**Tour de table**

## 16th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-16) 25-26 October 2022, Helsinki, Finland (hybrid meeting)

The representatives from the Member States, the Commission, the accredited stakeholder organisations from industry and NGOs, and ECHA are encouraged to summarize **briefly** below any **highlights/progresses** since the previous meeting in areas relevant for the work of the NMEG. The aim is to share information within the NMEG, and possibly identify **topics for future discussions**. NB: only non-confidential information should be shared.

### 1. Registration & IUCLID reporting

**ECHA**
By 30 September 2022, 713 registration dossiers covering nanomaterials were successfully submitted, resulting in a total of 158 substances covering nanoforms for which registration dossiers have been submitted following the updated REACH requirements.

### 2. Substance identity and characterisation of nanoforms (Annex VI)

**ECHA**
Regarding a nanomaterials nomenclature draft document, ECHA has reviewed the comments received from the NMEG and appreciates the input from the NMEG experts. The draft has been amended to take into account these comments. ECHA will continue to develop the nomenclature based on practical learnings, and communicate a final version to the NMEG and publish the nomenclature at a later date.

ECHA has been in contact with several registrants to support and advise them on correct reporting of nanoforms. This concerns especially incorrect reporting of set of nanoforms as single nanoform.

### 3. Phys-chem characterisation of nanomaterials (Annex VII)

**ECHA**
For update see under section 9. Guidance.

### 4. Hazard evaluation – human health

/

### 5. Hazard evaluation – environment

**ECHA**
For update see under section 9. Guidance.

### 6. Read-across and grouping for nanomaterials

**ECHA**
The work of the OECD Working Party on Hazard Assessment is ongoing on updating the Guidance on Grouping of Chemicals, Series on Testing & Assessment No. 194, ENV/JM/MONO(2014)4.
A separate group set up by the OECD WPMN is also still working on chapter 6.9 for this OECD Guidance (in the current version: "Initial considerations applicable

to manufactured nanomaterials"), to be integrated later in the overall Guidance. The second draft version was circulated by the drafting team in June h 2022 and has received again a considerable number of comments. The third version has been circulated for further commenting in October 2022.

## 7. Exposure assessment (e.g. exposure measurement, exposure mitigation)

/

## 8. Risk assessment

/

## 9. Guidance or good practice documents for registrants and stakeholders

**ECHA**
After the PEG meeting held in March 2022, the Guidance document Appendix R7-1 for nanomaterials applicable to Chapter R7a Endpoint specific guidance has been referred to PEG cross check in June 2022 after revision of schema and threshold on solubility and dissolution in water request for nanoforms. This revision was performed along with the testing and decision tree for Kow and dispersion stability for nanoforms.
The guidance underwent Committees' consultation in September 2022. It received mainly minor editing comments and updates based on adoption of either new OECD TG or Nanomaterial EC definition after both consultation steps. The appendix is now aligned to undergo CARACAL written consultation.
Adoption and publication of the revised version 4 is planned for December 2022 or January 2023 together with all comments received during the consultation process (see AP04 of NMEG-16 meeting for more information).

**MSCA-DE**
The German REACH-CLP-Biocide Helpdesk published a REACH Focus: Obligations of a downstream user in the context of nanoforms of a substance, which can be found under the following link: https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Publikationen/EN/REACH/BAuA/Fachbeitraege/Obligations_of_a_downstream_user_of_nanoforms.html

## 10. Relevant new research projects or strategies on nanomaterials

**MSCA-DE**
„Examination and further development of strategic approaches for dealing with advanced materials in chemical safety" - Study on NanoCarrier and their environmental behaviour The project considers NanoCarrier as a case study for advanced materials that pose challenges for chemical regulation and regulatory risk assessment. In the project, extensive investigations are carried out on existing NanoCarrier and those under development and their (potential) applications. From the overview obtained in this way, those NanoCarrier will be selected for further investigation that are expected to pose particular challenges for environmental assessment with regard to their appearance or their application. For the selected NanoCarrier, test strategies will be developed and applied, which enable an investigation of their environmental behaviour and the possible release of the transported active substance under environmentally relevant conditions. Under investigation are the mobility of the NanoCarrier, possible non-intentional release of the active substance, degradability of the remaining carrier. In this way, the influence of encapsulation on the change in the environmental behaviour of active substances will be determined as an example. The implications of the encapsulation for an appropriate assessment of the

environmental behaviour within the framework of risk assessment will be described in more detail. Duration: October 2022 to August 2025

## 11. Experience from stakeholder or public dialogues

**MSCA-RO**
The Development of a National Framework on Nanosafety in Romania
On June 10th the OECD Council of Ministers adopted a Roadmap for accession of Romania. In the list of activities it is intended to be proposed the topic of developing a National Framework for Nanosafety.
Since 2018, the Romanian Ministry of Environment has initiated a collaboration with the Malta Initiative on the promotion of nanosafety and several activities have been carried-out. There were also developed collaboration ties with the EU NanoSafety Cluster. It has been initiated the preliminary process of establishing a National Framework on Nanosafety in Romania by mapping the research groups, institutions and companies with competencies and experience on nanosafety issues.
A special partnership has been initiated with the Universities like the University of Bucharest and Ovidius University of Constanta for defining the concept of a National Center on Nanosafety.
The contact persons for further details:
University of Bucharest, Prof. dr. Eden Mamut, eden.mamut@g.unibuc.ro
Romanian Ministry of Environment, Dr. Claudia Dumitru, claudia.dumitru@mmediu.ro

