ECHA
EUROPEAN CHEMICALS AGENCY

Tour de table

17th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-17)
19 April 2023, Helsinki, Finland (online 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

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By 31 March 2023, 795 registration dossiers covering nanomaterials were successfully submitted, resulting in a total of 167 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

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5. Hazard evaluation – environment

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6. Read-across and grouping for nanomaterials

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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 ongoing, in a group set up by the OECD WPMN. The chapter will be integrated later in the overall updated Guidance. Currently the leads are working on the next version taking into account the comments from the 3rd commenting round.

JRC

The JRC has developed an online **course on Nanomaterials in EU Legislation** available at https://academy.europa.eu/search/index.php?search=nanomaterial. **Course details:** In this course, you will learn how European Union legislation addresses nanomaterials. You will learn what a nanomaterial is from a scientific point of view and what makes it special in a legal context. You will understand the European Commission's overarching regulatory definition of nanomaterial and how the challenges to implement it can be met. You will gain insights into the basis for EU legislation in general, the processes for developing it, different types of EU legislative acts and understand why there are differences.

Additionally, the JRC has finalised the **Guidance on the Implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial**. It will be published in April 2023. The DOI is https://doi.org/10.2760/143118 and as soon as the report layout is finalised the DOI will become active.

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

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8. Risk assessment

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9. Guidance or good practice documents for registrants and stakeholders

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An update to the 'Appendix to Chapter R.7a for nanomaterial' was published on 21.12.2022.
Finalisation of new and revised TG and GD documents relevant to nanomaterials assessment are expected by 2025. On this basis, revision needs of the entire series of appendixes to nanomaterials of R.7 guidance will be considered from 2025.

MSCA-NL

Together with European experts, RIVM has published an overview of the information requirements across different EU regulatory areas where nanomaterials receive specific attention. For each information requirement, a group of 22 experts identified **potential needs for further action to accommodate guidance and test guidelines to nanomaterials** with a focus on OECD. Apart from specific needs for action on specific information requirements, three overarching issues were identified: 1) resolve issues around nanomaterial dispersion stability and dosing in toxicity testing, in particular for human health endpoints, 2) further develop tests or guidance on degradation and transformation of organic nanomaterials or nanomaterials with organic components, and 3) further develop tests and guidance to measure (a) cellular reactivity of nanomaterials. Efforts towards addressing these issues and needs identified will result in better fit-for-purpose test methods for (EU) regulatory compliance. Moreover, it secures validity of hazard and risk assessments of nanomaterials. The results of the study accentuate the need for a structural process of identification of information needs and knowledge generation, preferably as part of risk governance and closely connected to technological innovation policy.

The European projects NANOMET and NanoHarmony jointly published a report in which they provide an **overview on progress in the development of OECD Test Guidelines and Guidance Documents** for nanomaterials. The report provides an overview of OECD TGs and GDs that have been published already and progress for those that are still on-going in the Test Guideline Programme. In a final section the report provides an overview of method developments in research projects that may be expected to be brought forward to OECD in the near future. By focussing on content descriptions of the different projects, the report provides a useful addition to the more timeline-focussed descriptions in the yearly update of the OECD Work plan for the Test Guidelines Programme. The NANOMET/NanoHarmony report is intended to be a living document that will be updated regularly.

The European project NanoHarmony will finish in September 2023 and is currently working towards the **NanoHarmony legacy**. This legacy comprises several items. As contribution to the Malta Initiative, NanoHarmony will provide the **scientific background for a range of different OECD documents** on different nanomaterials related topics, including surface chemistry, solubility and dissolution rate in water and biological media, dustiness, quantification of nanomaterials in biological samples, toxicokinetics, intestinal fate, bioaccumulation and ecotoxicology. Furthermore, it will provide **support for developers of OECD Test Guidelines** with an online process mentor and training materials, and exploring continuation of the yearly NanoHarmony workshops (e.g. in other EU projects) to facilitate exchange among experts involved in Test Guideline development. Last but not least NanoHarmony will provide a **White Paper** with recommendations to (further) optimise the Test Guideline development process, and to ensure a continuous effort in keeping test guidelines up-to-date with advances in material innovations, test method/technology developments, and new regulations and policy strategies. The White Paper will be presented in a **NanoHarmony Policy Meeting in Brussels on 23th May 2023**, together with the Position Paper of the Malta Initiative that advocates a European Test Methods Strategy that ensures continuous financial support for the systematic (further) development of OECD Test Guidelines.

10. Relevant new research projects or strategies on nanomaterials

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The **new European project MACRAMÉ** is aligned with the EU ambitions to secure the safety and sustainability of new chemicals, materials, products and processes in order to strive for zero pollution and toxic-free environments. The project concentrates on methodologies that are applicable to nanomaterials, and widens them to advanced materials in commercialised products. Within the project five advanced materials (products) are selected for sampling and characterisation during the life cycle; three based on graphene, one based on carbon nanotubes and one nanomedicine. Furthermore, potential impacts on (human) health and the environment in intended or unintended exposure situations in the product value-chain will be assessed. The developed and improved methods and techniques are further advanced for OECD test guidelines and standardization (CEN/ISO). Within the project RIVM will use air liquid interface (ALI) models developed and used within previous EU projects to assess potential hazard of the selected advanced materials after inhalation. In order to advance the best models towards OECD test guidelines and standards, there will be an exchange of ALI models. Both the chemical and medicine domain are represented in the selected materials and RIVM will help promote coordination between these regulatory frameworks in the field of advanced materials. As co-lead of WP1 on Bridging Communities & Refining MACRAMÉ Strategies RIVM will assess the needs of regulatory and policy frameworks.

