

Summary report of the 15th meeting of ECHA's Nanomaterials Expert Group (NMEG-15)

ECHA organised the 15th meeting of the Nanomaterials Expert Group (NMEG) on 3 May 2022 afternoon, remotely using secure Webex.

The meeting hosted 30 external registered participants, representing 12 EU Member States¹, Norway, the European Food Safety Authority (EFSA), the European Commission (DG ENV, DG Grow, JRC) and 6 accredited stakeholder organisations².

A. Closed session

A1. ECHA reminded the general approach for **Annex VI targeted compliance Check (CCH)** for nanomaterials, which is the first step of the planned two-tiered strategy for the CCH of dossiers reporting nanoforms, NFs (the second step focuses on Annexes VII-XI data requirements). ECHA described the key requirements when registering dossiers containing nanoforms and illustrated the difference between the registration of single nanoforms and the registration of a set of similar nanoforms.

In particular, it was reminded that:

- all NFs of a substance must be registered in one joint registration, and each NF must be characterised in accordance with REACH Annex VI, 2.4. Moreover, a full Annex VII-X dataset, clearly linked to each specific NF, must be provided.
- the formation of 'set of similar NFs' requires that two conditions are fulfilled: 1) the composition boundaries of the set are clearly defined (characterised as per Annex VI, 2.4) and 2) a robust justification is provided (which demonstrates that hazard, exposure and risk assessment of NFs in the set can be performed jointly).

The discussion was also illustrated using the main issues raised in the draft decisions to be sent to registrants on ongoing Annex VI CCHs.

For information, as of 8 April 2022, 149 registered substances contain nanoforms, and most of them report single nanoforms (not sets of similar nanoforms).

A2. BfR/DE summarised the **key points of the recent RAC opinion on the harmonised classification of MWC(N)T**. The **implications and challenges for regulating other (nano) fibres** were also presented and some substance identity aspects and the importance of iron impurities were discussed. DE-CA also announced that they are preparing Risk Management Option Analysis to assess and, if relevant, propose regulatory measures for generic fibre dust in REACH/CLP, and they are considering to re-open a Substance Evaluation on non-rigid MWCNT in the future.

B. Open session

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

B2. In the **update on ECHA activities**, ECHA briefly informed on the numbers of registered substances in nanoform, described EUON achievements and work plan and reminded of the ongoing guidance work.

B3. DG-ENV made a presentation on **Nanomaterials under Chemicals Strategy for Sustainability** and described the status of the **revision of the Commission**

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

² NIA, Eurometaux, Photoinitiator Platform, EFFCI, EUROTOX, and PSCI.

Recommendation 2011/696/EU and other ongoing actions. Only minor changes in the nanomaterial definition are foreseen.

B4. UBA/DE shared the joint considerations of BAuA, BfR and UBA on **Advanced Materials**, and showed the aspects that are relevant for nanomaterials.

B5. In relation to the current PBT guidance update, ECHA introduced a draft text that clarifies the **link between the PBT guidance update and the ECHA guidance documents for nanomaterials**. The draft text was shared with NMEG members before the NMEG-15 meeting and experts were invited to provide comments until May 31, 2022.

There was one **AOB on Nanomaterials nomenclature** (discussed at NMEG-14): the relevant examples were inserted in the Nanomaterials nomenclature draft document, and the draft was shared with NMEG members before NMEG-15. Experts were invited to provide comments until May 31, 2022.

The next meeting (NMEG-16) is planned to take place on 25-26 October 2022 and to be held in ECHA/Helsinki, if the covid pandemic situation permits.