Tour de table

14th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-14)
26-27 October 2021, Helsinki, Finland (remote 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 5 October 2021, 478 registration dossiers covering nanomaterials were successfully submitted, resulting in a total of 138 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
Registrants are expected to submit or update their dossier according to ECHA guidance. The dossier evaluation of several substances has started and the decision drafting is ongoing for several substances.

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

MSCA-DE
The research project for the development of a Test Guideline (TG) on particle size and size distribution of nanomaterials funded by the German Ministry for the Environment (BMU) was finalised during summer 2021. The project was commissioned by the German Environment Agency (UBA) and performed by the German Federal Institute of Occupational Safety and Health (BAuA) and the German Federal Institute for Materials Research and Testing(BAM). The final report that described the way how the draft TG was developed will be available soon at
https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/research-development-projects
The draft TG on particle size and size distribution of nanomaterials (WNT project 1.4, led by Germany) and the accompanying report on the interlaboratory test comparison that took place in 2019 was submitted to the WNT commenting round during summer 2021. Comments by WNT were received end of September. The large majority of comments were of editorial nature or questions for clarifications within the paragraphs. There was no disagreement on the general technical performance of the TG. Submission of a revised version of the draft TG to WNT for the 2nd commenting round is anticipated for late autumn 2021.

4. Hazard evaluation – human health

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5. Hazard evaluation – environment

MSCA-DE
At WNT-32, a new OECD Guidance Document (GD) to guide on the investigation of nanomaterials using OECD TG No. 312 ("leaching in soil columns") was adopted. The activity was led by Canada and Germany as WNT project 3.14 since April 2017. The objective of this activity was to improve the applicability of OECD TG 312 "leaching in soil columns" for the testing of mobility of nanomaterials in soils. As environmental behaviour and fate of nanomaterials is subjected to kinetic processes (agglomeration, sedimentation) mainly, there is currently no method available to appropriately determine fate of nanomaterials in soils as current methods applied for conventional chemicals are either not applicable, not reliable or not yet advanced/available for nanomaterials. Thus, the use of OECD TG 312 for determining fate of nanomaterials in soil became particular important and guidance for using the TG was needed. Elements which are considered in the new GD inter alia include the preparation of stock and test suspension, the application to the test system, choice of appropriate test duration and flow rate, reliable and robust (and cost-effective) analytics as well as appropriate data interpretation. The GD development was mainly executed by the support of an international core group of experts on a voluntary basis. A core element of GD development was an interlaboratory comparison (ILC) test which ran in 2019 (with 2 nanomaterials, 2 soils, data received from 7 labs from 4 countries). The GD received the Number 342.

6. Read-across and grouping for nanomaterials

ECHA
The EU project GRACIOUS (www.h2020gracious.eu) has developed a science-based framework to enable practical application of grouping and read-across of nanomaterials. In this context a white paper on nanoform similarity was compiled (https://www.h2020gracious.eu/library/publications).
Moreover, a case study on MWCNT registered under REACH was performed to further investigate the grouping and read-across of nanomaterials for regulatory risk assessment and to apply the GRACIOUS framework.

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

MSCA-DE
The REEG (REACH Exposure Expert Group) is designed to support the work by authorities in implementing the integrated regulatory strategy that covers evaluation and regulatory risk management under REACH/CLP legislation and the pre-regulatory activities set up to serve them (screening, RMOA). The group discusses scientific, technical and methodological topics related to use and exposure.
One of the agenda points of the REEG meeting planned for 25.10.2021 concerns **nanomaterial exposure**: the presentation will focus on open questions or fields for improvement for exposure assessment from the publication Schwirn et al. (2020) 'Environmental Risk Assessment of Nanomaterials in the light of new obligations under the REACH regulation - Which challenges remain and how to approach them?

