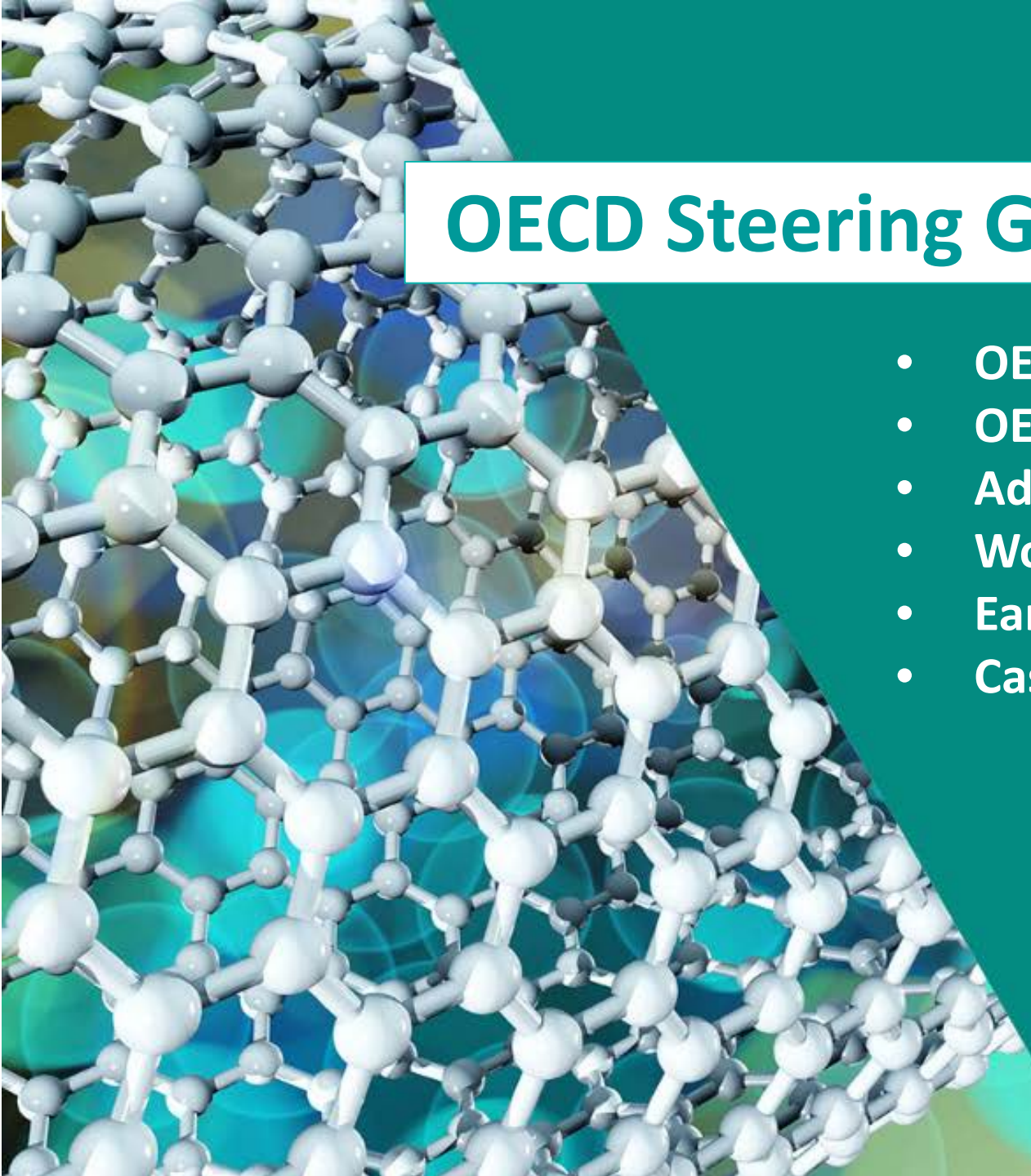


OECD Steering Group on Advanced Materials

- OECD
- OECD Steering Group AdMa and SSIA
- Advanced materials
- Working description
- Early4AdMa as a tool in Regulatory Preparedness
- Case studies

OECD
BETTER POLICIES FOR BETTER LIVES

38 Supportive **Member countries** and **EU** (DGs, JRC, other Agencies like EFSA)

Supportive **Stakeholders** (Env NGOs, Industry (BIAC), Animal Welfare org., Labor org; IGOs – i.e.: UNITAR-WHO) and Observer countries (i.e.; SA, Thailand, Malaysia)

OECD Chemicals and Biotechnology Programme

Development of Harmonised instruments for the safety assessment of chemicals, including Nanomaterials and Advanced Materials

Working Party on Manufactured Nanomaterials (WPMN)

- A global forum for policy discussions on innovative materials
- Assist in the implementation of safety policies and regulatory preparedness

Functioning

Developers: In-country experts | **Consensus builder**: OECD Secretariat

WPMN Steering Groups (comprising experts nominated by delegations)

- Safety Testing (Grouping, TGs/GDs needs)
- Exposure
- Safe(r) and Sustainable Innovation Approach (SSIA)
- Advanced Materials (AdMa)

OECD Steering Group Advanced Materials (AdMa)

Comprising representatives from 23 Delegations: Austria, Canada, Denmark, France, Germany, Hungary, Italy, Japan, Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, United Kingdom, United States, EU, Thailand, Env. NGOs, ICAPO, BIAC, ISO TC229.

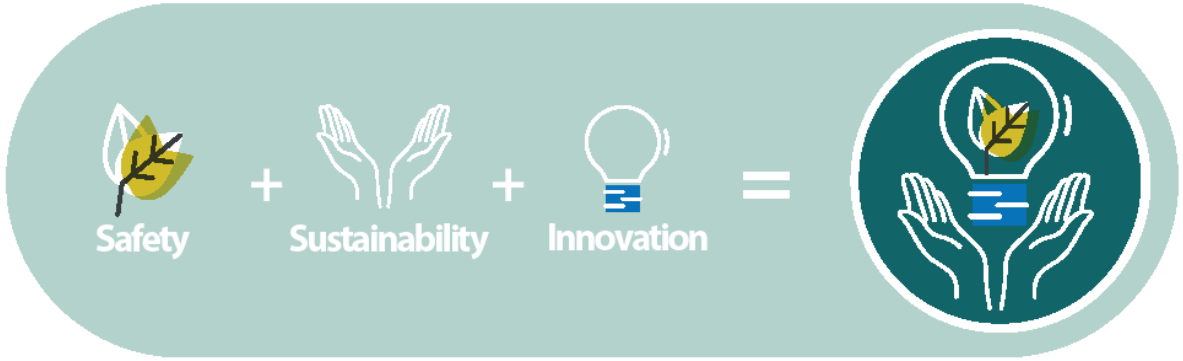
Rationale:

- Safety considerations on new materials should **not be limited to an upper size limit of 100nm**
- Many innovative materials possess/display an **additional complexity** (new or enhanced functionality and/or multiple components)
- Experience from **NMs useful knowledge** ground
- Enhance **Regulatory Preparedness** for safe application and use of all Advanced Materials (AdMa)
- **Sustainability** consideration incorporated throughout their life cycle

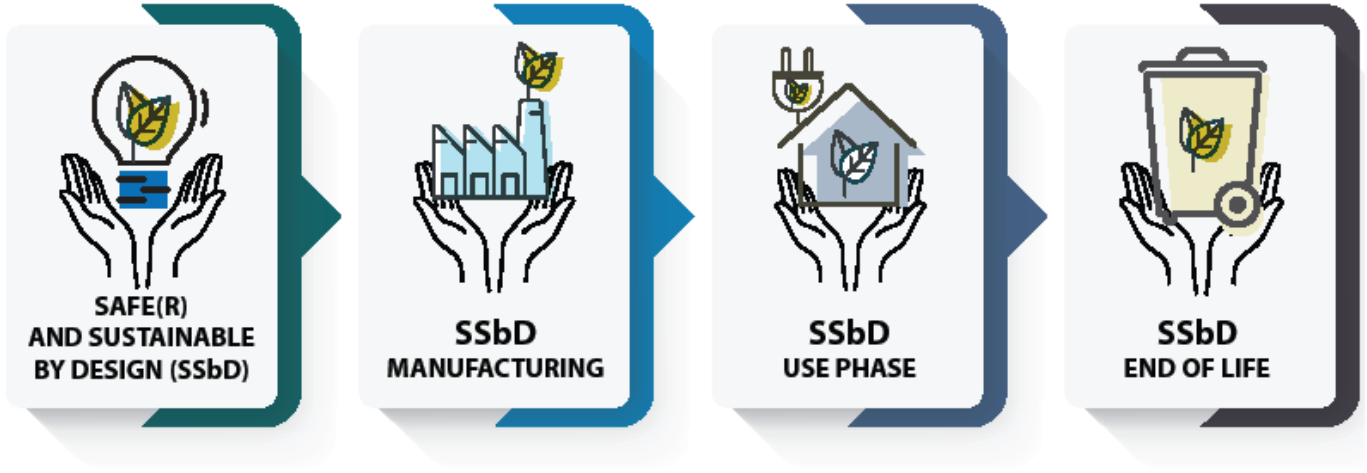
Current Tasks of SG AdMa:

- **Information gathering** on research and activities on AdMa of the delegations
- Develop of a **strategic approach to support Regulatory Preparedness (RP) and Safe-and-Sustainable-by-Design (SSbD) of AdMa** and their applications : Early4AdMa
- Carry out **case studies**
- **Develop recommendation** on the next steps

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**.

