

Summary report of the 19th meeting of ECHA's Nanomaterials Expert Group (NMEG-19)

ECHA organised the 19th (hybrid) meeting of the Nanomaterials Expert Group (NMEG-19) on 23-24 April 2024.

The meeting hosted 35 external registered participants, including 20 MSCA experts representing 14 EU Member States¹, and experts from the European Food Safety Authority (EFSA), the European Commission (DG ENV, DG Grow and JRC) and 5 accredited stakeholder organisations².

A. Closed session

A1. REACH Dossier Evaluation cases:

- Status of Annex VI targeted compliance checks on TiO₂, SAS & MWCNT: the decisions sent in 2023 requested clarifications on the sets of similar nanoforms. The updated information, recently submitted, is under follow up assessment to determine its compliance with Annex VI standard information requirements.
- Preparation of Annex VI targeted compliance check (CCH) on ZnO: the ongoing Substance Evaluation on ZnO had raised the need to address the issues identified with the characterization of the two sets of similar nanoforms (ZnO nano with hydrophobic surface treatment, ZnO nano without and with hydrophilic surface treatment).
- Update on testing proposals (TPs) for dossiers containing nanomaterials: several indicative criteria were identified to address the TPs received:
 - i. TP endpoint has an OECD Test guideline adapted for nanomaterials
 - ii. Dossier contains one nanoform or one set of similar nanoforms
 - iii. Dossier contains one dataset linked with the nanoform (NF) or set of NFs
 - iv. Test material for the TP is the registered NF or set of NFs

Based on these criteria, one TP case was identified and the draft decision is being drafted.

A2. Update on draft CLH proposal for synthetic amorphous silica (SAS)

On the basis of the adverse effects observed in 90-day inhalation studies with pyrogenic SAS and precipitated SAS, observed already at 1 mg/m³, NL considers that the available data are sufficient for the classification of synthetic amorphous silica (including silica gel, precipitated silica, colloidal silica and pyrogenic silica) as STOT RE 1 for inhalation with the respiratory system as target organ. NMEG members are encouraged to provide comments during the public consultation that will soon be launched on the CLH proposal for SAS.

A3. Update on ongoing ECHA project 'Nanomaterial Risk Assessment: a regulatory way forward for sameness and grouping approaches' (started in July 2023): The overarching goal is to propose a set of enforceable sameness criteria suitable for regulatory application as well as a suitable approach to register and assess sets of nanoforms. Four work packages are planned:

- WP1. Compilation of state-of-the-art regarding sameness (i.e. to define single nanoforms) and similarity (i.e. to accurately group nanoforms into sets of similar nanoforms) approaches for nanomaterials: 16 parameters were analysed (including size, shape, crystallinity, surface area, surface treatment, dissolution, dustiness).
- WP2. Analysis of available physico-chemical and hazard nanomaterial databases and online platforms and their interconnectivity: key aspects of evaluation are transferability (acceptable for most of the databases) and extractability (acceptable for eNanomapper and Sunshine databases).

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

² CEFIC, Ecopa, Eurocolour, NIA and PSCI.

- WP3. Expert interviews – ongoing
- WP4. Draft set of sameness and similarity criteria – to be completed

A4. Short update on **new ECHA project** 'Methodological developments and data generation for the assessment and building of sets of nanoforms' (start May 2024): the objectives are to identify and develop NAM-based techniques to facilitate the creation of 'sets of NF', and to develop a structure (framework) for the justification of sets of NF in the regulatory context (to address human health, environmental hazards, use and exposure models, including risk assessment).

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:

- informed on the ongoing update of the NMEG manual, in order to align with Committees: the main changes concern the definition of 'members' (experts nominated by MSCAs) and 'observers' (all other experts), and that an additional seat (5 seats instead of 4) will be attributed to industry and to NGO representatives at NMEG meetings.
- briefly presented the registration numbers as of 31 March 2024:
 - 169 substances for which nanoform information has been submitted;
 - 896 registrations with nanoform information that passed Technical Completeness Check;
- 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 (see [EUON website](#))
- provided a summary of the outcome of a recently published scientific EUON report: "A study on valid in silico modelling tools and read-across approaches, including creation of case studies on read-across for specific (types of) nanomaterials" (link to [Full report](#), published October 2023).

B3. DE-CA made a presentation related to REACH Restriction on "RMOA Substances in fibreform - First ideas about a restriction proposal". Focus was on biopersistent respirable fibres.

B4. ES-CA gave a detailed update on the progress on the [OECD Guidance document on TG305 on bioaccumulation of nanomaterials in fish](#). The aim is to prepare a draft guidance document that can be submitted for approval to OECD WNT meeting of 2025.

B5. DE-CA updated the group on the status of the [Malta Initiative priority list for making OECD TGs applicable for nanomaterials](#). Members were asked to investigate how their country/institute can be more active in supporting the development of OECD TGs for nanos.

B6. A representative from NIA illustrated the difficulties faced by companies to find laboratories that can perform required tests on nanomaterials.

B7. Industry experts then described the challenges they face to define the testing strategy to follow to perform reproduction toxicity testing for nanoforms of iron oxides.

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

The next meeting (NMEG-20) is planned to take place on 13-14 November 2024 (online).