ECHA
On 19 October 2021, OECD published four reports (No. 345 to 348) on the evaluation of tools and models for consumer, workers and environmental exposure. The reports are available here:
https://www.oecd.org/chemicalsafety/testing/series-testing-assessment-publications-number.htm

8. Risk assessment

EFSA
Documents published in august 2021:
- Two new guidance documents from EFSA's Scientific Committee will help to further clarify how EFSA's scientists approach the assessment of nanomaterials in the food and feed chain:
- Guidance on risk assessment of nanomaterials in the food and feed chain: animal and human health – provides a roadmap to progressively roll out and assist the assessment of nanomaterials
https://www.efsa.europa.eu/en/efsajournal/pub/6768
- Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles – relates to conventional materials that contain a fraction of small particles but don't meet the definition of engineered nanomaterials (see below).
https://www.efsa.europa.eu/en/efsajournal/pub/6769
- Both documents also set down data and information requirements for applicants when submitting materials for assessment as part of EU market authorisation procedures, e.g. for use as food additives or food contact materials."

9. Guidance or good practice documents for registrants and stakeholders

ECHA
Regarding the Guidance appendices R7 a, b and c under revisions for registration, human health (HH), physico-chemical (PC) and environment (ENV) endpoints for nanomaterials:
- For the updated **registration** guidance, the PEG meeting took place on 15 September 2021 and the comments received during the PEG consultation have been addressed. The updated draft guidance has now been shared with the PEG members for cross check (with a deadline on 15.10.2021). The next step is the consultation of Forum and CARACAL.
- For the updated **HH** guidance, MSC was consulted in May 2021, CARACAL in July-August 2021 and the CARACAL cross-check consultation ended in September 2021. The updated guidance was published on 04 October 2021. ECHA wants to thank the PEG members as well as the experts who provided comments during the different stages of this process.
- The **PC** and **ENV** guidance update process started in May 2021. R7a appendix is updated on PC and ENV endpoints, including granulometry, solubility, dissolution rate in water and environmental media, n-octanol/water partition coefficient and adsorption/desorption. A new section was added on Dustiness as this is a new nano-specific standard information requirement. Both R7b and R7c appendices are also under update. PEG consultation for R7a, R7b and R7c appendices foreseen for late 2021 or beginning of 2022 (drafts will be available on ECHA website at that stage).

EFSA
Documents published in august 2021:
- Two new guidance documents from EFSA's Scientific Committee will help to further clarify how EFSA's scientists approach the assessment of nanomaterials in the food and feed chain:
- Guidance on risk assessment of nanomaterials in the food and feed chain: animal and human health – provides a roadmap to progressively roll out and assist the assessment of nanomaterials.
https://www.efsa.europa.eu/en/efsajournal/pub/6768
- Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles –

relates to conventional materials that contain a fraction of small particles but don't meet the definition of engineered nanomaterials (see below). https://www.efsa.europa.eu/en/efsajournal/pub/6769
- Both documents also set down data and information requirements for applicants when submitting materials for assessment as part of EU market authorisation procedures, e.g. for use as food additives or food contact materials."

10. Relevant new research projects or strategies on nanomaterials

MSCA-DE
The German Environment Agency awarded a research project to the University of Vienna with the aim to develop a OECD Test Guideline (TG) on abiotic transformation of nanomaterials under environmental conditions. The project is funded by the German Ministry for the Environment.
In addition to dispersion stability and dissolution behaviour, whether and how nanomaterials are transformed over time via abiotic processes is also important for their behaviour and fate in the environment. This knowledge is significant to understand in which form and amount engineered nanomaterials are present in the environment. The research project aims to develop an OECD TG for a quantitative determination of the abiotic transformation processes of nanomaterials, taking into account relevant environmental parameters. The work builds on ongoing activities for the development of an OECD Guidance Document on environmental abiotic transformation of nanomaterials (WNT Project 3.16) developed in the course of EU H2020 Gov4Nano.
In addition, the project will also include investigations to validate a possible test protocol for determining the heteroagglomeration of nanomaterials under consideration of relevant environmental parameters. The basis for this will be the existing OECD test guideline 318 for the determination of dispersion stability of nanomaterials under environmental conditions, which is currently limited to the investigation of homoagglomeration of nanomaterials.

