Final minutes of the open session

of the 11th meeting

# of ECHA–NanoMaterials Expert Group (ECHA-NMEG-11)

Time: 3-4 May 2018

Place: ECHA, Margot Wallström conference room

Participants: Representatives from the Member States Competent Authorities (MSCA), European Commission (COM: DG Growth (DG Grow), DG Environment (DG ENV), DG Joint Research Centre (DG JRC)), ECHA-NMEG Accredited Stakeholder Observers (ASO) and ECHA participated in the meeting.

The participant list is in Annex 1.

Meeting documents: Presentations from the meeting are available on the dedicated CIRCABC site (https://webgate.ec.europa.eu/echa-scircabc)

I. Summary record of the proceedings

1. Introduction

The 11th meeting of the ECHA NanoMaterial Expert Group (NMEG) was held on 3-4 May 2018. The previous meeting was held on 7-8 November 2017. This one-day event was mostly an open session (lunch to lunch), except for a 1-hour closed-session at the end of the first day.

The purpose of the NMEG meeting is to discuss scientific and technical issues relating to the implementation of REACH, CLP and BPR for nanomaterials. This meeting was specifically focused on updates on the EU Observatory for Nanomaterials (EUON), on the revision of REACH Annexes and status of the definition of nanomaterials, on guidance development needs and on ISO nanotechnology activities related to OECD work, as well as on the GHS Sub Committee work on nanomaterial classification and the suggested contribution from the members of the NMEG. Additionally, the status of the draft OECD TG on dissolution in aqueous media and the environmental hazard and risk of nanomaterials grouping concepts and proof of principle were discussed during the second day.

A closed session (restricted to MSCAs, COM DGs, and ECHA) was held to discuss the lessons learnt from the substance evaluation on ZnO. A brief summary of the non-confidential discussion held during the closed session was presented in the open session for the Accredited Stakeholder Organizations (ASOs) at the beginning of the second day (AP 8).

A short overview of the presentations and discussion points in the group per agenda item are given below.

2. The 11th ECHA Nanomaterials Expert Group meeting

AP 1. Welcome and introduction

The chair of the meeting, Frank Le Curieux (ECHA), welcomed the participants to the 11th Nanomaterials Expert Group meeting. New participants were introduced to the group. The

draft agenda shared with the group in advance of the meeting was agreed.

The provisional dates for the next meetings were announced: the next meetings will be held on **6-7 Nov 2018** (NMEG-12) and **7-8 may 2019** (NMEG-13).

AP 2. Adoption of minutes of NMEG-10

The chair outlined that the updated version (after commenting period) of the draft minutes from the last meeting were shared on the dedicated S-CIRCABC site. No additional comment was received from NMEG members. The minutes of NMEG-10 are thus considered as adopted and will be published on the NMEG page of the ECHA website.[1]

AP 3. Tour de table:

The aim of the tour de table document is to share information on nanomaterials and to to propose potential topics for future discussion within the NMEG. Some colleagues made oral statements:

1. The representative from NL-CA reported on the policy conference organised by the Dutch Ministry of Infrastructure and Water Management together with RIVM under the title "Future approach to nanomaterials", held in the Netherlands on the 17-18 April 2018. Several representatives from EU and associated countries, COM, OECD, other international bodies and stakeholders attended the meeting. The discussions were based on the outcome of NANoREG and ProSAFE projects with special focus on the recommendations of the ProSAFE white paper. Several initiatives were identified and alliances have been created that will jointly take responsibility to implement these action plans. The report will be most probably available before the summer.
2. The RO-CA representative informed on the Nanosafety Regional Workshop for the Central and Eastern European Region. The event was organised in Lodz (Poland) on the 22-23 February 2018 by UNITAR in partnership with OECD and supported by the Polish Government. Summary of the workshop can be found in the following link: http://www.unitar.org/cwm/sites/unitar.org.cwm/files/uploads/meeting_summary_nanosafety_cee_final.pdf
3. SE-CA colleague presented the Nordic Chemical Group project (NKG) information campaign on REACH-relevant regulation for nanomaterials. The leading countries are NO, FI, DK and SE. As explained with the support of a short presentation, the project aims to develop a simple and easily usable web-tool (eNM-tool) to explain the requirements in the EU chemical legislation for nanomaterial. The intention of the nanomaterial (NM) module in eNM is to give an introduction on NMs and how to handle a registration for NMs. This would help small and middle sized companies dealing with NFs. The tool is comparable with the existing eREACH tool. As for the timelines, it will be released not later than the end of 2018. An update is foreseen before 1 January 2020.

AP 4. An update on the development of the EUON

ECHA gave a presentation on the latest developments on the European Union Observatory for Nanomaterials (EUON). The aim of the observatory is to provide objective and reliable information on the markets and safety of the nanomaterials in the EU. This will be achieved by collecting and analysing information from a wide variety of existing data sources, carrying out additional studies to fulfil identified knowledge gaps, and communicating on the collected information and studies to the public.

