Tour de table

19th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-19)
23-24 April 2024, Helsinki, Finland

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 31 March 2024, **869** registration dossiers covering nanomaterials were successfully submitted, resulting in a total of **169** substances covering nanoforms for which registration dossiers have been submitted following the updated REACH requirements.

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

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

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4. Hazard evaluation – human health

MSCA-NL

The Netherlands (RIVM) and UK (UKHSA) are leading the development of an **OECD Guidance Document to accommodate the toxicokinetic assessment of nanomaterials** (OECD TGP Project 4.146). Scientific input from the NanoHarmony project is used together with other (existing) information to come to guidance. The Guidance Document will discuss the dosing regimen, duration of the post-exposure period, time points for determining organ/tissue burdens and key organs/tissues to be analysed. The dissolution rate in physiologically relevant media is considered to steer the study design. Both the inhalation and the oral exposure routes will be covered in the new Guidance Document. NMEG members are invited to contribute to the project. Contributions to e.g. the overview of dissolution rates and a literature overview of toxicokinetics on CeO2 and SiO2 are very much welcomed.

5. Hazard evaluation – environment

ECHA

Annex VI-targeted compliance checks on:
- the sets of ZnO nanoforms have formally started on 28 February 2024. The assessment of the Annex VI information requirements will be caried out in the second term of 2024. A total of 2 sets of similar nanoforms of ZnO will be checked for compliance.

- the sets of TiO2 are under follow up assessment. Dossiers were updated in February 2024 and are currently ongoing assessment of the characterisers and justifications provided for the 9 sets of nanoforms addressed in the decisions.

6. Read-across and grouping for nanomaterials

ECHA

The work on the nanomaterial-specific chapter 6.9 for the update of the OECD Guidance on Grouping of Chemicals, Series on Testing & Assessment No. 194, ENV/JM/MONO(2014)4 is nearing completion. Case studies for human health and environment were included. The integration of the draft chapter has been discussed with the OECD Grouping Guidance drafting group. Final updates will be performed after the current commenting phase on the first draft of the overall Guidance.

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

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8. Risk assessment

MSCA-NL

RIVM is part of the NAMS4Nano project that is procured by EFSA. The project aims to **gain experience with New Approach Methodologies (NAMs) for nanomaterials**. This includes e.g. the bridging of information to non-nano counterparts. For various materials Integrated Approaches to Testing and Assessment (IATAs) are being developed to assess relevant questions in risk assessment. For other materials more general considerations are investigated. RIVM is (co-)chair for nanosilver, nanofibres and simple organism models. The project spans 4 years and started in April 2023. Work is ongoing on reviewing NAMs that are potentially useful for risk assessment on nanomaterials. Other ongoing work focuses on the development of a NAMs qualification system.

9. Guidance or good practice documents for registrants and stakeholders

MSCA-NL

The **SUNSHINE-project** has developed an approach that enables safety and sustainability assessment at each stage of product development from a lifecycle perspective. This qualitative SSbD self-assessment methodology was developed for industry and SMEs. The Tier 1 (self-assessment) methodology evaluates the safety, functionality and sustainability in the early R&D stages of the lifecycle of chemicals and materials. The approach was tested using two real industrial case studies. One case study focused on a nano-enabled anti-sticking coating for bakery molds that is free of PFAS (polyfluoroalkyl substances). The other case study looked at nano-drops of essential oil anchored to the surface of nanoclays and encapsulated in a polymeric film. The results indicate that these innovative materials have a high probability to have better safety, functionality and sustainability performance compared to conventional benchmark materials.

Another analysis within the **SUNSHINE-project**, looked at how different EU regulations (e.g. REACH) cover multi-component nanomaterials. This work has been presented in the 18th NMEG meeting to discuss the regulatory preparedness

of EU Regulations for the more complex multi-component nanomaterials (MCNMs). The main goal of this work is to develop a regulatory preparedness system where potential gaps in regulation can be identified and discussed with regulators. Currently discussions are ongoing to address the REACH-related issues with MCNMs.

MSCA-NL

Ensuring that innovations in materials can come to the market and comply with regulations requires collaboration between experts from science, industry and authorities to set priorities in required test methods. In March 2024, the Malta Initiative released its **Malta Initiative Priority List**. This list will help ensure that the harmonised methods that are required in the near future for nanomaterials and (other) advanced materials will become available.