PETA
PETA Science Consortium International is collaborating with Philip Morris International and British American Tobacco on the development of the AOP on Oxidative stress Leading to Decreased Lung Function (AOP411). The manuscript describing the AOP is currently under review.
In the follow up to a 2016 workshop co-organised with the US NTP Interagency Centre for the Evaluation of Alternative Toxicological Methods (NICEATM), PETA Science Consortium International is funding proof of concept testing to show the utility of in vitro approaches to assess respiratory toxicity. The project is using BEAS-2B cells (a human bronchial epithelial cell line) and MucilAirTM (a three-dimensional reconstituted model of human airway epithelium) to assess the ability of silanes to cause portal-of-entry effects on the human respiratory tract. More information on this project is available at: https://www.thepsci.eu/acute_inhalation_toxicity/
In collaboration with the German Federal Institute for Risk Assessment (BfR), the U.S. National Institute of Standards and Technology (NIST), and the U.S. Consumer Product Safety Commission (CPSC), PETA Science Consortium International published a paper titled 'Use of Cause-and-Effect Analysis to Optimize the Reliability of In Vitro Inhalation Toxicity Measurements Using an Air–Liquid Interface'.
PETA Science Consortium International has funded a study to transition the cell line A549 from fetal bovine serum (FBS) supplemented medium to xeno-free and chemically defined media. The manuscript describing the transition and the characterization of the cells is currently under preparation. A poster on this topic that was presented at the 11th World Congress on Alternatives and Animal use in the Life Sciences is available at: https://www.thepsci.eu/wp-

content/uploads/2021/09/2021-World-Congress_Transitioning-A549-Cells-to-FBS-Free-Media_Chary-et-al.pdf

MSCA-BE

ISSeP is the Scientific Institute of the Public Service of Wallonia specialized in environmental monitoring, in risk and nuisance prevention and in research and development. The Institute has conducted several studies to assess the impact of nanomaterials in the environment and developed a lab…
Please find below the abstracts of the projects and the related references of scientific communications.

- NANOGRA - MULTIDISCIPLINARY ASSESSMENT OF THE RISKS RELATED TO NANOMATERIALS
Contact : t.sinaba@issep.be
ISSeP - Elodie Bouhoulle, Hervé Breulet, Matthieu Hemart, Tiécoura Sinaba
Period : 2015-2018
Partners : INERIS, Namur Nanosafety Centre (UNamur)

Several tests were conducted to assess the ignitability and explosion violence characteristics of carbon black (CB) (N990), MWCNT (NC7000TM) and partially passivated aluminium nanopowders (NP). The results (measured MIE, Pmax and KSt) led to the conclusion that airborne carbon NP can generate an ATEX with moderate explosion intensity comparable to the ST1 class. They are slightly sensitive to electrostatic phenomena. Explosion parameters of carbon NP were generally found similar to their microscopic size analogue. The results showed that aluminium NP are sensitive to the risk of ignition by a phenomenon of electrostatic origin, and explosion violence seemed to increase when particle size decreases.
An exposure assessment to NMs was performed for the management of occupational risks during explosiveness testing in a 20 L explosion sphere for CB and MWCNT in a laboratory. Exposure was measured with a CPC in background and near field. The operator was also equipped with a portative particle counter DiscMini. Samples for TEM analysis were collected with a Mini Particle Sampler system. Background concentrations were monitored with a SMPS nanoparticle sizer.
A qualitative assessment was performed using the CB Nanotool 2.0 and StoffenManager Nano 1.0 control banding tools. The risk levels assessed by the CB tools tended to overestimate observed NP concentrations during the tests. The subjectivity associated with some input parameters for the risk assessment and the lack of information in the safety data sheets and literature generate uncertainties in the risk assessment results. One should be aware of these limitations while using CB tools.
Soils and sediments are a potential sink for engineered NP when released in the environment and sediment organisms are likely to be significantly affected by these contaminants. The ecotoxicogical section of NANOGRA aimed to assess the impact of spiked samples on sediment dwelling organisms Chironomus riparius and Heterocypris incongruens and to evaluate the mobility of the NPs from the sediment to the water column and the organisms. Experiments results showed no mortality for both species at environmentally relevant concentrations in lab conditions. Growth inhibition was only observed for chironomids and aluminium dioxide NPs at all concentrations (with a significant growth delay at the highest one). No teratogenic effect has been measured on these organisms.
Physicochemical analyses showed that NP agglomerate quickly in sediments and tend to remain in the sediment by gravity. nTiO2 seems to deagglomerate in the water column probably due to a surface erosion of the particle. Finally, NP concentrations in chironomids seem to be related to the concentration in sediment without observing an increased excretion.

