

13th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-13) 29-30 March 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 1 March 2021, 247 registration dossiers covering nanomaterials were successfully submitted, resulting in a total of 81 substances covering nanoforms for which registration dossiers have been submitted following the updated REACH requirements. A total number of the registration updates that have been rejected following incompleteness is six. Out of these, five registrations were successfully updated to cover nanoforms. At the moment of compiling this information a number of dossiers are still pending the second attempt to pass the technical completeness check (TCC). Currently above 80% of submissions pass the first TCC attempt and above 90% pass the second TCC.

A new manual *How to prepare registration dossiers covering nanoforms* was published in October 2020. The manual introduces the basic concepts that are specific to the registration of nanoforms and provides the user with detailed and practical instructions on how to fill in the relevant IUCLID sections. https://echa.europa.eu/documents/10162/22308542/howto prepare reg dossier

<u>nttps://ecna.europa.eu/documents/10162/22308542/nowto_prepare_reg_dossie</u> <u>s_nano_en.pdf/5e994573-6bf9-7040-054e-7ab753bd7fd6</u>

2. Substance identity (Annex VI characterisation)

ASO - ECOPA

Distinction between different form of nano materials plus considerations on smart nanomaterials (also applies to 3. Phys-chem characterisation of nanomaterials).

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

MSCA – DE

The German REACH-CLP-Biocide helpdesk published a document summarizing Q&As relevant for the registration of nanoforms of a substance. The idea of the document was to put separate questions into a broader context. The document is available in German only:

https://www.baua.de/DE/Angebote/Publikationen/Fokus/Stoffe-in-Nanoform.pdf?___blob=publicationFile&v=4

MSCA – BE

Federal Public Service Economy – National Standards – Nanometrology laboratory

Achievements during the last 3 years:

The Belgian National Metrology Institute SMD of the FPS Economy has a laboratory dedicated to nanometrology. The laboratory is active on the



development and validation of instruments for the metrological characterization of nanomaterials.

New services:

The laboratory is accredited ISO17025 for the calibration of the diameter and size distribution of spherical nanoparticles and Step-Height standards using Atomic Force Microscopy.

R&D developments:

The nanometrology laboratory is developing a platform to characterize the size and concentration of nanoparticles dispersed in liquid and complex media (gel, cream,...). This characterization platform is composed of a Field Flow Fractionation-based separation technique, alongside light scattering and scanning probe microscopy-based measurement techniques.

Research projects:

The nanometrology laboratory participates in 3 projects of the European Metrology Programme for Innovation and Research (EMPIR):

- 3DNano (2016-2019): Traceable three-dimensional nanometrology. The objective of this project was the realization of traceable calibration services for three-dimensional nanometrology. We contributed to the development and the characterization of new reference materials.

- nPSize (2018-2021): Improved traceability chain of nanoparticle size measurements. This project aims to develop methods, reference materials and modelling to improve the traceability chain, comparability and compatibility of nanoparticle size measurements.

- EMUE (2018-2021): Examples of Measurement Uncertainty Evaluation. This project provides a comprehensive set of worked examples illustrating how the principles of measurement uncertainty can support and give added value to normative and related practices. In particular our goal is to provide metrological traceability for nanoscale measurements and support instrument' users with comprehensive guidance on uncertainty estimation.

At the national level, the nanometrology laboratory has contributed to Belspo To2DeNano project: Towards a toxicologically relevant definition of nanomaterials. The main objective of To2DeNano project was to provide scientific insight on how to consider manufactured nanomaterials size distribution and agglomeration/aggregation status in a regulatory context, with regard to health hazard / toxicity.

Normalization:

The laboratory is active as expert in ISO/TC229 – CEN/TC352 Nanotechnologies and ISO/TC201 Surface chemical analysis.

