



OECD WORKING PARTY ON MANUFACTURED NANOMATERIALS
OECD Expert Meeting on Categorization of Manufactured Nanomaterials
Washington (USA) 17-19 September, 2014
(Starting at 8h20 on the first day)
DRAFT AGENDA

Background:

At the 10th meeting of the Working Party on Manufactured Nanomaterials (WPMN) in June 2012, the US Environmental Protection Agency (EPA) proposed to host an OECD Expert Meeting on Categorization of Nanomaterials. This proposal was endorsed by the WPMN as part of the strategy of the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials (hereafter Testing Programme) to hold a number of Expert Workshops to further identify lessons learned from the testing of manufactured nanomaterials and prepare OECD-level recommendations, guidance, and/or guidelines where warranted.

The OECD WPMN Expert Meeting on Categorization of Nanomaterials (developing nanomaterial categories) will take place 17-19 September 2014 in Washington DC, USA. Addressing various categorization strategies in a risk assessment framework and discussing these in close collaboration with the WPMN members and international experts is one important aspect that will need to be reviewed.

The goal of the meeting is to provide recommendations on how manufactured nanomaterials should be categorized for purposes of testing, read across/ Structure-Activity Relationships (SAR), risk assessment and risk management.

The workshop addresses the use of categories in the following areas: physical-chemical characterization; fate, exposure; ecotoxicity; human health toxicity; exposure assessment and risk assessment and risk management. This workshop therefore addresses the full range of risk assessment-relevant endpoints. Nevertheless, category approaches are to be used in a regulatory context, and can most appropriately be analysed within the context of a sufficient data set. These two parameters, use of categories and amount of available information, will provide the background to the specific areas selected for discussion.

Note: A **Background Document** has been prepared that includes a proposed **categorisation scheme**. We encourage participants to review this document as it provides the basis of the discussions.

AGENDA

17th September 2014		1 ST DAY
8h00	Registration	
8h20 - 8h30	Welcome Remarks	Jeff Morris (United States)
8h30 - 8h40	Background	Mar Gonzalez (OECD Secretariat)
8h40 - 8h55	General Introduction to the Agenda	Maria Doa (United States)
SESSION 1	CONTEXT FOR NEED FOR THE USE OF CATEGORIES, AND PERSPECTIVES ON THEIR APPLICATION TO NANOMATERIALS	
8h55 - 9h10	Introduction to Session 1: Importance of Categorization for Risk Assessment and Risk Management	Maria Doa (United States)
9h10 - 9h30	Keynote lecture: "OECD Member Countries' Approaches to Develop or Use Concepts of Grouping, Equivalence and Read-Across Based on Physical-Chemical Properties (GERA-PC) of Nanomaterials for their Hazard Assessment in Regulatory Regimes"	Takuya Igarashi (Japan)
9h30 – 10h30	<p>Panel: Use of Category Approach and Groupings of Nanomaterials Regionally and Nationally:</p> <p>1) "Development of a Classification Scheme under the Canada-United States Regulatory Cooperation Council Nanotechnology Initiative"</p> <p>2) "EU REACH Perspective of Categorization, Grouping and Read-Across"</p> <p>Q&A</p>	<p>Chair of the Panel: Kenneth Moss (United States)</p> <p>1) Brad Fisher (Canada) and Jim Alwood (United States)</p> <p>2) Jenny Holmqvist (European Union)</p>
10h30 - 10h50	COFFEE BREAK	
10h50 – 11h10	Keynote lecture on Physical-chemical Characterization	Monique Groenewold (The Netherlands)
11h10 -- 11h30	Keynote lecture on Fate Assessment: "Novel properties as an organizing concept for categorizing engineered nanomaterials for regulatory purposes"	Mark Wiesner (United States)
11h30 -- 11h50	Keynote lecture on Ecotoxicity Assessment: "Novel techniques for toxic nanoparticle categorization"	Suman Pokhrel (Germany)
11h50 – 12h10	Keynote lecture: "The use of Alternative Testing Strategies	Jo Anne Shatkin (Society for