Bouhoulle, E., Sinaba, T., Laruelle, B., Dalle M. Aguerre-Chariol O, Breulet, H. & Le Bihan, O. (2019). Evaluation des risques pour l'opérateur au cours d'essais d'explosivité de nanopoudres en laboratoire. Asfera – Congrès français sur les aérosols, Paris, France, 22-23/01/2019.
Sinaba, T., Breulet, H. & Bouhoulle, E. (2019). Ignition and explosion characteristics of four kinds of nanopowders, 6th NanoSAFE International Conference 5–9/11/2018, Grenoble, France. Published in Journal of Physics: Conference Series, Volume 1323.
Bouhoulle, E., Sinaba, T., Breulet, H. (2018). Ignition and explosion characteristics of four nanopowders. NANOSAFE 2018. Grenoble, France, 5-9/11/2018.
Bouhoulle, E., Sinaba, T., Breulet, H., Dalle, M., Aguerre-Chariol, O., Le Bihan, O. (2018). Risk assessment during explosion severity tests of carbon black and MWCNT in a laboratory. NANOSAFE 2018. Grenoble, France, 5-9/11/2018.
Bouhoulle, E., Sinaba, T., Luthers, C., Dalle, M., Aguerre-Chariol, O., Breulet, H., Le Bihan, O. (2018). Occupational exposure assessment in a laboratory during explosion tests of carbon black and MWCNT (poster). NanoTox 2018, 9th Conference on Nanotoxicology. Düsseldorf, Allemagne, 18-21/09/2018
Breulet, H. & Sinaba, T. (2019). Explosivity and Flammability of Nanopowders: New Challenges, Chemical Engineering Transactions 77, 223-228.
Hémart M., Breulet H. et Marneffe Y. (2017), « TiO2, CNT and Al nanoparticles risk assessment for sediment-dwelling organisms », poster présenté lors du 27th Annual Congress of Society of Environmental Toxicology and Chemistry (SETAC), Bruxelles, Belgique, 8-11/05/2017.
Hémart, M., Breulet, H., Marneffe, Y. (2017). TiO2, CNT and Al nanoparticles risk assessment for sediment-dwelling organisms (poster). SETAC 2017 Bruxelles, Belgique, 8 – 11/05/2017.
Hémart M., Sinaba T., Bouhoulle E. et Breulet H. (2016), « NANOGRA : a NANO Global Risk Assessment Project », dans Actes du 11th International Conference on the Environmental Effects of Nanoparticles and Nanomaterials (ICEENN 2016), Golden (Colorado), États-Unis, 14 – 18/08/2016.
NANH2O – How to characterise nanoparticles in natural waters and their transport in aquifers?
ISSeP - Ronchi B., Joris A., Frippiat C..

Contact : b.ronchi@issep.be

- Period : 2015-2019
Partenaires : Unité Hydrogéologie et Géologie de l'environnement de l'ULg, Département de Chimie Appliquée de l'ULg

The increasing use of engirneered nanoparticles (NP) leads to their release in the environment, i.e. in aquifers. However, their transport through aquifers remains unclear. This project aims to develop quantification methods of NP concentrations in groundwater samples on the one hand, and to characterize their transport through aquifers on the other hand. NP stability in solutions and its affinity with mineral grains depends on its surface charge which varies with pH conditions but also on the ionic strength of the solution. Consequently, nano-sized TiO2 (nTiO2) are expected to behave differently in silicate and carbonate aquifers as groundwater chemistry is influenced by the host rock mineralogy. Our study evaluates therefore different mineralization protocols to measure NP concentrations, the sedimentation rates of NP in different types of water and the transport of NP through sand columns of different mineralogies and glass beads columns. Tests revealed that NP agglomerate rapidly in natural water which accelerates sedimentation. Column tests showed that sandy materials filter NP from injected suspensions. Filtration is complete when natural silicate sands are used. In the case were glass beads or carbonate sands were used, very low concentrations were detected in the outflow of the columns. Attached NP in the column can however detach after flux increase or pH change. Attachment

mecanisms could be simulated in the software Hydrus 1D to reproduce restitution curves. Finally, the evolution of a NP pollution front through a soil profile was conceptualised according different detachment mechanims. This theoretical conceptual model can be used to formulate hypotheses for future research.

