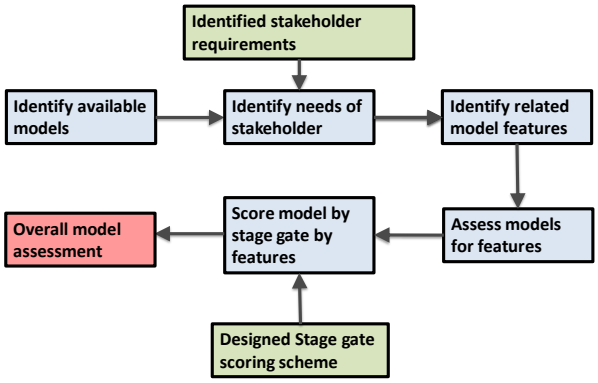
caLIBRAte
nano risk governance

Fact Sheet

Selecting environmental hazard, exposure and risk assessment models at different stage-gates

The caLIBRAte project has systematically evaluated tools proposed for nanomaterial environment flow, fate and exposure, uptake/ bioavailability, hazard and risk assessment against stakeholder needs. The project used the Stage-Gate concept as an approach to gauge the suitability of different models for the ecological risk assessment at different stages of nano-enabled development. Within the innovation chain, the level of information needed for, and required from, environmental assessment models increases at each stage. In early stages, with little information available, risk evaluation tools that can operate with limited data may best fit need. At later stages, where more complex and extensive data and outputs are relevant, models providing greater detail may be better suited.

Model identification and assessment exercise



- Material Flow Analysis Models
  - 7 models
- Fate and Transport Models
  - 8 models
- Hazard Assessment Models
  - 7 models
- Bioavailability and Bioaccumulation Models
  - 4 models
- Risk Assessment Models
  - 12 models

Models and tools for environmental assessment of nanomaterials

Five categories of models can assist stakeholders in the environmental risk assessment of nanomaterials in regulatory and different "safe-by-design" applications.

- Material flow models simulating nanomaterial flows into the environment from different sources and their transport between different environmental compartments
- Fate and transport models simulating nanomaterial movement within and between compartments, and nanomaterial transformations that may affect their state and form in the environment
- Hazard assessment models estimating the effects of nanomaterials on key apical endpoint and physiological traits in different environmental species
- Uptake/bioavailability models assessing nanomaterial uptake and accumulation in environmental organisms
- Risk assessment models providing estimates for the potential environmental risk of nanomaterials by comparing predicted environmental concentrations and hazards metric to influence decision making and management practice.

The caLIBRAte assessment sought to identify useful current models.

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Needs and perspectives for development of a nano-risk governance framework

Fact Sheet

Fit for purpose models for nanomaterial environmental risk assessment

Consulted stakeholders identified that it is important to establish nano-specific risk assessment procedures to manage potential risks of nanomaterials for workers, consumers and the environment.

The tools proposed for use at different stage-gates in any prospective nano-risk governance framework must be able to provide information based on nanomaterials, hazard, exposure, and environmental release data that can be collected in standardised assays that are easily implemented in a non-specialist research setting.

Using a specifically developed ranking scheme applicable at stage gates, (see Table) the different environmentally relevant models were compared. This has allowed a set of model with high potential for application in ecological risk assessment to be identified for testing.

	Environmental assessment model	Reference	Idea	Scope	Business case	R&D	Test & Validate	Launch	Monitor
MATERIAL FLOW	PMFA	35	1	2	2	8	14	16	13
	PMFA Version 1.0.0	34	4	8	13	18	23	18	16
	DPMFA	36	1	2	2	9	15	17	14
	Spatial-PMFA	37	1	2	2	8	12	14	12
	MFA	38	2	5	10	13	22	17	14
	No name	39	3	2	5	9	14	12	10
	LearNano	40	2	4	10	12	18	15	12
FATE	SimpleBox4Nano	14	4	9	15	18	22	17	14
	NanoDUFLOW	41	2	2	4	9	15	12	11
	Rhine model	11	2	2	4	8	14	11	9
	MendNano	42	1	2	2	7	12	14	11
	WSM/WASP7	43	1	2	2	7	13	15	12
	Rhone Model	44	2	2	4	8	14	11	9
	RedNano	45	1	2	2	8	13	15	12
	GWAVA with water quality module	46,47	2	2	4	9	14	12	10
HAZARD	US EPA SSD Generator	48,49	2	4	9	13	21	17	14
	SSWD	10	1	1	2	8	13	14	12
	NanoQSAR model	50,51	7	8	12	14	14	11	9
	Framework for oxidative stress potential	52	8	7	6	10	9	6	4
	nanoSAR	53	4	5	6	10	9	6	4
	nano-SAR (OCHEM, WEKA)	54	2	2	5	9	13	10	8
	Nanoprofiler 1.2	55	2	2	4	9	13	10	8
UPTAKE	Kinetic model/BCF	56	6	11	16	17	16	12	10
	Two component Efflux/uptake model	57	6	11	16	17	16	12	10
	Biodynamic model	58	6	11	16	17	16	12	10
	BLM concept model	59	6	11	16	17	16	12	10
RISK	FINE	60	6	6	8	12	14	15	13
	Precautionary Matrix for Synthetic Nanomaterials	8	22	20	19	17	13	14	13
	No name	61	8	9	15	16	18	14	13
	No name	34	7	8	14	20	27	23	21
	pERA	13	6	6	9	16	20	21	19
	LICARA nanoSCAN	9	9	11	14	16	16	13	11
	nanoinfo	62	6	6	10	17	25	22	19
	No name (AHS)	63	5	6	8	16	19	20	18
	GUIDEnano tool	None	6	6	10	18	26	22	20
	SUNDS 2nd tier	None	5	5	9	17	25	22	20
	SUNDS 1st tier	9	9	11	14	16	16	13	11

Models selected for testing

1) Environmental fate: SimpleBox4Nano, MendNano, NanoFASE

2) Environmental hazard: SSD/SSWD, NanoQSAR

3) Environmental risk assessment: GUIDENANO tool, SunDSS, Swiss Precautionary Matrix, LICARA NanoScan

This fact sheet is based on caLIBRAte Deliverable 3.2 : *Selecting environmental hazard, exposure and risk assessment models at different stage-gates* as the result of a collaboration between UK Research and Innovation (UK), Danmarks Tekniske Universitet (DK), Swiss Federal Laboratory (SW), Tampere University of Technology (FI), National Institute for Public Health and the Environment (NL) and Duke University (US).

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