[1] https://echa.europa.eu/regulations/nanomaterials/nanomaterials-expert-group

The EUON was setup in June 2017 in the form of a website containing information from existing sources. Recently the content has been supplemented by cross-linking the nanomaterials notified under the Regulation on cosmetics products, notified using the Cosmetic Products Notification Portal (CPNP) with the REACH substances database. Also a microsite dedicated to information for consumers was launched in March 2018.

In the next phase new content concerning different areas e.g. benefits of nanomaterials, different regulations applicable for nanomaterials, and detailed information on nanomaterials in the workplace will be included. Two databases, NanoData and eNanoMapper, will be also part of the observatory. In addition results of two external studies, i.e. 'Literature study of risks in the use of well-known pigments in consumer products and for workers' and 'Parameters and data sources used to produce market studies and their relevance and reliability', will be published. The participants of the NMEG-11 were strongly encouraged to give feedback on EUON and to suggest new content and improvements. One of the (newly added) sections of the Tour-de-table document can be used for that purpose.

In the response to the questions after the presentation it was outlined that it was not foreseen that any pre-announcement would be given to the stakeholders before the next update of the EUON website. Concerning next external studies, there are some ideas for the topics of the studies including e.g. a study on next generation nanomaterials. It was pointed out that initiatives similar to EUON are also taken at national level in different member states. This kind of additional information was welcomed by ECHA and links to/from EUON can be created to these initiatives. Finally, a wish to better communicate the timelines of the future studies where involvement of industry needed was expressed.

AP 5a. Revision of REACH Annexes and definition of nanomaterials

DG ENV presented to the NMEG the progress on the revision of the REACH Annexes and definition of nanomaterials, and explained the major qualitative milestones achieved in comparison to the updates presented in previous NMEG. In a nutshell:

- The proposal on the REACH annexes was voted in the REACH Committee on the 26th April 2018. The vote was unanimous.
- The review of the COM recommendation on the definition of nanomaterial (2011/696/EU) is still in progress and the public consultation is upcoming.

The adopted text for the revised REACH annexes for nanomaterials is available on the Commission website:

- text of the updated REACH to address nanoforms of substances.
- text of the updated Annexes I, III,VI, VII, VIII, IX, X, XI, and XII.

A recap of the main steps and an overview of the timelines was provided. The current proposal will be under scrutiny by the Council and the Parliament for 3 months following the vote at the REACH Committee. The mandatory application of all the implemented changes, which would include the update of all the existing dossiers, will start on 1 January 2020. The update of the existing dossier will assure that all the provisions in these changes are respected.

The original COM proposal was made available in October 2017 for public consultation. Based on the outcome of the consultation, the COM has modified the Annexes. The original proposal included:

- The introduction of nanoform (NF) concept and providing specific requirements in the form of NF characterisation.
- The introduction of new information requirements: dustiness, modified toxicokinetic requirements to give more weight to the generation of information where necessary (before compilation of information and additional physico-chemical properties information requirement introduced under Annex VIII of REACH).
- Not introduced: Changes into Annex II (Safety Data Sheets) are not taken now as changes will be introduced jointly with GHS changes.

The changes to the initial COM proposal:

- Explicit consideration to the generation of data on dissolution rate in water, environment and biological media (under water solubility 7.7).
- To consider dispersion stability and generate new data following the new OECD TG on dispersion when K_{ow} is not applicable.
- To ensure that there is data on acute toxicity. Now for NFs the Inhalation route is considered a default route under Annex VII instead of oral route. Mandatory also for low tonnages.
- For NFs long term ecotoxicological tests are foreseen also when there is low dissolution rate (not only low water solubility).
- There will be new information requirements under Annex VIII instead of in Annex IX (as previously proposed).

The final part of the presentation outlined the series of challenges in front:

- the implementation of the definition where the JRC is involved developing guidance
- the characterisation and identification of uses of NFs;
- the definition of sets
- the development of guidance and test guidelines for grouping and read across approaches for nanoforms.

Concerning the review of the definition of nanomaterial, there will be a 12 weeks public consultation. Based on the analyses of the feedback provided, COM will consider if it is necessary to modify the existing recommendation and if so which elements. Following Commission's adoption of the revised definition, it will be then taken up by different regulations following their own process. For REACH, this will require a committee procedure and analysis of any potential impact on the implementation of the changes.

In response to a question on the timeline for the public consultation on the definition of nanomaterials, DG ENV stated that the consultation is foreseen to be launched before the summer.

AP 5b. Guidance development needs

ECHA gave an update on the main guidance development needs triggered by the positive vote on the revised REACH Annexes for NM at the REACH Committee (26 April 2018), and its future entry into application (1 January 2020). The presentation also included an overview of the Malta initiative. Other guidance needs were out of the scope of this presentation.

It was outlined that one of the main update needs was the conversion of the Practical Guide 'How to prepare registration dossiers that cover nanoforms: best practices' into a guidance document. In addition, the general sections will require some modifications to cover for the changes in the terminology (e.g. inclusion of the term "set of nanoforms"). It will also be necessary to amend the sections regarding size, shape and surface chemistry and to develop a new section on specific surface area (SSA) to make the guidance adequate to the requirements of Annex VI. Additional explanations on Annex III and general issues on information requirements (context and application) are also foreseen.

