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The next steps in risk assessment of nanomaterials: A perspective from ECHA

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Nanotechnology is a rapidly emerging field described generally as the control and structuring of matter at dimensions typically between 1 and 100 nanometres to create materials, devices, and systems with fundamentally new properties and functions. As a result of such novel properties, nanomaterials are anticipated to have applications addressing a wide range of issues including health and the environment. However, the unique physicochemical properties that make nanomaterials so useful also make their interactions with biological systems difficult to anticipate and critically important to explore. Recent studies have shown conflicting results from the traditional assays, methods, and models that are used to assess interaction of ENM with biological systems. This inconsistency in findings between different laboratories significantly impedes the integration of research data for risk assessment and public health protection.

In the EU the safety of nanomaterials (NM) is regulated by a legal framework, which implicitly or explicitly (recent revisions) addresses NM. NM are implicitly covered by the substance definition of REACH Regulation 1907/2006. Under REACH a registration dossier has to be submitted if a substance is produced/imported in volume higher than 1 ton/year and a Chemical Safety Report has to be prepared if the volume is higher than 10 ton/year. The registrant has to either explicitly cover the nanoform in the dossier of the bulkform or submit a specific dossier for the nanoform.

With regard to reliable risk assessments, until now there is still the remaining issue to be resolved of whether or not specific challenges and unique features existing at the nanoscale have to be tackled and distinctively addressed, given that they may substantially differ from those encountered with bulk materials.

Biography

Zuzana Kloslova is a highly experienced Regulatory Toxicologist and regulatory affairs consultant with expertise in human health risk assessment. Her educational background has covered publichealth, regulatory aspects of (eco) Toxicology, Biostatistics, Biochemistry, Molecular Biology as well as Organic Chemistry.She has implemented main EU chemicals management policies (REACH, EU Environment and Health Action Plan 2004-2010, Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work, Council Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens).