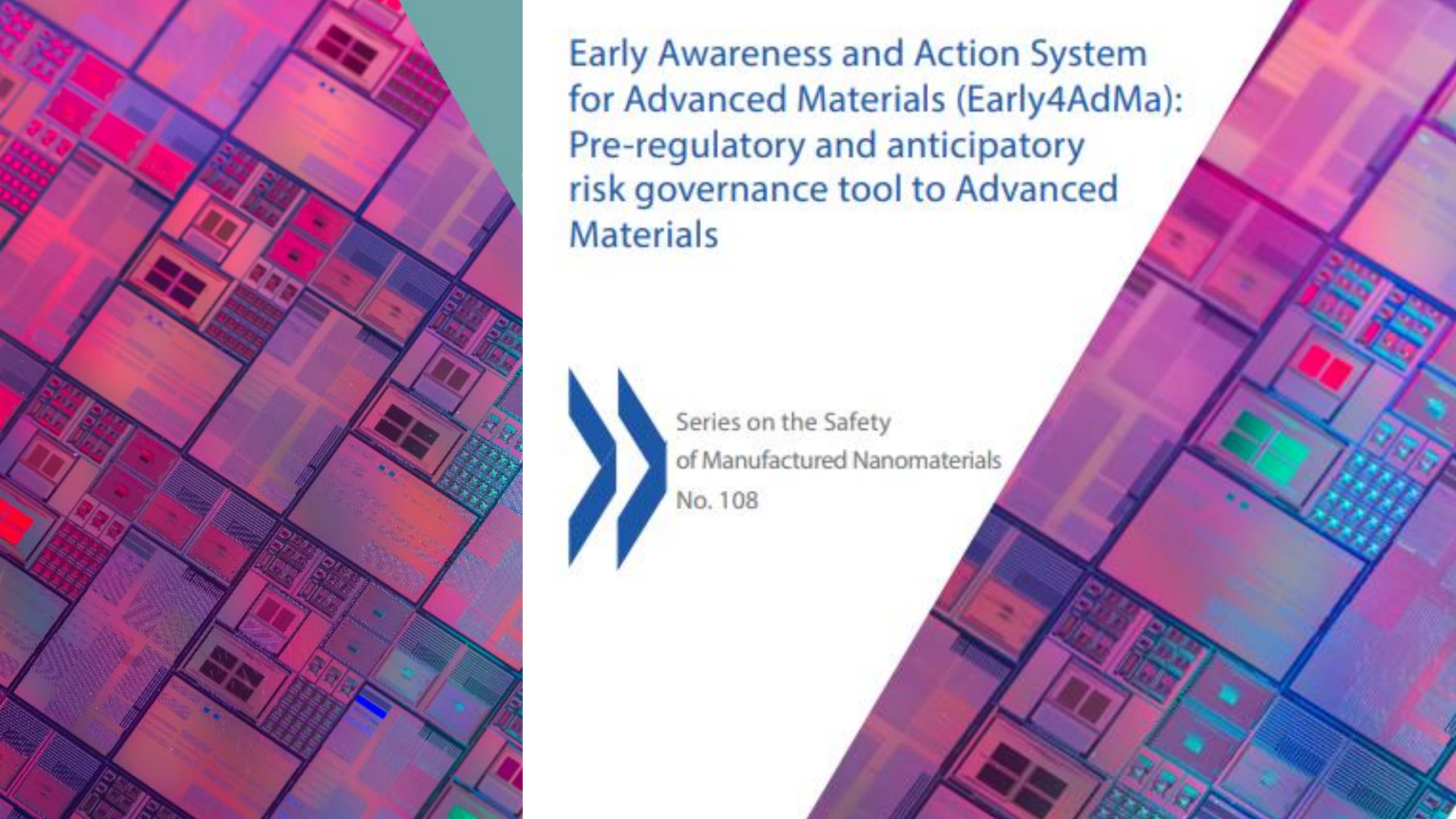




Webinar on Early Awareness and Action System for Advanced Materials (Early4AdMa)

Welcome to this OECD's Webinar, we will start in a couple of minutes.

Bienvenidos a este seminario Web de la OECD. Vamos a empezar dentro de unos minutos.



Early Awareness and Action System for Advanced Materials (Early4AdMa): Pre-regulatory and anticipatory risk governance tool to Advanced Materials



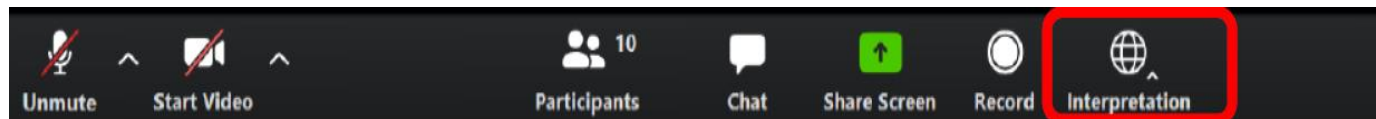
Series on the Safety
of Manufactured Nanomaterials
No. 108

Interpretation

If you do not see the “**Interpretation**” button on the **bottom of your screen**, make sure you **download the Zoom app** on your desktop, phone or tablet from the Zoom download center:

https://zoom.us/download#client_4meeting or via the direct links available in the chat box.

To listen:



Click on “**Interpretation**” button on the **bottom of your screen**

Choose your channel:

- English
- Spanish

Interpretación simultánea

Para acceder al botón de **Interpretación**, necesitan tener la aplicación Zoom

https://zoom.us/download#client_4meeting , disponible en el **Chat** de este seminario.

Para escuchar:

Haga click en el boton “**Interpretación**” que esta en la parte superior de su pantalla

Escoja el idioma:

- Ingles
- Español

Disclaimer

Interpretation of remote meetings on Zoom serves to facilitate communication and does not constitute an authentic record. Only the original speech is authentic. Interventions that are (read out) too fast or where the sound quality is insufficient may have to go uninterpreted.

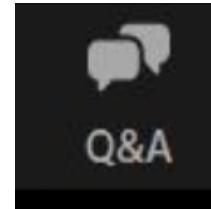
L'interprétation des réunions virtuelles sur Zoom permet de faciliter la communication et ne constitue en rien un verbatim officiel. Seul le discours original fait foi. Si les interventions sont lues ou prononcées trop rapidement, ou en cas de mauvaise qualité du son, l'interprétation pourra être interrompue.

La interpretación de reuniones virtuales en Zoom permite facilitar la comunicación y no constituye un registro oficial. Sólo da fe y es auténtico el discurso original. Intervenciones leídas o pronunciadas demasiado rápidamente, así como un sonido de mala calidad, podrán ocasionar una interrupción de la interpretación.

Zoom Instructions

Q&A fonction:

During the presentation you may have a question that you'd like to be answered.



Funcion Q&A:

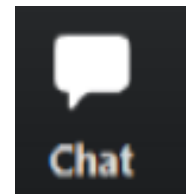
Preguntas y respuestas: si tiene preguntas durante la presentación, hágalo vía el botón Q&A.

Please send your questions at any time during the talk via the Q&A function in the Zoom control panel so it does not get lost in the Chat.

We will respond to as many questions as possible during the **Q&A** sessions.

Envíe sus preguntas en cualquier momento durante la charla a través de la función Q&A y no en el chat para que los expertos las vean. Responderemos a tantas preguntas como sea posible durante las sesiones de preguntas y respuestas.

Chat fonction: During the meeting we will share technical and useful information in the chat box.



Funcion Chat: En el Chat compartiremos información técnica y links útiles para saber mas el tema.

Assistance/ Asistencia Tecnica: via chat or/o Mar.Gonzalez@oecd.org or Kimiko.Yamamoto@oecd.org

This webinar will be recorded and will be made available in both languages afterwards:

Este seminario web se grabará y estará disponible en ambos idiomas posteriormente:

[Safe\(r\) and Sustainable Innovation Approach \(SSIA\): Nano-enabled and other Emerging Materials – OECD](#)
& <https://www.oecd.org/env/ehs/nanosafety/>

Today's Speakers



Kathrin Schwirn

Scientific employee
German Environment Agency (UBA)



Doris Völker

Scientific employee
German Environment Agency (UBA)



Agnes Oomen

Senior scientific officer and Professor
National Institute for Public Health
and the Environment (RIVM)



Blanca Suarez Merino

Director of Regulatory Affairs at the
Nanotechnology Industries Association (NIA)
Co-founder of TEMAS Solutions GmbH



Elmer Swart

Scientific officer
National Institute for Public Health
and the Environment (RIVM)



Wendel Wohlleben

Senior Principal Scientist
BASF SE



- 1 Welcome** **Mar Gonzalez, OECD**
- 2 OECD work on Advanced Materials** **Kathrin Schwirn, UBA**
- 3 Background to Early4AdMa and connection to SSIA** **Agnes Oomen, RIVM**
- 4 EARLY4AdMa** **Elmer Swart, RIVM**
 - **HARMLESS:** Blanca Suarez Merino / Wendel Wohlleben (BIAC)
 - **Nanocarriers:** Doris Völker, UBA
 - **Future Case Studies:** Kathrin Schwirn, UBA
- 5 Case Studies**
- 6 Concluding Remarks** **Agnes Oomen, RIVM**
- 7 Q&A** Moderator: **Mar Gonzalez, OECD**

OECD work on Advanced Materials

Speaker:



Kathrin Schwirn
Scientific employee,
German Environment Agency
(UBA)

**Umwelt
Bundesamt**

OECD Council

Environment Policy Committee

6 WPs and 3 Joint WPs

Chemicals and Biotechnologies Committee (CBC)

Development of Harmonised instruments for the safety assessment of chemicals

Other OECD substantive Committees

12 Working Parties (WP)

CBC is supported by:

- 38 Member countries as well as EC and its institutions
- Observer Countries (i.e. ZA, TH, MY)
- Stakeholder: Env NGO, Industry (BIAC), Animal Welfare org., Labor org., IGO (i.e. UNITAR; WHO)



OECD Working Party on Manufactured Nanomaterials (WPMN)

- Established in 2006
- A global forum for policy discussions on nanomaterials and since 2021 also advanced materials
- Assist in the implementation of safety policies and regulatory preparedness
- Implements the programme via Steering Groups (SG) comprising nominated experts

SG Testing and Assessment: guidance for hazard assessment, facilitate nanospecific OECD TG /GD development

SG Exposure: guidance for exposure assessment and mitigation

SG Safe(r) and Sustainable Innovation Approach (SSIA)

SG Advanced Materials (AdMa)

Functioning

Developers: In-country experts

|

Consensus builder: OECD Secretariat

What makes Advanced Materials important?