ECHA encouraged the members of the NMEG to provide their feedback. An informal discussion on technical issues could be scheduled before the publication of any draft to agree on the approach before the corresponding PEG consultation.

For the guidance on grouping and read across, only the section on identification of nanoforms needs to be changed. ECHA suggested to have a fast track procedure or a written consultation for this update.

The guidance on information requirements for physico-chemical, environmental and human health endpoints will also need to be updated. Relevant to the three parts is the need to make clear the waiving limitations in the new Annexes. Additionally, the specific changes for each sections were outlined:

- Physico-chemical: this section will require the revision of the data requirements for granulometry, the addition of an explanation on the dissolution rate, for the octanol/water coefficient limitations need to be included, as well as a section on dustiness (new requirement).
- Environment: there will be a revised section on bioaccumulation and it will be made clear that the requirements on dissolution, dispersion and transformation are mandatory (currently a recommendation).
- Human Health: only minor alignments are foreseen as most endpoints were already covered (with the exception of toxicokinetics and indirect genotoxicity to some extent).

The presentation also covered the needs and OECD developments, outlining the new obligations concerning the CSA and DU-CSR. In short, the need to cover all the nanoforms in the assessment; the need of a justification to demonstrate safety via read across from one form to another; and the use of a multimetric approach in the assessment.

Update on the Malta initiative

The Malta initiative is a European effort (initiated by Germany) to speed up the revision of the OECD test guidelines and guidance documents for nanomaterials. The overview presented the projects already approved as SPSF (Standard Project Submission Form), one on in vitro genotoxicity (lead by JRC) and a new GD to TG 305 Bioaccumulation in fish (lead by Spain and UK), as well as the draft SPSFs submitted recently to the WNT on particle size and size distribution (lead by Germany) and on (volume) specific surface area (lead by JRC). The presentation concluded with an overview of the projects launched by OECD WPNM.

In response to the questions after the presentation, it was outlined that for major updates ECHA will follow the formal procedure, i.e. PEG discussion. MSCAs and stakeholders will have to nominate experts for physico-chemical, environmental and human health endpoints. The timelines for the next PEG are still unknown. Concerning the questions raised on guidance on toxicokinetics, ECHA explained that the principles to be covered had not yet been decided. This will be discussed internally and consult with NMEG members if needed. Additionally, it was clarified that the recently submitted draft SPSFs of the TG are no longer drafts and that these were taken up as projects in the OECD WNT workplan (list to be updated).

AP 6. Update on ISO nanotechnology activities related to OECD work (e.g. Malta initiative)

Dr Denis Koltsov, Chair of ISO technical committee on nanotechnologies (ISO/TC229 (nanotechnologies)[2], gave an update on ISO nanotechnology activities related to or relevant for OECD work. He gave a short introduction of his background, his areas of responsibility and ISO/CEN committees in which he contributes.

He began by giving an overview of global nanotechnology standardization trends and listed the ISO, CEN, IEC and ASTM committees for nanotechnology. He outlined how these different bodies interact with each other (e.g. liaisons, joint working groups, enhanced liaison, the Vienna agreement between CEN and ISO) and with the OECD.

He gave an overview of the working groups in ISO/TC229 and the scope of the work covering

[2] International Organization for Standardization, Technical Committee 229 https://www.iso.org/committee/381983.html

standardisation in the field of nanotechnologies that includes either or both of the following:

1. Understanding and control of matter and processes at the nanoscale, typically, but not exclusively, below 100 nanometres in one or more dimensions where the onset of size-dependent phenomena usually enables novel applications,
2. Utilizing the properties of nanoscale materials that differ from the properties of individual atoms, molecules, and bulk matter, to create improved materials, devices, and systems that exploit these new properties.

Its specific tasks include developing standards for: terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulation; and science-based health, safety, and environmental practices.

He outlined that there are 64 published ISO standards under the direct responsibility of the committee and he has 40 ISO standards under development under its direct responsibility. It has 35 participating members, 16 observing members and 150-200 expert attendance at plenaries. He gave an outline of the purposes of the different standards and how standards can be accessed. He illustrated how standards rest on international guidelines and national regulatory schemes.

