



OECD WPMN Steering Group on Advanced Materials

Kathrin Schwirn (Chair: SG AdMa)



OECD Working Party on Manufactured Nanomaterials

- Since 2006 WPMN has been addressing human and environmental risk assessment of nanomaterials

Testing and Assessment (EU)

Continue assessing the need for developing TGs/GDs for Nanomaterials and Advanced Materials; Further Guidance for hazard testing & assessment

Exposure Measurements and Exposure Mitigation (US)

Guidance on release and exposure testing & assessment

Risk Assessment and Regulatory Programmes (CA)

Reviewing needs and priorities

- 2021 new Steering Groups were established

Advanced Materials (GER and NL)

Safer Innovation Approach (SIA; for more Sustainable Nanomaterials and Nano-enabled Products (leads NL, CA and BIAC))

- Working Description Sus and SSbD
- Identify solutions for its implementation



Motivation to work on Advanced Materials

- Over the years, it became more and more evident that safety considerations on new materials should not be limited to a upper size limit of 100nm
- For some of these materials, similar or additional challenges to those identified for nanomaterials can be expected in the framework of chemical safety
- Many of these materials possess/display an additional complexity, e.g. a new or enhanced functionality and/or multiple components
- Therefore, the question arises on whether a current risk assessment can always ensure the safe application and use of all Advanced Materials (AdMa)
- Some AdMa may also pose challenges regarding sustainability throughout their life cycle, including recycling and waste handling
- WPMN can contribute with its knowledge and experiences gained for nanomaterials



Organisation of SG AdMa

- Established at WPMN-21
 - former Ad-hoc Group AdMa
- Chair: Kathrin Schwirn (DE), Co-Chair: Agnes Oomen (NL)
- Delegates from 13 Member Countries, and 4 Observer
- Realisation
 - Monthly zoom meetings since October 2021
 - February 2022: 2-day Expert Meeting and joint meeting with OECD WPMN Steering Group on Safer Innovation Approach*

*ENV/CBC/MONO(2020)36/REV1: Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products



Tasks of SG AdMa

- Information gathering on research and activities on AdMa of the delegations
- Criteria to identify AdMa relevant for WPMN
- Development of a strategic approach to support Regulatory Preparedness (RP) and Safe-and-Sustainable-by-Design (SSbD*) of AdMa and their applications
 - Are regulations and assessment methods fit for AdMa?
 - Identification of concerns about and knowledge gaps to address safety and sustainability of AdMa
 - Developments of recommendations and options for actions for decision makers
- Carry out case studies
 - To learn about the cases
 - to verify and refine the strategic approach

*ENV/CBC/MONO(2022)30

[https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-CBC-MONO\(2022\)30 &doclanguage=en](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-CBC-MONO(2022)30 &doclanguage=en)



Working description of AdMa within WPMN

- To describe the playing field of AdMa within WPMN
- To describe in which context WPMN is engaged with AdMa
- Starting with but not limited to nano-scaled materials and materials containing nanomaterials
- Acknowledges that what is considered as an AdMa of relevance for WPMN may change over time, due to increased knowledge, technical progress or established regulatory implementation

Advanced Materials: Working Description

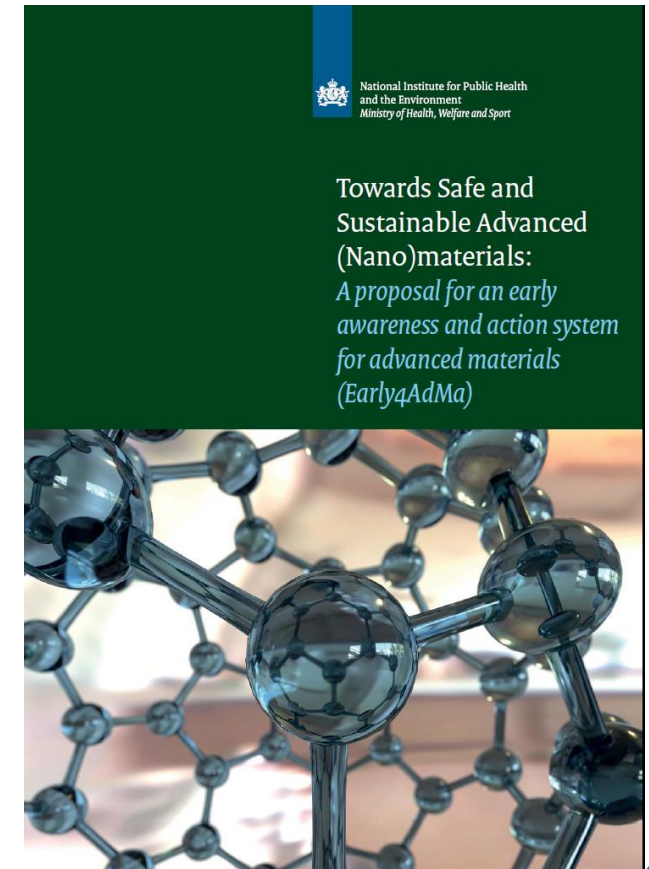
- I. The ***Working Party on Manufactured Nanomaterials' (WPMN) Working Description on Advanced Materials*** aims to illustrate the content of the Advanced Materials playing field and the purpose of WPMN's engagement regarding these materials².
- II. In this context, AdMa are understood as materials that are rationally designed to have
 - new or enhanced properties, and/or
 - targeted or enhanced structural featureswith the objective to achieve specific or improved functional performance³. This includes both new emerging manufactured materials, and materials that are manufactured from traditional materials. This also includes materials from innovative manufacturing processes that enable the creation of targeted structures from starting materials, such as bottom-up approaches. It is acknowledged that what are currently considered as AdMa will change with time.
- III. The considerations within the WPMN will build on the knowledge gained on manufactured nanomaterials, and possibly include other AdMa with relevance to safety, sustainability and regulatory issues considering their whole life cycle. Advanced Materials under consideration of WPMN are aimed to be assessed in order to improve their safety, sustainability and regulatory coverage within the strategic approach to identify knowledge gaps and recommendations for action. The AdMa in focus will evolve as additional knowledge is gained and appropriate strategies are developed.
- IV. Examples of possible cases of AdMa that could be considered are given in the Annex.



