caLIBRAte
nano risk governance

Fact Sheet
No. 1

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. Deliverable 2.1 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, and D3.1 **lists the criteria for environmental risk assessment (ERA) models/tools** along the product innovation stage-gates for NMs and NM-enabled products

the "Cooper Stage-Gate®" product innovation model

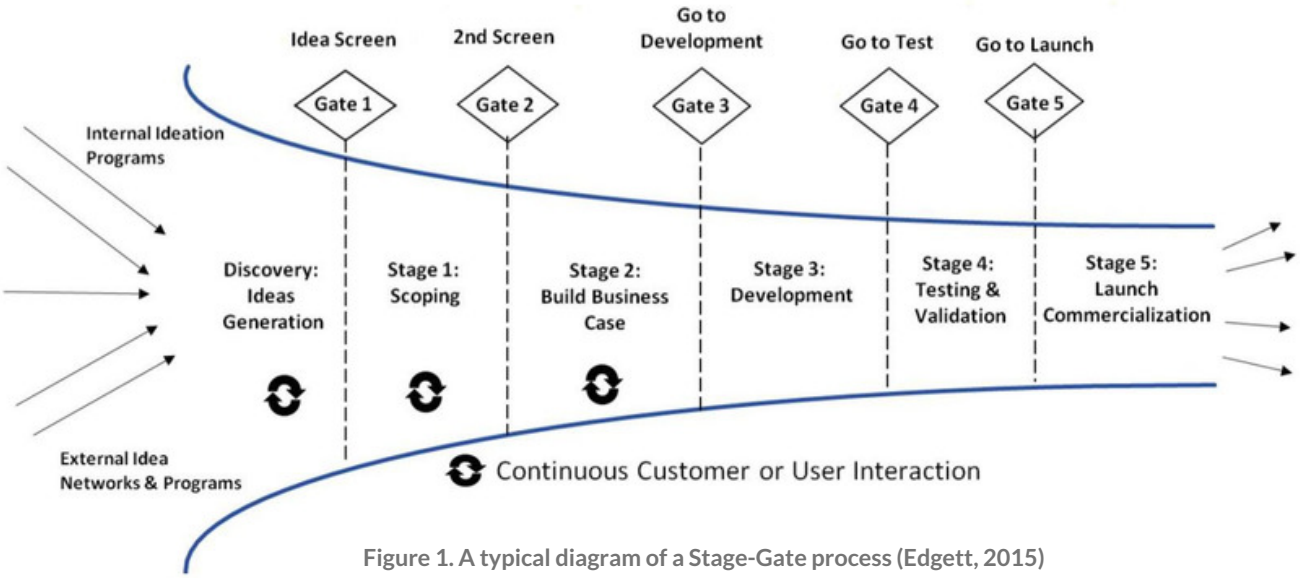

Figure 1. A typical diagram of a Stage-Gate process (Edgett, 2015)

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 fill in this matrix.

www.nanocalibrate.eu

Keld Alstrup Jensen
kaj@arbejdsmiljoforskning.dk

This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement 686239

important findings

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

- It matters **under which regulation a material or product will fall**, 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**.
- The **most important populations** are indicated to be **workers** and then **consumers**, with **inhalation** expected to be the most important exposure route. These deserve priority, therefore, in the setup of the SoS.
- All 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 do want to know **which information was used to get to 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***

www.nanocalibrate.eu

Keld Alstrup Jensen
kaj@arbejdsmiljoforskning.dk

Contact us to learn more about caLIBRAte and how you can become involved in its development

This project has received funding from the European Union's Horizon 2020 research and innovation programme under Grant Agreement 686239