- **AdMa promises technical solution for major challenges of our (future) society**
 - For energy transition, health, construction, mobility, agriculture and electronics sectors
- **Large investments have been undertaken to develop AdMa and to bring them into application**



See for example: European Commission¹, European Member States², Industry, and academia^{3,4,5,6}

1 EU CSS - <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf> ; Horizon Europe calls

2 e.g. <https://www.werkstofftechnologien.de/en/>

3 [Materials 2030 Manifesto](#) - Systemic Approach of Advanced Materials for Prosperity – A 2030 Perspective

4 European Technology Platform for Sustainable Chemistry

5 [Materialen NL platform](#) (2020) Dutch Materials Agenda – Accelerating material technologies

6 <https://www.ami2030.eu/> (AMIRi (60 organisations developing AdMa), SUSChem, EUMat, Manufacture EU)

Why is the OECD WPMN addressing Advanced Materials

- Experience addressing risk assessment of nanomaterials (since 2006)
- Safety considerations on new materials should not be limited to an 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 AdMa
- Some AdMa may also pose challenges regarding sustainability throughout their life cycle, including recycling and waste handling

OECD Steering Group Advanced Materials (AdMa)

Established in 2021

Comprising representatives from 24 Delegations: Austria, Canada, Denmark, France, Germany, Hungary, Italy, Japan, Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, United Kingdom, United States, EU, Croatia, Thailand, Env. NGOs, ICAPO, BIAC, ISO TC229.

Aim: strategic approach to support Regulatory Preparedness (RP) and Safe-and-Sustainable-by-Design (SSbD) of AdMa and their application

Tasks of the current programm of work:

- **Information gathering** on research and activities on AdMa of the delegations
- **Working description on Advanced Materials** (September 2022) [ENV/CBC/MONO(2022)29]*
- Develop of a **framework that supports Regulatory Preparedness (RP) and Safe-and-Sustainable-by-Design (SSbD) of AdMa** and their applications : **Early4AdMa*** published in September 2023 [ENV/CBC/MONO(2023)35]
- Carry out **case studies** *
- **Develop recommendation** on the next steps

* OECD Publication on the safety of manufactured nanomaterials are available online at <https://www.oecd.org/chemicalsafety/nanosafety/>

Advanced Materials within OECD WPMN

- ✓ To describe the playing field of AdMa within WPMN
- ✓ To describe in which context WPMN is engaged with AdMa
- ✓ Starting 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 process or established regulatory implementation
- ✓ Annex provides examples of AdMa



ENV/CBC/MONO(2022)29

Unclassified

English - Or. English

16 January 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

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.

ENV/CBC/MONO(2022)29

[https://one.oecd.org/document/ENV/CBC/MONO\(2022\)29/en/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2022)29/en/pdf)

OECD's WPMN strategy for addressing Advanced Materials

Development of International Standards for regulatory enforcement and innovation enhancement

Integrate Advanced Materials when developing standards and associated tools. For example:

- OECD's Test Guidelines
- Guidance Documents
- Reports

See: <https://oe.cd/nanomet> & <https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm>

Early Awareness and Action System for Advanced Materials (Early4AdMa)

Identify Actions needed and make recommendations, for example:

- the need for standardized methods

- Safety and sustainability issues of new materials and link this to innovation phase

Anticipate safety + Sustainability issues at the earliest stage of Innovation

Bringing Safety and Sustainability consideration at the earliest stage of innovation



OECD's Safe(r) and Sustainable Innovation Approach (SSIA)

See: <https://oe.cd/ssia>

Background to Early4AdMa and connection to SSIA

Speaker:

Agnes Oomen

Senior scientist and Professor,
National Institute for Public Health and the
Environment (RIVM)
University of Amsterdam (UvA)



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport



WPMN Strategic Approach for AdMa

Development of a Strategic Approach to support Regulatory Preparedness and Safe and Sustainable by Design of AdMa and their applications

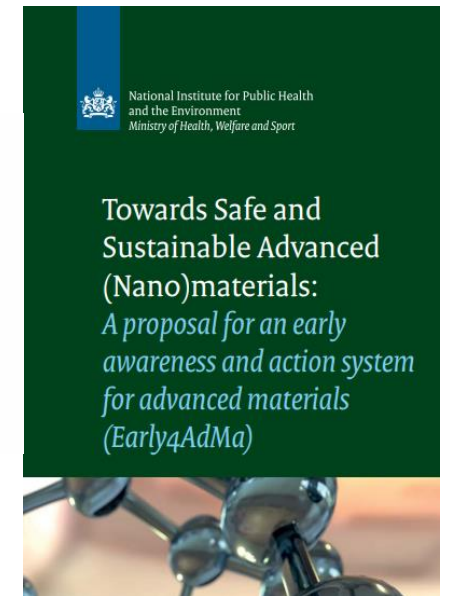
- Are regulations and methods/tools fit for AdMa?
- Identification of concerns about safety and sustainability and knowledge gaps
- Developments of recommendations and options for actions for decision makers

How is the Strategic Approach developed?

- ✓ **Early4AdMa** system as a **basis** for developing the Strategic Approach
- ✓ Experience with and feedback from **cases**


Early4AdMa approach

- First developed by RIVM, BfR, BAuA, UBA
- Further refined by **OECD WPMN Steering Group on Advanced Materials**
- **Aims:**
 - Identify and describe potential safety (both environmental and human), sustainability and regulatory issues for AdMa at an **early** stage
 - Anticipatory risk governance approach to allow for timely decision-making
- **Target audience:** Risk assessors and Regulators; can also be useful for Innovators and Researchers



Case Studies



 Antibacterial 2D Advance Nanomaterials (MXenes)

Feb 2022



 Fiber aerogel mat for façade insulation

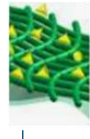
Nov. 2022




 Nanocarriers

June 2023

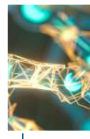


 Silver cellulose articles/ encapsulate cosmetic

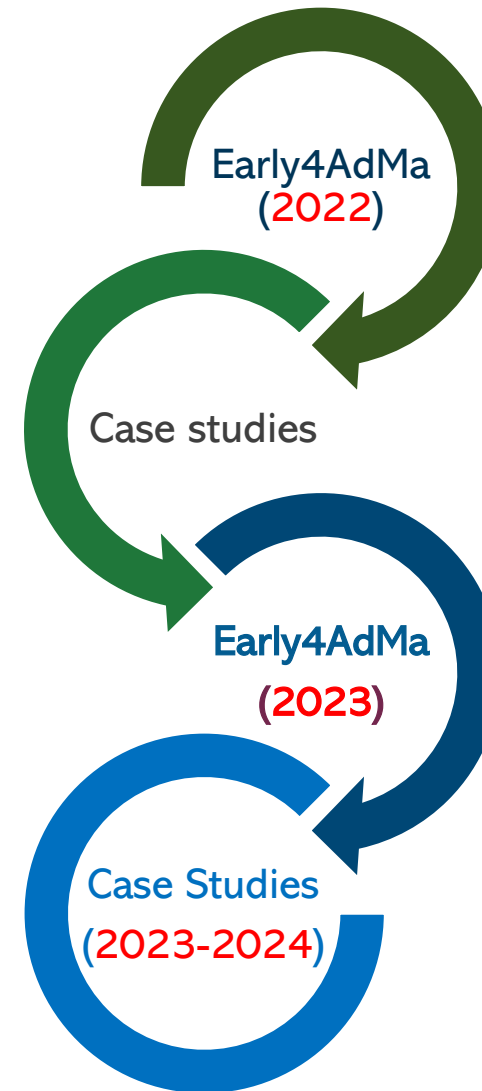
 Graphene Based Materials

 3D Printing



 GO + & Nano-SiO2

underway



Review the applicability of the strategic approach to identify refinements needed (MXenes + Fiber aerogel)

Identification of information needs and warnings on specific AdMas and development of recommendations for action regarding safety and sustainability

Early4AdMa approach

- Early4AdMa publicly available
- Not a final document
 - Further cases ongoing
 - To be updated as relevant



See the accompanying *Early4AdMa Excell Tool*: <https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/early-awareness-and-action-system-for-advanced-materials-tool.xlsx>

References:

OECD - <https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/early-awareness-and-action-system-for-advanced-materials-pre-regulatory-anticipatory-risk-governance-tool.pdf>

OECD Working Party on Manufactured Nanomaterials (WPMN)

- Established in 2006
- A global forum for policy discussions on nanomaterials and since 2021 also advanced materials
- Assist in the implementation of safety policies and regulatory preparedness
- Implements the programme via Steering Groups (SG) comprising nominated experts

SG Testing and Assessment: guidance for hazard assessment, facilitate nanospecific OECD TG /GD development

SG Exposure: guidance for exposure assessment and mitigation

SG Safe(r) and Sustainable Innovation Approach (SSIA)

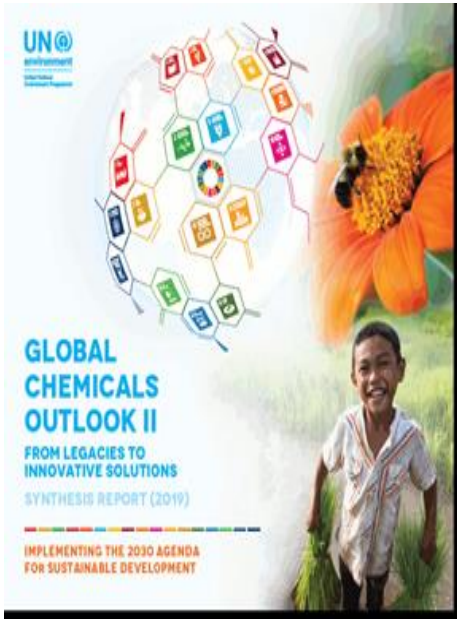
SG Advanced Materials (AdMa)

Functioning

Developers: In-country experts

|

Consensus builder: OECD Secretariat

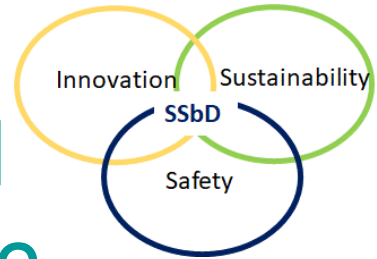


GLOBAL CHEMICALS OUTLOOK II:

- The global goal to minimize adverse impacts of chemicals and waste **have not been achieved** (desired by 2020).
- Solutions exist, but **more ambitious worldwide action** by all stakeholders remain an urgency



OECD's WPMN developed the Safe(r) and Sustainable Innovation Approach (SSIA)

