



Steering Group on Advanced Materials at the OECD WPMN

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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

Why are AdMA relevant for WPMN?

- 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 nano materials 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

Advanced Materials (AdMA) within OECD WPMN

- To describe the playing field of AdMa within WPMN
- To describe in which context WPM 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 1 provides an overview on, e.g. examples of AdMa

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://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-CBC-MONO\(2022\)29 &doclanguage=en](https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-CBC-MONO(2022)29 &doclanguage=en)

What makes AdMA 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
- Involvement of, e.g.
 - European Commission¹ and 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

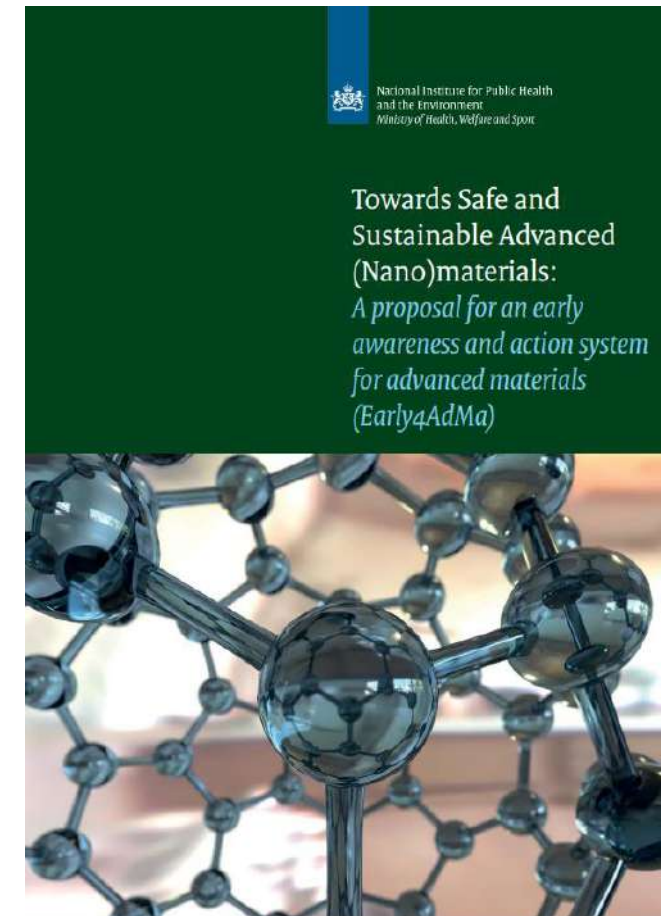
6 <https://www.ami2030.eu/> (AMIRi (60 organisations developing AdMa), SUSChem, EUMat, Manufacture EU)

How does WPMN approaches AdMA ?