Strategic Approach for AdMa

- On the basis of the proposed **EARLY4AdMa** system
 - Developed under the lead of NL (RIVM)
 - Contribution by GER (colleagues from BfR, BAuA, UBA)
- Tiered Approach with Questions on Safety and Sustainability including a Scoring-System
 - Discussion and Identification of Warnings
 - Prioritisation of Warnings
 - Derivation of Recommendations for Actions
- General Agreement but further refinement needed to meet the needs of WPMN
- Discussion and exercises during the SG AdMa Expert Meeting in February 2022 and upcoming EU H2020 Harmless Workshop in November 2022

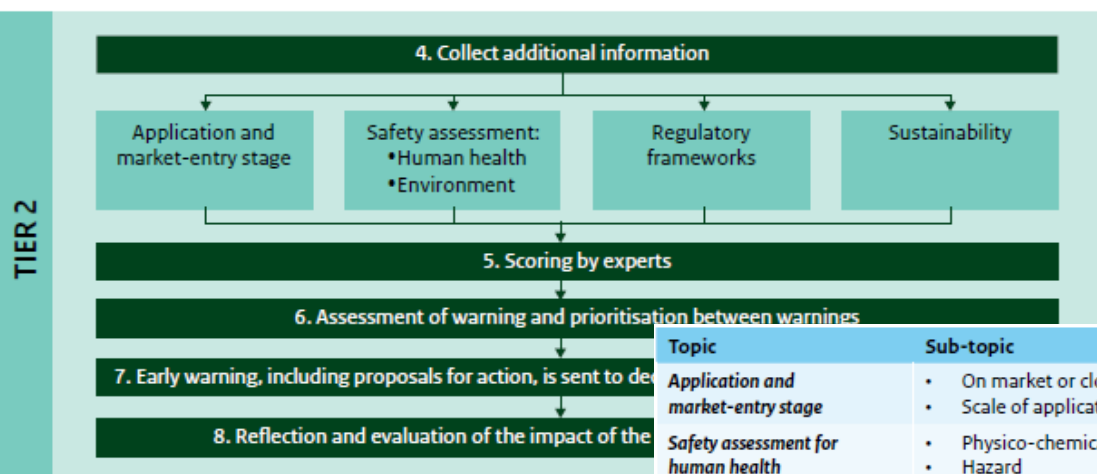
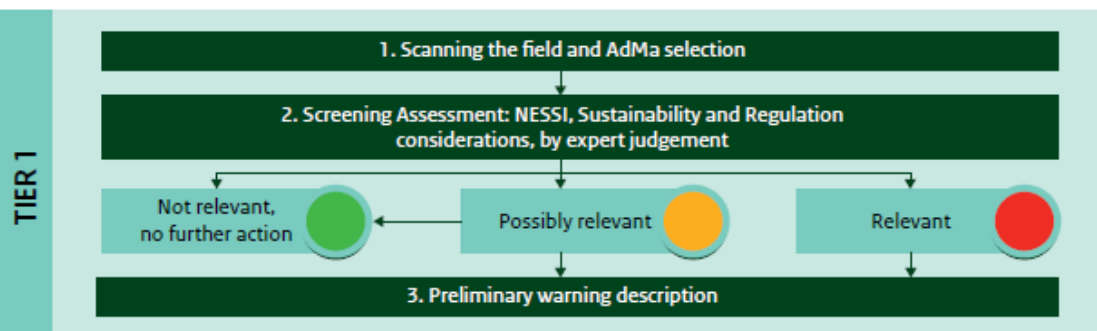
➤ **EARLY4AdMa: *Early Awareness and action for AdMa***



