Minutes

of the 8th meeting

# of ECHA–NanoMaterial Working Group (ECHA-NMWG-8)

Time: 08-09 November 2016

Place: ECHA, Margot Wallström conference room

Participants: Representatives from the Member States Competent Authorities (MSCA), European Commission (DG Growth (DG Grow), DG Environment (DG ENV), DG Joint Research Centre (DG JRC)), ECHA-NMWG Accredited Stakeholders Observers (ASO), EFSA 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://circabc.europa.eu/)

1. Introduction

The 8th meeting of the ECHA NanoMaterial Working Group (NMWG) was held on the 8-9th Nov 2016. The previous meeting was held on the 11-12th Nov 2015. The purpose of this one day and half meeting was to share updates on developments relating to the implementation of REACH, CLP and BPR for nanomaterials since the previous meeting. This included updates on the ongoing guidance updates for nanomaterials, the status of the revisions of the REACH annexes for nanomaterials, the revision of the EU recommendation for the definition of nanomaterial, the EU observatory for nanomaterials (EU-ON), updates on OECD WPMN activities, substance evaluation learnings and the CLP Regulation and Nanomaterials.

The implementation of recommendations from an audit on the working group by the ECHA internal auditor were also discussed and in particular, proposals to change the name of the working group to an expert group (in line with other ECHA expert groups) and to have more information in the public domain on the working of the group and the participants. One proposal from the audit is to make the meeting minutes public. The meeting minutes below have been drafted with this recommendation in mind.

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

2. The 8th ECHA Nanomaterials Working Group meeting

AP 1. Welcome and introduction

Frank Le Curieux (ECHA) the chair of the NWMG opened the 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:

- 2017: 16-17 May and 7-8 Nov
- 2018: 15-16 May and 6-7 Nov

A reminder was given on the conflict of interest implementation for the WG.

AP2. Minutes from the 7th meeting and Tour de Table

Minutes from the 7th meeting: The chair outlined that draft minutes from the last meeting were shared on 18 Dec 2015. Comments received were taken into account and the final version in the CIRCABC folder (follow-up) in Q1 2016. In the absence of any further input, they are considered as final.

Tour de table: The chair outlined that the aim of the tour de Table document was to share relevant information and possibly identify topics for future discussion. Many contributions were received both for the May – June 2016 document and also for the October document. Both are available in the CIRCABC folder and everyone is invited to read them.

The group was invited by the chair to share any other updates:

Updates from MSCA

- updates were given on EU ProSafe Project[1] and the joint meeting with NANoREG and the OECD to be held on the 29th Nov-1st Dec 2016 in Paris. This will be followed by an expert group meeting to be held in March 2017 in the Netherlands to discuss findings of the EU ProSafe Project, including the 2016 Paris meeting.

Other updates from ECHA:

- Board of Appeal decisions[2] for 4 of the Appeals against dossier evaluation final decisions that concerned nanomaterials are now available (these were discussed as a separate agenda point).
- Proposal for harmonized classification for titanium dioxide received many comments in the public consultation[3]
- A nanomaterial[4] has recently received active substance approval under the Biocidal Products regulation

AP 3. Update on NMWG organisation

The chair gave an update on the NMWG organization in terms of mandate and the recommendations from an internal audit on ECHA expert groups. It was outlined that the **following actions** are foreseen under the **current mandate** of the group

[1] http://www.h2020-prosafe.eu/
[2] More information on ECHA Board of Appeal decisions can be found here: https://echa.europa.eu/about-us/who-we-are/board-of-appeal
[3] Link to the comments received during the public consultation can be found here: https://echa.europa.eu/documents/10162/4fd87a5d-e671-43e4-a3b8-30e51a723107
[4] This approval was presented at the NMWG-8 meeting as the first for a nanomaterial, but it is actually the second:
- first approval for a nanomaterial biocide on 23 April 2014 for "synthetic amorphous silicon dioxide described as wet silica", http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0408&from=EN)
- recent approval (11 October 2016) of the Biocidal Products Committee was for "pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated", https://echa.europa.eu/documents/10162/0fdc6131-fc99-4b77-828c-4601724fb4ea

- Update of the NMWG mandate
- Renewal of NMWG representatives (launch a new expression of interest among accredited stakeholders)

The chair gave an outline of the main changes to the mandate. These were summarized as the change in the name for the group, to make a clearer link between ECHA and NMWG work plans, to remove outdated text, to list members on a dedicated page on the ECHA website, to review the mandate every 2 years. A draft of the updated mandate will be sent to NWMG and CARACAL representatives for their comments.

Nominations of experts for 2017-2018 will be launched by the end of 2016 for the period Jan 2017-Dec 2018. One permanent expert is foreseen to ensure continuity and consistency. Auxiliary experts may be appointed for the duration of the nomination or on ad-hoc basis.