11. Experience from stakeholder or public dialogues

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In close collaboration, the three H2020-projects Gov4Nano, NANORIGO and RiskGONE have gained a tremendous **knowledge on risk governance and risk assessment of nanomaterials**, including meaningful insights about risk governance challenges and issues. These insights are considered relevant for efficient and effective risk governance of advanced (nano)materials. They are reported in a memorandum on risk governance of advanced materials that

suggests four lines of policy actions to fill gaps regarding knowledge, connection with innovation policies and regarding harmonization and standardization. With this memorandum the projects aim to raise awareness that the specific issues regarding safety (and sustainability) of advanced (nano)materials are not automatically covered in projects and activities under the Chemicals Strategy for Sustainability (CSS), and to gain active support for the identified lines of action from stakeholders, including the European Commission, Member States, industry, the research community, and NGOs. The memorandum served as a key background document for the projects' **joint conference in Paris**. For this conference, the projects gathered a broad range of different experts and stakeholders to discuss the key results. Four multistakeholder roundtables were organised there to discuss different thematic areas: 1) Harmonisation & Standardisation, where we need to reduce the pacing problem of test methods by fostering early awareness and harmonisation and standardisation, 2) Risk Governance Portal and Tools, where there is a need for a common platform to find developed and emerging tools that can support a sustainable future, 3) Data Management, where data/knowledge sharing, ontologies and platforms need to be in place for future development of FAIR data, and 4) Organisation of Risk Governance, where there is a need to choose the appropriate organisational form to support the implementation of various initiatives for advanced materials and foster co-creation among stakeholders. Outcomes of the projects and the Paris discussions were presented in an online event on "Future-proof Approaches for Risk Governance". A summary document on the outcomes of the joint conference is currently being prepared and will be made available shortly.

12. Any other scientific and technical issue

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In March 2023, UBA published a position paper on advanced materials and the field of tension between their promising use and possible challenges for environmental and health protection and other sustainability dimensions. Advanced materials may play an important role for the transition to a more sustainable society. The position concentrates on topics in the remit of UBA, such as the energy transition, circular economy and chemical safety. The position paper describes opportunities, challenges, and conflicting goals for safety and sustainability that might go hand in hand with the use of advanced materials. This is shown in more detail for three types of advanced materials. The position describes corner stones that UBA believes are essential for dealing with these conflicting goals in order to promote safe and sustainable material innovations and their applications
https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/advanced-materials#what-are-advanced-materials

Nanocarrier promise benefits for various fields of applications. For instance, for medicinal products. Applications for other fields are approaching (e.g., pesticides, biocides, cosmetics, food). Nanocarrier features an example of AdMa with many different types and application, thus differentiated discussion and an early warning assessment is needed. UBA organises within the SG AdMa of the WPMN an Online Workshop on NanoCarrier. The workshop will allow to gain an overview on the topic followed by discussion on selected types of NanoCarriers for selected application areas. Discussion will take place in break out group sessions following the approach described in the Early4AdMa (https://www.rivm.nl/documenten/Early4AdMa-brochure). The Workshop will take place online at the 14th-15th June, 2023. Nomination for participation can be made via the OECD WPMN Secretariat.

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 being developed by the OECD WPMN Steering Group on Advanced Materials (AdMa). The Early4AdMa system is used as a basis for the development of the Strategic Approach. Experience from cases and other input is used to refine the approach. The Netherlands is co-chair of the OECD WPMN SG AdMa. RIVM has developed the Early4AdMa system together with UBA, BAuA and BfR. Further testing of the Strategic Approach within the OECD SG AdMa with cases like nanocarriers and graphene is foreseen.

13. Classification and labelling

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Silver: The RAC opinion on the CLH for **Silver** (EC no: 231-131-3 CAS no: 7440-22-4) has been published. The opinion, as well as the proposal and comments received during the Consultations can then be accessed from this link: Silver.

Silanamine (SID description of the substance: 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica; pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide): In the RAC-65 plenary meeting in June 2023, RAC will consider the request under Article 77(3)(c) (see Mandate) for reconsideration of the conclusion of RAC to classify **Silanamine** as Acute Tox 2 via the inhalation route (H330). This mandate is based on a recent study conducted by Industry which as part of the process was the subject of a recent targeted consultation (for details see silanamine).

MWC(N)T: The first discussion of RAC opinions adopted in 2022 has been held at the meeting of CARACAL on 29 March 2023, including the opinion for **multiwalled carbon (nano) tubes** (see the ECHA website at MWC(N)T)

MSCA-DE

As already done within the REACH revision process, DE proposed in the Council Working Party on Technical Harmonisation (Dangerous Substances - Chemicals) to introduce a definition of the term "form of a substance" to the CLP regulation.

14. EUON

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The reports resulting from the below-mentioned desk-studies were published on the EUON website: Reports – European Observatory for Nanomaterials (europa.eu):

- 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 knowledge base was updated with new market data: https://euon.echa.europa.eu/nanodata

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

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16.None of the above

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