4. Hazard evaluation – human health

ASO – ECOPA

Necessity to confirm similarity with bulk material and identification of missing information. [this item also applies to 5. Hazard evaluation – Environment]

MSCA – SE

[see 5. Hazard evaluation – environment]

MSCA – NL

In 2020, also two review papers relevant for risk assessment of titanium dioxide (TiO2) were published. First, a review by RIVM on the 'Mechanism of action of



TiO2: recommendations to reduce uncertainties related to carcinogenic potential' (<u>10.1146/annurev-pharmtox-101419-100049</u>),, in which adverse outcome pathways are considered and the available information on each of the key events is presented. A second review, by RIVM and WFSR, on 'Possible effects of TiO2 particles on human liver, intestinal tissue, spleen and kidney after oral exposure' (<u>10.1080/17435390.2020.1778809</u>) aims to better understand the contradictions reported in adverse effects of TiO2 and whether such effects can be expected at conditions relevant for humans. This review combines clinical and tissue histopathological observations, adverse outcome and pathways, concentrations from oral animal studies, as well as concentrations in human post mortem organs that were recently published by RIVM and WFSR (10.1080/17435390.2020.1718232).

5. Hazard evaluation – environment

MSCA – SE

Biocidal product regulation:

SE has submitted a CLH-dossier for elemental silver in September 2020, where the toxicological data to a major part is based on studies on nanosilver. We have suggested 2 different entries to Annex VI, one for silver and one for nanosilver. For human health the prosed classification is identical for silver and nanosilver, whereas the proposals for the environmental classification are different, due to different solubility of the forms. If this is accepted by RAC, it would be the first metal which has a separate nano-classification. The public consultation of the dossier has just been finalised.

SE furthermore is the evaluating competent authority (eCA) for the evaluation of a biocidal active substance: "Silver adsorbed on silicon dioxide (as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale)". The evaluation is parked at the moment due to the request for more data.

[this item also applies to 4. Hazard evaluation – human health]

6. Read-across and grouping for nanomaterials

MSCA – NL

The main goal of the EU project GRACIOUS (<u>www.h2020gracious.eu</u>) is to generate a science-based framework to enable practical application of grouping and read-across of nanomaterials. The project has developed a draft framework that has been presented at a workshop at the OECD and discussed with regulatory (ECHA, EFSA, OECD delegations), industrial and academic stakeholders. The comments were used to adapt the framework (which has recently been published in NanoToday; doi: 10.1016/j.nantod.2020.100941) and to target further research. The project has continued to seek input from stakeholders to ensure that the framework effectively meets the needs of both regulators and industry. The GRACIOUS Framework provides (examples of) scientific hypotheses identifying endpoints relevant to grouping and read across. The use of integrated approaches to testing and assessment (IATAs) facilitate effective data gathering to justify the grouping and read across. Application of the Framework will allow movement away from the case-by-case risk assessment paradigm, thereby improving the efficiency of risk analysis and decision making for safer design of quality nanomaterials. The project will finish in September 2021 and current activities mainly focus on finalising the blueprint of the Framework and development of an accompanying guidance document. Methods for assessing the similarity between nanomaterials are being developed. Examples to showcase grouping and read across of nanomaterials are in



development. RIVM is a main partner in this project, as work package lead and playing a crucial role in the development of the Framework and engagement of stakeholders.

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

MSCA – NL

Commissioned by ECHA, RIVM and Triskelion B.V. conducted a literature study aimed to identify experimental and material related factors determining the dermal penetration and absorption of nanomaterials used in consumer products and occupational settings. In general, it was concluded that dermal absorption is at most very low for the nanomaterials investigated in the studies. Rodent skin studies were considered not very relevant, due to substantial differences in skin between rodents and human and lack of knowledge on how this affects skin penetration. The authors recommend to use ex vivo studies with human or porcine skin to evaluate dermal absorption of nanomaterials. Standardised study protocols, including full characterisation of nanomaterials, are needed to conclude on nanomaterials related factors that determine dermal absorption. The report is available at the European Union Observatory for Nanomaterials (euon.echa.europa.eu/web/euon/reports)

8. Guidance or good practice documents for registrants and stakeholders

ECHA

Regarding the Guidance appendices R7 a, b and c under revisions for HH, PC and ENV endpoints for nanomaterials:

- For the updated **HH** guidance, the PEG cross-check consultation ended in March 2021 and the next step is the consultation of Committees, before consultation of CARACAL. The publication of the updated guidance is foreseen in Q3/2021. ECHA wants to thank the 29 PEG members that represented DG-ENV, DG-Grow, EFSA, JRC, member states (DE, DK, IT, LV, MT, NL, NO, PL, PT and SE), industry associations (CEFIC, ETRMA, Eurocolour, Eurometaux, FECC, ECETOC, EuPC, FEPA, European Cement Association, SMEunited) and NGOs (ECOPA, EEB, EUROTOX, PETA).