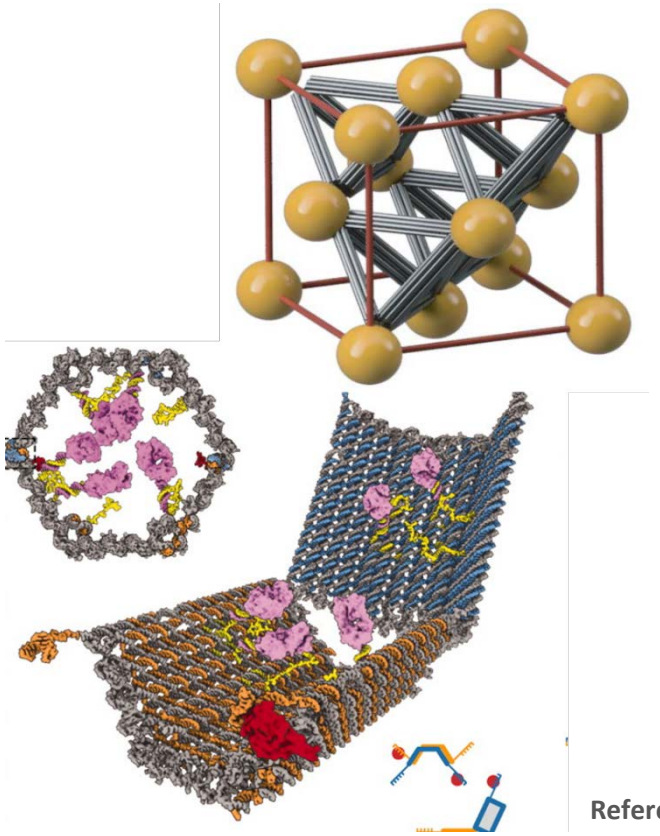


SSIA relies on **dialogue** between industry and regulators at **an early stage of the innovation process** and is facilitated by a **Trusted Environment.**

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

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

Advanced materials: what are they?



- “Smart materials”, “next-generation materials”, “materials for tomorrow”, “innovative materials”
- Diverse in physical structure and chemical composition
- Innovation is advancing from ‘simple’ nanomaterials to complex ‘advanced’ nanomaterials
- Rationally designed to achieve new functionalities
- What is considered an AdMa is time dependent
- OECD working description of AdMa[1]
- Examples: advanced metal alloys, metal-carbon hybrids, bionano (e.g. DNA origami), graphene family materials, MXenes[2] and other 2D materials, other [3]

References:

1 OECD Working description: OECD 2022 Advanced Materials: Working Description - Series on the Safety of Manufactured Nanomaterials No. 104 NV/CBC/MONO(2022)29, see: https://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

2 MXenes: $M_{n+1}X_nT_x$ M=transition metal; X=carbon or nitrogen; T=O, OH, F and/or Cl

3 See also Giese et al. 20201 (UBA 132/2020); Advanced materials: Overview of the field and screening criteria for relevance assessment

Working Description Advanced Material

OECD Working Party on Manufactured Nanomaterials' Working Description on Advanced Materials

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 materials[2].

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 features

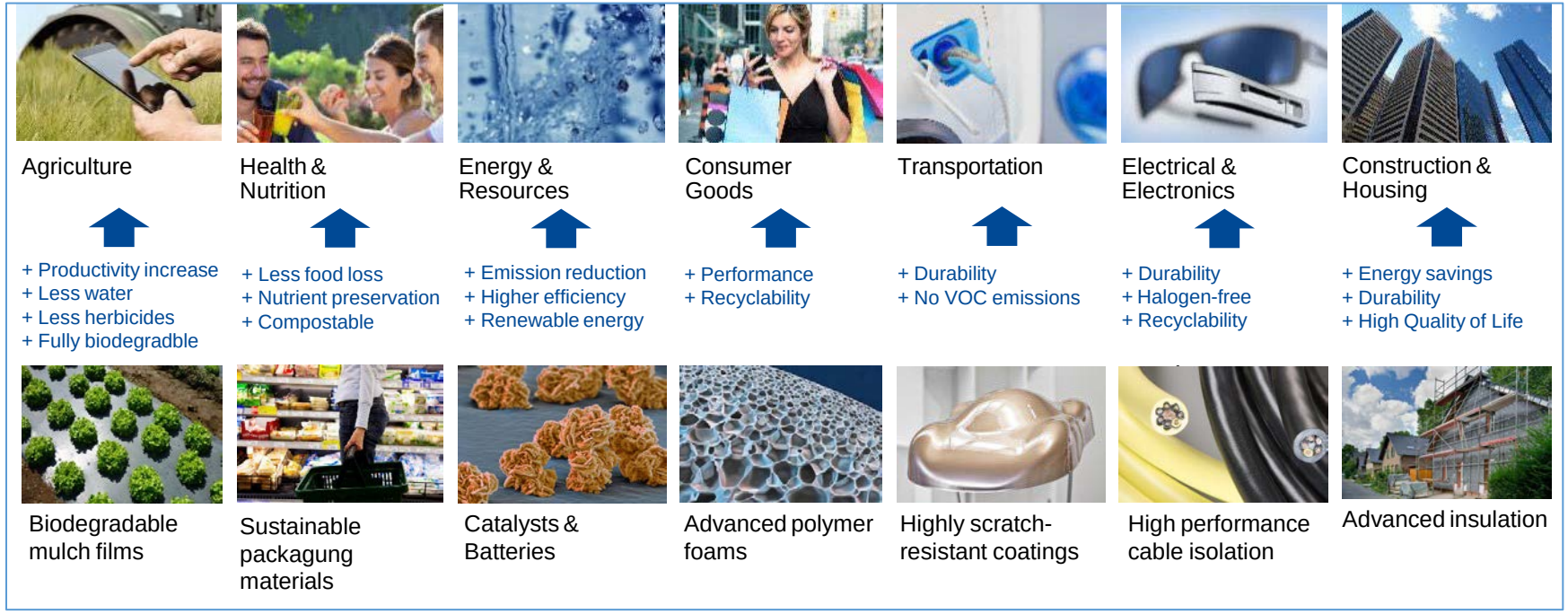
with the objective to achieve specific or improved functional performance[3]. This includes both new emerging manufactured materials, and materials that are manufactured from traditional materials. This also includes materials from innovative manufacturing processes that enable the creation of targeted 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.