He gave an overview of the work program relating to physico-chemical, environmental and human health endpoints and the working groups for each standard/project. In the last part of his presentation, he gave an outline of a selection of standards under development that may be of interest:

- **TS 80004-6** (Revision of ISO/TS 80004-6:2013): Nanotechnologies -- Vocabulary -- Part 6: Nano-object characterization
- **ISO/NP TS 23302** Nanotechnologies -- Guidance on measurands for characterising nano-objects and materials that contain them
- **TS 19590:2017** Nanotechnologies -- Size distribution and concentration of inorganic nanoparticles in aqueous media via single particle inductively coupled plasma mass spectrometry
- **TS 21362** Nanotechnologies -- Application of field flow fractionation for characterization of nanomaterial contents
- **ISO 21363** Nanotechnologies -- Protocol for particle size distribution by transmission electron microscopy
- **ISO 19749** Determination of size and size distribution of nano-objects by scanning electron microscopy
- **TS 21361** Nanotechnologies -- Quantification of airborne nanoscale carbon black and amorphous silica in a manufacturing environment
- **PWI 21357** Nanotechnologies -- Measurement of average nanoparticle size and assessment of agglomeration state by static multiple light scattering (SMLS) in concentrated media
- **TR 21386** Nanotechnologies -- Considerations for the measurement of nano-objects, and their aggregates and agglomerates (NOAA) in the environment
- **ISO 9277:2010** Determination of the specific surface area of solids by gas adsorption -- BET method
- **ISO 22412:2017** Particle size analysis -- Dynamic light scattering (DLS)
- **ISO 19430:2016** Particle size analysis -- Particle tracking analysis (PTA) method

In response to questions after the presentation, he outlined that ISO standards are not regulatory documents and that ISO works with all stakeholders. He outlined the hierarchy of ISO documents: a technical report is informative; technical specifications give a prescriptive set of measurement (normative) to be performed to demonstrate fulfilment of specifications; international standards are normative with an extra dimension that it is self-regulation by industry. He outlined that TC229 has not published international standards to date and that three are currently under development.

He outlined that the standard that refers to "products and applications" refers to biosensor applications. There was some discussion on how to participate in TC229 and the importance of tracking all comments received

AP 7. Lessons learned from Substance Evaluation on ZnO – Closed session

[AP 7 was a closed session – see separate minutes]

AP 8. Brief report for ASOs on closed session

The representative from DE-CA informed the ASO of the purpose and outcome of the closed session (AP 7, restricted to MSCAs, COM DGs, and ECHA).

The intention of the presentation was to introduce the strategy used for the substance evaluation of ZnO, to share the lessons learnt and to explain the background of the forthcoming draft decision. It was highlighted that the intention of the discussion at the NMEG was not to discuss any details of the draft decision, neither to modify the draft decision. It was also outlined that all information is currently confidential and therefore, there are not files available with the presentation. The draft decision on the evaluation of ZnO requesting further information is to be sent to the Registrant(s) in June 2018.

In brief, in October 2016 a questionnaire was send to all 120 registrants of ZnO. The lead registrants as well as 6 identified "nano-registrants" were invited to a meeting. The aim of the meeting was to understand the individual registrant manufactures/imports. The discussions were helpful in preparing the draft decision. In March 2017 the CoRAP list was published and the final submission of the dossier to ECHA was in March 2018.

As lessons learned it was highlighted that:
- Substance evaluations of nanomaterials under REACH are more complex compared to "non-nanoforms", especially when coating is considered,
- The regulatory uncertainty and burden has been considered when designing the draft decision, taking into account adequacy and proportionality of the information request.

The briefing, although limited, was welcome by the representatives from the ASOs.

During the questions session, the following was noted:
- With regard to IUCLID 6, it was discussed whether the fields concerning nanoforms help to provide a clear picture of the material used by the applicants. In IUCLID 6 the type of particle and information on coatings needs to be included.
- Concerning the question whether the dossier was descriptive enough, DE-CA clarified that compared to other dossier they observed some progress. The nanofoms as well as test substances were reported. The dossier also contained information on coatings but not very detailed. However, DE-CA was not sure if the information was enough for the purposes of the evaluation.
- DE-CA also confirmed that the request in the draft decision concerns the nanoforms. Additionally, DE-CA explained that one of the dossiers contained sufficient information. That was the reasons why this submitter was not invited to the pre-meetings.
- In a more general discussion, it was also suggested that it should be possible to make reference within a dossier to information contained in other dossiers, in order to avoid the need of making huge documents.

AP 9. Dissolution rate in aqueous media

In this presentation DE-UBA gave an overview on the current draft OECD test guideline (TG) on dissolution rate in aqueous environmental media.

In 2003, OECD discussed the need to have information on dispersion stability and

transformation for nanomaterials to support the test strategies regarding environmental fate and behaviour. In November 2013, Project 3.10: New TG on dissolution rate of nanomaterials in aquatic environment was submitted to the OECD WNT. The project was approved in 2014 and discussed at the Expert Meetings held in Vienna (2014) and Dessau (2015). The first draft of the TG on dissolution was commented by the WNT Expert Group in April 2017. The revised draft was sent to OECD WNT in April 2018.

The current draft TG includes a batch test including two stages:

i. "Screening dissolution test" to identify nanomaterials that fully dissolve within 24h, and
ii. 48h "Full dissolution test" for nanomaterials which do not or only partly dissolve after 24h -> determination of dissolution rate.

The TG aims to provide a consistent standard method for determining the dissolution dynamics of > 30 nm spherical metal and metal oxide nanomaterials dispersed in an aqueous medium. It will be validated using spherical metal and metal oxide nanomaterials <50nm. It is also expected that the TG may be applicable to smaller nanomaterials and the general principles of the TG will be applicable to materials other than metals and metal oxides.