	to Advance Risk Analysis of Nanoscale Materials“	Risk Analysis - SRA)
12h10 – 12h30	Discussion	
12h30 – 13h20	LUNCH	
13h20 – 13h45	Keynote lecture on Health Assessment : "Grouping of Nanomaterials for Health Assessment- Genotoxicity"	Maria Donner (BIAC)
13h45 – 14h10	Keynote lecture on Health Assessment : “The State-of -the Art Health Effects of Nanomaterials and their Regulatory Implications“	Tom Van Teunenbroek (The Netherlands)
	“Example of the Grouping of Nanomaterials for Health Assessment in a National or International Regulatory Context: How to extend/verify the Concept: “Taqun” whole body inhalation system for speeding up the toxicity studies for categorization of manufactured nanomaterials“	Jun Kanno (Japan)
14h10 – 14h30	Keynote lecture: "Grouping of Nanomaterials by Release Type? "	Thomas Kuhlbusch (Germany)
14h30 – 14h50	Keynote lecture : “Can a Grouping Approach Help Solve Some Key Nanomaterial Exposure Assessment Challenges?”	Charles Geraci (United States)
14h50 – 15h10	COFFEE BREAK	
SESSION 2	RISK ASSESSMENT AND RISK MANAGEMENT	
15h10 -16h30	Risk Assessment: Utilization of Categories in Risk Assessment <u>Stimulus presentations:</u> “The Use of Categories in Risk Assessment: A perspective of the WPMN’s work on Risk Assessment and Regulatory Programmes ” Yasir Sultan (Canada) “The ITS-NANO Approach to Risk Assessment, including Grouping and Ranking“ Vicki Stone (Uunited Kingdom) "Evaluating the Evidence to Develop Occupational Exposure Bands for Nanomaterials" Eileen Kuempel (United States) "Overview of Risk Assessment and Factors to Consider for Differing Regulatory Programmes" Tala Henry (United States)	Co-chairs: Yasir Sultan (Canada) and Maila Poulamaa (European Union)

16h30 – 17h00	Panel on Risk Management Speakers: Maria Doa (United States) Henrik Laursen (European Union) Brad Fisher (Canada)	Co-chairs: Maria Doa (United States) and Henrik Laursen (European Union) Rapporteur: Shaun Clancy (BIAC)
17h00 – 17h20	COFFEE BREAK	
SESSION 3	PHYSICAL-CHEMICAL CHARACTERIZATION <i>Participants will be invited to review the proposed categorisation scheme (see Background Document) and discuss the following issues:</i>	
	<ul style="list-style-type: none"> • <i>Are the proposed categories presented in the Background Document a reasonable starting point for general categorization? For further categorization?</i> • <i>Are the proposed categories a reasonable starting point for further sub-categorization as is?</i> • <i>What physical-chemical endpoints are most applicable for assessing environmental toxicity? For human health endpoints?</i> • <i>What specific activities would be needed to provide sufficient evidence for the use of categorization in these questions for risk assessment and risk management?</i> • <i>What information is required for assessing the validity of each (sub)category?</i> • <i>What categories are applicable across multiple endpoints?</i> 	
17h20-18h20	Physical-chemical Characterization Stimulus presentations: “An industrial perspective” Scott Brown (BIAC) “A metrological perspective” Angela Hight Walker (United States)	Co-chairs: Vicki L. Colvin and Angela Hight Walker (United States) Rapporteur: Scott Brown (BIAC)
18h20 –18h30	Day 1 Summary of the Discussion	Maria Doa (United States)
18h30	END OF DAY 1	

2ND DAY		
18th September 2014		
8h30 — 8h40	Welcome and Overview of Day 2 Agenda	Maria Doa (United States)
SESSION 3	PHYSICAL-CHEMICAL CHARACTERIZATION (Cont.)	
8h40 – 9h30	Physical-chemical Characterization	Co-chairs: Vicki L. Colvin and Angela Hight Walker (United States) Rapporteur: Scott Brown (BIAC)
9h30 – 10h00	Report of the Session 3 on Physical-chemical Characterization and Recommendations	Scott Brown (BIAC)
10h00 – 10h20	COFFEE BREAK	

