMs and NM-enabled products



A typical diagram of Stage-Gate process (Edgett, 2015)

Identifying criteria

Criteria were listed and set out against the innovation stages in a criteria-innovation stage matrix. Stakeholders from regulatory bodies, NGOs, industry associations, large industries, SMEs and insurance were then approached and asked to complete the matrix.

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Important findings

Stakeholder feedback on the criteria-innovation stage matrix enabled the following conclusions and requirements for the development of a caLIBRAte SoS:

- Which regulation a material or product falls within is significant, this should therefore be built into the SoS.
- SMEs will benefit most from a simple to use SoS, that has all the risk assessment expertise hidden inside the system, as they lack this expertise.
- It is most important that the SoS can be run as a stand-alone model (i.e. be able to run on a computer within the company network so that no confidential data leave the protected network), to warrant data security and confidentiality, although some stakeholders have indicated to desire a web -based system.
- A good indication of high risk materials in stage 1 and 2 (red flag) is required and a clear (more quantitative and regulatory accepted) indication of risks within a specific regulatory framework in the later stages.
- Foreseeable changes in fate and ecotoxicity testing and related regulatory frameworks must be included/considered by the SoS, e.g. with regards to units, or inclusion of spatial and temporal dynamics in NM behavior
- As testing material is generally only available from stage 3 (R&D) onwards, earlier stages can only include QSARs and grouping approaches to obtain a hazard indication.
- Priority populations in the SoS are indicated to be workers and then consumers, with inhalation expected to be the most important exposure route.
- Stakeholders who considered all of the stages in their feedback, agree that the hazard and exposure outcomes and exposure outcomes per route, should be given.
- Stakeholders want to know which information was used to reach the risk estimate and what approach that has been taken in case there were multiple data for one input parameter. They do not think a worst case risk estimate is useful, except whenever a potential occupational health risk is foreseen for their own employees that are involved in the R&D process

This fact sheets is based on caLIBRAte Deliverable 2.1, Identification of the output demands and input criteria for human exposure, hazard, risk assessment models at the different Cooper innovation stage-gates, considering stakeholder requirements and Deliverable 3.1 List with criteria for environmental risk assessment models at different stage-gates considering requirements of various stakeholders as the result of a collaboration between Nederlandse Organisatie voor toegepast-natuurwetenschappeljik Onderzoek (NL) and National Institute for Public Health and the Environment (NL), Finnish Institute of Occupational Health (FI), Gaiker (ES) and Tampere University of Technology (FI).

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