Actions following recommendation from the internal audit
The chair outlined that in line with a Commission decision[5], an audit of all ECHA expert groups was undertaken in Q3 2016. For the NMWG, the auditor made recommendations that would trigger the following actions

1. Communicate yearly the NMWG rolling plan
    - Keep an overview of future and past contributions
    - Set an annual plan for general topics
    - Take the rolling plan into implementation by the group
    - Communicate the rolling plan for 2017
2. Publish list of members on the ECHA website
3. Consider publication of the meeting minutes
4. Change name to NM expert group (consistency with other ECHA EGs)

A dedicated webpage for the nanomaterial expert group would be created where information would be available in the public domain. There was general support from the group for the webpage. It is anticipated to be available in Q1 2017.

The chair outlined proposals for each of these actions.

For (**1**) the chair outlined proposals for the rolling plan and the group was requested to provide comments on the plan and to propose topics for discussion at the next meeting. The proposals focus on the impact the following would have on the implementation of REACH, CLP and BPR:

- Review of EU recommendation for nanomaterial and guidance on methods to identify nanoforms
- Review of REACH annexes (and ECHA guidance)
- Outcome of appeals on ECHA decisions
- Adaptation of OECD test guidelines for nanoforms
- EU observatory for nanomaterials (EU-ON)

Other possible topics
- Exposure and risk assessment for NMs
- Criteria applicable for C&L for NMs

In the discussion, the group made the following additional proposals for consideration

- Relevance of Klimisch scores
- CLP regulation and the ongoing UN GHS actions relating to nanomaterials

[5] Commission Decision C(2016) 3301, "Establishing horizontal rules on the creation and operation of Commission expert groups" 30.05.2016

- Need to ensure that the topics taken up by the group are not already being discussed in other groups (e.g. OECD)
- Focus on implementation issues (i.e. how to take decisions from other groups into implementation)
- Options to include topics from "brain-storming" by the group
- Useful to include topics relating to exposure and risk assessment
- Include case studies

All members of the group were invited to provide comments and proposals in writing.

For (**2**), it was outlined that the action to publish the list of NWMG members would in principle follow other expert groups (i.e. the PBT expert group[6]). The aim would be to publish a list in Q1 2017 after the renewal of expert nominations for 2017-2018. Members having specific concerns that would prevent publication of their names on the website were requested to inform the ECHA secretariat.

In the discussion, requests for clarification were made on how the affiliation of experts from companies that participate for stakeholder groups would be communicated. It was proposed to follow what other ECHA expert groups already do and also to take learnings from other institutions into account.

For (**3**), it was outlined that the action to make the meeting minutes available in the public domain is part of the broader implementation of Commission decision on expert groups aiming at transparency and openness in the workings of these groups.

In the discussion, there was general support for publication of minutes. There was also general agreement that it would be useful to take the learnings from other groups who make their minutes available into account. Representatives from other Agencies and MSCAs volunteered to provide their organizations templates for meeting minutes intended for the public domain.

- Considerations of how to attribute contributions from participants
- Proposals to create 3 broad groups ECHA/MSCA, IND, NGO
- Query whether publication is mandatory according to the COM decision

The chair requested that comments and proposals be provided in writing.

For (**4**), it was outlined that the name would be adapted to follow the format of other ECHA expert groups. The adapted name would be "Nanomaterials Expert Group (NMEG)". There was general agreement that the change of name would not have any significant impact on the work of the group.

AP 4. Update on Nanomaterial Guidance/consultation process

In this "for information" agenda point, ECHA gave an update on the status of the ongoing guidance update process for the four updates relevant for nanomaterials implementation under REACH.
In the discussion, the impact of the recent decision from the BoA[2] relating to the terminology used in the guidance was flagged and it was clarified that this had already been taken into account in the drafting stage. It was noted that these guidance documents refer to the implementation of current REACH for nanomaterials and it was queried how they would be

[6] List of PBT expert group participants available on the ECHA website: https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pbts-and-vpvbs/echas-pbt-expert-group/list-of-pbt-participants

compatible with the revised REACH annexes when they enter into force. It will be assessed whether the guidance is compatible with the revised Annexes and the guidance will be updated if necessary.

AP 5. Ongoing and planned guidance development by EFSA for nanomaterials in agri/food/feed products

A representative from the European Food Safety Agency (EFSA[7]) gave an overview of their work on nanomaterials for agri/food products.

It was outlined that there are 10 panels to provide scientific advice from "farm to fork" and up to 5 panels are potentially involved in risk assessment of nanomaterials. There is a scientific committee (SC), comprising all the chairs of the panels, to provide over-arching guidance. There is a special working group on nano guidance development and this guidance is aimed to supplement existing sector-specific guidance for risk assessment linked to the relevant legal requirements per sector. Two tasks of the working group were summarized:

- 2016-2018 update of the 2011 guidance for human/animal health risk assessment
- 2017-2019 *denovo* development for environmental risk assessment

The current expertise of the working group was outlined. An overview of the input needed for the guidance on human/animal health and cooperation with other organization that have guidance for other uses of nanomaterials was highlighted.