AdMa: why do we need them?

AdMa considered to be key to solving global challenges

- E.g. EU Green Deal[1], EU Chemical Strategy for Sustainability[2] (CSS), EC's communication on Advanced Materials for industrial Leadership, Advanced Materials 2030 Initiative[3], Innovative Advanced Materials Initiative (IAMI), partnership Innovative Advanced Materials for Europe (IAM4EU)



Many potential applications

Figure from AMI2030[3]

References:

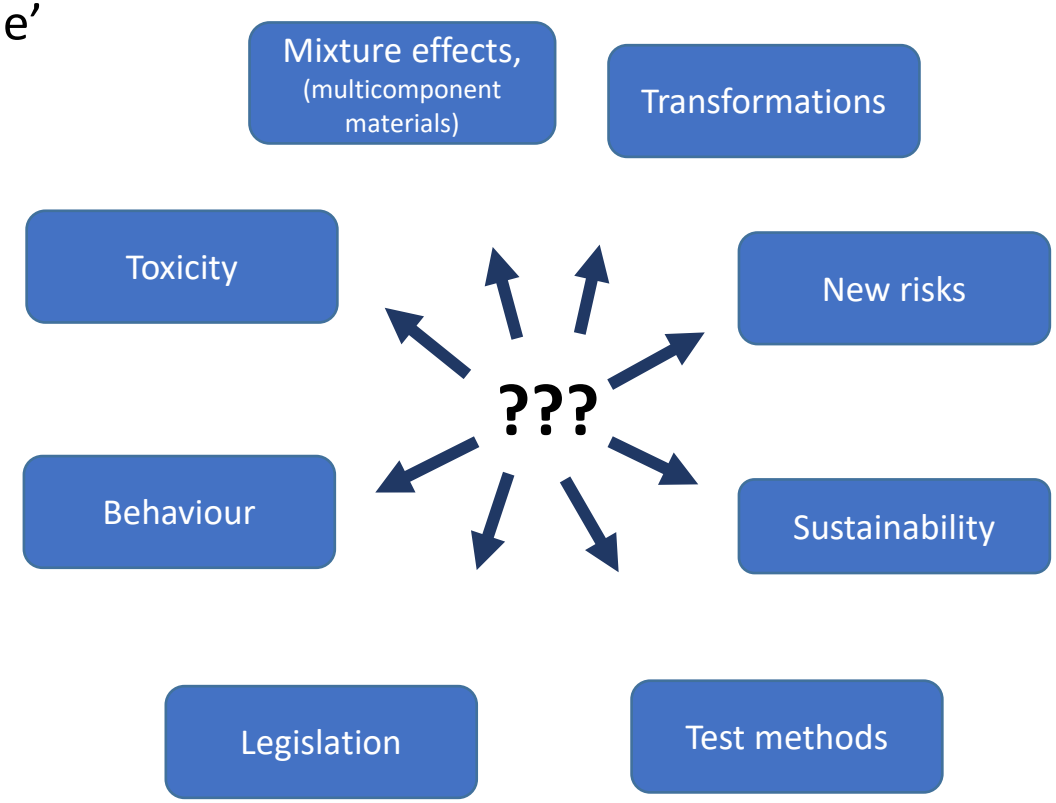
1 The European Green Deal https://eur-lex.europa.eu/legal-content/NL/TXT/?qid=1588580774040&uri=CELEX:52019DC0640

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

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

Advanced materials: why should we care?