The TG also provides information on the test design, *i.e* concentration ranges, and reference materials, preparation of stock dispersion and test medium to be selected.

As compared to the previous draft TG, there seems to be a considerable improvement with regards to the ability to be validated. The TG is less complex and it is more focused on the actual endpoint. However, there are still some aspects concerning the scope and the requirements that need to be clarified (e.g. the 50 nm NM for validation versus "TG consistent for NM> 30 nm).

The presentation was closed with the summary of the next steps and activities. The following steps in the process will include the discussion of the draft by the WNT/WPMN Expert Group on environmental fate of nanomaterials and the call for participating laboratories, to join the round robin test. Additionally, since this TG is thematically linked with other ongoing or planned TGs/GDs, at the Technical Expert Meeting in August 2018 hosted by Germany, an exchange with the members of the other projects is foreseen to align approaches. Besides, OECD WNT plans to host a meeting with TG/GD leads and the WNT Expert Group on Environmental Fate of NM and WNT Expert Group on Ecotoxicity of NM early October 2018.

The discussion after the presentation focused on several questions raised by the participants concerning the origin of the size limit of 30 nm, on the possibility of using different test media and on the concept of dissolution 'rate'. It was noted that the reviewed REACH Annexes refer to dissolution rate while the test guideline under preparation addresses the dissolution, but not specifically the dissolution rate. These issues still need to be addressed by the WNT Expert Group. On a question on the suitability of the 48 h dissolution time, DE-CA explained that in their opinion it is more interesting what happens with the material that is not dissolved within 24 h. Concerning the analytical method, the TG is not very concrete on the method to be used. There are several examples but not details on how the analytical measurement needs to be performed. This issue could be addressed during the commenting period.

AP 10. Environmental hazard and risk of nanomaterials: grouping concepts and proof of principle

During the meeting a new screening approach was presented by Dr. Kerstin Hund-Rinke from Fraunhofer Institute for Molecular Biology and Applied Ecology IME, Germany. The aim was to relate physico-chemical properties of different nanomaterials to their ecotoxicity. For this a comprehensive characterization of NMs in aquatic test media was performed, as well as aquatic short-term tests (algae, daphnids, fish embryo: OECD 201, 202, 236) and terrestrial tests (microflora, earthworm: ISO 15689, OECD 222).

25 subtypes of nanomaterials were used, 8 ion releasingNMs and 17 non-ion releasing NMs, which differed in solubility, hydrophobicity, charge, zeta-potential, crystalline structure, morphology, size, surface charge and surface modification.

It was observed that the solubility, reactivity, zeta-potential, morphology and size seem to be relevant; while agglomeration and surface area were less relevant. It was noted that the influence of zeta-potential was less obvious.

Regarding sensitivity of test organisms and tests, they observed that algae and daphnids showed to be much more sensitive than fish embryos. This difference was discussed to possibly be due to the fish embryo physiology (it has a protective chorion), as well as at that stage the embryos do not ingest from the media nor have the gills developed.

Regarding toxicity to algae, they realised that although the OECD TG allows to use different algae species, when they exposed 2 different species of algae to the nanomaterials (*Rhaphidocelis subcaptitata* and *Desmodemus subspicatus*), similar results with the least toxic ions were observed, but significant differences on toxicity were found for non- ion releasing nanomaterials. They concluded that the use of one species of algae should be preferred.

In general, they observed a higher toxicity to the aquatic organisms of the ion releasing nanomaterials when compared to the non-ion releasing nanomaterials. They further found indications that attachment efficiency to (at least) algae is important for non-toxic-ion releasing NMs. Morphology was also observed to be of high relevance, where algae was very sensitive for many NMs (spherical nanomaterials and some tested fibres), while Daphnids were very sensitive for all tested fibres.

In soil ecotoxicity testing, they concluded that soil properties seem to reduce the influence of the various physico-chemical properties of the NMs, and concluded that they only found two hazard groups, ion releasing and non-ion releasing nanomaterials.

They further used these findings to group the nanomaterial for a hazard profile based on physico-chemical properties (*i.e* in aquatic organisms based on solubility, reactivity and morphology; in soil organisms based on solubility only).

A similar approach was taken for exposure, which was divided in release and fate groups. Release groups were determined by production volume, use of strictly controlled conditions, release into the environment as free nanomaterial and aging (slow release to the environment from articles). Fate grouping was also included in exposure, where for aquatic compartment (water and sediment) chemical transformation and transformation for dissolution were taken into account, while for terrestrial compartment besides the previous two, agglomeration and mobility were also included.
Finally, the hazard groups were compared to the exposure groups in order to provide a tentative risk, based on a traffic light coloured matrix (high, medium and low).

It was concluded that the grouping approach presented, can be used as a screening tool to aid in prioritising the identification of *a priori* highest concern NMs. As part of the discussion it was noted that this is a qualitative tool and cannot be used to replace regulatory decisions or strategies.