Ronchi, B., Joris, A., Veschkens, M., Fripppiat, C. (2019) Fate of TiO2 nanoparticles in carbonate and silicate aquifers. Poster à la conférence Groundwater Quality – 9-12/09/2019, Liège, Belgique.
Joris, A., Ronchi, B., Canisius, M.-F. & Frippiat, C. (2017). Mineralization of Titanium nanoparticles for the determination of Titanium in groundwater samples (poster). 19th International Symposium on Advances in Extraction Technologies (EXTECH 2017). Santiago De Compostella, Spain, 26-30/06/2017.
Ronchi, B., Joris, A., Mahy, J., Heinrichs, B., Veschkens, M. & Frippiat, C. (2017). Fate of TiO2 nanoparticles in carbonate and silicate aquifers. Goldschmidt2017 Conference (poster). Paris, 13-18/08/2017.

- NANOBIOM - Etudier l'impact environnemental réel de l'utilisation énergétique de la biomasse

ISSeP : Igor Dyakov, Benjamin Bergmans, Hervé Breulet
Contact : i.dyakov@issep.be
Durée : 2017-2020
Partenaires : COOPEOS, ULg, VUB, Engie, INERIS, CRM

Particle emission from three small scale biomass combustion appliances for heating and energy production were measured in laboratory conditions and in-field. Several biomass materials including the byproducts of forestry and pellets of wood and non-wood origin were used as fuels. Measurements were focused on particle number concentrations as this factor is considered to be potentially hazardous to human health and environment. An elaborated measurement technique using the Electrical Low Pressure Impactor (ELPI+) that can detect particles from 6 nm to 10 µm with 14 size classes of resolution was implicated. The overall concentration of particles in flue gases decreases with decreasing the power of combustion device. However, the emission can significantly vary if the distinct cases are considered. The levels of measured particle concentrations were approximately from 4.4×106 cm-3 to 3.1×108 cm-3. They depended on the sort of fuel, the appliance employed and the regime of combustion. The measurements of the gaseous emissions of main combustion products and the specific components were carried out as well to demonstrate the quality of the combustion and the contamination of the fuel. The study would promote the optimization of exploitation of the biomass heating appliances, improving their emission factors, performance and efficiency.

Cornette, J.F., Coppieters, T., Desagher, D., Annendijck, J., Lepaumier, H., Faniel, N., Dyakov, I., Blondeau, J. and Bram, S., (2020). Influence of the Dilution System and Electrical Low Pressure Impactor Performance on Particulate Emission Measurements from a Medium-scale Biomass Boiler. Aerosol and Air Quality Research, 20, 499-519.
Dyakov, I.V., Bergmans, B., Idczak, F., Blondeau, J., Bram, S., Cornette, J., Coppieters, T., Contino, F., Mertens, J., Breulet H. (2021). Intercomparative Measurements of Particle Emission from Biomass Pellet Boiler with Portable and Stationary Dilution Devices. Accepted for publication in Aerosol Science and Technology. Cornette, J., Dyakov, I., Plissart, P., F. Bourgois, F., Bram, S., Blondeau, J. (2020), Circular Economy in Conjunction with Wood Chip Boiler equipped with Electrostatic Filter. Presentation at 9th ETP Annual Conference, 2020 (online).

Dyakov, I.V., Bergmans, B., Idczak, F., Breulet H. Characterisation of Particle Emissions from Domestic Boiler Burning Different Biomass Pellets. Poster at CEM 2018 Budapest Hungary.

- KU Leuven - recent publications:

1. Murugadoss, S., Godderis, L., Ghosh, M., Hoet, P.H. (2021). Assessing the Toxicological Relevance of Nanomaterial Agglomerates and Aggregates Using Realistic Exposure In Vitro. Nanomaterials, 11 (7), Art.No. 1793. doi: 10.3390/nano11071793 Open Access
2. Murugadoss, S., Vinković Vrček, I., Pem, B., Jagiello, K., Judzinska, B., Sosnowska, A., Martens, M., Willighagen, E.L., Puzyn, T., Dusinska, M., Cimpan, M.R., Fessard, V., Hoet, P.H. (2021). A strategy towards the generation of testable adverse outcome pathways for nanomaterials. ALTEX. doi: 10.14573/altex.2102191
3. Murugadoss, S., Das, N., Godderis, L., Mast, J., Hoet, P.H., Ghosh, M. (2021). Identifying nanodescriptors to predict the toxicity of nanomaterials: a case study on titanium dioxide. Environmental Science-Nano, 8 (2), 580-590. doi: 10.1039/D0EN01031F
4. Mülhopt, S., Schlager, C., Berger, M., Murugadoss, S., Hoet, P.H., Krebs, T. with Paur, H-R. (corresp. author), Stapf, D. (corresp. author) (2020). A novel TEM grid sampler for airborne particles to measure the cell culture surface dose. Scientific Reports. doi: 10.1038/s41598-020-65427-w (professional oriented) Open Access
5. Murugadoss, S., Brassinne, F., Sebaihi, N., Petry, J., Cokic, S.M., Van Landuyt, K.L., Godderis, L., Mast, J., Lison, D., Hoet, P.H., van den Brule, S. (2020). Agglomeration of titanium dioxide nanoparticles increases toxicological responses in vitro and in vivo. PARTICLE AND FIBRE TOXICOLOGY, 17 (1), Art.No. ARTN 10. doi: 10.1186/s12989-020-00341-7 Open Access
6. Sironval, V., Scagliarini, V., Murugadoss, S., Tomatis, M., Yakoub, Y., Turci, F., Hoet, P., Lison, D., van den Brule, S. (2020). LiCoO2 particles used in Li-ion batteries induce primary mutagenicity in lung cells via their capacity to generate hydroxyl radicals. PARTICLE AND FIBRE TOXICOLOGY, 17 (1), Art.No. ARTN 6. doi: 10.1186/s12989-020-0338-9 Open Access
7. Murugadoss, S., van den Brule, S., Brassinne, F., Sebaihi, N., Mejia, J., Lucas, S., Petry, J., Goddersi, L., Mast, J., Lison, D., Hoet, P.H. (2020). Is aggregated synthetic amorphous silica toxicologically relevant? PARTICLE AND FIBRE TOXICOLOGY, 17 (1), Art.No. ARTN 1. doi: 10.1186/s12989-019-0331-3 Open Access
8. Murugadoss, S., Lison, D., Godderis, L., Van den Brule, S., Mast, J., Brassinne, F., Sebaihi, N., Hoet, P. (2017). Toxicology of silica nanoparticles: an update. Archives of Toxicology, 91 (9), 2967-3010.

PhD thesis

9. Murugadoss, S., Hoet, P. (sup.), Godderis, L. (cosup.) (2020). Toxicological relevance of nanoparticle agglomerates and aggregates: A step towards a toxicologically relevant definition of nanomaterials. (Copy is available)

11. Experience from stakeholder or public dialogues

COM-DG ENV

In May-June 2021, the Commission performed a targeted stakeholder consultation as the last step in the review of the Commission recommendation 2011/696/EU. Over 130 responses have been received. All responses are available at https://ec.europa.eu/environment/chemicals/nanotech/review_en.htm

Information on the full review process including the summary of responses will be made available in the Commission Staff Working Document, planned for publication by the end of 2021. More details on the results and plans will be presented at NMEG-14 meeting.

12. Any other scientific and technical issue

MSCA-DE

Within the research project "Advanced materials - Thematic conferences: Assessment of needs to act on chemical safety" (interim report available at https://www.umweltbundesamt.de/publikationen/advanced-materials-overview-of-the-field-screening), the third and final thematic conference was executed as online conference on 14 June 2021. The first conference (Dec 2019, UBA Germany) focused on gaining an overview of the heterogenous field of advanced materials. The 2nd conference (executed as two online meetings in June and September 2020) concentrated on (i) approaches to cluster the field advanced materials and approaches to prioritise those to assess their relevance for chemical safety and discussed (ii) challenges of (types of) advanced materials with regard to chemical safety, as well as examples of advanced materials already identified of potential concern for chemical safety and/or circular economy.

Objective of the third thematic conference was the discussion of governance options for advanced materials. For this aim, the German higher federal authorities developed a draft joint perspective ("Risk Governance of Advanced Materials: Consideration from the joint perspective of BAuA, BfR and UBA") which guided through the discussions. Inter alia, the document includes considerations on the application of an early warning system including the identification of "materials of concern", options to improve regulatory readiness with respect to material innovations, and considerations to promote safe and sustainable by design of advanced materials. Furthermore, it highlights the current situation and needs for both preparatory, but also regulatory motivated research and outlines the need for exchanges and mechanisms of interactions with relevant stakeholders.