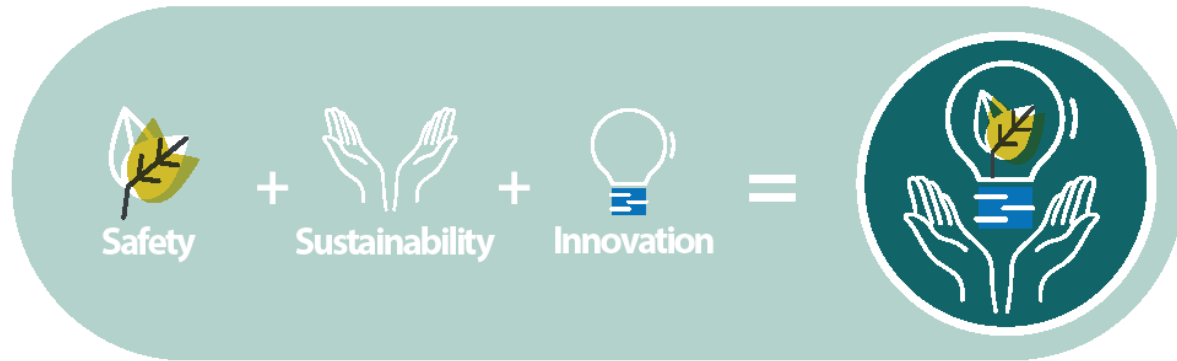


- Need to address safety and sustainability for early stages of innovation
- To ensure green and sustainable innovation it is necessary to bring closer Safety and Sustainability
- **AdMa use as an example since they can be developed to promote green and sustainable innovation.** Address global concerns (i.e.: water remediation; energy transition; biomedical, energy materials systems, and the food and agriculture industry)

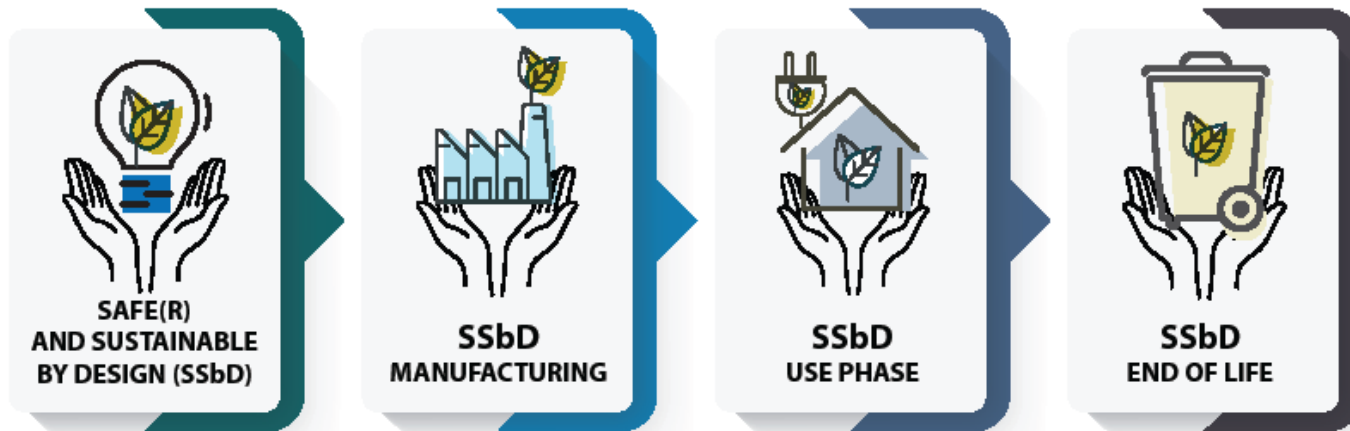
SEE: OECD Webinar on the Safer and Sustainable Innovation Approach for more sustainable nanomaterials and nano-enabled products (Nov. 2022)

<https://youtu.be/9TsiogF3nHg>

SAFE(R) AND SUSTAINABLE INNOVATION APPROACH (SSIA)



SSIA combines the **SSbD** and **Regulatory Preparedness (RP)** concepts in order to **identify and minimize** the possible **health and environmental risks, and sustainability impacts** of innovative materials, products, applications, and processes in a **timely manner during the innovation process**.



**SAFE(R)
AND SUSTAINABLE
BY DESIGN (SSbD)**

**SSbD
MANUFACTURING**

**SSbD
USE PHASE**

**SSbD
END OF LIFE**

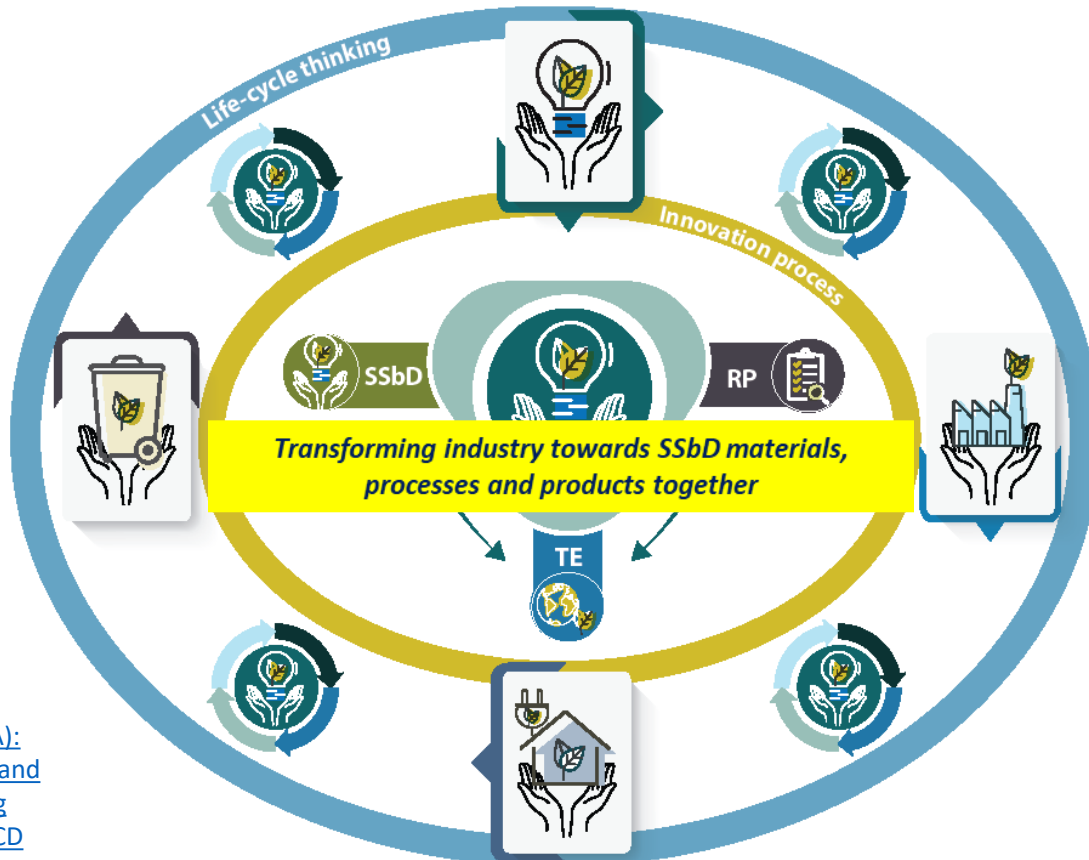
SSIA relies on **dialogue** between industry and regulators at an **early stage of the innovation process** and is facilitated by a **Trusted Environment**.

The **SG AdMa** intends to link with the **Steering Group Safer and Sustainable Innovation Approach (SG SSIA)** via cases and in constant collaboration

Read the report: [Safe\(r\) and Sustainable Innovation Approach \(SSIA\): Nano-enabled and other Emerging Materials - OECD](#)



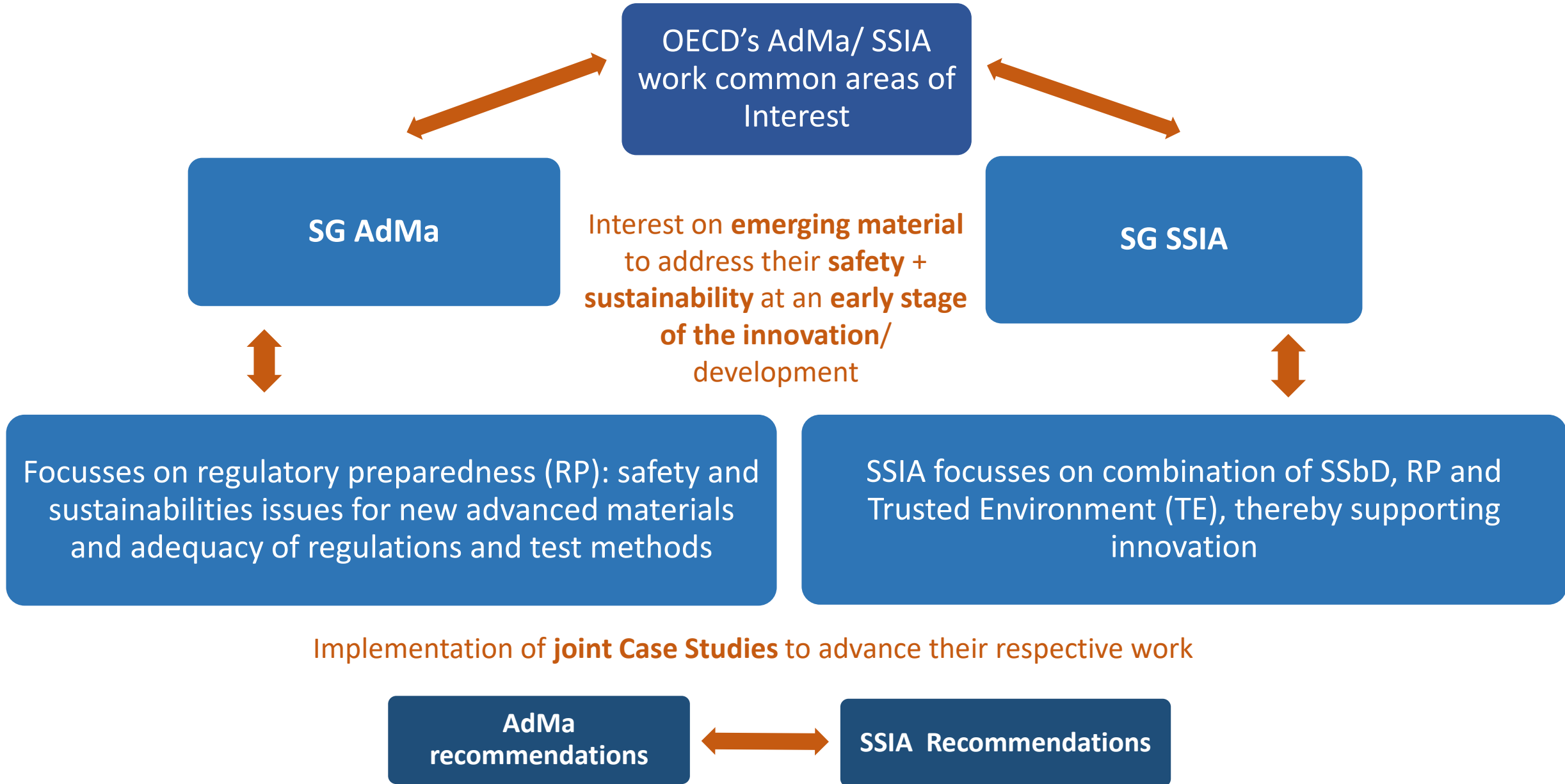
1. To **support innovation** and to ensure that **nanomaterials and advanced materials** are developed in a **safe and sustainable** way supported by a circular economy
2. To support a dynamic process for identifying and **prioritizing the elements to be considered for safety and sustainability**. This requires **continuous dialogue and/or collaboration between regulators and innovators**, and other relevant stakeholders.