- The **PC** and **ENV** guidance update process started in March 2021. Granulometry, Dustiness but also dissolution, dispersion and any other advances in fate and ecotoxicology testing of nanoforms will be reviewed.

9. Relevant new research projects or strategies on nanomaterials

MSCA -SE

The Swedish Foundation for Strategic Environmental Research (MISTRA) funded the MISTRA Environmental Nanosafety program from 2014 until 2018. The consortium was comprised of 5 Swedish universities (Chalmers Technical University, Gothenburg University, Lund University, Royal Institute of Technology, and Karolinska Institutet) and one industrial partner (AkzoNobel), and it was coordinated by Chalmers Technical University. MISTRA has now decided to fund a 4-year extension of the Environmental Nanosafety program. The second phase of the program was launched in 2019 and the consortium is coordinated by Lund University. In addition to the aforementioned partners, the Technical University of Denmark (DTU) also participates in the consortium. Furthermore, four industry partners are now involved in the program: Höganäs AB, Nouryon, SYSAV, and Tetra Pak. The program represents the largest nanosafety/nanotoxicology project in Sweden with a total budget of 90 MSEK. The aim is to develop research, knowledge and best practices on risks associated with nanomaterials and their



impact on the environment. There is a strong synergy with the nanosafety platform, SweNanoSafe, through the expert panel of the platform.

The MISTRA Environmental Nanosafety project hosted an online workshop in May 2020 together with the national strategic innovation platform, SIO Grafen. Fifty participants representing different stakeholders including academia and industry took part in the discussions on nanomaterials in the work environment, nanomaterial regulations, etc. The vision, according to SIO Grafen, is that Sweden is among the world's top ten countries in deploying graphene on an industrial scale by 2030. Notably, Chalmers University of Technology in Gothenburg coordinates the Future Emerging Technologies (FET) Graphene Flagship, a 10-year (2013-2023) project with 150 academic and industrial partners across Europe. Karolinska Institutet (Stockholm) has participated in the work package on health and environment (human and ecotoxicology) since the Flagship project started.

SweNanoSafe (see heading 12) monitors national participation in international nanosafety projects, including the H2020 project Gov4Nano, with close collaborations with two other risk governance projects funded under the same call, i.e., RiskGONE and NanoRIGO, all focused on risk governance, and NanoSolveIT, a project that is focused on nano-informatics and the development of IATAs. SweNanoSafe, in partnership with the Institute of Environmental Medicine, also contributes to the planning of the Partnership for the Assessment of Risk from Chemicals (PARC) in Horizon Europe. In addition to these projects belonging to the nanosafety cluster, Sweden participates in the nanomedicine-focused project, BIORIMA ('biomaterial risk management') and coordinates the hazard assessment of nanobiomaterials (NBMs) in the latter project. The project aims to develop an integrated risk management framework for NBMs used in advanced therapy medicinal products (ATMP) and medical devices (MD). BIORIMA partners are currently planning the next international nanotoxicology conference with GRACIOUS and PATROLS.

MSCA – BE 1) KU Leuven:

Project BR/154/A4/To2DeNano – Towards a toxicologically relevant definition of nanomaterials Coordinator(s): Peter H. Hoet and Lode Godderis (KU LEUVEN) Partners: - KU LEUVEN - Peter H.Hoet, Lode Godderis and Sivakumar Murugadoss (KU Leuven) - Sciensano - Jan Mast and Frederic Brassinne - UCL - Dominique Lison and Sybille van den Brule - FPS Economy - Jasmine Petry and Noham Sebaihi Context: The current European Union (EU) definition of manufactured nanomaterial (MNM) covers "particles, in an unbound state, or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm"(EU 2011). This definition was proposed only in the context of regulatory purposes but the toxicological relevance applomerates and appregates (AA) has not been assessed in detail.

Objective: The main objective of To2DeNano project was to provide scientific insight on how to consider MNM size distribution and agglomeration/aggregation status in a regulatory context, with regard to hazard.



Major conclusion: (1) Agglomeration and aggregation of MNMs influence their toxicity/biological activity. (2) Agglomeration and aggregation did not seem to mitigate the toxicological activity of MNMs and hence the AA are toxicologically relevant, and should be included in the definition of MNMs (3) We also conclude that the 100 nm threshold in the current EU definition may not be appropriate to classify MNM with regard to hazard.

