Genotoxicity testing strategies for nanomaterials in food and feed and test guidelines

Maria Dusinska

Health Effects Laboratory, Department of Environmental Chemistry, NILU- Norwegian Institute for Air Research, Kjeller, Norway

Hazard characterisation is a key component of risk assessment as it provides information on potential adverse effect and dose–response relationships. Knowledge of modes of action by which engineered nanomaterials (ENMs) may exert their adverse effect, as well as exposure routes, duration of exposure and concentrations are crucial for hazard characterization.

The successful determination of hazards associated with ENMs depends on an intimate knowledge of interactions of the ENMs with target biological materials. In line with current scientific studies that provide insights to physicochemical properties, exposure assessment and hazard characterisation of ENMs, the European Food Safety Authority (EFSA) has updated the Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (Guidance on Nano-RA) together with Guidance on Technical requirements for regulated food and feed product applications. These two new guidance documents elaborate nanospecific considerations relating to physicochemical characterisation, and methods and techniques that can be applied in ENM risk assessment. They also address nanospecific considerations for *in vitro* and *in vivo* toxicological studies.

Full hazard characterisation involves studying adverse effects induced by ENMs evaluating a range of endpoints both *in vitro* and *in vivo*. The testing strategy for genotoxicity (as one of the most critical adverse effects) covers these key endpoints – gene mutation, clastogenicity and aneugenicity; in addition, cellular uptake must be assessed. Though methods for assessing genotoxicity of chemicals are well established and OECD test guidelines exist, they might need modification to be fully applicable for hazard assessment of ENMs. Thus, there is currently effort both from scientific consortia as well as from the OECD to speed up development of an OECD test guideline for hazard assessment of ENMs.

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