- For novel foods[8], it was outlined no applications are being received as the new legal framework is being implemented.
- For food contact materials[9], applications have been received for engineered nanomaterials. Exposure scenarios consider migration to food. An overview of the EFSA register of questions was given.
- For food additives[10], examples of dossiers under the re-evaluation program were given. It was outlined that size distribution will be requested and there is no cut-off for the nano-fraction in the current regulation. It was highlighted that it can be difficult to know the contribution of nano fractions in products on the market.
- For feed additives[11], it was mentioned that an assessment of bulk material was ongoing and where cooperation with food additives evaluation was established.
- For pesticides[12], it was outlined that EFSA assesses the active ingredients while the formulations are assessed by the member states. Member states have asked EFSA for harmonized guidance on nano-formulated pesticides. This will be included in the guidance updates foreseen for 2016-2019.
- For Contam[13], it was outlined that there is a need for standardization of analytical methods to assess the presence, identity and quantity of micro and nano plastics in sea food. Toxicokinetic and toxicity research is needed.

[7] http://www.efsa.europa.eu/

[8] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance) available at http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2283&from=en

[9] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC available at http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:02004R1935-20090807

[10] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32008R1333

[11] REGULATION (EC) No 1831/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on additives for use in animal nutrition available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32003R1831

[12] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

[13] CONTAM panel https://www.efsa.europa.eu/en/panels/contam

A contract has been outsourced to collect information on nano carriers used in agri/food/feed, and next year also a contract is foreseen to collect information on environmental risk assessment for nanomaterials used in agri/food/feed. Links to the outcomes from a previous contract (systematic literature review 2014[14]) were given.

The link to scientific elements that were provisionally discussed while updating the 2011 EFSA guidance document for risk assessment of nanomaterials were shared[15].

It was outlined that the latest review of the EU recommendation for nanomaterial will be used as the working definition. It was mentioned that still practical limitations for physico-chemical characterization exist. It was outlined that the current safety testing strategy is determined by the extent of exposure and exposure scenarios provide indicators on how to carry out toxicity testing.

The planned activities on guidance updates relating to environmental risk assessment will include physico-chemical properties, environmental fate, and other factors.

In the conclusions, it was reiterated that EFSA covers many regulated use areas and to date little nano-specific data have been submitted. It was highlighted that for guidance development, data and standard methods are needed. For data, EFSA opinions give suggestions to interested parties and give indications to the regulatory relevance of published studies in the scientific literature. For the standards, EFSA is in contact with relevant organisations, such as from DG JRC.

In the discussion, the following were noted

- a proposal was made to include cooperation with EFSA in the NMWG rolling plan discussed under AP3
- Complexity of the process as multiple characterization steps are foreseen
- The legal status of the Plant Protection Products (PPP) guidance being drafted
- Measurement methods and how to quantify nano in products.

The representative outlined that work is ongoing and that cooperation and input are welcome.

AP 6. NAS BoA decision overview

ECHA gave an overview of the recent four BoA decisions for Appeals submitted against final decisions under dossier evaluation[16]. The registration concerned "silicic acid, sodium aluminium salt" (known by the acronym "NAS") and appeals were received from 4 recipients of Annex VI requests relating to substance identification.

In the discussion, the following were noted

- Importance of wording used in decisions and guidance
- What can be learnt from the outcomes and how this group could provide input
- Communication of outcomes
- Discussion on terminology took place during the 7th NMWG meeting.
- PEG process ongoing will ensure endorsement of guidance terminology
- Improvements in reporting options in IUCLID 6

[14] http://www.efsa.europa.eu/en/supporting/pub/621e
[15] http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf
[16] A-008-2015, A-009-2015, A-010-2015, A-011-2015

It was generally appreciated that this agenda point was discussed in an open session so that all members could join the discussion.

AP 7. Update on REACH annex review process and impact assessment

COM gave an update on the current status of the revisions being made to the REACH annexes for nanomaterials. It was outlined that the proposal (proposed changes and the impact assessment report) is ready. The next steps are:

- An inter-service consultation
- Submission for wider discussion (more than one discussion round is possible before adoption) in the REACH committee aiming for the Feb 2017 meeting (earliest date)
- Parallel submission to 60 day WTO notification and a 4 weeks for public feedback, if chosen
- Vote in the REACH committee followed by adoption by the Commission

It was noted that the revisions proposed have been outlined in earlier NMWG meetings and discussed at CASG-nano meetings. CASG-nano is expected to serve as technical support to committee discussions as needed. The revised definition on nanomaterial will be used in the Annexes. In terms of implementation, the changes will not be mandatory for the June 2018 deadline and the exact deadline is to be decided. Technical support for implementation is being encouraged prior to the deadline.