SSIA aims to **support innovation** and to ensure that **nanomaterials and advanced materials** are developed in a **safe and sustainable** way supported by a circular economy

To support a dynamic process for identifying and **prioritizing the elements to be considered for safety and sustainability.**

This requires **continuous dialogue and/or collaboration between regulators, innovators,** and other relevant stakeholders.



Early4AdMa

Speaker:



Elmer Swart
Scientific officer
National Institute for Public
Health and the Environment
(RIVM)



National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Background and aim

- (Advanced) materials are key to solving global challenges ^{1, 2, 3}
- New or altered physical-chemical characteristics and functionalities → uncertainties on safety, sustainability and applicability regulation
- Key to act on potential issues before problems arise

References:

¹ The European Green Deal. <https://eur-lex.europa.eu/legal-content/NL/TXT/?qid=1588580774040&uri=CELEX:52019DC0640>

² EU CSS - <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

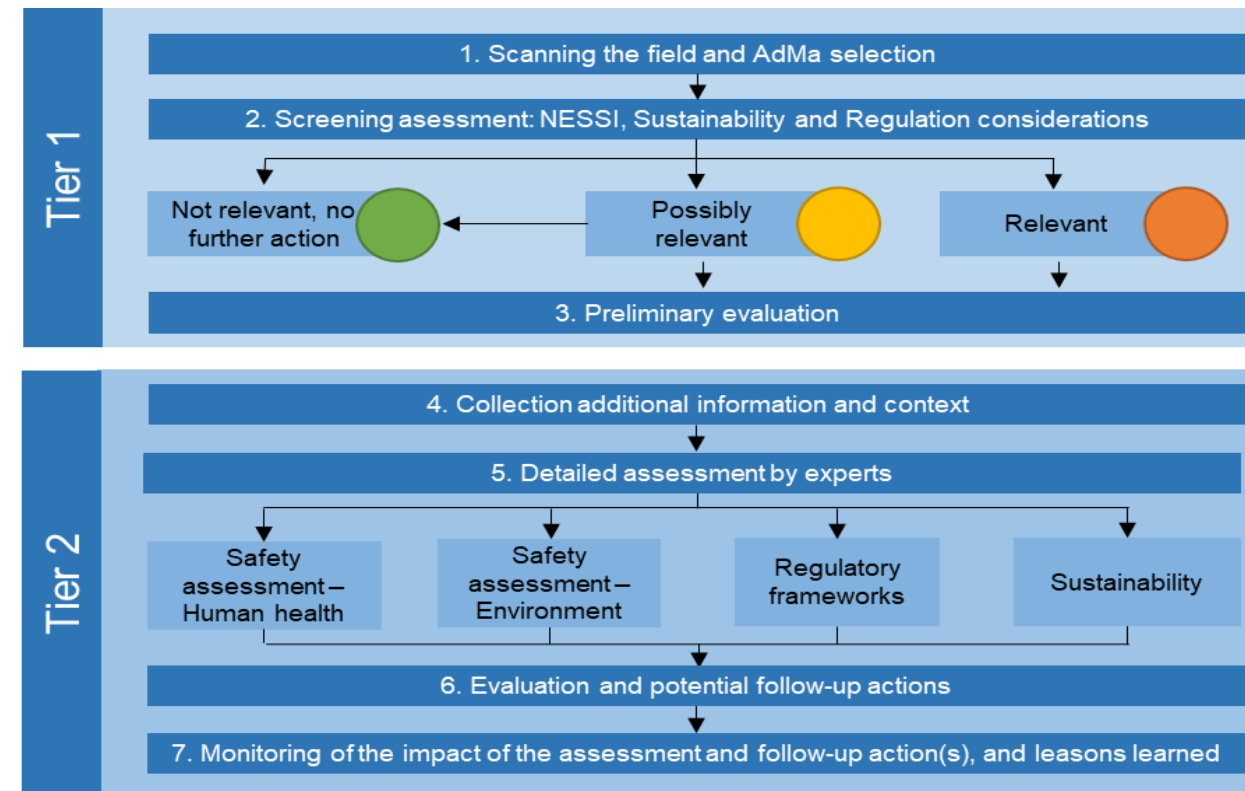
³ Advanced Materials 2030 Initiative (AMI2030) - www.ami2030.eu



Early4AdMa system

- **Early4AdMa:** tool in anticipatory risk governance approach to allow for timely decision-making
- Relies on **existing data** and **expert assessment**
- **Step-wise approach:** in two tiers and seven steps
- **Outcome:** report describing the context, potential issues and suggested follow-up actions for a (group) of advanced materials

Schematic overview of the tiers and steps of the Early4AdMa system.

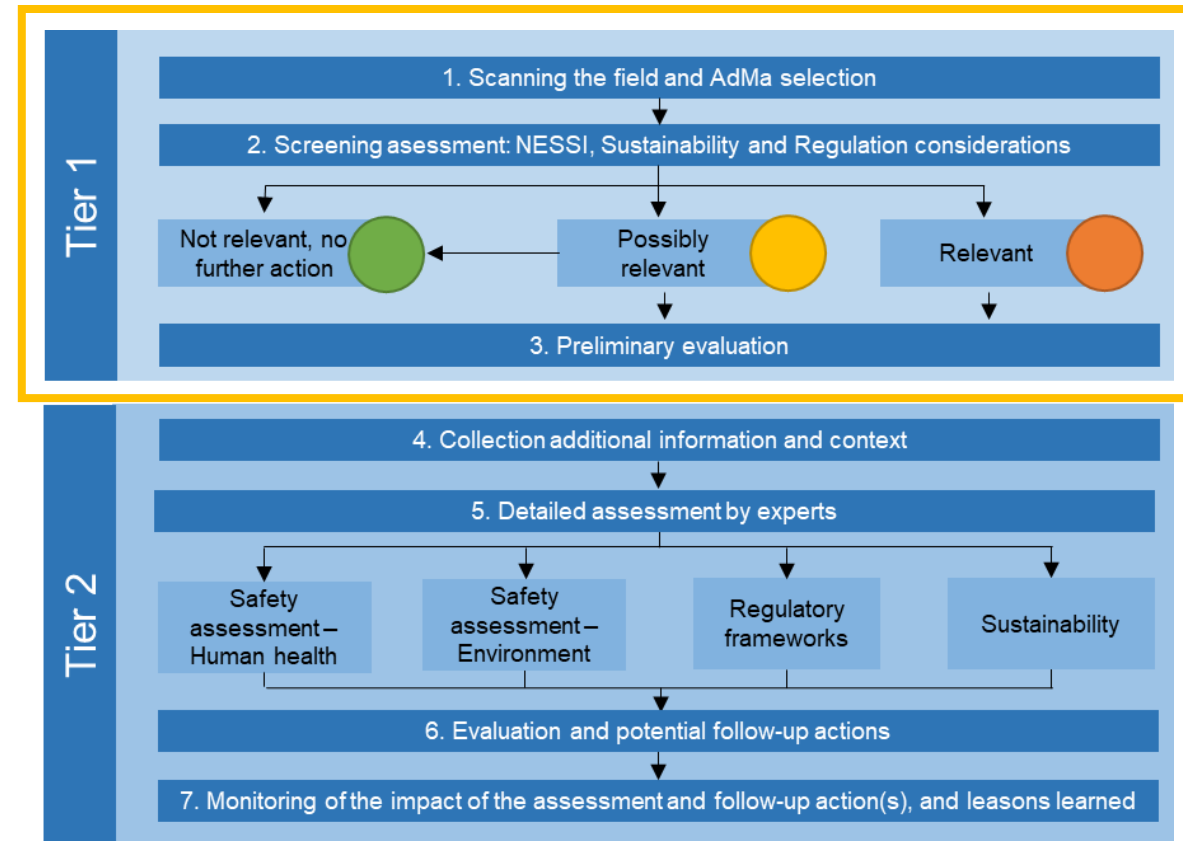


Tier 1

Tier 1 broad screening assessment:

- Aims to identify AdMa for further assessment
- **Tier 1 is an optional step**
- Scanning the field
- Identification of potential issues through **quick screening**:
 - NESSI
 - Sustainability
 - Regulation
- Preliminary evaluation

Schematic overview of the tiers and steps of the Early4AdMa system.

