Summary report of the 14th meeting of ECHA's Nanomaterials Expert Group (NMEG-14)

ECHA organised the 14th meeting of the Nanomaterials Expert Group (NMEG) on 26-27 October 2021, remotely using secure Webex, with two half-day sessions (closed on 26.10 afternoon; open on 27.10 morning).

It is reminded that the NMEG mandate was updated and the list of members of the NMEG was renewed at the beginning of 2021.

The meeting hosted 43 external registered participants, representing 16 EU Member States[1], Norway, the European Food Safety Authority (EFSA), the European Commission (DG ENV, DG Grow, JRC) and 7 accredited stakeholder organisations[2].

A. Closed session

A1. ECHA described the general approach for the **Annex VI compliance check (CCH)**, which focuses on the identification of the substance and the characterisation of the nanoforms (NFs). The Annex VI CCH is the first step of the planned two-tiered strategy for the compliance check of dossiers reporting NFs (the second step is the Annexes VII-XI CCH, which addresses the physico-chemical and hazard data requirements).

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, specific for each NF, must be provided (each full Annex VII-X dataset must be clearly linked to the specific NF).

The formation of 'set of similar NFs' is a derogation possibility allowed by REACH, under the conditions that 1) the composition boundaries of the set is 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 Annex VI CCH will depend on the types of NFs registered: 1) for single NFs, it will check the characterisation parameters (Annex VI, 2.4) of each NF; 2) for sets of NFs, it will assess whether a) the boundaries are clear, and b) the justification is robust and supported by relevant data. The issue was illustrated using examples from synthetic amorphous silica, titanium dioxide and multiwall carbon nanotubes dossiers.

The discussion gave ECHA the opportunity to clarify several points for MSCAs and COM colleagues. It was also reminded that the concept of 'set of nanoforms' (which refers to all hazard endpoints, to exposure and to risk) differs from the read-across adaptation (which refers only to one specific endpoint).

For information, by 5 October 2021, 138 registered substances contain nanoforms, most of them reporting single nanoforms (not sets of nanoforms).

A2. Germany-CA then made a presentation on "Grouping and read-across of nanomaterials for regulatory risk assessment: **a case study on multi-wall carbon nanotubes (MWCNTs)** registered under REACH applying the GRACIOUS framework". It was explained that two grouping hypotheses developed according to putative modes of action of MWCNTs (rigid respirable high aspect ratio nanomaterials (HARN), and respirable poorly soluble particles of low toxicity (PSLT)) could not be convincingly supported.

A3. ECHA then described the **Nanomaterials nomenclature** proposed to be used under REACH, which would be a unified recommendation for naming nanoforms/sets of nanoforms

[1] AT, BE, DE, DK, ES, FI, FR, IT, LT, LV, NL, PL, PT, RO, SE and SK.
[2] Cefic, NIA, EFfCI, Eurogroup for Animals, Eurocolour, EUROTOX, and PSCI.

based on information requirements already described in Annex VI, 2.4. After the meeting, ECHA plans to share the Nanomaterials nomenclature document (including some examples) so that NMEG members can provide comments via written procedure.

A4. ECHA mentioned the **NMEG consultation to support the PBT EG**. The consultation of MSCA and COM colleagues took place between May and June 2021, and it was the first time the PBT EG consulted the NMEG members (in relation to the bioaccumulative properties of two nanoforms substances). Based on comments received, further information is needed to clarify the exact forms registered under REACH and generate more robust log Kow data. The input from NMEG members was considered very valuable by the PBT EG secretariat and by the evaluating members state (BE).

B. Open session

The date of the next meeting was confirmed: NMEG-15 will be on 3-4 May 2022. After the meeting, a Doodle survey indicated that the best dates for NMEG-16 was 25-26 October 2022.

B1. A brief report on the non-confidential issues discussed during the closed session (Day 1) was given to accredited stakeholders during the open session.

B2. The presentation on the Status of **current work on OECD TGs/GDs for nanomaterials** described the several ongoing projects, with the different tasks and the foreseen timelines. The best way of disseminating such information to stakeholders was discussed. ECHA will explore how the EUON can be used to support communication on the work on the TGs/GDs. The updated OECD documents are found at https://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

B3. RIVM/NL shared the **lessons learnt from the substance evaluation on silicon dioxide** (the report can be found at https://www.echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e1807e44e8). It was reminded that i) substance evaluation can be used for nanomaterials, but only when a concern can be demonstrated; ii) this substance evaluation has led to additional REACH requirements for nanomaterials, in order to demonstrate safe use; and iii) the new data, generated as a result of this substance evaluation, confirmed NL concerns and can be used for follow-up actions, starting with a CLH proposal (the SiO2 form(s) to be concerned by the CLH notification still has to be determined).

B4. DG ENV described the 'Status of the **review** and potential revision of the Commission Recommendation 2011/696/EU on the **definition of nanomaterial**'. The main outcome of the consultation (which ended at end of June 2021) is available at https://ec.europa.eu/environment/chemicals/nanotech/review_en.htm. It is anticipated that only minor changes will be made compared to the existing definition. The current plan is to adopt the new definition, accompanied by a staff working document by February 2022. After adoption, the new definition should be taken up in all sectors following own processes and timing.