In the discussion the following was addressed:

- Date of entry into force
- Timing of the vote for the REACH committee
- Timeline for implementation and factors that may affect it
- Implementation of the revised definition
- Notification to the World Trade Organisation (WTO).

AP 8. Update on review of EC recommendation for definition of nanomaterials – Plan for guidance

COM gave an update on the documentation development to support the revised recommendation for definition for nanomaterial. It was clarified that the objective was not to change the current scope but rather to clarify the terms and facilitate implementation. The main elements of change to the definition were summarized. At the request of COM, DG JRC will prepare technical guidance documents to facilitate the implementation of the definition. This will be in the form of two technical reports, one concurrent with the adoption of the revised recommendation and one ca. 12 months after this. The exact timelines are dependent on the adoption of the revised recommendation.

The provisional roadmap was outlined

- Draft revised definition finalised Nov-Dec 2016
- Public consultation Nov-Dec – Jan-Feb 2017
- Revised definition adoption Feb/Mar 2017
- 1st DG JRC report concurrent with adoption
- Second DG JRC report end of 2017

The first technical report will include clarification of concepts and terms used in the definition while the second will describe technical a tiered approach to technical implementation and measurements. The second report will make use of information developed under EU project

NANODEFINE[17] which will end at the same time. An example of size measurements from the NANODEFINE project was given and it was outlined that decision tree concepts will be incorporated into the second technical report.

In the discussion, the following was noted:

- The need for protocols for application of specific methods
- Inclusion of generic reference for carbon-based elongated nano-particles and platelets
- Case studies to demonstrate how constituent particle size may be determined
- 50% particle size distribution threshold would be kept as default
- The role of the volume specific surface area (VSSA) in the revised recommendation (conditions for applicability, conditions for use as a proxy and its relation to the particle size distribution)
- Concerns that the VSSA may be used in future to determine what is not a nanomaterial
- Relevance of the output from the NANODEFINE project

AP 9. ECHA's implementation of the European Union Observatory for Nanomaterials (EU-ON)

ECHA gave an overview of the implementation of the EU Observatory for Nanomaterials (EU-ON). It was outlined that the Observatory is part of the three on-going policy initiatives by COM (the revision of the REACH annexes and the EU recommendation for a definition of nanomaterial are the other two) to generate substance specific information on nanomaterials. The Observatory is in line with the transparency principles being implemented by ECHA in terms of dissemination of information on chemicals. The Info Card and Brief Profiles were given as examples of other recent transparency initiatives taken by ECHA.

The background for the EU-ON was outlined. The origin of the observatory was a request by the European Parliament to COM as well as initiatives at member state level to set up nanomaterial registries. ECHA will be given the responsibility for the implementation of the EU-ON. As it is a new task for the Agency, it will be implemented via a delegation agreement by COM.

The objectives were summarised:

- To be a respected and trustworthy source of information;
- To provide a vehicle for contribution from all actors to ensure all perspectives and aspects are covered in a balanced way,
- To raise awareness and increase knowledge among consumers, regulators, industry workers, NGOs and employers by providing neutral information about nanomaterials on the EU market
- To contribute to better access to relevant information relating to safety to aid identification of risks and appropriate risk management measures;
- To integrate existing information (e.g. databases) in a systematic manner under one centralised umbrella
- To contribute to the public debate on nanomaterials

The differing needs and questions of regulators, scientists and researchers, consumers and the general public, workers, NGOs, industry and stakeholders were highlighted.

The three step implementation plan was outlined. The foreseen end-dates for the three phases given were: phase one - Q2 2016, phase two - mid 2017 and phase 3 - end of 2019.
In phase 1, the focus will be on making use of existing synergies. Web content foreseen will include an outline of what are nanomaterials, links to relevant EU legislations and how they apply to nanomaterials, international perspectives (e.g. OECD, UN, WHO) and providing an overview of ongoing research. Links will be made with ongoing internal work (dissemination

[17] http://www.nanodefine.eu/

portal, mapping of external inventories, set up external networks. In phase 2, the content will be expanded to include piloting a consumer friendly microsite, include regulatory frameworks at national level and product specific information for consumers. Internal work foreseen will include integration of relevant external sources of information and substance specific search functionalities, to work with external partners and to incorporate data from external research projects.
In phase 3, the website will move into full operation and will include international regulations of interest, produce information aimed at target audiences and explore the option to provide product inventories by using data from existing schemes.

The need and challenge to reach the target audiences was highlighted. The observatory microsite for consumers will be a pilot to include content aimed at the general public within the ECHA domain.
In the concluding remarks, it was highlighted that the IT implementation may be costly and this may bring a need to balance expectations.