Based on input from this perspective, areas of discussion at the thematic conference included "(i) early warning and systematic approaches to identify and prioritize advanced materials, (ii) regulatory action needs, and (iii) the application of safe and sustainable-by-design principles. During the conference, these considerations were complemented by presentations and alternative views of different stakeholders. It is intended to consider outcomes and learnings from the conferences for the finalisation of the joint perspective document and transfer it to WPMN to support its future work on advanced materials.

The final project report that summarieses the discussions and conclusions from all the thematic conferences is under finalisation and will be published soon at: https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/research-development-projects

The final version of the German higher federal authorities joint perspective is currently under finalisation and will be published soon at, e.g.: https://www.umweltbundesamt.de/en/publications

13. Classification and labelling

ECHA

In 2020 the Committee for Risk Assessment (RAC) adopted its first opinion addressing the hazardous properties of a nanomaterial substance (the RAC opinion can be accessed from here). RAC concluded that Silanamine (a pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide) should be classified as STOT RE 2 (lungs) (inhalation) and Acute Tox 2 via the inhalation route.

Following discussion at CARACAL-41 on 19 October 2021, only the entry for STOT RE 2 (lungs) (inhalation) has been included in the 18th ATP. The proposed entry for classification as Acute Tox 2 was not included, pending re-evaluation of this

classification by RAC once the report from a mechanistic study commissioned by IND becomes available.

14. EUON

ECHA
The following studies have been concluded/are ongoing:
- A study on waste, recycling and the circular economy for nanomaterials (concluded- expected publication by Nov. 2021)
- An assessment of the current market for nanomaterials in the EU (ongoing- expected conclusion by November 2021)
- Study on (bio)degradation and safe by design for nanomaterials (ongoing- expected conclusion Q2 2022)

COM-DG Grow
COM and ECHA are close to concluding a new Contribution Agreement thereby providing ECHA with resources to continue the operation of the EU Nanomaterials Observatory in the coming years.

PETA
PETA Science Consortium International has published the EUON Nanopinion "Using non-animal approaches for the assessment of nanomaterial".

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

EFSA
Suggestion of topic for a future NMEG meeting, in case a substance is of interest for both ECHA and EFSA: 'Assessments on food additives that may contain a fraction of nanoparticles and require nano specific considerations for their safety assessments'.

16.None of the above

ECHA
At SETAC Europe 32nd annual meeting (Copenhagen and online, 15-19 May 2022), a session on nanomaterials has been proposed: '*Environmental Risk Assessment for nanomaterials – challenges and solutions for knowledge transfer and active dialogue between research and regulation*'. The aim is to provide a transparent communication platform bringing scientists, regulators, and industry together to discuss recent scientific developments in experimental and in silico characterisation, environmental hazard and exposure assessment of nanomaterials. The session will only be accepted if enough abstracts are received. The chairs for the session are Amaia Rodriguez Ruiz (ECHA), Claus Svendsen (CEH, UK, scientific partner), and Kai Paul (Blue Frog Scientific, Consultancy). We warmly welcome you to **submit abstracts** before **1st December 2021** and to share this information in your network.

PETA
As a result of Brexit, the Germany-based PETA Science Consortium International e.V. was founded to carry forward the work of the UK-based PETA International Science Consortium Ltd. Any work from December 2020 onwards was carried out as PETA Science Consortium International e.V.
PETA Science Consortium International co-organised a series of three webinars on "Using In Silico and In Vitro Approaches for Next Generation Risk Assessment of Potential Respiratory Toxicants" with the US Environmental Protection Agency

(EPA), Unilever, and Syngenta. The series included presentations and group discussions with experts from industry, academia, and regulatory agencies and can be accessed here: https://www.thepsci.eu/inhalation-webinars/
In collaboration with the U.S. EPA, Bergeson & Campbell, Corteva Agriscience, and Japan Tobacco International, PETA Science Consortium International is co-editing a special issue titled Chemical Testing Using New Approach Methodologies (NAMs) for the journal Frontiers in in vitro Toxicology. This special issue will include case study examples of NAMs that may be applied to regulatory decision-making.