	SESSION 4 ENVIRONMENTAL FATE	SESSION 5 HUMAN HEALTH (PART 1)
<p><i>Each session will define which physical-chemical properties are most important for the assessment respectively.</i></p> <p><i>Each session will address the following questions:</i></p> <ul style="list-style-type: none"> • <i>Are the proposed categories presented in the Background Document a reasonable starting point for general categorization? For further categorization?</i> • <i>Are the proposed categories a reasonable starting point for further sub-categorization as is?</i> • <i>What specific activities would be needed to provide sufficient evidence for the use of categorization in these questions for risk assessment and risk management?</i> • <i>What information is required for assessing the validity of each (sub)category?</i> • <i>What categories are applicable across multiple endpoints?</i> • <i>To what extent can Structure-Activity Relationships (SAR) be used?</i> 		
10h20 – 12h20	<p>SESSION 4 ENVIRONMENTAL FATE</p> <p>Co-chairs: Willie Peijnenburg (The Netherlands) and Elijah Petersen (United States) Rapporteur: Steffi Friedrichs (BIAC)</p> <p><u>Stimulus presentations:</u></p> <p>"Nanomaterial classification considerations for environmental fate" Iseult Lynch (United Kingdom)</p> <p>"Nanotechnology Categorization by Environmental Fate and the Implications on Exposure and Hazard" Al Kennedy (United States)</p> <p>"Environmental Fate Break out Group" Thomas Kuhlbusch (Germany)</p>	<p>SESSION 5 HUMAN HEALTH (PART 1)</p> <p>Co-chairs: Jenny Holmqvist (European Union) and Juergen Schnekenburger (Germany) Rapporteur: Myriam Hill (Canada)</p> <p><u>Stimulus presentation:</u></p> <p>"BASF approach of grouping of nanomaterials" Karin Weinch (BIAC)</p> <p>" <i>In vitro</i> and <i>in vivo</i> Approaches to Assessing the Pulmonary Toxicity of Nanomaterials, and How They Can Inform Categorisation" Vicki Stone (United Kingdom)</p>
12h20 - 13h30	LUNCH	
PLENARY REPORTS AND CONCLUSIONS FROM SESSIONS 4 AND 5		
13h30 - 14h00	Reports of the Breakout Session 4 – Recommendations	Steffi Friedrichs (BIAC)

14h00 – 14h30	Reports of the Breakout Session 5 – Recommendations	Myriam Hill (Canada)
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	SESSION 6 ENVIRONMENTAL TOXICITY	SESSION 7 HUMAN HEALTH (PART 2)	SESSION 8 EXPOSURE ASSESSMENT
<p><i>Each session will review the proposed categorisation scheme (see Background Document) and address the following questions:</i></p> <ul style="list-style-type: none"> <i>• Are the proposed categories presented in the Background Document a reasonable starting point for general categorization? For further categorization?</i> <i>• Are the proposed categories a reasonable starting point for further sub-categorization as is?</i> <i>• What specific activities would be needed to provide sufficient evidence for the use of categorization in these questions for risk assessment and risk management?</i> <i>• What information is required for assessing the validity of each (sub)category?</i> <i>• What categories are applicable across multiple endpoints?</i> <i>• To what extent can Structure-Activity Relationships (SAR) be used?</i> 			
<p>14h30 – 15h30</p>	<p>SESSION 6 ENVIRONMENTAL TOXICITY</p> <p>Chair: Greg Goss (Canada) Rapporteur: Eric Bleeker (The Netherlands)</p> <p><u>Stimulus presentations:</u></p> <p>"Categorization of NM regarding ecotoxicity" Kerstin Hund-Rinke (Germany)</p> <p>"Decision Trees and Aquatic Toxicity Testing for Nanomaterials" Greg Goss (Canada)</p>	<p>SESSION 7 HUMAN HEALTH (PART 2)</p> <p>Co-chairs: David Warheit (BIAC) and Phil Sayre (United States) Rapporteur: Agnes Oomen (The Netherlands)</p> <p><u>Stimulus presentations:</u></p> <p>"Development of Equivalence Criteria for Nanomaterials by Intratracheal Administration Study" Masashi Gamo (Japan)</p> <p>"5-day Inhalation Protocol and Results for Grouping of Nanomaterials" Karin Weinch (BIAC)</p>	<p>SESSION 8 EXPOSURE ASSESSMENT</p> <p>Chair: Vladimir Murashov (United States) Rapporteur: Kim Rogers (United States)</p> <p>Session 1: Facilitator : Chuck Geraci (United States)</p> <p><u>Stimulus presentation:</u></p> <p>"The 'Source Domain' Concept: Different Release Processes and Associated Exposure" Derk Brouwer (The Netherlands)</p> <p>Session 2: Facilitator : Treye Thomas (United States)</p> <p><u>Stimulus presentation:</u></p> <p>"Case Studies in Consumer Exposure to</p>