In the discussion, the following was noted:

- Some members outlined their plan to continue with the initiation of their own nano registries
- The need to balance expectations on content with cost considerations
- Integration of content with other sites and in particular existing external data bases
- Reflections on how the quality/reliability of the content available on the site will be verified/validated
- The need for a sound adaptation of existing chemicals legislation for a successful implementation of such an instrument
- The urge among in particular NGOs and some MS to find approaches for tracking nanomaterials in products
- Translation policy

ECHA reiterated that validation of content will be considered and that the comments from the group would be taken into account

ECHA made a request to the group to consider if they would like to be a "sounding board" in the development of content for the site. The group was invited to contact the ECHA secretariat to express their interest.

AP 10. Findings of ERC EnvNano project relevant for REACH, CLP and Biocides Regulations

An overview of the presentation slides was given by ECHA as the MSCA representative could not attend the meeting because of sickness. The presentation gave recommendations based on findings from the EU EnvNano research project. Highlights were discussed. More information on the EnvNano project can be found on the project webpage[18].

AP 11. Overview of outcome of OECD WPMN Expert Meeting of April 2016 on Grouping and Read-across for the Hazard Assessment of Manufactured Nanomaterials

In this presentation, DG JRC gave an overview of the objectives, outcomes and recommendations for further work from the OECD WPMN expert group meeting on grouping and read-across for the hazard assessment of manufactured nanomaterials. An introduction to the work of the OECD WPMN[19] was given. The OECD WPMN has several steering groups

[18] http://www.envnano.env.dtu.dk/
[19] http://www.oecd.org/env/ehs/nanosafety/

(SG) one of which is focussed on testing and assessment. This SG aims at reviewing and where appropriate proposing new test guidelines and guidance documents for endpoints to ensure an appropriate hazard characterization of nanomaterials. Alternative methods such as *in vitro* and grouping/read-across approaches are within its scope. It was outlined that the SG has organised a series of expert group (EG) meetings and the grouping/read-across EG meeting was the 8th.

An overview of the relevance of grouping and read-across in the hazard assessment of nanomaterials was given. The objectives of the EG meeting were presented; reach a common understanding on the aspects that need to be considered when applying grouping/read-across in a regulatory context; provide input for a possible update of the 2014 guidance of grouping of chemicals section 6.9 "initial considerations applicable to manufactured nanomaterials"; provide elements for a roadmap/timetable for the OECD to come up with guidance proposals

The agenda and discussion points were presented. The first day addressed sharing experiences and discussing what could be extracted from the experiences in terms of lessons learnt, best practices and recommendations. Day 2 was devoted to break out groups on criteria to be considered for read-across in the context of (1) human health hazard assessment and (2) environmental hazard assessment; (3) adaptations needed compared with conventional read-across and (4) criteria for hazard assessment and the quality of the data required.

The outcomes were summarised; grouping and read-across for hazard assessment of nanomaterials based on the general scheme for usual chemicals is in general possible; nanomaterial specific guidance is needed to address sameness and similarity between nanomaterials within the same substance identity and those with different identities; what information is needed to develop a robust justification for read-across between nanomaterials. It was highlighted that there is sufficient information available to draft guidance and that updates would need to be foreseen as more knowledge becomes available and case studies are conducted.

The recommendations for further work were summarized as: terminology clarifications needed; guidance to be developed and tested with case studies; OECD test guidelines to continue to be adapted for nanomaterials, harmonized dispersion protocols to be further developed and harmonized templates to enhance comparability of test results to be developed

The final report from the meeting has been declassified and will be available on the OECD website[20] in the immediate future.

In the discussion, the question of how to address the current uncertainties was raised.

AP 12. Assessment of the HH and ENV test methods used to generate the sponsorship program data

In this presentation, ECHA gave an overview of its assessment of the test methods used to generate data in the OECD WPMN sponsorship program[21]. An overview of the testing program was given for the 11 nanomaterials selected. It was outlined that for human health endpoints, 206 summaries are available in 30 information categories. For environmental endpoints, 375 robust study summaries are available in 40 information categories. The aspects assessed for regulatory significance from the available data were outlined; this included (1) method

[20] Final report published on the 04.11.2016 is available here http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)59&doclanguage=en

[21] OECD Testing Programme of Manufactured Nanomaterials http://www.oecd.org/chemicalsafety/nanosafety/testing-programme-manufactured-nanomaterials.htm

description (2) stated other information; (3) observations. The test materials used per endpoint were summarized for human health and environmental endpoints. Reliability scores assigned to the studies were presented (Klimisch scores, GLP). Concerns were raised that scores might be misleading, in particular when material characterization and sample preparation lacked standardization or documentation was limited. The observations made during the assessment for OECD test guidelines studies for human health and the environment were summarized using the following; conditions reported adequately, deviations observed; method reported adequately. Main deviations noted for repeated dose inhalation studies were presented as an example. For the environmental studies done to OECD test guidelines, the percentage of studies that reported sample preparation, characterization, measured concentrations, type of medium during the study were highlighted.

