Summary report of the 13th meeting of ECHA's Nanomaterials Expert Group (NMEG-13)

On 29-30 March 2021, ECHA organised the 13th meeting of the Nanomaterials Expert Group (NMEG). For the first time, it was organised remotely using secure Webex and included two afternoon sessions – a closed one on 29 March and an open one on 30 March. This summary report covers both sessions.

The NMEG members welcomed the opportunity to resume live exchanges, after the break in 2019 and 2020.

Two noteworthy events happened at the beginning of 2021:

- The NMEG mandate was updated (and further aligned with the mandates of PBT and ED expert groups) and published on the NMEG web page.
- The experts nominated to members of the NMEG were renewed (see list of members, also published on the NMEG web page).

The meeting hosted 45 external registered participants, representing 16 EU Member States[1], Norway, the European Food Safety Authority (EFSA), the European Commission and eight accredited stakeholder organisations[2].

The meeting presentations were distributed ahead of the meeting.

1. Main outcomes of discussions on ECHA operational issues (individual cases)

No individual cases were discussed at the meeting. However, several topics related to REACH operations were discussed.

ECHA gave an overview of the state of play of the evaluation of nanomaterials under REACH, with a particular focus on registration statistics and the key challenges faced during the first year of registration (after the amended REACH annexes entered into force on 1 January 2020). As of 1 March 2021, nanomaterial-specific information has been submitted for 81 substances and 247 registration dossiers covering nanoforms have passed a technical completeness check (including 61 lead registrations).

While initially dossiers often did not pass the technical completeness check, the rate of failure is going down. Among the dossiers reporting nanoforms, about 75 % cover single nanoforms, and the remaining cover sets of nanoforms.

ECHA shared the planned *Compliance Check (CCH) Strategy for Nanomaterials* with the group. The following two-tier approach was explained:

1. CCH targeted on Annex VI to REACH (identification of the substance and characterisation of the nanoforms) as a first step:
2. CCH focused on Annexes VII-XI (physico-chemical and hazard data requirements).

In 2021, Annex VI targeted CCHs are planned for multi-wall carbon nanotubes and for titanium dioxide. ECHA identified a potential role for the NMEG in recommending study protocols in the absence of adopted OECD Test Guidelines.

The discussion allowed ECHA to answer some questions and clarify a few points. NMEG members did not raise major concerns with the proposed CCH strategy.

Then, two presentations explained downstream user (DU) obligations. ECHA first clarified the main principles described in the draft Q&A on DUs (this draft should be circulated outside ECHA

[1] AT, BE, DE, DK, ES, FI, FR, IT, LT, LV, NL, PL, PT, RO, SE and SK.
[2] Cefic, ECETOC, ECOPA, EEB, Eurocolour, Eurometaux, EUROTOX, and PSCI.

for comments in April-May 2021, and the tentative period for final publication of the document is by summer 2021). The German Member State competent authority (MSCA) presented a few practical DU cases received by the German REACH-CLP-Biocides helpdesk that provided a useful illustration of the topic. The key role of the HelpNet was emphasised, and a potential role for the NMEG to support the HelpNet was suggested.

2. Main outcomes of discussions on critical scientific issues

No individual cases were discussed at the meeting.

3. General nanomaterials-related topics

ECHA made a short update on NMEG administrative issues. In particular, the main change in the updated NMEG mandate was highlighted. Future NMEG meetings will be organised only if:

i) members express the need to discuss a critical scientific topic and/or an operational issue (individual case); and

ii) appropriate documentation is provided to enable a fruitful discussion.

On the other hand, if NMEG members want to share information, without a need for discussion or agreement, this should be done through the *tour de table* document. This change will be fully implemented from the next NMEG meeting (NMEG-14) onwards.

Indicative dates for NMEG-14 and NMEG-15 were proposed. Note: based on NMEG members feedback after the meeting, the NMEG-14 indicative date was changed from 3-4 November 2021 to 26-27 October 2021.

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

ECHA provided an update on activities under the EU Observatory for Nanomaterials (EUON) and the 2021 workplan and invited all NMEG members to use EUON to make their expert voice heard.

In relation to ongoing guidance update activities, ECHA clarified the state of play of the nanomaterial guidance:

- for registration – new appendix for nanomaterials; nomination of PEG members was just launched;
- for human health – PEG consultation was completed; committees commenting phase is next;
- for environment & phys-chem – internal drafting is ongoing.

Two external experts summarised some learnings from the Horizon 2020 GRACIOUS project which addressed the Grouping and Read-Across of Nanomaterials. One presented case studies which test the GRACIOUS hypotheses and associated Integrated Approaches to Testing and Assessment (IATAs). The other provided an overview on the development of a quantitative assessment methodology for nanoform similarity.

It was made clear during the discussions that there is a significant difference between the concept of grouping/read-across (which may apply only to one specific hazard endpoint) and the concept of a set of similar nanoforms (which applies to all hazard endpoints).

Germany touched on the exposure aspects, with a presentation on (nano)fibre materials at workplaces.

The Netherlands summarised the key learnings from the RIVM/EFSA report on *Environmental Risk Assessment of Nanomaterials Applied in the Food and Feed Sector*. The analysis of this report showed that several findings could be applied to ECHA assessments under REACH or the Biocidal Products Regulation.