The Malta Initiative Priority List is a list of prioritised actions to support the development and amendment of these required OECD TGs. The Priority List has been compiled with the help of experts in the field of physical chemical properties, human and environmental toxicity. These experts include representatives from industry, academia and regulatory bodies.

10. Relevant new research projects or strategies on nanomaterials

ECHA

An update of the project 'Nanomaterial Risk Assessment: a regulatory way forward for sameness and grouping approaches – ECHA/2023/14' will be given during NMEG-19 meeting. The project as reached the first milestones and the first findings will be shared.

MSCA-DE

For information, the Malta Initiative has published its Priority List on making OECD TGs/GDs applicable for nanomaterials and advanced materials.

The Priority List can be accessed via the Malta webpage:
https://malta-initiative.org/what/#MI-Priority-List

MSCA-DE

UBA commissioned a survey with the topic of "Advanced materials for the energy transition - study to survey the state of knowledge and technology on the application of advanced materials in the various technologies for the production and storage of renewable energies". The aim of the project is to create an overview of current and future applications of advanced materials in the various technologies for the generation and storage of renewable energies and energy sources. The task of the project is to research the state of knowledge and technology on current and future applications of advanced materials in the various technologies and to compile a systematic overview. In addition, for the 10 most relevant advanced materials the overview is to be expanded to include information on chemical safety and sustainability of the advanced materials used. The project will run from 12/23 - 07/24 and is being carried out by the German Federal Institute for Materials Research and Testing (BAM).

MSCA-NL

The **NanoSafety Cluster** started a Task Force on Safe & Sustainable Advanced Materials which resulted in the "Roadmap Safe and Sustainable Advanced and Innovative Materials 2024-2030". This document is intended to provide input into the Strategic Research and Innovation Agenda of "IAM4EU" and other relevant partnership programs. This roadmap includes the primary research areas relevant to safety and sustainability of both nanomaterials and other advanced and innovative materials. Specific areas addressed in the roadmap are: (i) FAIR research output & (Meta) Data Management, (ii) Integration of Safety into Innovation, (iii) Integration of Circularity and Sustainability into Innovation, (iv) Translation & Valorisation of SSbD, (v) Harmonisation and Standardisation, and (vi) Regulatory Preparedness and Governance. For each of these areas a description is provided of the current state-of-the-art. Unresolved aspects and emerging issues are identified, as well as the needs to close the gaps within each area.

MSCA-NL

Testing strategies form the basis for the risk assessment of chemicals and materials. The **new European project CHIASMA** focuses on the development, refinement, application and innovation of these strategies. The selected methodologies are a combination of computational and experimental approaches relevant for human exposures. These methodologies should eventually support regulatory decision making. In the project, there is capacity to optimize and standardize a battery of *in vitro* assays. CHIASMA aims to assess the biological and regulatory relevance of these assays, and to address their transferability between partners within the consortium. The selected test battery will be integrated into a safe and sustainability be design (SSbD) framework to support REACH and CLP. The *in vitro* assays will be used to address the toxicity of demonstration cases. These case studies are centred around PFAS, (nano)-pesticides and 2D materials. RIVM is involved in all facets of the project. These include model validation, human relevant exposures, data handling and regulatory relevance. In addition, RIVM is co-lead for the work package responsible for the assessment of method transferability. RIVM will also be involved in engagement of relevant stakeholders.

MSCA-FR

NanoMesure France is a non-profit association founded in September 2022 by the LNE (French National Laboratory for Assays and Method), FEBEA (French Federation of Beauty Companies) and France Chimie (Federation of French chemical producers) whose ambitions are to provide a single entry point for structuring a nanomaterials industry based on reliable and comparable data by working on access to information, connecting stakeholders and improving the quality of measurement data. The association has 47 members for now, in the domain of material and chemistry, nanomedicine, cosmetics, service providers/Analytical platforms, instrumentation and other (water management, tyres, construction, …). Working groups operate in 4 big sectors to tackle problems identified in characterisation of nanomaterials and ensure proper data generation for manufacturers, suppliers, users and authorities.
The association ongoing work is related to solve the problem in properly characterising samples according to JRC flowcharts, focusing on the confirmatory step by electron microscopy as complex and very complex cases were identified. The association prepare a guide on how to tackle these issues. Members are also working on a flowchart dedicated to the identification of NMs and distinguish between pure substance, mixture (of the same grade or different substance). Finally, one of the purposes of the association is also to build a database on competent laboratories in the identification and characterisation of NMs.