Remarks noted in the assessment were presented. For studies done to test guidelines these included test conditions not being adequately reported, absence of trends in the observed deviations, and non-nano reference materials used. For studies done to non-test guidelines remarks related to dispersion stability, bioaccumulation and additional endpoints.

The conclusions highlighted that the assessment of the data generated in the sponsorship program is just beginning. For the assessment done by ECHA, the assumptions made and the limitation were outlined. The assessments are available in an Excel based database. The number of studies that did not report sample preparation was given and it was highlighted that unclear test method description impacts the assessment of the quality of the study. It was also highlighted that ca. 70 % and 50 % of human health and environmental summaries respectively were conducted according to OECD test guidelines and that this will be useful in future work on guideline development.

The next steps in the project were outlined in terms of reporting.

In the discussion the following was noted:

- Necessity of detailed descriptions of sample preparation and test method used
- Both study summary records and detailed/raw data (when available) should be considered
- Catalogue data based on reliability
- Conclusions that can be made based on the assessment outcome
- Communicating deficiencies/inadequacies noted in the assessment
- The need to consider why the testing program was initiated when making conclusions
- The results could be useful for the UN GHS classification exercises on nanomaterials, to identify data with sufficient detail to assess the reliability and relevance for classification purpose
- Plans to continue the program and resource considerations.

AP 13. Update OECD nano activities

In this presentation ECHA outlined the ongoing work at OECD level on nanomaterials and the relevance for this work to the Agency for the implementation of the REACH Regulation. The importance of standards and test guidelines was reiterated. The scope of the OECD working party on nanomaterials (OECD WPMN) was outlined. The presentation was discussed with AP 12.

The objectives and future challenges for the WPMN in its renewal program of work were outlined. The rolling work-plan for activities was introduced with activities planned under (1) horizontal projects (2) testing and assessment programs (3) risk assessment and regulatory program. An overview of priorities proposed by WPMN members was given. These included standardized methods for phys. chem. characterization; the need for information generated under REACH to be conducted according to appropriate test methods; testing to be done

according to GLP or similar standards; models for exposure assessment; development of alternative methods.

The Projects related to NM in the OECD Test Guidelines (TG), (ENV/JM/TG(2016)22) managed by the WPMN were listed.

In the conclusions it was reiterated that the Agency supports an increased international harmonisation around hazard/risk assessment methodologies of chemicals.

A series of questions relating to statements made by the WPMN, the revision of the work program, the priorities set and the schedule of activities were made to the group and the floor was opened for discussion.

The following discussion points were noted:

- The relevance of test guidelines and mutual acceptance of data (MAD) also in the context of NM
- Resources at EU level
- Orphan test guidelines and the need for progress
- Consideration of exposure data in addition to hazard data and the need for progress on methodologies and measuring techniques including release from products
- Efforts to better communicate outcomes from ongoing research projects in terms of guideline development and regulatory purposes. Consider inviting relevant task forces of DG Research at the next NMWG meeting.
- Test guideline prioritization for specific endpoints such as phys. chem.
- Particle toxicology considerations.

ECHA proposed to form an ad-hoc group and discuss via email or conference calls common priorities at EU level and concrete proposal for how to achieve them under the work as governed by the WPMN. Expressions of interest in joining the group can be made by contacting the ECHA secretariat.

AP 14 Lessons learned SEv Ag

A representative from the evaluating member state (eMSCA) for the substance evaluation of the silver registration gave reflections on the process now that the final decision has been issued.

The rationale for the selection of the silver registration for substance evaluation was outlined. The registration cover both nano and non-nano silver forms but the level of reporting made it challenging to determine the forms that were registered and their corresponding uses. The focus of the evaluation was to address environmental concerns. The concern to be addressed under SEv was whether there was sufficient information in the registration dossier to cover all forms of silver registered. In particular, whether silver ion is a "worst case" in a testing strategy and whether the most potent nanoforms had been tested.

A key lesson learnt was summarised to address the correct registrants, it is necessary to know which registrant is registering what forms. This makes it possible to directly address the correct parties.

It was outlined that the initial requests made to the registrants evolved during the decision making stage as more information from the registrants became available. Some requests were dropped as it became apparent that only few nanoforms were registered. A key lesson learnt was that information may not have been shared among registrants and that it may be

challenging to avoid new information becoming available during the decision making process.

The final SEv decision included requests for ecotoxicology data to be generated on the smallest silver particle with the highest specific surface area and for phys. chem. data to be generated on the test materials selected. Where it was determined that silver ion is not the worst case, requests relating to quantitative information on fate of the nanosilver form in soil. Information on the uses of the nanoforms registered was also requested.