Moreover, it was also concluded that this risk grouping does not indicate which parameters are responsible for risk, and that a detailed analysis is required.

During the discussion the followings were also raised:

- Short-term toxicity studies were favoured in order to have a larger toxicity database. The main aim was not to provide hazard information as such, but to find correlations

on physico-chemical parameters and possible effects, and maybe some mode of action.
- Long-term toxicity tests performed with *Eisenia fetida* (OECD 222) showed to have much less sensitivity than the tested microorganisms with the NMs tested in this study.
- Dispersion stability is measured in distilled water, while the testing media have a completely different chemistry, and thus a different dispersion stability. Due to this difference, the dispersion stability alone would be difficult to be used as a column II adaptation for aquatic ecotoxicity testing.

More information at:
- Final report to UBA-project (project no. 3714 67 417 0)[3]
- Material characterization: data determined in project sponsored by German Environment Agency (project no. 3714 67 417 0)
- Ecotoxicity: data determined in project sponsored by German Environment Agency (project no. 3714 67 417 0)
- Further results are to be published.

AP 11a. GHS Sub Committee work on nanomaterial classification & suggested contribution from members of ECHA NMEG – proposal for NMEG comments – rev. 1

The presentation by TUKES (FI-CA) provided the background to the UN GHS activity on the applicability GHS criteria to nanomaterials, which she noted had progressed slowly, and the envisaged role of the NMEG in this work. The presentation focused on the comments received from NMEG delegates on the proposed work topics and the questions posed to the NMEG in the follow-up to the paper presented at NMEG 10 concerning the involvement of NMEG in this work.

The proposed work topics were (1) Case studies on classification of NMs and (2) A literature review on the applicability of GHS criteria to NMs. Overall, based on the responses topic (1) was considered to provide a good starting point for the work.

On the main question "Do you support the idea that NMEG contribute to the GHS work in general?", there was general support from 4 experts but another 4 had doubts regarding whether this was within the scope of NMEG work and/or available resources. FI-CA responded that the topic was within the scope of the NMEG, since the terms of reference of the committee indicated that "*The mandate of the ECHA-NMEG is to provide informal advice on scientific and technical issues regarding implementation of REACH, CLP and Biocidal Products Regulations (BPR) in relation to nanomaterials, such as: […] Any other scientific and technical issues on nanomaterials related to REACH, CLP and BPR*". The responses to the more specific questions relating to this work are summarised in the presentation slides.

FI-CA concluded by thanking the members for their constructive contributions. She also referred to funding which had been obtained by FI along with other Nordic countries with which a consultant has been engaged to contribute to aspects of this work (the subject of Agenda Item 11b).

AP 11b. Nordic Chemical Group project: CLP Regulation and nanomaterial classification (presentation of screening phase, discussion of future work)

Poul Bo Larsen (PBL) (DHI, Environment and Toxicology, Denmark) presented the screening phase and discussion of future work of the Nordic Chemical Group project on the CLP Regulation and nanomaterial classification.

[3] Considerations about the relationship of nanomaterial's physical-chemical properties and aquatic toxicity for the purpose of grouping. March 2017.
https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2017-11-07_texte_102-2017_gruppierung-nanomaterialien.pdf

PBL described the scope of the project as supporting the work of the GHS Sub-committee to review the applicability of the GHS to manufactured nanomaterials taking into account the progress of international scientific work. The objectives included a classification exercise primarily using data covering the last 5-10 years on single walled carbon nanotubes (SWCNT), silver, silicon dioxide and zinc oxide which had been generated within the OECD nanomaterial testing programme and the NanoReg project, but also data from the Nanosafety cluster and from REACH registration dossiers. For the screening phase, PBL pointed to a recent relevant WHO document "*Which hazard category should specific nanomaterials or groups of nanomaterials be assigned to and how*?" (Lee et al, 2017[4]), which examined all OECD test programme data with a view to applying the current GHS criteria for classification on nanomaterials. Although this document did not address a number of issues, including discussion of the data in relation to the classification criteria, appropriateness of the criteria for nanomaterials for the classification of nanomaterials or the extent to which classification should apply to all forms of the nanomaterials, it was considered valuable for obtaining an overview of data regarding relevant end-points for each of the nanomaterials listed above. Based on the paper by Lee et al. (2017) and REACH registration dossiers for the selected substances, the DHI proposal was to consider in-depth assessments against the GHS criteria for specific target organ toxicity after repeated exposure (STOT RE) for all four substances, and in addition skin sensitisation for silver and mutagenicity and eye irritation for the SWCNT.

PBL indicated that the draft report would be submitted to the Nordic Steering group members by the end of August 2018 and the final report by the end of September.

