

Summary report of the 18th meeting of ECHA's Nanomaterials Expert Group (NMEG-18)

ECHA organised the 18th (hybrid) meeting of the Nanomaterials Expert Group (NMEG-18) on 20-21 November 2023.

The meeting hosted 42 external registered participants, including 26 MSCA experts representing 15 EU Member States¹, Norway, the European Food Safety Authority (EFSA), the European Commission (DG ENV, DG Grow and JRC) and 7 accredited stakeholder organisations².

A. Closed session

A1. Regulatory case discussion: DE-CA explained the status of the **REACH substance evaluation (SEv) on zinc oxide**, where the [decision](#) requested in 2019 data on human health and environmental endpoints. No further request is planned for the environmental assessment, even though the DE-CA does not share some of the conclusions drawn from it by the registrant. For the human health endpoints some toxicological concerns require clarification.

A2. ECHA made an update on the ongoing project '*Nanomaterial Risk Assessment: a regulatory way forward for sameness and grouping approaches*' which should provide crucial inputs to support ECHA in the assessment of REACH dossiers containing nanoforms. ECHA encouraged NMEG members to share in writing questions they may have on the project, and to express interest for being considered for expert interviews.

A3. DE-CA provided some insights from the current EFSA NAMS4NANO project and how it can contribute to implement NAMs in risk assessment for nanomaterials.

B. Open session

B1. ECHA made a **summary for the accredited stakeholders** on the (non-confidential) main points of the discussion held in the closed session.

B2. The **update on ECHA activities**:

- briefly presented the registration numbers as of 31 October 2023:
 - 169 substances for which nanoform information has been submitted;
 - 858 registrations with nanoform information that passed Technical Completeness Check (TCC);
- reminded the ongoing evaluations on substances containing nanoforms:
 - compliance check decisions targeted on Annex-VI: on [Titanium dioxide](#), [silicon dioxide](#) and [multi-walled carbon nanotubes \(MWCNT\)](#);
 - substance evaluation decisions: on [titanium dioxide](#) and [zinc oxide](#);
- described the EUON achievements and plans.

B3. DE-CA/BAuA shared experiences of BPR authorisation process related to the presence of nanoform in biocidal product.

B4. DE-CA/BAuA also made a presentation related to the Annex VI of the CLP regulation and the possibility to identify fine powders (some of which might be in nanoform) by indicating the surface specific area (SSA). Pros and cons were discussed.

¹ AT, BE, CZ, DK, DE, ES, FI, FR, IT, LT, NL, PL, PT, RO and SE.

² CEFIC, ECETOC, Ecopa, EEB, Eurometaux, NIA and PSCI.

B5. Two hours of the meeting were dedicated to the discussion on the continuation of the Malta initiative: the achievements of the NanoHarmony European project were summarised, and the discussion aimed at identifying a priority list for making OECD TGs/GDs applicable for nano and advanced materials. NMEG members were encouraged to fill-in the survey on the Malta initiative priority list.

B6. A coordinator of 'SUNSHINE' described the main learnings from this EU project, in relation to the Regulatory preparedness of REACH for multi-component nanomaterials (MCNMs).

B7. An expert explained how an Integrated Approach to Testing and Assessment (IATA) may support the grouping of nanomaterials in aquatic systems and the identification of relevant nanoforms in a view to have a safe(r)-by-design approach.

B8. The next presentation focused on Soil Species Sensitivity Distributions (SSDs) and using silver and its different nanoforms as an illustration. This approach should allow to construct a soil ecotoxicity database.

B9. ECHA then provided a summary of the outcome of two recently published scientific EUON³ reports:

- The potential impact of graphene, graphene oxide and other 2D materials on health and environment (link to the [report](#))
- Nano-specific alternative methods in human hazard/safety assessment under different EU regulations, considering the animal testing bans already in place for cosmetics and their ingredients (link to the [report](#))

More information about this NMEG meeting (and previous ones) can be found on the [NMEG webpage](#).

The next meeting (NMEG-19) is planned to take place on 23-24 April 2024.

Substance discussed at the 18th NMEG meeting:

EC number	Substance name	Regulatory Process	Session
215-222-5	Zinc oxide	REACH Substance Evaluation	Closed

³ European Union Observatory for Nanomaterials