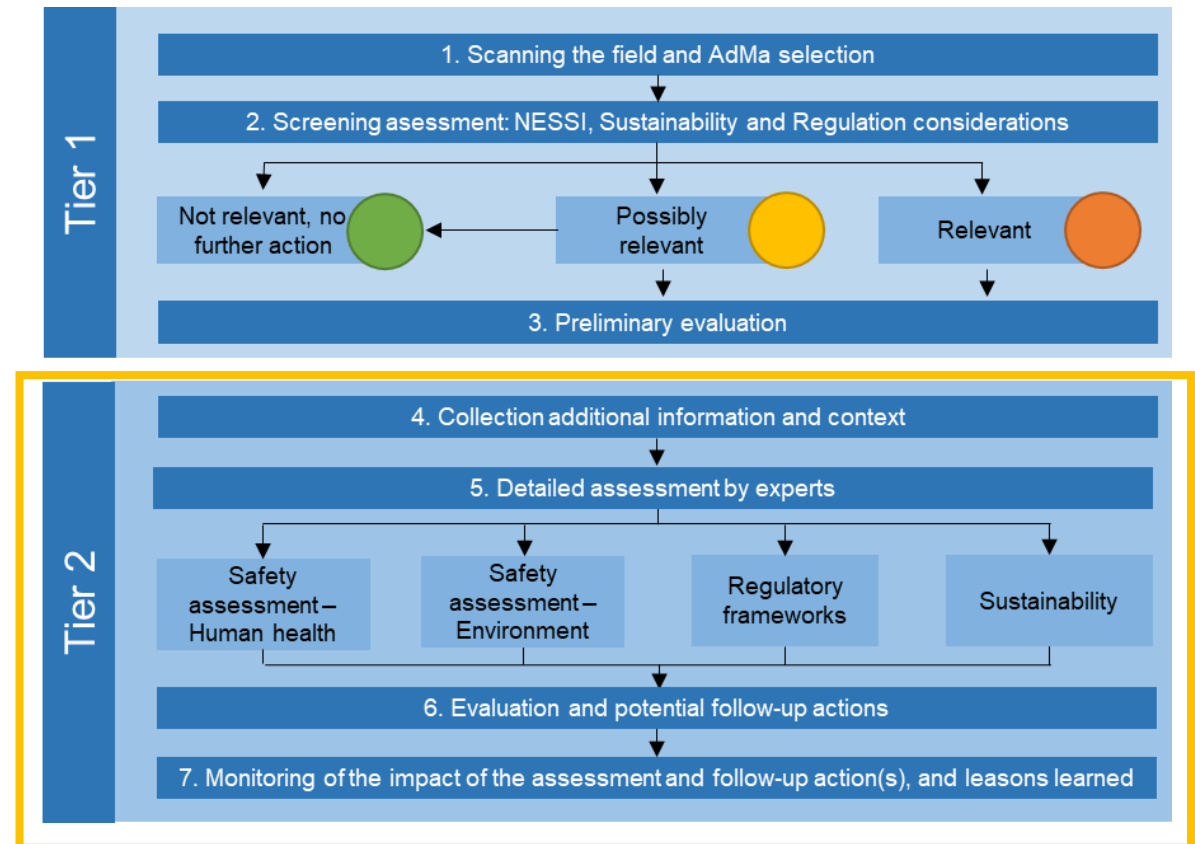


Tier 2

Tier 2: Detailed screening assessment

- **Context section** (step 4):
- Questions on **safety, sustainability** and **regulatory frameworks** (step 5)
- **Final evaluation** of identified potential issues and follow-up actions (step 6)

Schematic overview of the tiers and step of the Early4AdMa system.



Context section (step 4)

Aim:

- Helps answering the questions (step 5) in a way that is relevant to the case
- Provides the context and relevance for the final evaluation

Content:

- Focus of the assessment: which material and applications are considered?
- Market entry stage
- Benefits, social-economical aspects
- Anticipated release compartments and (transformation) forms (during life cycle)
 - Each to be considered in the assessment

Context

- Application area¹

1 Health-care and medicine	2 Con- struction	3 (New) energy	4 Trans- portation	5 Home and personal care	6 Packaging	7 Agri- culture	8 Textiles	9 Electronic appliance	10 Other
-------------------------------	------------------------	----------------------	--------------------------	-----------------------------------	----------------	-----------------------	---------------	------------------------------	-------------

- Focus of assessment: material (as a whole incl. all its applications) or material in (one or more) specific product
- Benefit, benefit for whom, and anticipated magnitude of benefit (as compared to a conventional material/product)
- Socio-economic considerations (criticality raw materials, child labor etc)
- Market-entry stage
- (Anticipated) scale of application (of material, and if specific product(s) are considered, fraction related to product(s))
- Relevant **anticipated** release compartment and (transformation) forms during life cycle (see table):

	During production ²	During use	End-of-life	Other ³
Compartment(s) of release (e.g. air, water, soil)				
Form(s) of release (e.g. pristine, embedded in matrix, transformed, corona formation)				
Mechanism(s) of release (e.g. due to use, weathering, sanding)				

Schematic overview of step 4 of the Early4AdMa system.

Detailed assessment (step 5)

- **Step 5:** list of questions each of four topics:
 - **Human safety**
 - **Environmental safety**
 - **Regulatory frameworks**
 - **Sustainability**
- Four possible answers: 'Yes', 'No', 'Unknown' and 'Not applicable'
- 'Yes' indicates a potential issue → reported in final evaluation
- Specific guidance included

Some of the questions for the topic 'Applicability of regulatory frameworks'

Sub-topic	Question	Yes	No	?	NA	Comment/clarification
Sample preparation and analytics	Are there issues expected with the analysis of the characteristics of AdMa as pristine material? → Guidance					
	Are there issues with sample preparation for determination of physicochemical properties, hazard, <u>toxicokinetics</u> , fate or exposure assessment of the specific material likely, e.g. due to the absence of guidance, protocols or existing protocols are not adequate? → Guidance					
	Are there issues expected with the analysis of the AdMa in complex matrices in view of exposure, environmental fate or toxicokinetic analysis? → Guidance					
Applicability Regulatory Frameworks	Is the material(s) or application(s) of the material outside of the scope of current chemical or sector specific legislation(s)?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation do the information requirements for substance identification lack provisions that explicitly address the nano/multicomponent/advanced character of the material? → Guidance					
	If the answer to the previous question is "yes": If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation do the information requirements for substance identification lack provisions that allow addressing the nano/multicomponent/advanced character of the material?					

Final evaluation (step 6)

- **Contents of the final reporting are not strictly defined**
- **Suggested contents are:**
 - A context section (step 4) that describes the material, the focus of the assessment, manifestation forms throughout the life cycle, benefits etc.
 - A summary in text of the detailed assessment conducted in step 5. A graphical summary of the outcome may also be included.
 - A proposal for potential follow-up actions

Example of a graphical summary:



Who should use the system?

- The system is developed for use as a pre-regulatory risk governance tool and the output should help regulatory decision makers to take action to address potential issues with a AdMa. It thus aims to facilitate regulatory preparedness.
- Input from research, industry and innovators is required, e.g., to collect information on the physical-chemical characteristics, benefits and application
- It is envisioned that the assessments within the system are conducted by a **group of experts**, ideally with representation from **different sectors** (i.e., regulation, academia and, industry and innovation) and experts with **different expertise**
- The system may also be used for **other purposes** (e.g., by industry), e.g., to facilitate SSbD

Early4AdMa is an expert assessment based system

- Expert assessment is the basis of the system
- Questions can be answered based on specific literature
- Often no specific information is available
- expert assessment to the extent feasible ; or
 - a) IF not feasible: **unknown** as an answer

How to deal with uncertainty?

- In the early stages of product development, data on safety and sustainability of a material is scarce or lacking
- Goal of the system is not to provide a definitive safety/sustainability assessment, rather the goal is to identify potential issues including information gaps **so that follow-up actions can be taken**
- The absence of clear evidence does not mean that experts should fill in ‘unknown’ by default
- Assessments are performed in a conservative way: **an indication**, rather than clear evidence, **is sufficient to identify** an issue of concern or gap of information
- Example question: “Is there an indication of persistency due to low dissolution or degradation rate in any physiologically relevant media?”
 - ‘Yes’ for an AdMa composed of materials that does not (or hardly) dissolve, even in absence of specific information on persistency/dissolution

Case Studies - HARMLESS

Speakers:



Blanca Suarez Merino

Director of Regulatory Affairs at the
Nanotechnology Industries Association (NIA)
Co-founder of TEMAS Solutions GmbH

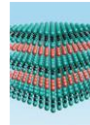


Wendel Wohlleben

Senior Principal Scientist
BASF SE



Case Studies



Antibacterial 2D Advance Nanomaterials (MXenes)

Feb 2022



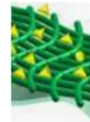
Fiber aerogel mat for façade insulation

Nov. 2022

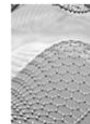


Nanocarriers

June 2023



Silver cellulose articles/ encapsulate cosmetic



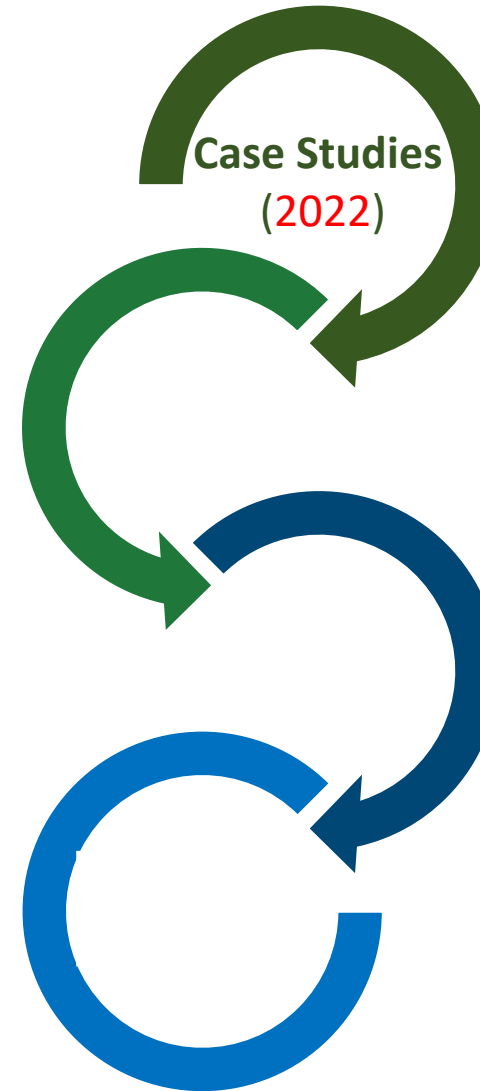
Graphene Based Materials



3D Printing



Case studies under discussion with Sunshine



Review the applicability of the strategic approach to identify refinements needed (MXenes + Fiber aerogel)

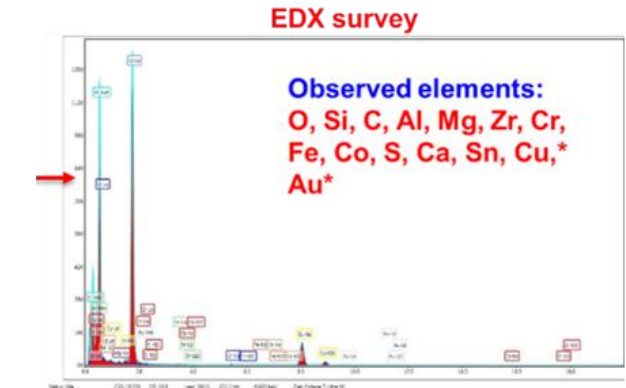
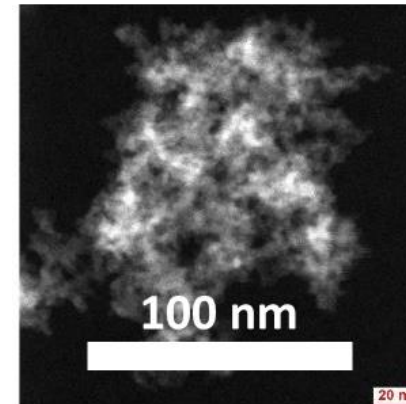
Façade insulation by fibre-aerogel-mats