During the discussion, the following issues were noted:

- How is the quality of the inhalation toxicity data taken into account? Testing in accordance with new guidelines (such as the recently revised OECD guideline for repeated dose toxicity via the inhalation route) is more likely to provide useful information.
- Although the testing program was not aimed at generating classification information *per se*, at this screening level DHI would examine the studies for each chosen endpoint to see whether they match the classification criteria. Different types of data may be used to make an overall weight of evidence determination.
- Only the skin sensitisation (and not respiratory sensitisation) data for silver would be looked at, although in the WHO report respiratory and skin sensitisation were considered together.
- Since there are only limited data sources and few endpoints the limitations would also need to be described.
- It was also suggested that the reporting group of the WHO might be contacted for extra information on issues identified.
- Preconditions for classification are intrinsic and not extrinsic properties and it needs to be specified on the label which route applies (as well as other information). There are potentially several difficulties and adjustment for these may require adding notes to the classification. The project can be used to focus on certain types of effects where needed but it is unlikely that it will provide definitive answers to all the issues.
- In general discussion on whether the criteria were fit for classification of NM due to their particulate nature, it was noted that:
    - Scientific groups should be asked to discuss whether the findings are only particle effects and not NM effects. This is the subject of discussion at the Commission.
    - Some subtle effects were seen at low concentrations, hence perhaps these could be markers for toxicity.
    - Can intratracheal instillation data also be used for classification?
    - Experts should discuss the relevance of the overload phenomenon to classification

[4] Lee et al., Which hazard category should specific nanomaterials or groups of nanomaterials be assigned to and how? WHO 2017. http://apps.who.int/iris/bitstream/handle/10665/259682/WHO-FWC-IHE-17.4-eng.pdf;jsessionid=9EAFDA0D6F9874B8DC72BE9053F9BE2C?sequence=1

- Classification provides no additional information, but the question applies more broadly than only to NM.
- It is difficult to see the relevance of classification as there is uncertainty on characterisation and measurement of test materials as well as contradictory results. Should the uncertainty of the data be considered using e.g. weighting factors?
- Classification may not apply to all NMs. In future there will be a focus more on endpoints where justifications for classification are seen.
- NMs have a range of different solubilities, hence particle toxicity is only part of the story.
- The project will not look at classification of mixtures at all. In the UNGHS activity, the focus for now is on substances.

The chairman thanked the presenters for the presentations and the members for the discussion.

AP 12. Update on NMEG rolling plan – Wrap-up and conclusions

The chair provided an update on the rolling action plan and reminded the topics that are currently on the rolling plan for 2018-2019:

- Guidance development:
  - JRC is in the lead for the development of the guidance related to the EU definition for nanomaterial. Depending on the progress, this topic may be presented at NMEG-12 meeting (6-7 Nov 2018).
  - ECHA is starting to organise the guidance update following the adoption of the revised REACH annexes for nanomaterials. This topics should be presented/discussed at NMEG-12 meeting. Moreover, a specific workshop may be organised back-to-back with NMEG-12 in order to allow additional discussion.
- Revision of OECD TGs/GDs (Malta initiative): the NMEG will provide scientific and technical input on common generic issues to ensure regulatory relevance and applicability of TGs/GDs. Depending on the progress, the possible workshop organised back-to-back with NMEG-12 may also address the Malta initiative.
- Discussion on specific NM cases: Examples on approaches for hazard assessment (incl. grouping and read across) for nanomaterials may be presented at NMEG-12.
- Upcoming CLH proposals and Biocides dossiers involving nanomaterials are monitored.
- Learning from research projects is planned to be discussed in collaboration with the Nano Safety Cluster (possibly at NMEG-12).
- Review of applicability of GHS/CLP criteria for NMs: the outcome of the Nordic Chemical Group project on CLP and nanomaterial classification may be discussed at NMEG-12.
- Several administrative issues will have to be handled by the end of 2018: the review of NMEG mandate, the renewal of nomination for NMEG experts for 2019-2020.

ECHA will distribute a draft rolling plan on 1 June 2018, at the same time as draft minutes of NMEG-11, and the NMEG members will be invited to provide comments by 2nd July 2018.

END OF ECHA-NMEG-11 MEETING

II. List of participants of open session of NMEG-11

Surname	First Name	Country/Organization
Aitasalo	Tuomas	ECHA
Alessandrelli	Maria	Italy
Amenta	Valeria	ECHA
Andersen	Sjur	Norway
Baricic	Peter	DG GROW
Bleeker	Eric A.J.	Netherlands
Boisen	Anne	Denmark
Bonev	Chavdar	Bulgaria
Bonnomet	Vincent	ECHA
Carlander	David	NiA
Constantin	Camelia	ECHA
Deydier	Laurence	ECHA
Dobrak-Van Berlo	Agnieszka	Belgium
Dumitru	Claudia Sorina	Romania
Einola	Juha	Finland
Ekokoski	Elina	Finland
Esposito	Dania	Italy
Falck	Ghita	ECHA
Gaidukovs	Sergejs	Latvia
Helminen	Ulla	ECHA
Herzberg	Frank	Germany
Holmqvist	Jenny	ECHA
Hoy	Simon	United Kingdom
Hund-Rinke	Kerstin	IME
Jacquet	Cyril	ECHA
Jomini	Stéphane	France
Jurgelėnė	Živilė	Lithuania
Kapanen	Anu	ECHA
Karjalainen	Ari	ECHA
Kinzl	Maximilian	Austria
Kobe	Andrej	DG Environment
Koltsov	Denis	ISO
Krop	Hildo	ETUI
Larsen	Poul Bo	DHI
Le Curieux	Frank	ECHA
Lehtilä	Reko	ECHA
Leinonen	Riitta	Finland