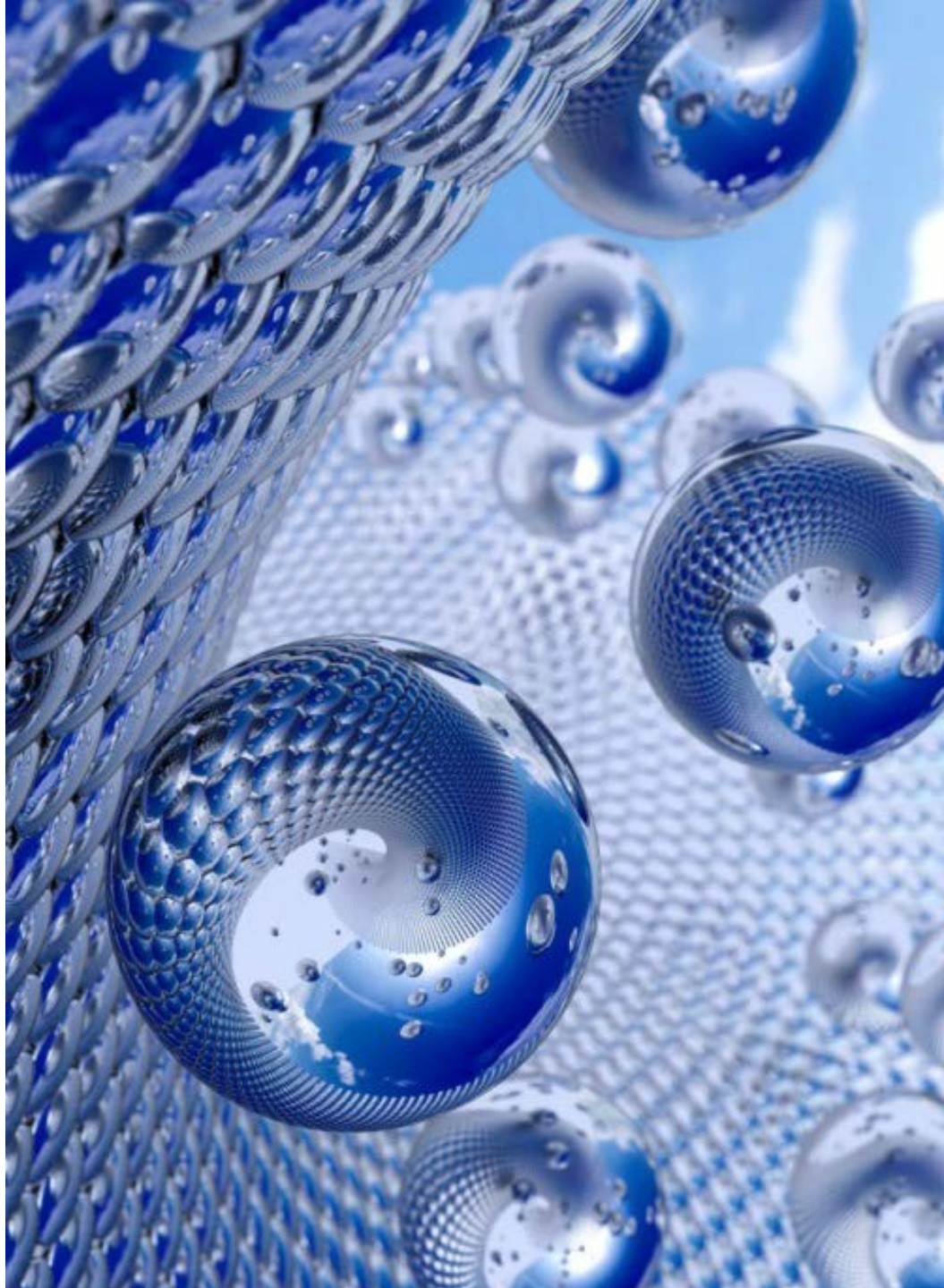
- Behaviour and toxicity may be different compared to ‘simple’ nanomaterials and soluble chemicals
  - Mixture effects, transformations, new functionalities > new risks?
- Applicability of existing regulation
  - Are adaptations to legislation/regulation/test methods for nanomaterials sufficient?
- Policy ambitions to increase sustainability
  - How to address and consider both safety and sustainability



Advanced materials: how to address these issues?

- A **screening tool** may help to identify and anticipate on safety and sustainability issues of advanced materials
  - Including applicability of test methods, suitability of sample preparation
- Identify if further actions are needed
- Early4AdMa is attempt to such a system