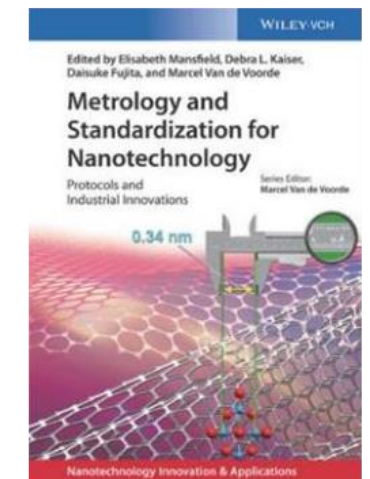
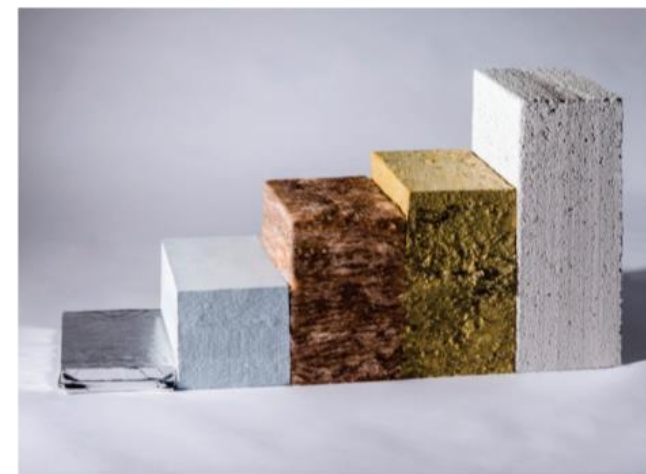
The HARMLESS project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 953183

approaching specific concerns by modifications within SSbD design space

- **SSbD concern**
 - High internal porosity of aerogel, if fragmented
 - Fibre fragments, organic modifications
- **SSbD design space**
 - Composition, choice of fibre support, organic modification, optionally inorganic coatings to protect against mechanical stresses.
- **Intended functionality**
 - Thermal insulation with record effectiveness at low thickness, e.g. around windows, campers, ...
- **Conventional alternative**
 - Mineral wool mats (3 times thicker →)
 - Polymer foams panels



Singh et al (2021) J. Haz. Mater. 422: 126771.

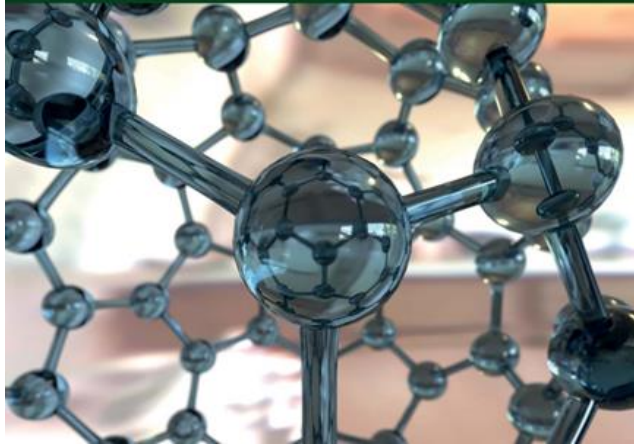


Workshop scope:

1 case study

1 + 4 concepts

Towards Safe and Sustainable Advanced (Nano)materials: A proposal for an Early Warning, prioritisation and action system (EWARN)



MATERIALS 2030 MANIFESTO

Systemic Approach of Advanced Materials for Prosperity – A 2030 Perspective
7 February 2022

1 source of prosperity of an changes of the 21st century, role.

with Marja Gabriel, European Youth, the undersigned are invited to collaborate, wing vision:

ten and digital transi- through a systemic sers and citizens and

3 sustainability in agriculture, as well as completing the challenges humanity is facing must have an interconnected mals can and must deliver e sustainability features of a technologies. Sustainable i opportunities on multiple in and digital transitions is tween advanced materials, prt the evolution of materials

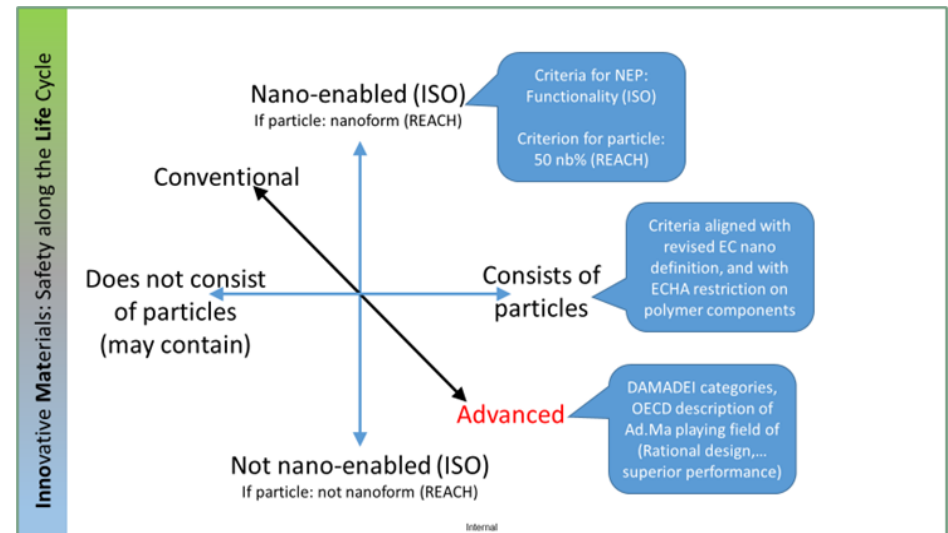
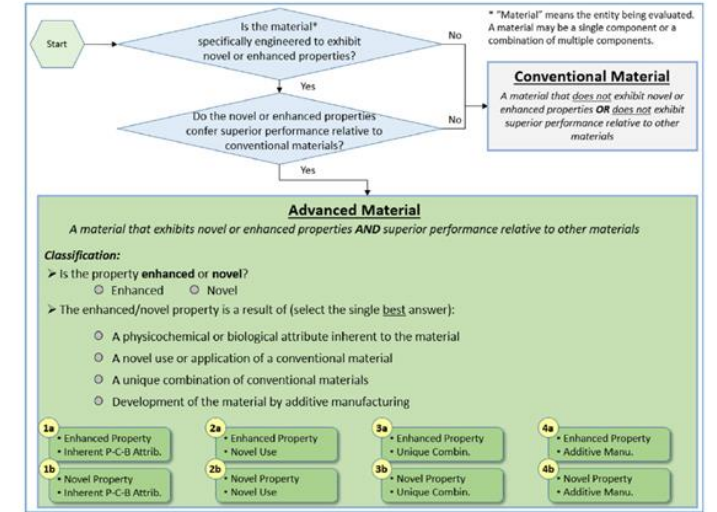
es – high performance g, simulation and screening ion processes, unlocking nce, which in turn drives s will lead to new safe and and advanced materials with

Figure 3 – Advanced materials applications and cross-cutting challenges as relevant enablers for nine selected markets. This figure is not to be understood as an exhaustive research roadmap.

EC Group of Chief Scientists, Advanced Scientific Dialogue – A systemic approach to the energy transition in Europe (June 2022) and EC Group of Chief Scientists, Advanced Scientific Dialogue – A systemic approach to the digital transition in Europe (June 2022)

A Definition and Categorization System for Advanced Materials: The Foundation for Risk-Informed Environmental Health and Safety Testing

Alan Kennedy,¹ Jonathon Brame,¹ Taylor Rycroft,^{1,*} Matthew Wood,^{1,2} Valerie Zemba,³ Charles Weiss Jr.,⁴ Matthew Hull,^{5,6} Cary Hill,^{5,6} Charles Geraci,⁷ and Igor Linkov¹



Prospective environmental risk screening of seven advanced materials based on production volumes and aquatic ecotoxicity

Rickard Arvidsson^{a,*}, Gregory Peters^a, Steffen Foss Hansen^b, Anders Baun^b

^a Division of Environmental Systems Analysis, Chalmers University of Technology, Vera Sandbergs Allé 8, 412 96 Gothenburg, Sweden.
^b Department of Environmental Engineering, Technical University of Denmark, Byngningstorvet, Building 115, 2800 Kongens Lyngby, Denmark.

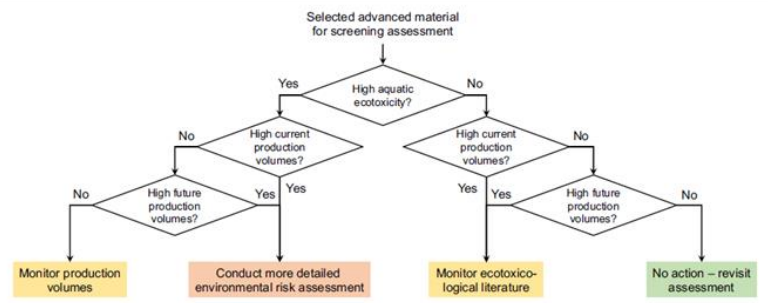


Fig. 2. Recommended actions depending on the outcome of the proxy measure risk screening approach.