Mendonça	Elsa	Portugal
Moore	Gregory	Sweden
Nahmias	Marco	ETRMA
Navas	José M	Spain
Quinn	Bernadette	ECHA
Rasmussen	Kirsten	DG Joint Research Centre
Rodriguez Ruiz	Amaia	ECHA
Rodriguez Unamuno	Virginia	ECHA
Schwirn	Kathrin	Germany
Serrano Ramon	Blanca	Cefic
Spirlet	Christine	Eurometaux
Stoddart	Gerlinda	PISC
Sumrein	Abdelqader	ECHA
Tanarro	Celia	ECHA
Vest Christophersen	Daniel	DHI
Vomastkova	Milada	Czech Republic
Weiss	Angelina	Germany
Wiench	Karin	ECETOC

By WEBEX/phone connection:

During the Agenda points in plenary of Day 1 and 2:

Reinhilde Schoonjans (EFSA)

Apologies:

Josje Arts (CEPE), Elanor Ball (UK), Felix Carvalho (EUROTOX), Angela Ivask (EE), Mojca Kos Durjava (SI), Jodie Melbourne (PISC), Reinhilde Schoonjans (EFSA), Bogdan Walkowiak (PL).

III. Final Agenda

11th meeting of the ECHA Nanomaterials Expert Group (ECHA-NMEG-11)
3-4 May 2018, Helsinki, Finland
MARGOT WALLSTRÖM CONFERENCE ROOM

Final agenda
Chair: Frank Le Curieux, Evaluation 3, ECHA

DAY 1 – Thursday 3 May 2018		
13.30	Registration (30 min)	
14.00	**1. Welcome and introduction** (10 min)	Chair, all
14.10	**2. Adoption of minutes of NMEG-10** (10 min)	Chair, all
14.20	**3. Tour de table** (10 min)	All
14.30	**4. An update on the development of the EUON** (30 min)	Abdel Sumrein, ECHA E2
15.00	Coffee Break (30 min)	
15.30	**5a. Revision of REACH Annexes and definition of nanomaterials** (20 min)	Andrej Kobe, DG ENV
	5b. Guidance development needs to address the updated REACH Annexes for nanomaterials (25 min)	Celia Tanarro, ECHA A2
16.15	**6. Update on ISO nanotechnology activities related to OECD work (e.g. Malta project)** (40 min)	Denis Koltsov, ISO
17.00	**7. [CLOSED SESSION] Lessons learned from Substance Evaluation on ZnO** (1 h)	DE-CA
18.00	*Reception*	
19.00	**End of day 1 of NMEG-11 meeting**	
DAY 2 – Friday 4 May 2018		
09.00	**8. Brief report for ASOs on closed session** (15 min)	Angelina Weiss, DE-CA
09.15	**9. Dissolution rate in aqueous media** (45 min)	Kathrin Schwirn, UBA, Germany Kerstin Hund-Rinke, IME, Germany
10.00	**10. Environmental hazard and risk of nanomaterials: grouping concepts and proof of principle** (1 h)	
11.00	Coffee Break (30 min)	
11.30	**11a. GHS Sub Committee work on nanomaterial classification & suggested contribution from members of ECHA NMEG – proposal for NMEG comments – rev. 1** (10 min)	Elina Ekokoski, FI-CA
11.40	**11b. Nordic Chemical Group project: CLP Regulation and nanomaterial classification (presentation of screening phase, discussion of future work)** (50 min)	Poul Bo Larsen & Daniel Vest Christophersen DHI, Environment and Toxicology, Denmark
12.30	**12. Update on NMEG rolling plan – Wrap-up and conclusions** *(20 min)*	Chair
13.00	*Lunch*	
14.00	**End of ECHA-NMEG-11 meeting**	

IV. Main Action Points from NMEG-10 (7-8 November 2017)

CONCLUSIONS / DISCUSSIONS	ACTIONS REQUESTED
AP 2 – Minutes of NMEG-10	
NMEG adopted the draft minutes as provided for the meeting.	**ECHA** to upload final version of the minutes on NMEG- S-CIRCABC and on ECHA NMEG website without undue delay.
AP 12 – NMEG Rolling Plan update for 2018-20209	
NMEG took note of the main elements of updated NMEG Rolling Plan for 2018 by ECHA.	**ECHA** to upload on NMEG S-CIRCABC, for comments, the updated NMEG rolling plan following the NMEG-11 meeting.
AP 12 – Wrap-up and conclusion	
NMEG chair wrapped up the main action points of NMEG-11 at the meeting.	**ECHA** to include the main action points from NMEG-11 meeting in the draft minutes.