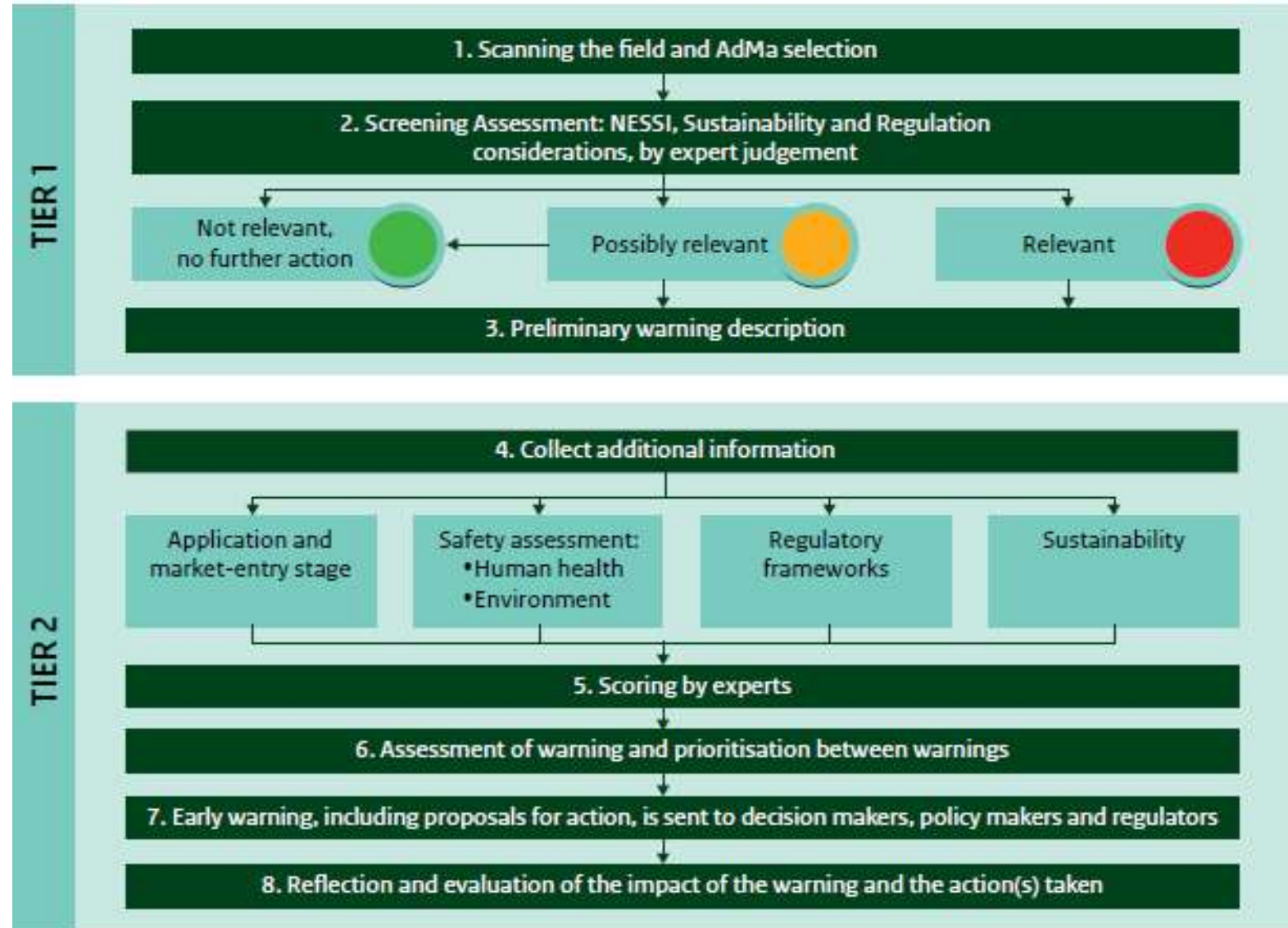
- Information gathering on research and activities on AdMa of the delegation
- Development of a strategic approach to support RP and SSbD of AdMa and their applications
 - Are regulations and assessment methods fit for AdMa?
 - Identification of concerns about and knowledge gaps to address safety and sustainability of AdMa
 - Developments of recommendations and options for actions for decision makers
- Identifying AdMa relevant for WPMN
- Carry out case studies
 - To learn about the cases
 - to verify and refine the strategic approach

WPMN strategic approach for AdMa

- Use Early4AdMa as a **basis** for developing the Strategic Approach.
- **What is the Early4AdMa system?**
- Developed by Dutch and German national institutes and first tested at WPMN¹
- Early warning system
- Timely identification of safety and sustainability issues for advanced (nano)materials and possible follow-up actions to inform decision making
- Can serve as a screening tool in a risk governance approach

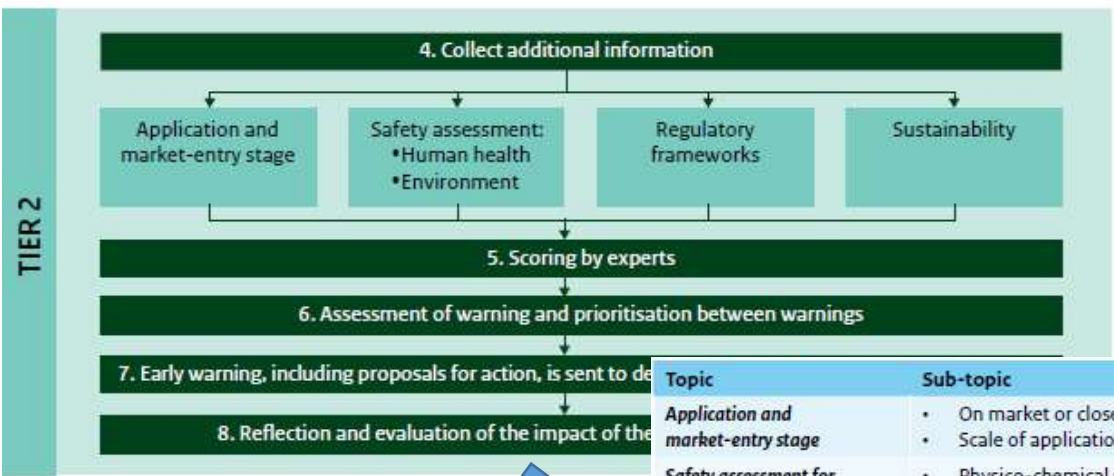
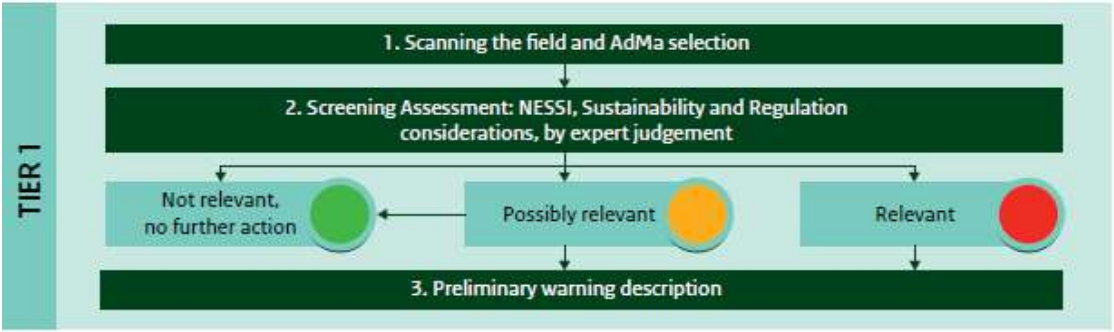