Workshop participants & prior knowledge

61 Participants:

Large industry (4.9%)

NGOs (3.3%)

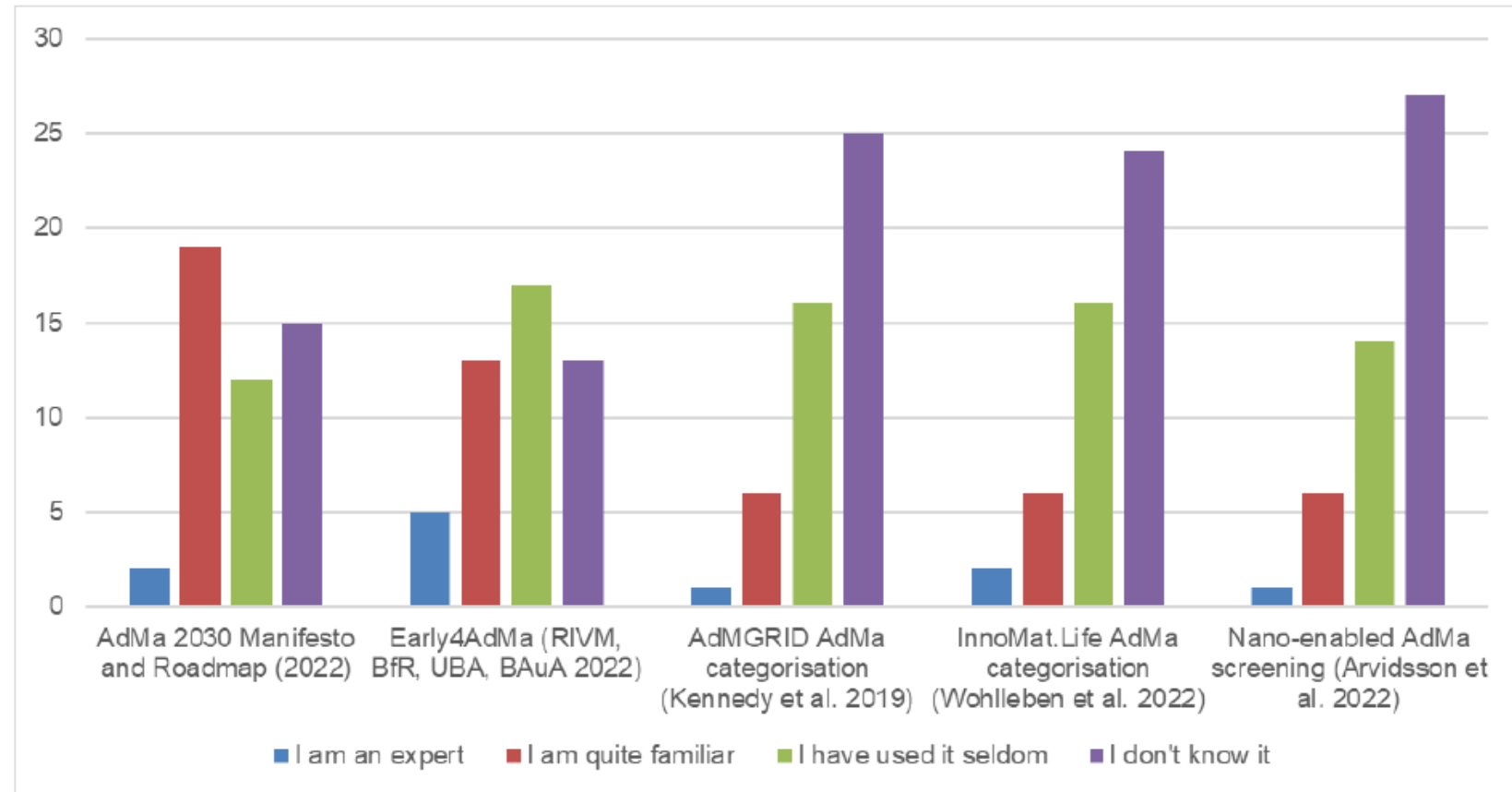
Policy makers (11.5%)

Regulators (13.1%)

Scientific community (59%)

SMEs (4.9%)

Unknown (3.3%)



Workshop learnings

(breakout moderated by Prof. Anders Baun, DTU)

Arvidsson et al.

Pros

- Simplicity
- Based on OECD test guideline, data rich
- Graphical visualisation
- Guiding questions

Easy to use
Graphical visualisation

Cons

- May miss regional hotspots
- Does not consider “no data”
- Focuses only on aquatic toxicity
- Difficult to assess borderline data

Too Global for SSbD purposes
Does not provide proxy to address toxicity (eg through leaching, dissolution or grouping)

Workshop learnings

(breakouts moderated by Agnes Oomen, RIVM and Andrea Haase, BfR)

Early4AdMa

Pros

- Good example of translating ideas into practical aspects for regulators
- Very useful, easy to use for experts, considers all issues
- Easy to follow approach to provide qualitative output, good to identify gaps
- Complementary to the SSbD JRC framework

Easy to implement for experts due to guiding questions

Useful for gap analysis

Cons

- Not suitable for early stage, large amount of detailed data needed
- Time consuming and experts required
- Sustainability of use not addressed
- More guidance required
- Scoring system unclear

Uncertainty is insufficiently addressed

Elaboration on the scoring system is needed

Workshop learnings

(breakout moderated by Wendel Wohlleben, BIAC / BASF)

InnoMat Life

Pros

- Identification of conventional vs advanced materials
- Flexibility, it allows to use any definition.
- Focuses on unknown and unregulated materials
- InnoMat.Life is not a risk screening, but a start to identify the typical use scenario coming next and compare with conventional materials.

Flexible

Diff. Between AdMa and conventional materials

Cons

- Materials may be overlooked
- Release is not considered
- Atypical use is not considered

Release and

unintentional use are not considered

Workshop conclusions

32. The feedback gathered in this workshop allowed for the positioning of each scheme along the innovation process, with schemes such as InnoMat.Life representing an early categorisation scheme and more data demanding schemes such as Early4AdMa are situated further down the innovation process. Low-tier schemes such as Arvidsson *et al.* and InnoMat.Life may be integrated as earlier steps in the more complex Early4AdMa scheme and may guide safety and sustainability assessment by better definition of conventional material and industry segment as point of comparison, as this is especially needed for SSbD decisions in industry.

33. The attendants also highlighted that Early4AdMa may be used by regulators for identification of knowledge gaps and possible concerns prior to the implementation of the European Commission's Safe and Sustainable by Design Framework. Availability of requested data was one main issue expected to be driving the future use of these schemes. For the case study performed here, the required data for InnoMat.Life was more readily available as compared to the Arvidsson and Early4AdMa schemes. In addition, the Early4AdMa scheme lacked guidance and contained some unprecise questions.

34. The level of expertise required per scheme was also assessed. Early4AdMa requires experts from different disciplines (chemists, toxicologists, sustainability experts). During the session it was also acknowledged that a second layer of analysis may be required for Early4AdMa, to take into account correct weighting of results and potential biased answers since several experts were required to fill the scheme.

35. Some missing elements were identified by the attendants, which included unintended use and thus not considered material release from aerogel insulation mats. Moreover, a global scheme such as Arvidsson *et al.* may fail to detect regional hotspots. Each of the schemes could be modified to remove deficiencies.

36. This workshop represents the first practical evaluation of the applicability of foresight schemes to a high-TRL industrial case study. The results of the workshop can be used to improve each of these schemes, so they can become more useful tools to guide safe and sustainable AdMa development.

Workshop report publicly available
since 7. Sept. 2023



Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2023)34

Unclassified

English - Or. English

7 September 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

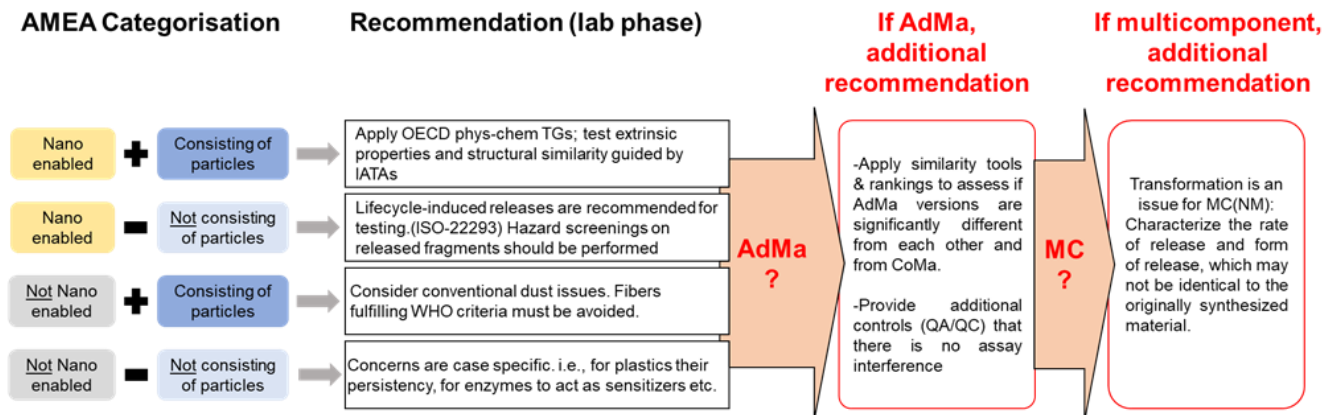
Advanced Materials Assessment Schemes HARMLESS - OECD Working Party on
Manufactured Nanomaterials (WPMN) Workshop Report

Series on the Safety of Manufactured Nanomaterials
No. 107

Two tangible results from workshop

HARMLESS "AMEA" builds on InnoMat.Life categories and adds what OECD workshop participants missed: specific recommendations, lifecycle consideration, entry to DSS, re-design of SSbD-versions of AdMa during R&D. (illustrative figure only)

Workshop report publicly available since 7. Sept. 2023



Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2023)34

Unclassified English - Or. English

7 September 2023

**ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE**

**Advanced Materials Assessment Schemes HARMLESS - OECD Working Party on
Manufactured Nanomaterials (WPMN) Workshop Report**

Series on the Safety of Manufactured Nanomaterials
No. 107

Under peer review (special issue on AdMa in Env. Sci. Nano)
 Submission is open until end Nov. 2023

Case Study: Nanocarriers

Speaker:



Doris Völker

Scientific employee
German Environment
Agency (UBA)

Umwelt
Bundesamt 

Case Studies



Antibacterial 2D
Advance Nanomaterials
(MXenes)