Publications

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.

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.

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.

Murugadoss, S., Das, N., Lison, D., 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. doi: 10.1039/d0en01031f.

2) IMEC :

Imec will participate in the PEROSH (Partnership for European Research in Occupational Safety and Health) project "Training on emerging risks in R&D and production of new and advanced materials and nanomaterials: providing systematic approaches to deal with uncertainties". The project leverages on the expertise of a vibrant professional community from both the industry and academia. The objective of the project is to review and compare risk management and communication approaches of European occupational health and safety organizations in dealing with emerging risks in R&D and production of advanced materials. For two years, the project plans to produce generic and harmonized training modules for businesses involved in R&D and production of advanced materials and nanomaterials. The project is coordinated by the Italian Workers Compensation Authority (INAIL) and includes 10 partnering organizations from 7 European countries.

3) VITO: Nano-achievements:

Unit Sustainable Health:

• We will run a case study this year about in vitro inhalation testing of nano TiO2. The TiO2 nanomaterial is obtained from the JRC nanomaterials database (JRCNM01005a (NM-105) nanoTiO2). The cases study is funded by "Dienst Dierenwelzijn" from the Departement Omgeving of the Flemish Government.

Unit Sustainable Chemistry:

• spICPMS as a starting point for analysis of different nanoparticles

o FWO senior postdoc fellowship functionalized nanoparticles – bringing characterization to the next level using a complementary analytical toolkit @UGent and VITO (2019-2022)

o Supporting projects whit spICPMS analysis



 MAGDEx: properties of micro and nano-particles synthesized through GDEx
npSCOPE: physico-chemical characterization of nanoparticles as such and incorporated into biological tissue.

- NanoCarb: analysis of glyco-nanoparticles for applications in advanced nanomedicine

- Strategic Initiative Materials (SIM), recyclable materials MaRes program, Get-A-Met project

• Novel ICP-MS method on the analysis of microplastic

O MS4Plastic - Mass spectrometry for the characterization of micro- and nanoplastics: H2020-MSCA-IF-2020 – Marie Skłodowska-Curie actions (MSCA) Individual fellowship - start 2022

Unit Sustainable Materials

• 3D printed nano-particle bearing materials for chemistry and energy applications

MSCA – NL

In January 2021 the new EU project SUNSHINE has started. SUNSHINE is the acronym for Safe and sUstainable by desigN Strategies for HIgh performance multi-component NanomatErials. The main goal of this project is to develop and implement Safe & Sustainable by Design (S&SbD) strategies for products enabled by multi-component (advanced) nanomaterials (MCNM), including high aspectratio nanomaterials (HARNs). To this end, the project will generate essential knowledge, tools and data on the exposure, hazard and functionality characteristics of these materials, especially those arising from their unique properties and interactions (e.g. mixture effects due to the multi-component nature of the materials). To facilitate the uptake and utilisation of the S&SbD strategies by industry, especially SMEs, the project will deliver them as part of a user-friendly e-infrastructure designed to: (1) facilitate collaboration and information exchange between actors along nanotechnology supply chains (developers, producers, downstream users) to promote the development and implementation of S&SbD strategies for MCNM-based materials, products and processes; (2) support SMEs and large industries in the selection and application of simple, robust and cost-effective experimental, modelling and grouping/readacross approaches to acquire/generate the data needed to test the effectiveness of the S&SbD strategies; (3) enable risk-benefit analysis of the S&SbD-modified materials and products at each stage of the innovation process to ensure that they are safe for the human health and the environment without compromising their technical and/or commercial probability of success The S&SbD strategies that are effective in reducing the risks from MCNMs, while retaining product performance and economic viability, will be proposed for full scale industrial implementation. In addition, the project will contribute to Regulatory Preparedness by providing recommendations on improvement and adaptation of the current regulatory hazard, exposure and risk assessment guidance (e.g. REACH, Biocides, Consumer Products, Food and Feed, Medical Technologies) and standard guidelines (OECD, ISO, CEN) for MCNMs. RIVM is coordinating a work package on regulatory preparedness where the concept of S&SbD will be developed for MCNMs. This includes actively participating in building the safe innovation approach (SIA) system of people

participating in building the safe innovation approach (SIA) system of people (academia, industry, regulatory risk assessors). The SIA combines S&SbD with Regulatory Preparedness. The SIA system of people will identify roles and conditions to get the SIA for MCNMs to work in practice. Other RIVM activities are in testing methods (environmental fate, in vitro and in vivo tox.), modelling (environmental fate modelling, SimpleBox4Nano), and grouping and read-across (i.e. development of integrated approaches to testing and assessment (IATAs) to generate the data needed for hypothesis-driven grouping of MCNMs).