It was outlined that current OECD test guidelines may not describe test conditions in sufficient detail for nanomaterials. A key lesson learnt was that a full description of the test methods needs to be given.

General observations were summarized:

- 1-year evaluation is feasible with a targeted approach
- An overview of the uses for the substance is useful to request as it is difficult to request (nanospecific) exposure information
- Communication with Registrant(s) proved to be very useful
- Expertise on physicochemical properties (of nanomaterials) was essential for the eMSCA
- Requests need detailed descriptions of the test methods for nanomaterials
- Requests for basic information is essential but it is difficult to frame such requests around a concern based justification as knowledge on the relationship between identity and toxicity may be lacking. This can lead to proportionality considerations. It was highlighted that the revisions to the REACH annexes for nanomaterials are urgently needed.
- It was reiterated that the physico-chemical characterization data serves two purposes (1) identification (what is registered) and (2) how to interpret the test data.

In the discussion the following was noted:

- Data generated may aid correlating specific physico-chemical characteristics with test outcomes
- Presentation and discussion was appreciated as other nanomaterials will be under SEv in the coming years
- IUCLID 6 functionalities to facilitate reporting
- Queries on the low number of nanoforms of silver registered, overlap with Biocidal Products Regulation
- Whether nano silver may be generated by parties that consider themselves down-stream users
- The importance of dialogue between the eMSCA and the registrants
- Tiered approaches in SEv decision.

AP 15 CLP Regulation and Nanomaterials

In this presentation from ECHA, an overview was given on the CLP regulation, the harmonized classification and labelling process (CLH) and the CLP inventory with a focus on nanomaterials. Ongoing activity relating to nanomaterials under CLP/GHS was summarized.

It was outlined that the CLP regulation came into force in 2009 and implements the UN GHS classification criteria[22] in the EU. UN GHS classification criteria are applicable in many parts of the world.

[22] https://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html

The Agency's objectives in the implementation of CLP were briefly outlined. They included compilation of consolidated lists of C&L substances of concern such as those listed in Annex VI to the CLP regulation; provide guidance for the classification and labelling of substances and mixtures, implement UN GHS criteria in the EU. The Agency's main tasks for the implementation of CLP were outlined; manage proposals for harmonized classification and labelling (CLH) and provide the secretariat for the risk assessment committee (RAC), maintain the classification and labelling inventory, process applications for alternative chemical names for substances in mixtures and to provide scientific and technical advice relating to CLP.

The impact of classification was outlined from safety datasheets to down-stream regulation of uses. The classification process was summarized and the hazard classes and categories highlighted. The differences between self-classification and harmonized classification were introduced. Unlike self-classification under CLP, harmonized classifications are given in Annex VI to the CLP Regulation and are legally binding. Other regulations (BPR and PPP) also normally require harmonized classification for active substances.

The CLH process steps were outlined. Intentions for proposals are listed in the Registry of Intentions, proposals for harmonized classification are submitted as dossiers on which ECHA conducts an accordance check. From the submission of a dossier which is in accordance, after which it is subjected to public consultation, the Risk Assessment Committee (RAC) have a maximum of 18 months to adopt an opinion on the proposed classification. Key actors (dossier submitter, the Agency, the RAC and RAC rapporteurs, COM) and their roles and responsibilities were summarized. The status of proposals submitted to date were given. A short overview of the ongoing harmonized classification proposal for titanium dioxide was given.

Due to time limitations, self-classification under CLP was not presented, except to state that the classification and labelling inventory of the notifications is maintained by ECHA has been available since February 2012, and that there are now over 6 million such notifications referring to more than 125,000 substances.

The implementation of the CLP Regulation for nanomaterials was outlined. It was highlighted that while nanomaterials are not specifically mentioned in the legal text, the Regulation refers to "forms or physical states in which a substance or mixture is placed on the market and in which it can be reasonably used". This means that the form in which a chemical is placed on the market needs to be considered and that it is in principle possible that different forms of substances may have different hazard profiles and correspondingly different classifications. Examples of entries in Annex VI of CLP were given to illustrate this (Lead massive and lead powder). It was noted that there are currently no entries in Annex VI of CLP for nanoforms of substances. In the CLP inventory, there are entries where notifiers have selected "nanomaterial" as the substance form. It was also reminded that in principle a harmonized classification for a substance applies to all forms, if not otherwise stated.

The final part of the presentation gave an overview of ongoing work in an "informal correspondence group (ICG) on nanomaterials" relating to considerations of whether UN GHS criteria need adaption for nanomaterials. It is a working group of the UN GHS sub-committee[23]. The terms of reference for the group were given[24] and included review of whether GHS needs to be amended in order to ensure that nanoforms of substances are included within scope of GHS, to review GHS C&L criteria for their applicability to nano- and non-nanoforms of substances; to review GHS safety data sheet content for applicability to substances in nanoform; to report back to the sub-committee with the outcomes and proposals as relevant. An overview of the issues to be addressed by the ICG was given. The impact of the work of the ICG was outlined and it was highlighted that any changes to GHS tend to be reflected in CLP. The Agency's interaction with the ICG was outlined.