Feb 2022



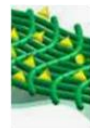
Fiber aerogel mat for
façade insulation

Nov. 2022

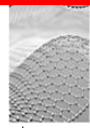


Nanocarriers

June 2022



Silver cellulose articles/
encapsulate cosmetic



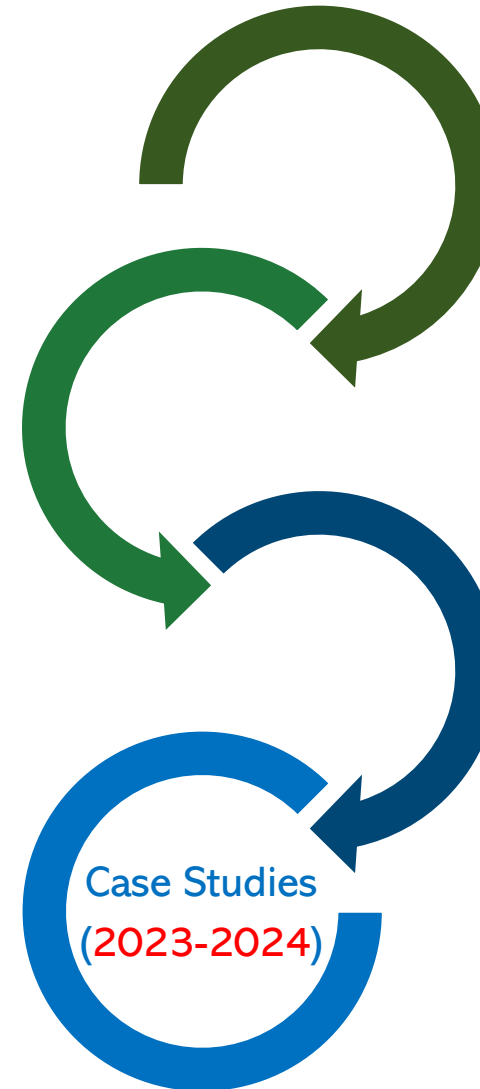
Graphene Based
Materials



3D Printing



Case studies under
discussion with
Sunshine



Identification of information needs and warnings on specific AdMas and development of **recommendations for action regarding safety and sustainability**

Rationale for the Nanocarrier Case

- Nanocarriers promise benefits for various fields of applications e.g., targeted application, new therapies, less demand of an active substance
- First applications established for medicinal products, applications for other fields are approaching (e.g., pesticides, biocides, cosmetics, food)
- Nanocarriers feature an example of AdMa with many different types and applications, thus differentiated discussion and early warning assessment needed
- Early4AdMa: identify knowledge gaps and signals of possible concerns regarding safety and sustainability as well as to formulate action needs

Within the case study Nanocarriers are understood as carrier systems for active substances whose external dimensions are smaller than around 1000 nm in at least one dimension. They are used, among other things, for protection, targeted transport to the site of action and sustained release of an active substance.

OECD Online Expert Workshop 14/15 June 2023

- up to 64 participants from 18 member and observer countries, EC, BIAC, ICAPO, IUPAC
- stakeholders from regulatory bodies, academia, industry, NGO

Scope of the Nanocarrier Case

- Setting the scene
 - Overview on Nanocarriers, applications, and synthesis
- Breakout group discussion, round 1: Assessment by Early4AdMa Step 5
 - Identify and discuss signals on topics “safety assessment human health”, “safety assessment environment”, “regulatory frameworks”, “sustainability”



Cosmetics

Example: skin care application

Plant protection products

Example: fungicidal application

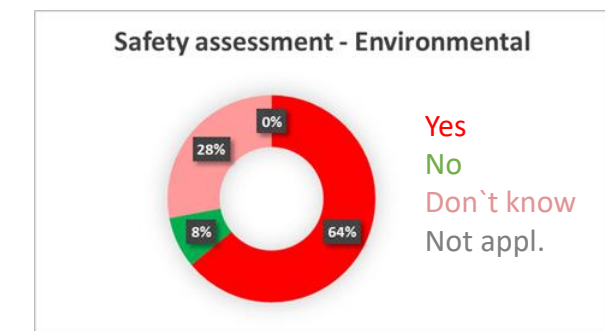
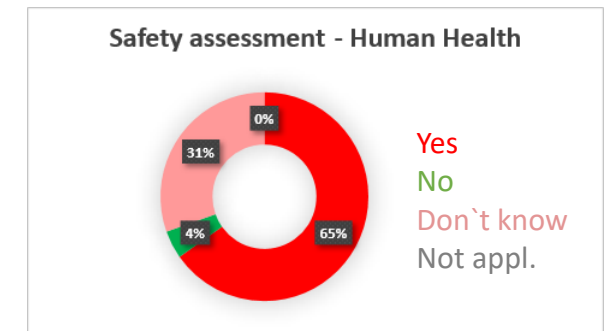
Pharmaceuticals

Example: chemotherapeutical application

- Breakout group discussion, round 2: Evaluation and formulation of follow up actions
 - Identifying “topic of biggest concern”, “biggest data gap” of the respective application
 - Formulate follow up actions (and addressees for action) based on discussion from Session 1
 - Give feedback on gaps and ambiguities of the Early4AdMa

Lessons learned from the Nanocarrier Case

- Due to the complexity of Nanocarriers, differentiated considerations are to be made with respect to the implications originating from the carrier versus those originating from the cargo (active substance) but also versus those originating from the entirety of the Nanocarrier
- For the discussed cases, the identified implications for safety mainly originate from the active substance while the contribution of the carrier remains low or unknown
- This requires an adequate reflection on the origin of the signals in the reporting
- Identified knowledge gaps include toxic potential of the carrier, change in fate/effect of the active substance due to the carrier, resource demand during the whole life cycle, waste considerations during production...
- Only a few regulatory frameworks consider the influence of nanocarrier within their obligations or provide sufficient guidance for assessment (differs between countries/regulatory areas)
- Test methods are needed to investigate and evaluate the extent to which transport/protection via a carrier can influence the fate and effect of (already well studied) active substances



Outcome of Early4AdMa step 5 on human health and environmental safety for the Nanocarrier example for fungicidal application

Recommended next steps

- With regard to the signals identified for Nanocarriers:
 - Obtain an overview of ongoing research activities to (1) to fill data gaps and (2) to substantiate the identified signals
 - Close remaining data gaps to provide information on
 - the influence of the carrier on fate/effects of the active substance
 - resource consumption over the whole life cycle and waste considerations during e.g., production
 - Review and amend where necessary affected obligations and assessment guidance
 - Establish harmonised test methods and analytical methods
- With regard to the applicability of Early4 AdMa:
 - Identify step 5 questions which may afford a differentiated response for the different building blocks of an AdMa to aid cases with similar challenges like for nanocarrier (i.e., cases for which signals are driven mainly by one [non-advanced] component)
 - Propose solutions how to deal with such questions while ensuring that the overall assessment relates to the entirety

Future Case Studies

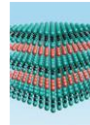
Speaker:



Kathrin Schwirn
Scientific employee,
German
Environment Agency
(UBA)

**Umwelt
Bundesamt**

Case Studies



Antibacterial 2D
Advance Nanomaterials
(MXenes)

Feb 2022



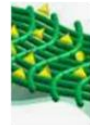
Fiber aerogel mat for
façade insulation

Nov. 2022



Nanocarriers

June 2023

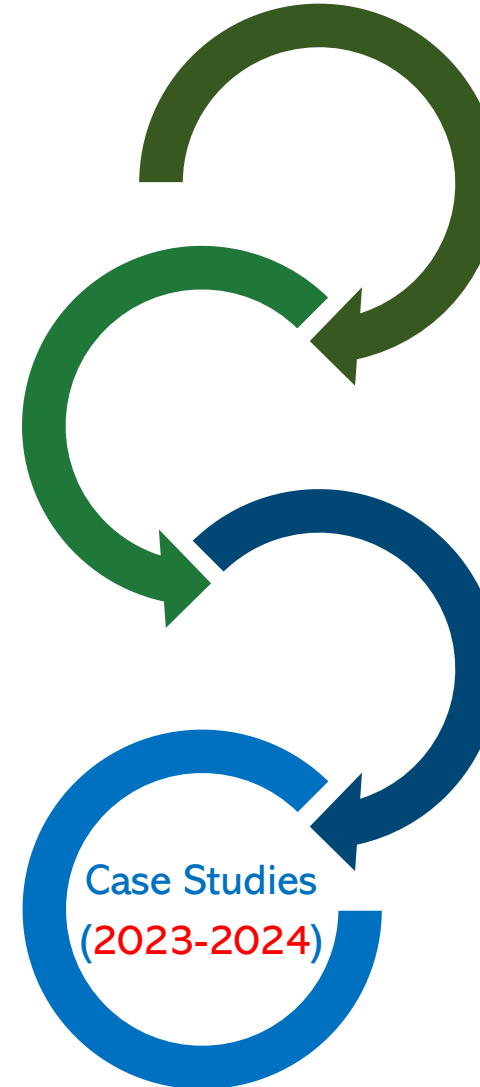


Silver cellulose articles/
encapsulate cosmetic

Graphene Based
Materials

3D Printing

Case studies under
discussion with
Sunshine



Identification of information needs and warnings on specific AdMas and development of recommendations for action regarding safety and sustainability

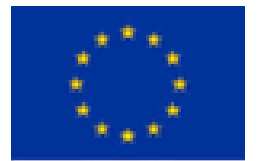
Case Study together with EU H2020 Project



Comparative assessment of two methodologies: OECD strategic approach and SUNSHINE methodology

Application of the two methodologies to two multicomponent nanomaterials in order to identify

- Target user
 - Similarities
 - Complementarities
 - And areas for collaboration
-
- multicomponent nanomaterials to be examined with potential to
 - Improve fire safety
 - Improve performance of building materials



Future Case Studies

Graphene based materials

- Spain, Germany, and Sweden have expressed an interest in developing a case study on Graphene.
- Liaise with the Graphene Flagship and explore collaboration opportunities
- Coordinate inputs with the proposed project proposal by South Africa
- Looking for additional delegations interested in participating to this case study

3D Printing

- The United States initiated a project on studying 22 filament materials generated by 3D printing and they would like to submit information on 2 for which there is already data.
- Germany has expressed interest to contribute
- Looking for additional delegations interested in participating to this case study
- Next Step: organize a discussion with interested participants and proposed next steps

Concluding Remarks

Concluding remarks

This webinar provided information on

- Activities within the OECD SG AdMa
 - Early4AdMa system as a tool for regulatory preparedness
- Application to cases

Reach out

Early4AdMa

- Invitation to use the Early4AdMa system ([Early4AdMa Excell Tool](#))
- Invitation to bring cases to the OECD SG AdMa
- Feedback on the Early4AdMa system is appreciated and will be used for future updates

General

- Invitation to identify new relevant AdMa/approaches to identify new AdMa
- Share ideas to bring signals into awareness and potential follow-up actions on specific AdMa into practice

Questions?



Do you want to know more about the OECD work on Nanomaterials and Advanced Materials?

- **Websites:** <http://www.oecd.org/chemicalsafety/>;
<https://www.oecd.org/science/nanosafety/>;
<https://www.oecd.org/chemicalsafety/safer-and-sustainable-innovation-approach/>
- **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>

 **YouTube** <http://bit.ly/youtube-chemical-safety>



[@OECD_ENV](https://twitter.com/OECD_ENV)

Contact: Nanosafety, AdMa, SSIA: mar.gonzalez@oecd.org