11. Experience from stakeholder or public dialogues

MSCA-NL

The **Horizon Europe project IRISS** is a three-year project that started 1st of June 2022. The project forms an International ecosystem for accelerating the transition to Safe-and-Sustainable-by-Design materials, products and processes. The project has two main goals. First it will develop an EU led SSbD International community. Secondly it will develop SSbD roadmaps for the practical application of SSbD. These roadmaps focus on needs for research, skills, competences and education, and on knowledge and information sharing. Within IRISS, there are seven value chains involved: automotive, construction, electronics, energy, fragrances, packaging and textiles. In one of their activities IRISS had a dialogue about SSbD with regulators. Here the regulators' roles and views with regards to SSbD were gathered and discussed.

12. Any other scientific and technical issue

MSCA-NL

A strategic approach to identify and describe **potential safety, sustainability and regulatory issues of advanced materials** at early stages of their development or use is developed by the OECD WPMN Steering Group on Advanced Materials (AdMa). This strategic approach used an earlier version of the Early4AdMa system, which is adapted based on experience from case studies and other feedback. The **updated Early4AdMa system** is available at the OECD website and orally explained in a recent webinar. The relevance of further updates of the system will be considered in the future.

The system is being applied to further cases: nanocarriers, graphene related material, 3D-printing as an advanced manufacturing process, SUNSHINE cases and an update for MXenes are anticipated. These cases will focus on identifying relevant signals on safety, sustainability and regulatory applicability. Delegates, organisations and projects are invited to apply the Early4AdMa system, preferably in collaboration with the OECD WPMN SG AdMa, and bring relevant AdMa to the attention of the OECD WPMN SG AdMa.

The Netherlands is co-chair of the OECD WPMN SG AdMa. RIVM has developed the first version of the Early4AdMa system together with UBA, BAuA and BfR, lead the MXenes case and contributes to the other cases.

The Netherlands is co-chair of the OECD WPMN Safe and Sustainable Innovation Approach (SSIA) Steering Group. SSIA is the combination of safe-and-sustainable-by-design (SSbD) and regulatory preparedness. Two reports are expected for declassification. A first one deals with building trust and enhancing dialogue for SSbD innovation. This provides tools for organizing trusted environments. A second report summarises SSbD tools, frameworks, and platforms for nanomaterials and nano-enabled applications.

13. Classification and labelling

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14. EUON

ECHA

EUON has opened a call for new study proposals
aimed at addressing knowledge gaps to nanomaterials within the EU market, such as:
• questions related to the health and safety aspects of nanomaterials, including hazard and risk assessment;
• specific issues surrounding the uses and associated risks, benefits of nanomaterials; or
• information about markets of nanomaterials.
Proposals are requested to be sent to nano-observatory[at]echa.europa.eu by **30 April 2024**.
More information on the call: https://euon.echa.europa.eu/view-article/-/journal_content/title/closing-nanomaterials-information-gaps-euon-welcomes-new-study-proposals

15. Suggestion of discussion topic for next NMEG meeting (NMEG-18)

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16. None of the above

MSCA-NL

The Dutch Institute for Public Health and the Environment (RIVM) has published the first issue of its **new international newsletter: "RIVM on Advanced Materials** – Covering scientific and European policy developments on safety and sustainability". With this newsletter RIVM aims to inform international scientists and policy makers on the safety and sustainability of nanotechnology and advanced materials. Information is gathered based on RIVM's participation in international meetings and (research) projects, as well as from several other source, e.g. scientific literature and regulatory developments. We hope that sharing this information and our reflections on it will benefit your work. Five times a year an issue of "RIVM on Advanced Materials" will be published on our website. To ensure you will not miss an issue, you can subscribe to this newsletter.

17. Upcoming events

> NMEG-20: 13-14 November 2024