[23] https://www.unece.org/trans/danger/publi/ghs/mandate_e.html
[24] https://www.unece.org/fileadmin/DAM/trans/doc/2013/dgac10c4/ST-SG-AC10-C4-2014-9e.pdf

In the discussion the following was noted:

- Relevance of particle size on properties
- Proposals to include CLH/CLP points on the NMWG rolling plan
- Proposals that the work of the ICG would monitor the work done in the OECD and whether the study summaries from the WPMN could be integrated to this work
- Proposals that the NMWG would contribute to the work of the ICG
- Group entries under CLH
- Scope of entries under CLH
- Grouping/read-across in the context of RAC assessment of CLH proposals.

The chair requested that the expert proposing a NMWG contribution to the work of the ICG contact the NMWG secretariat with an outline of their proposal.

AP 16. Wrap-up and conclusions

The Chair provided a brief summary of the main actions agreed during the meeting. In particular, he mentioned that the members of the NMWG will be contacted by email in relation to the updated organisation of the NMWG, e.g. publication of list of NMWG members, updated mandate, nomination of expert for 2017-2018, preparation of minutes in a view to publish them on ECHA website, preparation of rolling plan for 2017.

NMWG members are encouraged to contact NMWG secretariat (nanomaterials@echa.europa.eu) and express interest:

- in relation to the EU Observatory on Nanomaterials, to be part a "sounding board" in the development of content for the site.
- Regarding OECD nano activities, to be part of an ad-hoc group to prepare questions this group would like answered by the WPMN.

The Chair expressed his appreciation to the colleagues for their contribution to this 8th NMWG meeting, for the organisation, for the attendance and for the active participation as presenters or in the discussions. The meeting was then closed.

END OF ECHA-NMWG-8 MEETING

Annex I - List of participants

Surname	First name	Organisation name
Alessandrelli	Maria	National Institute of Health (ISS)
Andersen	Sjur	Norwegian Environment Agency
Ball	Elanor	Health and Safety Executive
Baun	Anders	Technical University of Denmark
Bleeker	Eric	RIVM
BOISEN	ANNE	Danish Epa
BORGES	TERESA	General-Directorate of Health
Capon	France	European Precious Metals Federation
Carlander	David	Nanotechnology Industries Association
Dobrak-Van Berlo	Agnieszka	FPS Health, Food Chain Safety and Environment, DG Environment, Risk Management of Chemical Substances
Doome	Roger	IMA-Europe
Drlickova	Martina	Ministry of Economy of the Slovak Republic
Einola	Juha	Tukes
Ekokoski	Elina	Finnish Safety and Chemicals Agency (Tukes)
Esposito	Dania	National Institute for Environmental protection and
Feketéné	Réka	National Health Center
Gaidukovs	Sergejs	RTU FMAC, LGMEC
Geoffroy	Laure	INERIS
Herzberg	Frank	MSCA Germany (BfR)
Ivask	Angela	National Institute of Chemical Physics and Biophysics
Jomini	Stéphane	Anses
Kinzl	Max	Umweltbundesamt GmbH
Kobe	Andrej	European Commission - ENV
Kos Durjava	Mojca	National Laboratory of Health, Environment and Food
Krop	Hildo	ETUI
Melbourne	Jodie	PETA International Science Consortium Ltd.
Michel	Cecile	ANSES
Moore	Gregory	Swedish Chemicals Agency
PUOLAMAA	Maila	EC
Rauscher	Hubert	European Commission JRC
RIEGO SINTES	Juan	European Commission JRC
Schoonjans	Reinhilde	European Food Safety Authority
Schwirn	Kathrin	MSCA Germany (UBA)
Serrano Ramon	Blanca	Cefic
Spirlet	Christine	International Zinc Association
Walkowiak	Bogdan	Lodz University of Technology
Wiench	Karin	ECETOC
Zellermann	Anna-Maria	MSCA Germany (BAuA - Federal Office for Chemicals)
Aitasalo	Tuomas	ECHA
Cendic	Katarina	ECHA
Constantin	Camelia	ECHA
Deydier	Laurence	ECHA
Falck	Ghita	ECHA

Helminen	Ulla	ECHA
Holmqvist	Jenny	ECHA
Jacquet	Cyril	ECHA
Kaija	Jenni	ECHA
Kapanen	Anu	ECHA
Karjalainen	Ari	ECHA
Le Curieux	Frank	ECHA
Polecinski	Malgorzata	ECHA
Quinn	Bernadette	ECHA
Sumrein	Abdelqader	ECHA
Tannaro	Celia	ECHA
Tunnela	Outi	ECHA
Zormpas	Alexis	ECHA