## 12. Any other scientific and technical issue

**MSCA-DE**
Berkner et al. Environmental Sciences Europe (2022) 34:71 "Too advanced for assessment? Advanced materials, nanomedicine and the environment" Advanced materials, and nanomaterials, are promising for healthcare applications and are in particular in the spotlight of medical innovation since rapidly developed nano-formulated vaccines provide relief in the SARS-CoV-2 pandemic. Further increased rapid growth is to be expected as more and more products are in development and reach the market, benefcial for human health. However, the human body is not a dead end and these products are likely to enter the environment, whereas their fate and efects in the environment are unknown. This part of the lifecycle of advanced medicinal products tends to be overlooked, if the perspective is human-centered and excludes the connectedness of human activity with, and consequences for our environment. Gaps are reviewed that exist in awareness, perspective taking, inclusion of environmental concerns into research and product development and also in available methodologies and regulatory guidance. To bridge these gaps, possible ways forward start to emerge, that could help to fnd a more integrative way of assessing human and environmental safety for advanced material medicinal products and nanomedicines.

**MSCA-FR**
State of ANSES review on the proposed update of nanoparticle definition set out by the Commission.

**MSCA-NL**
In collaboration with BfR, BAuA and UBA, RIVM developed a novel early warning system – named Early4AdMa – to identify emerging safety and sustainability issues of advanced nanomaterials. This system can be applied by regulators, risk assessors, as well as innovators (see brochure for details). It aims to provide a

tool that can be used in an anticipatory risk governance approach in order to proactively avoid the occurrence of potential unexpected risks of advanced (nano)materials. Addressing safety and sustainability issues early in the innovation chain can support innovation by preventing problems later on. The system was discussed in a workshop by the OECD Steering Group on advanced materials in February 2022, in which hands-on experience with a case study was achieved. The OECD WPMN Steering Group on Advanced (nano)Materials (SG-AdMa) will use the system as a basis for developing a strategic approach for advanced materials. Experience from other case studies will be gained and used as input for the development of the strategic approach for advanced materials under OECD WPMN.

## 13. Classification and labelling

**ECHA**
The CLH proposal for **Silver** (EC no: 231-131-3 CAS no: 7440-22-4) submitted by SE included data was subjected to Consultation from 19 October to 18 December 2020. Further targeted consultation of documents relevant to selected endpoints were also conducted during the CLH process. The proposal was for silver, including nanosilver to be classified as Skin Sens 1, Muta 2 and Repr 1B; H360FD, Aquatic Acute 1 and Aquatic Chronic 1 (with M-factors of 10 for both aquatic acute and chronic classifications for non-nanoforms and M=1000 for aquatic acute and M=100 for the aquatic chronic classifications for the nanoforms). The proposals were discussed in the RAC plenary in November 2021 and March 2022 as well as in the RAC CLH WG meetings in January and April 2022. The opinion adopted at the RAC plenary in June 2022 was for classification of massive, powder and nano -forms of silver as Repr 2 (sexual function and fertility, H361f) and STOT RE 2 (H373, nervous system), and for the powder and nano -forms to be classified with M-factors of 10 and 1000, respectively, as both Aquatic Acute 1 and Aquatic Chronic 1. The CLH opinion will be published in due course, and the opinion, as well as the proposal and comments received during the Consultations can then be accessed from Silver.

RAC has received a request under Article 77(3)(c) for reconsideration of the conclusion of RAC to classify **Silanamine** (SID description of the substance: 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide) as Acute Tox 2 via inhalation (H330) based on a recent study conducted by Industry.

## 14. EUON

**ECHA**
The following studies are on-going:
- Valid in silico modelling tools and read-across approaches, including creation of case studies on read-across for specific (types of) nanomaterials
- Nano-specific alternative methods in human risk/safety assessment under different EU regulations, considering the animal testing bans already in place for cosmetics and its ingredients

The EUON aims to launch two new studies in 2023:
- Review of the potential for release of pristine nanoforms after embedding into articles and toxicology of nanoform containing particles
- Review on nano-enabled pesticides & fertilizers

The EUON will publish reports by end 2022 on the following studies:
- Market study of the EU market on nanomaterials, including substances, products, uses, volumes and key operators

- A study on (Bio)degradation, persistence and safe by design of nanomaterials
- Assessment of the potential impact of graphene, graphene oxide and other 2D materials on health, and the environment

NanoData is available now on the EUON website. Automatic redirection from the old NanoData website is no longer available. NanoData URL update: https://euon.echa.europa.eu/nanodata.

## 15. Suggestion of discussion topic for next NMEG meeting (NMEG-16)

/

## 16.None of the above

/