→ Tool to facilitate Regulatory Preparedness

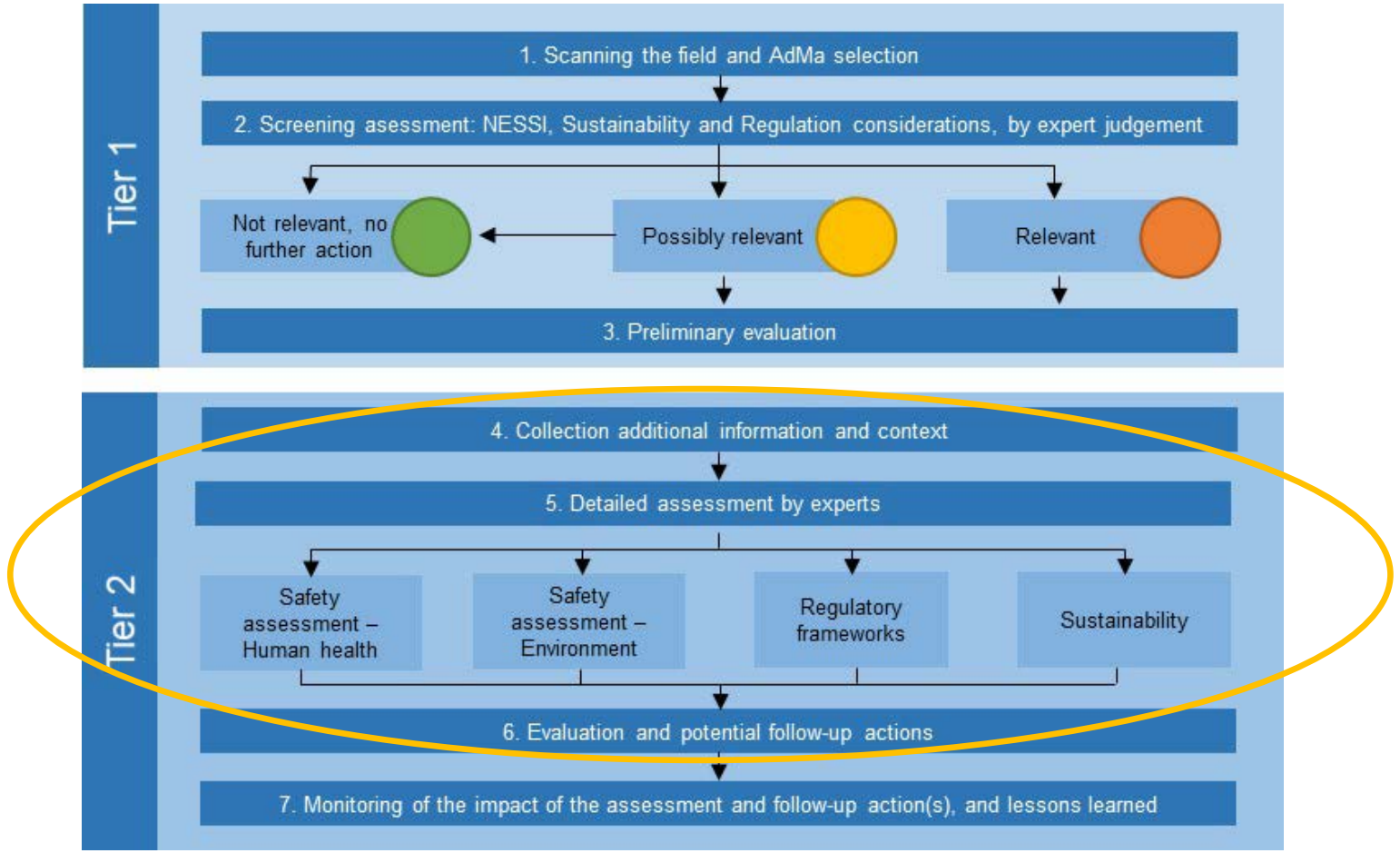


Early4AdMa approach

- First developed by RIVM, BfR, BAuA, UBA
- Further refined by **OECD Steering Group AdMa**
- 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
- Applied to various cases

References:
OECD - https://one.oecd.org/document/ENV/CBC/MONO(2023)35/en/pdf
Early4AdMa first concept - https://www.rivm.nl/documenten/Early4AdMa-brochure

Early4AdMa Strategic Approach



Context (as part of step 4)

Context

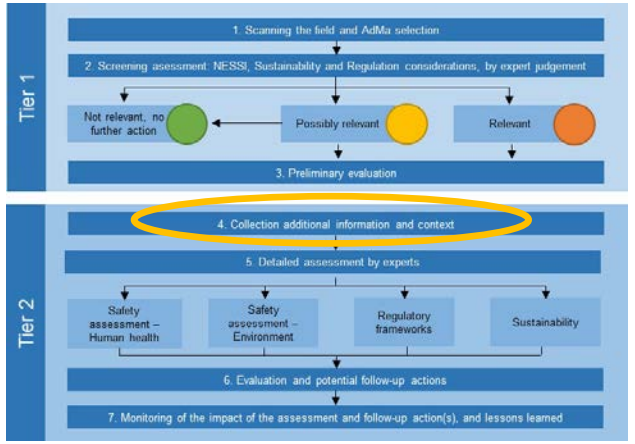
- Application area[1]

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)				

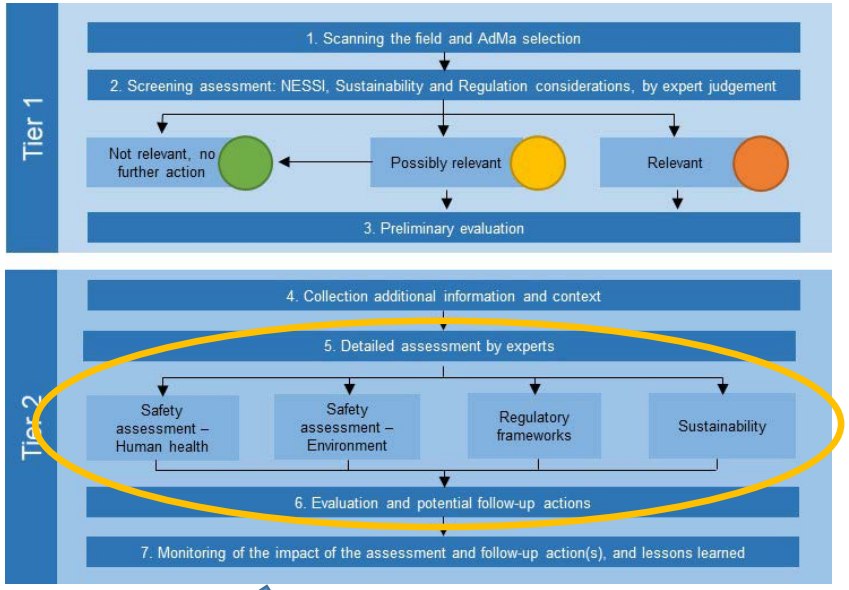
Figure. Schematic overview of step 4 of the Early4AdMa system. 1 These application area categories were taken from the manifesto of the Advanced Materials 2030 Initiative. 2 During production of the material and/or during production of an AdMa-enabled product. 3 Other life stages like mining of raw materials or transport.



