

POLICY AND EXPLOITATION FACTSHEETS

FACTSHEET 1

ENVIRONMENTAL EXPOSURE MODELLING FOR NANOMATERIALS: MEETING EU RESEARCH, REGULATORY, STAKEHOLDER AND POLICYMAKER NEEDS

The NanoFASE project was funded to provide a science-based, integrated nanomaterial Exposure Assessment Framework needed to address risk-based chemical assessment and management policy complying with regulatory requirements from the EU and other legislatures.

An integrated Exposure Assessment Framework should provide characterisation protocols, standardised assays and models for stakeholders to assess nanomaterial exposure in a way that is (i) acceptable for regulatory registrations, (ii) cost-effective for industry in terms of product-to-market processes, and (iii) understandable at all levels to support public and consumer confidence.

Understanding how nanomaterials are incorporated into products and how they are used determines their release potential into the environment. Understanding processes that determine post-release fate of nanomaterials in the environment is an essential part of a science-based, integrated nanomaterial Exposure Assessment Framework. The NanoFASE project has significantly enhanced the conceptual design of laboratory and modelling methods available for use in such a framework.

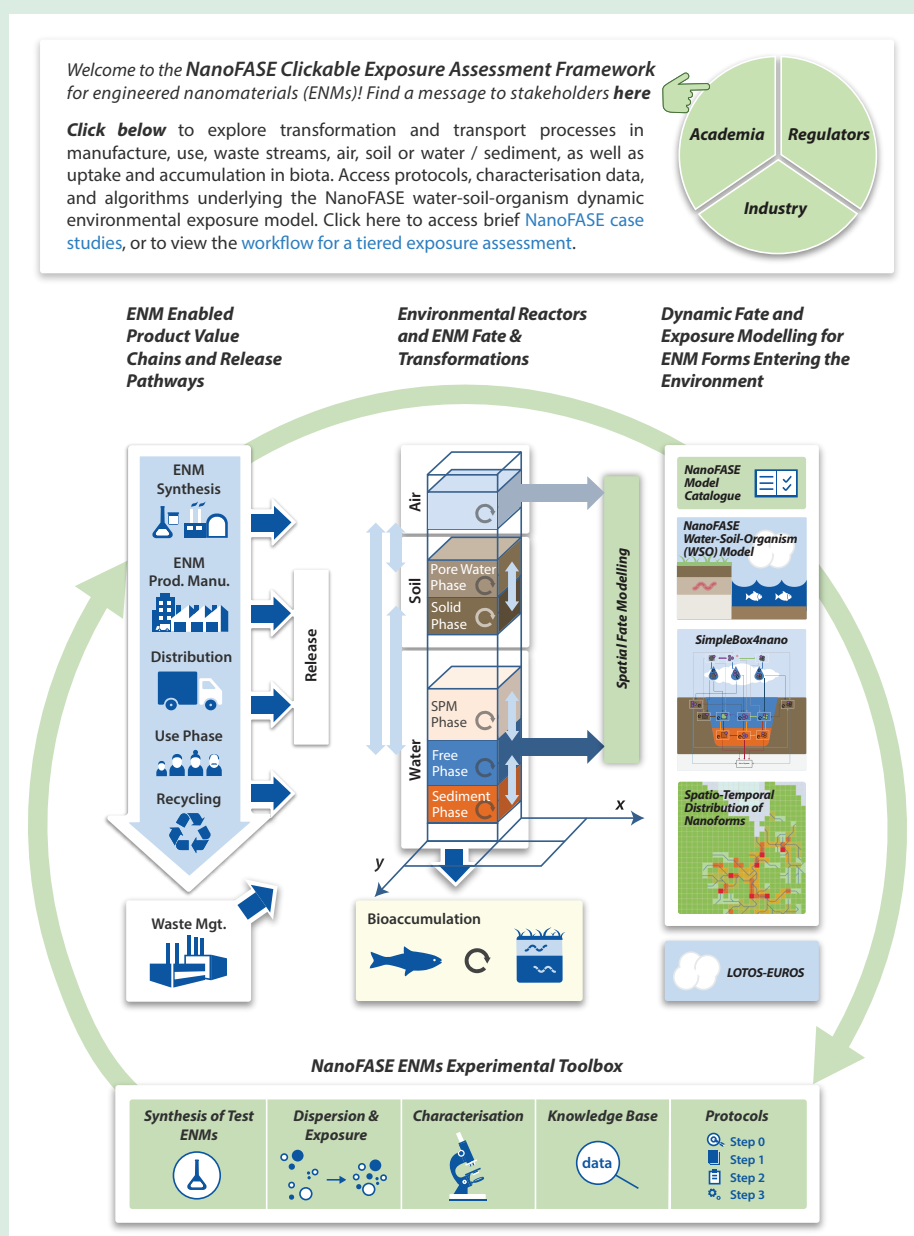
Having reviewed the key issues of model evaluation and validation in the context of the current status of analytical capabilities for quantifying nanomaterial concentrations in the environment, NanoFASE proposed that partial model validation can be achieved by comparing the outputs of models with varying levels of complexity; this can be a way forward in situations in which capabilities do not currently allow for model evaluation against field data.

Through continual engagement with regulatory bodies, policymakers, stakeholders, and other researchers, NanoFASE experts ensured the regulatory relevance of the [exposure modelling tools developed within the project](#). Some of the topics covered included: (i) the aspects that exposure modelling tools should cover for regulatory exposure assessment of nanomaterials; (ii) establishment of the nanomaterial fate parameters that are needed to run exposure models; (iii) conceptualization of how fate parameters can be assessed using standardised measurement methods and modelling (e.g. using the NanoFASE model catalogue and methods); (iv) the outputs the models need to provide for regulatory purposes; and (v) the ways different working groups could support the implementation



RECOMMENDATIONS

- The NanoFASE Exposure Assessment Framework is presented as a searchable resource and can be used by both academics and industrial communities to assess engineered nanomaterial (ENM) potential release and mechanisms which determine fate and distribution in the environment.
- Exposure models have different levels of complexity and can have different applications. The SimpleBox4Nano model is an intermediate screening type approach which is sufficient for regulatory needs. The NanoFASE model has additional features including higher spatial resolution, temporal and chemical effects.
- Clearly defined parameters for exposure modelling are essential as are guidelines for their measurement. These should include limits to precision and accuracy of quantities determined, whether they are from existing OECD Test Guidelines or new methods being developed specifically for nanomaterials.



RELATED NANOFASE DELIVERABLE REPORTS

D1.1: Presentation of exposure assessment framework specification

D1.2: Report on the pathway analysis

D1.3: Exposure assessment framework

All NanoFASE deliverable reports are available at: <http://www.nanofase.eu/documents/reports>