[Early4AdMa brochure | RIVM](#)



EARLY4AdMa



Topic	Sub-topic
Application and market-entry stage	<ul style="list-style-type: none">On market or close to marketScale of application
Safety assessment for human health	<ul style="list-style-type: none">Physico-chemical propertiesHazardKineticsExposure
Safety assessment for the environment	<ul style="list-style-type: none">Physico-chemical propertiesHazardFateExposure
Applicability of regulatory frameworks	<ul style="list-style-type: none">Identification of the adequacy of relevant regulatory frameworks, applicability assessment of underlying test methods and assessment strategies
Sustainability	<ul style="list-style-type: none">Raw materials and resourcesManufacturing, production, transport and useEnd-of life (recyclability and reusability)

Topic	Potential actions
Application and market entry stage	<ul style="list-style-type: none">Obtain more information on how close the material/product is to the market, the potential scale of application, and whether the material/product has a significant societal or economic benefit. For example, by industry consultations or investigating trends in patents and publicly funded research projects.Gather detailed information of (anticipated) applications. For example, by industry consultations.
Safety assessment (human health and environment)	<ul style="list-style-type: none">Reduce uncertainties by generating additional (safety) data.Consider substitution of materials of concern and/or regulatory actionEncourage development of suitable (standardised) test methods and improve assessment strategies.Develop guidance and best practices.
Applicability of regulatory frameworks	<ul style="list-style-type: none">Share knowledge with the involved Agencies, Ministries, Authorities and Committees (e.g. EC, EMA, ECHA, EFSA, SCCS, SCHEER*) to allow timely consideration whether/which current regulatory frameworks need adaptations.Define guidance, and best practices.Encourage development of suitable (standardised) test methods, or improve assessment strategies.
Sustainability	<ul style="list-style-type: none">Encourage improved sustainability based on identified areas of most relevance, e.g.<ul style="list-style-type: none">Minimalization of critical raw material useReduction of global warming potentialMinimalization of energy, water and land consumptionReduction of environmental footprintEffective recyclability and reusability
Other	<ul style="list-style-type: none">Encourage safe-and-sustainable-by-design, circular economy, substitution.Facilitate interaction between relevant stakeholders.Regularly monitor developments of innovations.

Table 6. Applicability of Regulatory Frameworks. High scores indicate that the risks are not likely to be considered by current regulations.

Descriptor	Question ^a	Answer (score)			Comment/clarification
		Yes (0 or 3)	No (0, 3 or 9)	? (1)	
Applicability Regulatory Frameworks (max. 12 points)	Does the material(s) or application(s) fall within the scope of one or several current chemical legislation(s)? (score: yes=0, borderline situation for different frameworks=3, unknown=1, no=9).				
	If the material(s) or application(s) falls within the scope of relevant (regional) legislation, do the information requirements cover the potential exposure/release, kinetic/fate and hazard issues (section 3.2 and 3.3) for the AdMa? (score: no=3, unknown=1, yes=0)				
	Are the existing test methods and assessment strategies (e.g. guidance) considered applicable for the AdMa? (score: no=3, unknown=1, yes=0)				
Total marks (max. 12)					
Total relative score (=total marks/12)					



Next steps

- Implement comments to further develop and refine the strategic approach for the needs of WPMN during autumn/winter 2022-23
- Explore use as tool for communication between innovators and regulators
 - What is needed for this purpose?
- 2023 onward apply the further elaborated strategic approach to case studies
 - In cooperation with the OECD WPMN Steering Group SIA



Possible Case Studies

Aim:

- Review the applicability of the strategic approach for possible further refinements (iterative process)
- Identification of information needs and possible concerns as well as derivation of recommendation for action regarding safety and sustainability
- Examples proposed by delegates of SG AdMa:
 - 3D Print
 - NanoCarrier
 - Graphene
 - EU H2020 project ASINA – silver cellulose particles/encapsulate cosmetic ingredients
 - EU 2020 project HARMLESS - aerogel-fibre-mats for insulation panels



Possible points for cooperation

- EMN could provide expertise to the case studies, e.g. on
 - field of application
 - material science
 - possible hazard and exposure and related assessment tools
 - sustainability aspects
 - propose further cases
- EMN could provide support to OECD to implement potential recommendations derived from the case studies, e.g.
 - closing information gaps
 - development of assessment methods (e.g. characterisation, analytics)
 - development of guidances



Thank you for your attention!

- Website: <http://www.oecd.org/chemicalsafety/>; <https://www.oecd.org/science/nanosafety/>
- EHS Programme Brochure: <http://www.oecd.org/env/ehs/Environment-Health-Safety-Brochure.pdf>
- EHS Newsletters: <http://www.oecd.org/chemicalsafety/environment-health-safety-news.htm>



The registration form :

https://meetoe.cd1.zoom.us/webinar/register/WN_OmLZlTOkSvmrwAMxRiAk_A