Aim Context:

- To help answer the sets of questions in a manner that is relevant to the case (e.g. by considering the material or the AdMa-enabled product, the relevant compartment(s) and anticipated form(s) of release)
- To provide the context for identifying signals, as relevant, and the weight of the signal.

EARLY4AdMa



Step 5

Table 1. An overview of major topics and sub-topics that are part of step 5. Questions related to each subtopic can be found in '**Early4AdMa assessment system (details on step 5)**'.

Topic	Sub-topic
Safety assessment for human health	Physico-chemical properties Hazard Kinetics Exposure
Safety assessment for the environment	Physico-chemical properties Hazard Fate Exposure/environmental release
Applicability of regulatory frameworks	Sample preparation and analytics Applicability regulatory frameworks
Sustainability	Raw materials and resources Manufacturing, production, transport and use End-of life (recyclability and reusability)

Table 2. Overview of potential follow-up actions related to topics as can be identified in step 5. Note: the list of potential actions are merely examples and is not exhaustive.

Topic	Some suggestions for follow-up actions
Safety assessment (human health and environment)	• Reduce uncertainties by generating additional (safety) data. • Consider substitution of materials of concern and/or regulatory action. • Consider risk management measures, e.g., to reduce exposure or release.
Applicability of regulatory frameworks	• Share knowledge with the involved Institutions, Regulatory Agencies, Ministries, Authorities and Committees to allow timely consideration whether/ which current regulatory frameworks need adaptations. • Develop guidance and best practices. • Encourage research to underpin the development of suitable (standardised) test methods and improve assessment strategies. • Encourage development of suitable (standardised) test methods or improve assessment strategies.
Sustainability	• Encourage improved sustainability based on identified areas of most relevance, e.g. o Minimalization of critical raw material use o Reduction of global warming potential o Minimalization of energy, water and land consumption o Reduction of environmental footprint o Effective recyclability and reusability
Other	• Encourage safe-and-sustainable-by-design in further material/product development, encourage substitution. • Facilitate interaction between relevant stakeholders. • Regularly monitor developments of innovations.

Graphical summary

Step 6

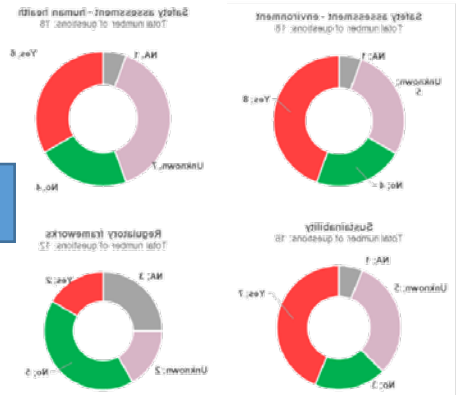


Table 5. Questions to assess potential issues related to 'Applicability of Regulatory Frameworks'. When a question is not applicable for the advanced material under investigation, this can be indicated in the '**NA**' column. '**?**' indicates unknown. Any relevant consideration may be provided in the comments section. For some questions, additional guidance on how to answer the question is provided in **Annex 1**. This is indicated by '**→Guidance**'.

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, toxicokinetics, 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?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation, do the information requirements lack provisions that cover the potential **human health** safety issues (section 3.2) for the AdMa?					
	If the material(s) or its application(s) falls within the scope of relevant (possibly sector-specific) legislation, do the information requirements lack provisions that cover the potential **environmental** safety issues (section 3.3) for the AdMa?					

