

The regulatory future of nanomaterials is coloured

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Why this presentation? Regulation of nanomaterials Regulatory peculiarities for NM in L&P Your question Discussion

Why this presentation? Not only regulators should care





Why this presentation?

Nano is nano is not nano





Why this presentation?

Basics of regulatory risk assessment





Definitions...

«Nanomaterial» (simplified)

| MARCA CAR | |
|------------------------|---|
| EU-Proposal (2011) | Primary Particle Size: 1-100 nm in 1 or more dimensions; ≥ 50% (number size distribution) of particles in this size range. |
| US-EPA | Primary Particle Size: 1-100 nm in 1 or more dimensions; Manufactured for its unique and novel properties. |
| Switzerland (ChemV) | Primary Particle Size: 1-100 nm in 1 or more dimensions; Manufactured to use its nanospecific properties. |



Principal drivers for inclusion of nanospecificity Europe and Switzerland

Different (eco)toxicological profiles • Specific (eco)toxicological endpoints (including triggers for data waiving) • **Exposure** pathways • Transparency in the registration dossiers •



Regulation for chemicals

Switzerland: Autonomous monitoring

Manufacturers are responsible for assessing the risk of substances and formulations for human health and the ecosystem.

- Packaging
- Classification and labeling
- Exposure assessment (scenarios) for dangerous chemicals if market volume >10t/a
- Safety Data Sheets





Regulation for chemicals

Switzerland: Notification of new chemicals and nanomaterials

Data on toxicity and fate for non-nanoscale substances and (tonnage threshold > 1t/a). No tonnage threshold for reporting if classified as "dangerous"

- Chemical composition, mean particle size and shape (mandatory)
- Particle size distribution, specific surface area, crystal structure, aggregation, surface coatings and functionalization (if available)





Regulation for nanomaterials Europe

MECHA

Appendix R7-1 for nanomaterials applicable to Chapter R7b Endpoint specific guidance Version 2.0 May 2017

Nanomaterials with associated potential risks, are covered by existing legislation under REACH, in particular by the new, nanospecific amendments.





MECHA

Guidance on information requirements and chemical safety

Appendix R10-2 Recommendations for nanomaterials

applicable to Chapter R.10 Characterisation of dose

[concentration] - response for environment

hemical safety

Appendix R14-4 Recommendations for nanomaterials

applicable to Chapter R.14 Occupational exposure

estimation

Regulation for nanomaterials: Nanoforms Europe





Regulation for nanomaterials: Registration dossier Europe





Regulatory peculiarities for nanoscale substances in paints and lacquers Relevant regulation is sector-specific

REACH, for importers, converters, refiners, traders, and users of chemicals

Then CLP for Classification, Labelling and Packaging and all regulations for occupational protection (Challenge: intermediate products).

Biocidal properties: EU BPR



Regulatory peculiarities for nanoscale substances in paints and lacquers Points of discussion after January 1, 2020





Your question – our answer

Regulatory considerations for PTFE

 Es gibt einige Fette die f
ür Baumaschinen vorgeschrieben sind und PTFE als Festschmierstoff enthalten.
 Verlustschmierung: PTFE gelangt als Nanopartikel systematisch in grossen Mengen in die Umwelt.

PTFE wenig toxisch aber persistent

 Weiterer Anwendungsbereich in der Lebensmittelbranche (Aufdicker) mit potenzieller Emission im Haus



Your question – our answer

Regulatory considerations for PTFE

- Intentionally in nanoform or in residues?
- REACH is the relevant regulation (tonnage driven RA)
- Polymers are currently exempt from REACH registration or evaluation processes, although they are subject to authorisation or restriction if an EU member state chooses to include them in proposals.
- ECHA is working on a proposal for polymer (microplastic) restrictions, aiming to finalise it by 2022
- Public consultation until Sept 20: Implications and definition of microplastic 100 nm - 5 mm relevant for PTFE powders







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