



Does European regulation improve trust in nanomaterials?

Safer Chemicals Conference 2021

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#SAFERCHEMICALS

Looking back – developments on nanomaterials



2007-2012

- Nanomaterials are different than 'bulk materials'
- Commission's recommendation for definition
- REACH Implementation Projects
- CARACAL subgroup on nanomaterials
- Group assessing already registered nanomaterials

2012-2017

- Guidance for nanomaterials published
- Nanomaterials expert group established
- First substance evaluation on nanomaterials concluded
- REACH review on nanomaterials
- Test guidelines applicability investigated
- OECD sponsorship programme

2017-2021

- Guidance updates
- Research projects supporting development of OECD Test Guidelines and Guidance Documents
- REACH annexes adapted for nanoforms of substances

REACH requirements for nanoforms

General provisions

- Apply to all new and existing registrations with nanoforms
- Apply to all nanoforms when total registration tonnage of a substance is above 1 tonne per year/registrant
- Chemical safety report should include assessment of nanoforms for exposure and risk
- Downstream user awareness of obligations when modifying nanoforms

Information requirements

- Set in REACH Annex VI: characterisation of nanoforms
- Possible to register nanoforms using sets of nanoforms, if specific scientific conditions met
- Additional information requirements in Annex VII-X for nanoforms

Compliance check for nanoforms

Step 1: Targeted on Annex VI - characterisation of nanoforms

- Assessment done for each reported nanoform or set of nanoforms
- Sets of nanoforms must have:
 - clear boundaries; and
 - robust justification, including hazard, exposure and risk assessment

Step 2: Annex VII-X – standard information requirements

- Standard information requirements, once step 1 is clarified



Risk management initiatives

- Several restrictions and restriction proposals cover substances with nanoforms:
 - Tattoo inks (based on CLH hazards) – pigments known to contain nanoforms
 - Microplastics – nanoplastics included in the restriction proposal
 - Concerns related to measuring nanoplastics (under 100 nanometres)

Support for companies



Practical guidance “How to prepare registration dossiers covering nanoforms” published in April 2021



Updates expected for:

- Appendix to the guidance on registration of nanoforms of substances
- Guidance on information requirements and chemical safety report for both human health and the environment



Webinars and support for different industry sectors

Where are we now?

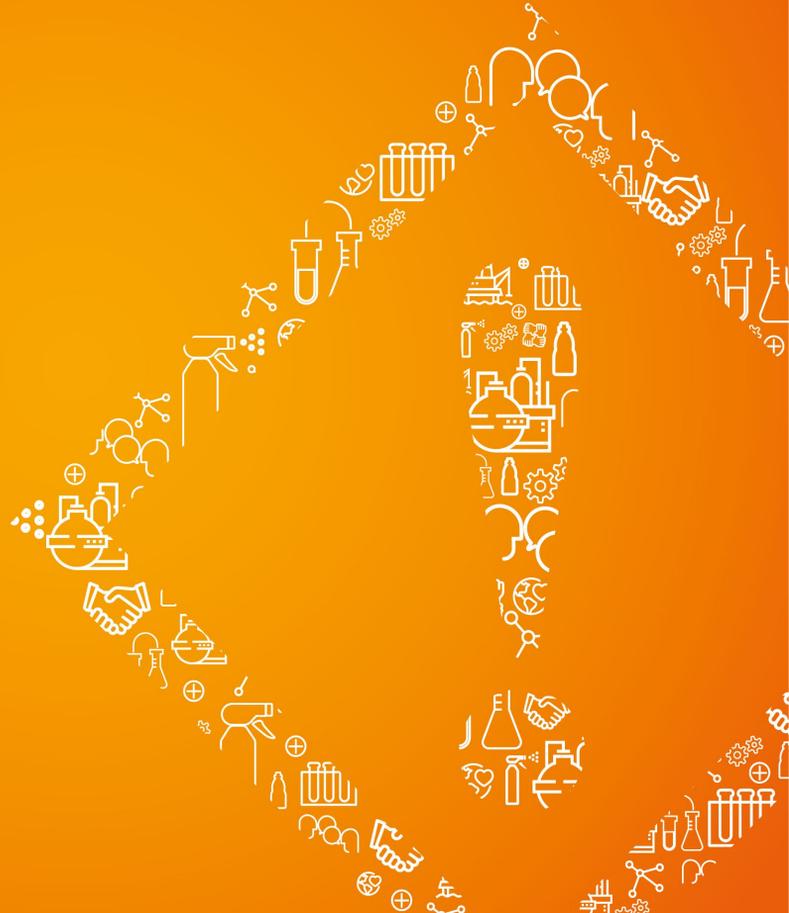
- By 1 September 2021, 441 registrations for 130 substances covering nanoforms received
 - This is fewer than anticipated - based on data from other regulations and national inventories, we estimated that around 300 substances exist as nanoforms on the EU market
- Some companies still not aware of their obligations
- There is a lack of data on hazards of nanoforms -> registrants bridge data gaps by using alternative methods
- Some registrants expressed uncertainty of the applicability of certain test methods -> prevents data generation



Road ahead

- Companies must submit registrations with data on nanomaterials to demonstrate safe use of nanoforms in accordance with REACH
- Continued support to companies through guidance and tools to help them fulfil the information requirements in REACH
- Use the Nanomaterials expert group to align regulatory approaches across Member States
- Continued efforts to raise company awareness about the requirements and obligations

Key points and conclusions



Regulations contribute to creating trust

- Study by the European Union Observatory for Nanomaterials indicates high trust in scientists and public authorities
- The goal of REACH is to ensure that chemicals and nanoforms are safely used on the EU market
- REACH ensures that information about nanoforms of substances is shared, which improves transparency between companies, regulators and consumers



Key points and conclusions



Further work is needed to improve the safe use of nanoforms under REACH (increasing the number of registrations, awareness raising, developing guidance, revising OECD test guidelines)



Lack of nano-specific data may hamper regulatory decision making related to nanoform safety



Regulation and science-based decision making are important for building society's trust in nanomaterials. We all need to play our part!



Thank you!

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