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From lab to life: Qualification as a bridge to fast-track the use of animal-free methods in risk assessment

In many cases, assessing the health risks of chemicals still relies on results from animal studies. However, numerous animal-free test methods—collectively referred to as New Approach Methodologies (NAMs)—are already available. While some show promise for further exploration in risk assessment, their use in regulatory decision-making remains limited without validation and endorsement as OECD Test Guidelines. A generic NAMs Qualification System has emerged as a novel approach to accelerate the regulatory application of suitable NAMs in a specific setting, aligning closely with the objectives outlined in the [EU Commission's Roadmap](#) to phase out animal testing. The NAMs4NANO consortium, as mandated by the European Food Safety Authority (EFSA), has now proposed an [implementation plan](#) for a generic NAMs Qualification System for use in the food and feed sector.

The generic NAMs Qualification System is an expert-driven process that establishes the scientific validity (i.e., reliability and relevance) of a method for a well-defined context of use. This means to specify how the method will be applied—including the type of information it provides and its role in decision-making. Existing qualification systems operate in frameworks such as the U.S. Food and Drug Administration's (FDA) Drug Development Tools program and the European Medicines Agency's (EMA) qualification of novel methodologies for pharmaceutical research and development.

The [NAMs4NANO consortium](#), as mandated by the European Food Safety Authority (EFSA), has proposed a generic framework for a NAMs Qualification System tailored to the food and feed sector, along with an initial implementation example for nanomaterial (NM) risk assessment ([Haase et al., 2024](#)). Following a public consultation phase, the consortium engaged with key stakeholders—including the Organisation for Economic Co-operation and Development (OECD), the European Chemicals Agency (ECHA), the EU Scientific Committee on Consumer Safety (SCCS), EMA, and the EU Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM)—and collected feedback through scientific workshops, meetings, and conferences. The extensive responses on both the proposed Qualification

System and the criteria for assessing the regulatory readiness of NAMs, enabled an analysis of potential challenges that could hinder the implementation of a NAMs Qualification System in the food and feed sector. Practical testing allowed for refinements and amendments of the proposed readiness criteria. Notably, the strong interest from diverse stakeholders underscores the significant potential of Qualification as a practical tool to enable Next Generation Risk Assessment (NGRA).

The proposed implementation plan for the NAMs Qualification System remains open for comments and suggestions to further refine the approach until 31 October 2026. Stakeholders are also invited to submit external case studies for testing the qualification criteria, including applications beyond the field of nanotechnology until 31 October 2026. The consortium will continue its dialogue with key stakeholders and external experts to advance this initiative.

Further information on nanomaterials on the BfR website:

Health risk assessment of nanomaterials

https://www.bfr.bund.de/en/health_risk_assessment_of_nanomaterials-30439.html

Nanomaterials Research

https://www.bfr.bund.de/en/nanomaterials_research-10431.html

FAQ Nanomaterials: Tiny particles mediate manifold properties:

https://www.bfr.bund.de/en/nanomaterials_tiny_particles_mediate_manifold_properties-8568.html

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