			ENPs; A Life Cycle Perspective" Rob Reed (United States)
15h30 – 15h50	COFFEE BREAK		
	SESSION 6 ENVIRONMENTAL TOXICITY (CONT.)	SESSION 7 HUMAN HEALTH: Part2 (CONT.)	SESSION 8 EXPOSURE ASSESSMENT (CONT.)
15h50 – 16h50	Chair: Greg Goss (Canada) Rapporteur: Eric Bleeker (The Netherlands)	Co-chairs: David Warheit (BIAC) and Phil Sayre (United States) Rapporteur: Agnes Oomen (The Netherlands)	Chair: Vladimir Murashov (United States) Rapporteur: Kim Rogers (United States)
	PLENARY REPORTS AND CONCLUSIONS FROM SESSIONS 6 AND 7		
16h50 – 17h20	Reports of the Breakout Session 6 – Recommendations		Eric Bleeker (The Netherlands)
17h20 – 17h50	Reports of the Breakout Session 7 – Recommendations		Agnes Oomen (The Netherlands)
17h50 – 18h00	Summary of day 2		Maria Doa (United States)
18h00	END OF DAY 2		

19 September 2014		3 RD DAY
8h30 – 8h40	WELCOME AND OVERVIEW OF DAY 3 AGENDA	
8h40 – 9h10	Reports of the Breakout Session 8 – Recommendations	Kim Rogers (United States)
9h10 – 10h10	Synthesis of Results – What can be deduced across endpoints discussed in the Breakout Sessions 2-7	Panel: Chairs of Breakout Sessions 2-7
10h10 – 10h30	COFFEE BREAK	
SESSION 9	SESSION 9 RISK ASSESSMENT	
10h30 - 12h00	<p>Session 9 Risk Assessment: Utilization of Categories in Risk Assessment</p> <p><u>Stimulus presentations:</u></p> <p><i>"The Swiss Precautionary Matrix – a supporting tool for industry and regulators"</i> Tobias Walser (Switzerland)</p> <p>"A Theoretical Example of Using Concepts of Grouping in a Regulatory Submission" Shaun Clancy (BIAC)</p>	<p>Chair: Yasir Sultan (Canada)</p> <p>Rapporteur: Kirsten Rasmussen (JRC European Union)</p>
12h00 – 13h10	LUNCH	
SESSION 9	SESSION 9 RISK ASSESSMENT (Cont.)	
13h10 – 14h10	Session 9 Risk Assessment (Cont.)	<p>Chair: Yasir Sultan (Canada)</p> <p>Rapporteur: Kirsten Rasmussen (JRC European Union)</p>
14h10 – 14h40	Risk Assessment Reports of the Session 9 – Recommendations	Kirsten Rasmussen (JRC European Union)
14h40 – 15h00	COFFEE BREAK	
15h00 – 16h00	Risk Management –Recommendations for better risk management tools	Maria Doa (United States) and Henrik Laursen (European Union)
16h00 – 16h30	Summary of the Meeting	
16h30	END OF DAY 3 – ADJOURN	