What does
Early4AdMa
look like ?





Early4AdMa



Topic	Sub-topic
Application and market-entry stage	<ul style="list-style-type: none"> On market or close to market Scale of application
Safety assessment for human health	<ul style="list-style-type: none"> Physico-chemical properties Hazard Kinetics Exposure
Safety assessment for the environment	<ul style="list-style-type: none"> Physico-chemical properties Hazard Fate Exposure
Applicability of regulatory frameworks	<ul style="list-style-type: none"> Identification of the adequacy of relevant regulatory frameworks, incl applicability assessment of underlying test methods and assessment:
Sustainability	<ul style="list-style-type: none"> Raw materials and resources Manufacturing, production, transport and use End-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 action Encourage 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 use Reduction of global warming potential Minimalization of energy, water and land consumption Reduction of environmental footprint Effective 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. Higher 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)					

Step 5: scoring by experts

Table 3. Application and Market-entry stage Higher scores indicate that the application is already on the market or near to market and large-scale application is occurring or foreseen.

Descriptor	Question ^a	Answer (score)			Comment/clarification
		Yes (9,6 or 3)	No (0)	? (1)	
Scale of application (max. 12 points)	Is (one of) the (intended) application(s) of the AdMa for use at large (e.g. used by many consumers, at high amounts), medium scale or limited scale? Score: yes, large scale=9, yes, medium scale=6, limited scale=3, unknown=1, no=0				
	Is use of the AdMa in more than one application foreseen? Score: yes=3, unknown/possibly=1, no=0				
On market or close to market (max. 12 points)	Is the AdMa already on the market, in pilot production and demonstration, or 'beyond concept of validation'?				

Table 5. Safety assessment - Environment. Higher scores indicate that there are indications for issues related to the environment. Unless indicated differently, score refers to: yes=3, no=0, unknown/possibly=1. An indication for a specific physico-chemical property, hazard, (toxico)kinetic behaviour or exposure is sufficient to attribute the maximum score. Unknown (=?) can also be interpreted as 'maybe' in case the indications are weak.

Descriptor	Question ^a	Answer (score)			Comment/clarification
		Yes (3 or 6)	No (0)	? (1)	
Physico-chemical properties (max. 15 points)	Is there an indication of new or enhanced properties (e.g. electric, electromagnetic) related to the nano/multicomponent/advanced character of the impact on risk? Is there an in				

Table 4. Safety assessment - Human Health. Higher scores indicate that there are indications for human health issues. Unless indicated differently, score refers to: yes=3, no=0, unknown/possibly=1. An indication for a specific physicochemical property, hazard, (toxico)kinetic behaviour or exposure is sufficient to attribute the maximum score. Unknown (=?) can also be interpreted as 'maybe' in case the indications are weak.

Descriptor	Question ^a	Answer (score)			Comment/clarification
		Yes (3 or 6)	No (0)	? (1)	
Physico-chemical	Is there an indication of new or enhanced properties (e.g. electric, electromagnetic) related to the nano/multicomponent/advanced character of the impact on risk? Is there an in				

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

Descriptor	Question ^a	Answer (score)		
		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)			

Table 7. Sustainability. Higher scores indicate that there are indications for issues related to sustainability.