10. Experience from stakeholder or public dialogues

MSCA -SE

SweNanoSafe is a national cooperation platform for nanosafety. The assignment stems from the government report "Safe development – a national action plan for the safe use and handling of nanomaterials" (SOU 2013:70) which, among other things, proposed measures for communication and collaboration. Through the regulatory letter to the Swedish Chemicals Agency (KemI) from the Ministry of the Environment and Energy (Government Decision 2019-12-19), Karolinska Institutet is allocated funds to "further develop a platform for safe handling of nanomaterials that can contribute to achieving the environmental quality goal of a non-toxic environment and protect human health".

The NanoSafety platform consists of a Steering group, and Expert Panel, a Research network, an Education network, a project group and a web site (Swenanosafe.se).

The overall objectives are:

1. Knowledge building, knowledge transfer and communication, as well as facilitating collaboration between academia, authorities, business and organizations in the nanosafety area through a joint forum. 2. Identify and highlight obstacles to the safe handling of nanomaterials and work to ensure that the obstacles are remedied by proposing solutions and actively contributing to improvement work.

The platforms does not: conduct research, perform risk assessments or perform tasks that are within the framework of each authority's assignment regarding nanomaterials.

Recent activities including coordinating networks, holding workshops and public dialogues, and publishing assessments and other reports, concern (see also heading 11):

- Proposals for national measures for safe use, handling and development of nanomaterials. SweNanoSafe Report 2020:3 (also in Swedish 2020:2)
- Functional and Safe Nanomaterials Collaboration between Academia and Industry. SweNanoSafe Report 2020:1
- Nanomaterials in the construction industry a life cycle perspective. SweNanoSafe Report 2019:2
- National Workshop on Nanosafety Research & Education. SweNanoSafe Report 2019:1

Ongoing:

- Three workshops during autumn 2020 on the need for education among different target groups. To be published a report plus a roadmap for continued activities to develop new training.
- Nanomaterials in the building/construction area: To be published

11. Any other scientific and technical issue

MSCA – NL

Advanced materials are increasingly being recognized as drivers for innovations for the European market and are thought to play an important role in the societal transitions towards a circular economy and the energy transition. The topic of advanced materials is being explored in the Netherlands, aiming at ways for timely anticipation on developments within such material science. With the aim of facilitating the safe and sustainable design, production, use and end-of-life



treatment of advanced materials, RIVM has initiated activities towards a systematic identification of emerging issues of advanced nano-based materials. The exploration consists of working on a signalling approach to systematically gather information relevant for decision making, and gain experience by working on case advanced materials. RIVM developed a stepwise approach towards identifying the specific characteristics that potentially may develop into future risks or into sustainability issues of advanced materials. The stepwise approach has been applied to case studies. A scientific publication is prepared presenting the signalling approach and some case studies. The OECD WPMN included Advanced Materials in its Programme of Work 2021-2024. The OECD Ad hoc Group on Advanced Materials is chaired by Germany and co-chaired by JRC and the Netherlands. The core group of chairs and co-chairs is preparing a work plan to address the challenges of advanced materials in line with the different areas of work of the WPMN. The work plan will be discussed with the ad-hoc group.

The OECD project Moving Towards a Safer Innovation Approach' for More Sustainable Nanomaterials and Nano-enabled Products: Overview of existing risk assessment tools and frameworks, and their applicability in industrial innovations was led by France, the Netherlands and BIAC. The objectives of this project were: 1) to develop working descriptions for a safer innovation approach concept, including the Safer-by-Design concept; and

2) to develop inventories of risk assessment tools and frameworks to

a) help industry implement a 'Safer Innovation Approach' for NMs and nanoenabled products and

b) to help regulators anticipate regulatory challenges posed by innovations such as NMs and nano-enabled products.