Case Studies

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

HARMLESS

Umwelt Bundesamt

BfR
Bundesinstitut für Risikobewertung

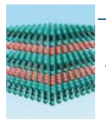
ASiNA

SUNSHINE

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

Lead US: EPA, FDA, CPSC

ES, SE, DE, ZA, NL, UK, BIAC, several EU Projects

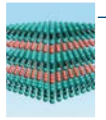

Antibacterial 2D Advance Nanomaterials (MXenes) — Feb. 2022


Fiber aerogel mat for façade insulation — Nov. 2022

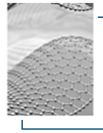

Nanocarriers

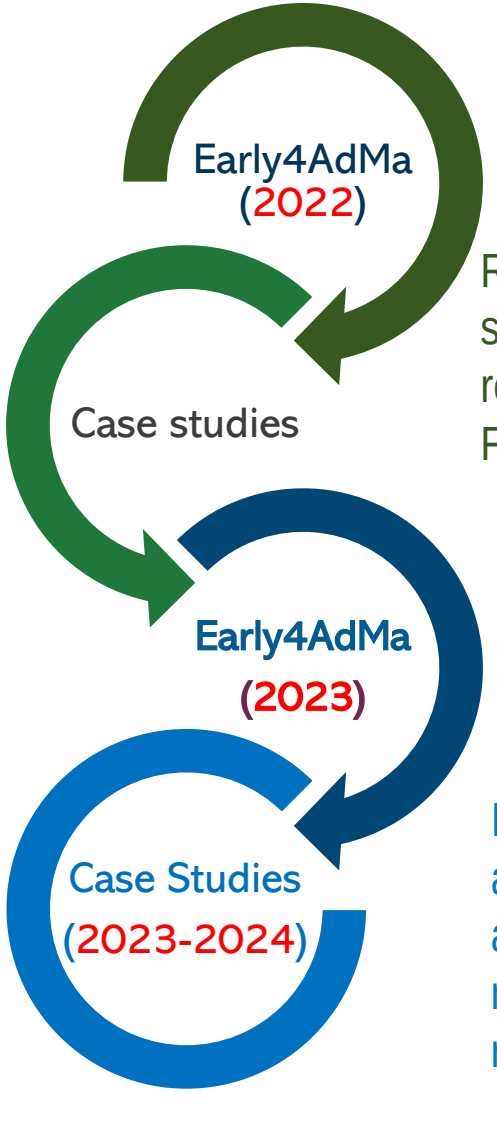

Silver cellulose articles/ encapsulate cosmetic — June 2023


Comparison Study SUNSHINE-Early4AdMa — April 2024


MXenes — May 2024


3D Printing — June 2024

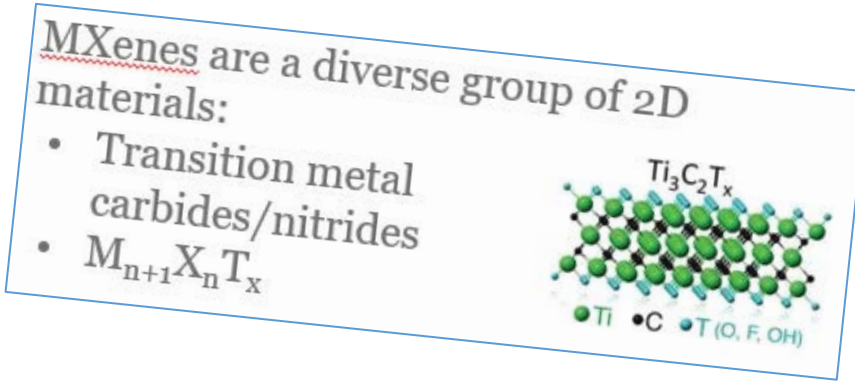

Graphene Family Materials — Nov. 2024



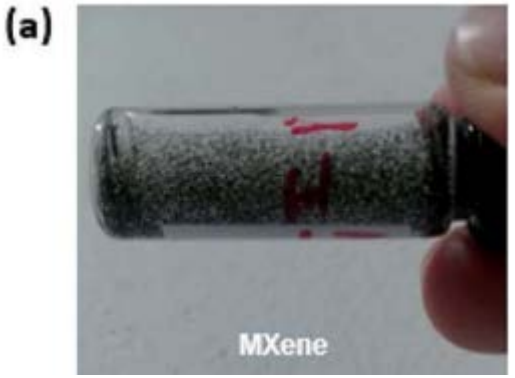
Review the applicability of the strategic approach to identify refinements needed (MXenes + Fiber aerogel)

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

Preliminary findings workshop MXenes



- **Promising material**, many possible applications
- No indications for high toxicity, BUT **limited quality** of studies and studies mostly limited to acute effects.
  - Sample preparation protocols for adequate **dispersion** needed for 2D materials that do not damage materials
  - Inclusion quality controls, harmonization assays, reference materials etc
- **Characterisation** of MXenes often absent or limited
  - Are properties used for nanomaterials sufficient?
  - Characterisation and identification needed
    - link between exposure and hazard info
    - grouping and read-across
- Insight in transformations
- High energy and toxic chemicals needed for production, no info on recyclability



Dispersion state of the pristine Mxenes in brine.
Lim et al., RSC Adv., 2020, 10, 25966

Acknowledgement

- Early4AdMa
  - Elmer Swart, Eric Bleeker, Mar Gonzalez, Andrea Haase, Philipp Hebel, Rolf Packroff, Willy Peijnenburg, Francis Peters, Hubert Rauscher, Kathrin Schwirn, Lya Soeteman-Hernandez, Vicki Stone, Doris Völker, Kimiko Yamamoto, Agnes Oomen
- MXenes
  - Elmer Swart, Bengt Fadeel, Samia Ouhajji, Kathrin Schwirn, Doris Völker, Agnes Oomen

OECD SG AdMa

OECD Secretariat: Mar Gonzalez

Kathrin Schwirn
Scientific employee
German Environment Agency (UBA)

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

OECD's Early Awareness and Action System for Advanced Materials (Early4AdMa)

Early4AdMa: https://doi.org/10.1787/326fb788-en

OECD Working description AdMa: https://doi.org/10.1787/4b5ba38d-en

Workshop report nanocarriers: https://doi.org/10.1787/b25d8c0c-en

Thank you