Descriptor	Question ^a	Answer (score)			Comment/clarification
		Yes (0 or 6)	To a limited extent (3) or unknown (1)	No (0 or 6)	
Raw Materials and Resources (max. 30 points)	Are critical raw materials ^b used? (score: yes=6, to a limited extent =3, unknown=1, no=0) Are the raw materials used classified as hazardous or persistent (CLP)? (score: yes=6, to a limited extent =3, unknown=1, no=0) Does the process of extracting the raw materials require high energy, water, or land consumption and/or have an impact on global warming potential (emission of greenhouse gases)? (score: yes=6, to a limited extent =3, unknown=1, no=0)				



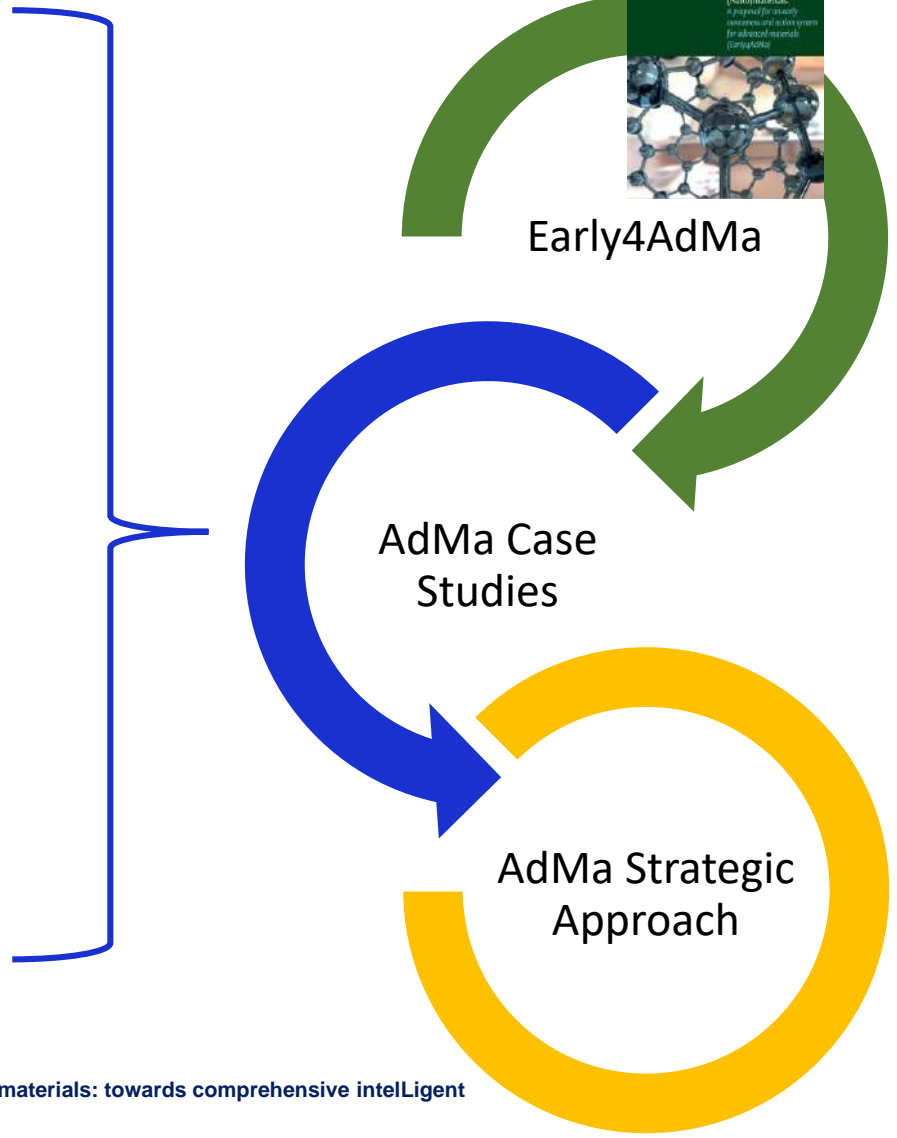
NanoCarriers

3D Printing

Graphene

Fibre-aerogel-mats for façade insulation
Harmless

Silver cellulose articles/encapsulate cosmetic
ASINA



Other approaches

- Arvidsson et al.
- Kennedy et al.
- InnoMat.Life
- 2030 Materials Manifesto
- Other???

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

*HARMLESS: Advanced High Aspect Ratio and Multicomponent materials: towards comprehensive intelligent Testing and Safe by design Strategies

*ASINA: Anticipating Safety Issues at the Design Stage of Nano Product Development



Webinar on Safer and Sustainable Innovation Approach for More Sustainable Nanomaterials and Nano-enabled Products

- OECD (2022), [Sustainability and Safe and Sustainable by Design: Working Descriptions for the Safer Innovation Approach](#), OECD Series on the Safety of Manufactured Nanomaterials, No. 105.
- OECD (2020), [Moving Towards a Safe\(r\) Innovation Approach \(SIA\) for More Sustainable Nanomaterials and Nano-enabled Products](#), OECD Series on the Safety of Manufactured Nanomaterials, No. 96.

For those of you who would like to watch **the webinar**, a [video recording](#) and the [presentations](#) are now available.

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>