The final report was published in December 2020 as No. 96 in the OECD Series on the Safety of Manufactured Nanomaterials.

12. Classification and labelling

ECHA

In 2020 the Committee for Risk Assessment (RAC) adopted its first opinion addressing the hazardous properties of a nanomaterial substance. RAC concluded that Silanamine (a pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide) be classified as STOT RE 2 (lungs) (inhalation) and Acute Tox 2 via the inhalation route. The proposed entry has been included in the 18th ATP. The RAC opinion and related documents can be accessed from <u>Silanamine,... - Registry of CLH intentions until outcome - ECHA (europa.eu)</u>

13. None of the above

MSCA - DE

Advanced Materials – 3rd Thematic Conference Advanced Materials – Recommendations for action on chemical safety A way forward to meet challenges posed by Advanced Materials

June 14, 2021 at the Umweltforum (Pufendorfstraße 11, 10249 Berlin) and online (hybrid conference)

The numerous types and combinations of so-called advanced materials, as well as their (future) applications and the potentially existing chemical safety concerns have been subject to discussions at three international conferences, which are part of a research project commissioned by the German Environment Agency (UBA) and financed by the German Ministry of the Environment, Nature Protection



and Nuclear Safety (BMU). At the first conference in December 2019 several presenters from national authorities, the ECHA and academia illustrated the versatility of advanced material types and their applications.

At the first part of the second (online) conference, a proposal to structure the field of advanced materials, which was developed in the scope of the German research project, was presented. Additionally, a set of criteria and indicators to screen advanced materials in order to identify those, which would require further assessment was proposed and discussed.

The second part of the second (online) conference was dedicated to identifying the (types of) challenges of advanced materials for ensuring chemical safety and a circular economy. Examples of advanced materials were presented highlighting which aspects might complicate (regulatory) risk assessment and management

either due to an inadequate legislative framework and/or a lack of suitable (risk) assessment instruments.

The aim of this last conference is to conclude from the prior discussions in terms of what challenges should have priority in the authorities' work and which options for actions would be suitable to ensure chemical safety.

The conference is addressed to stakeholders from policy, science, industry and NGOs who are dealing withregulatory implications of advanced materials in the context of chemical safety and circular economy.

MSCA - DE

Update UBA's publication:

Nanomaterials in the Environment - Current state of knowledge and regulations on chemical safety; Recommendations of the German Environment Agency

Nanomaterials can have different or new properties in comparison with conventional chemicals and materials. Meanwhile the substance legislations was partially adapted by nano-specific provisions; for parts however adaptation needs still exist. As a result, specific environmental risks cannot be fully described and assessed as well as appropriate measures to minimize the risks cannot be taken. Emphasis of this paper is to outline the adopted as well as necessary further development of chemicals regulations for nanomaterials with regard to the environment from UBA's perspective.

Updated Version of November 2020 can be found at: <u>https://www.umweltbundesamt.de/publikationen/nanomaterials-in-the-environment</u>

MSCA - SE

For information, here are the links to the Commission communication of October 2020 on Chemicals Strategy for Sustainability: <u>CSS</u> (and <u>annex</u>). It is noted that this communication mentions the 'need to use coherent terminology, in particular to define chemicals (e.g. nanomaterials)', the 'review the definition of nanomaterial', the 'reattribution of technical and scientific work' and the concept of "One Substance One Assessment" (OSOA).

MSCA -BE

Belgian Nanoregistry:

A report on the nanomaterials put on the Belgian market is published every year on the website of our registry:

https://www.health.belgium.be/en/environment/chemical-

<u>substances/nanomaterials/register</u>. Currently only the annual reports for years 2016, 2017 and 2018 are available. The report from 2019 will soon be published, while the 2020 report is expected around mid-2021.

Furthermore, BE CA ordered an in-depth analysis assessing data quality of the dossiers submitted during the trade years 2017 and 2018. The outcomes of this



study (obtained results, conclusions and recommendations) together with a poster presenting a summary of the 2017 results will be made available on the nanoregistry website.

BE CA is continuously working on the improvement of our nanoregistry.

15. Suggestion of discussion topic for next NMEG meeting (NMEG-14)

COM – DG GROW

- progress in standardisation of test methods.

- alignment of nanomaterial definitions.