

Risk Assessment in the context of the Life Cycle of AdMA and the current legal framework for chemical regulation

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- OECD's WPMN (2022) working description of Advanced materials (AdMa):
 - *“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.*

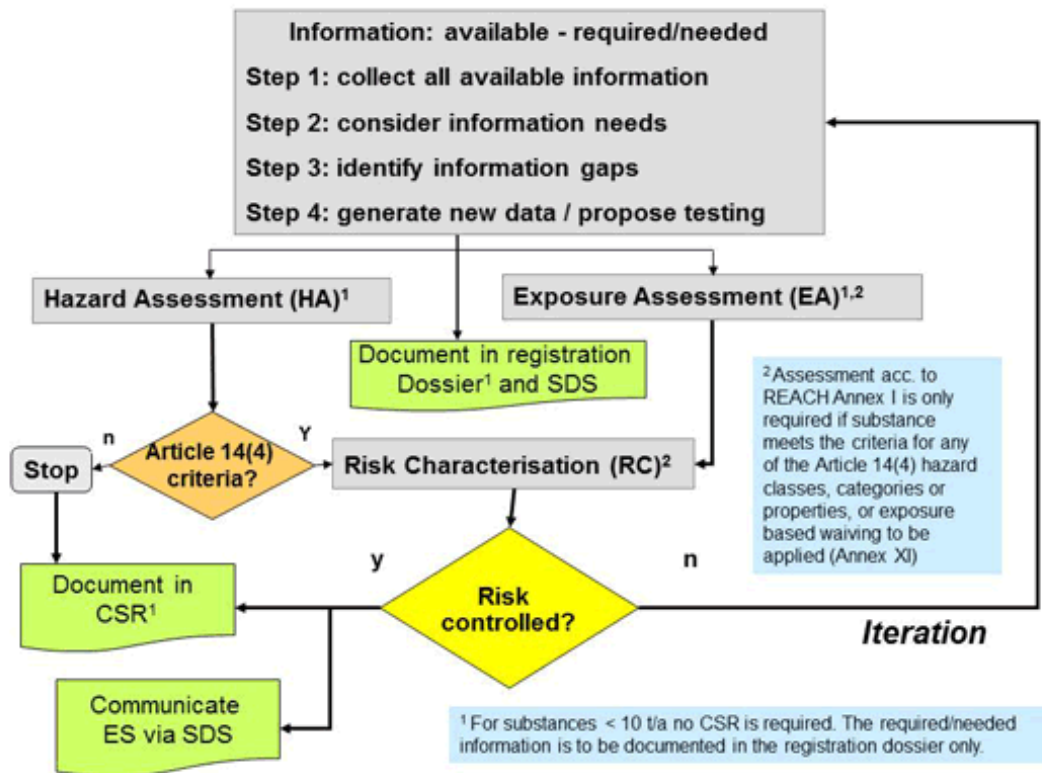
This includes both new emerging manufactured materials, and materials that are manufactured from traditional materials.

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 advanced material will change with time.”

[https://one.oecd.org/document/ENV/CBC/MONO\(2023\)35/en/pdf](https://one.oecd.org/document/ENV/CBC/MONO(2023)35/en/pdf)

- Currently, ECHA doesn't have legal mandate under REACH to regulate AdMa or **materials** as such but only individual substances.
- A pre-regulatory risk governance tool, Early4AdMa (ENV/CBC/MONO(2023)35), is anticipating to inform policy making on potential issues posed by advanced materials that can be addressed at an early stage.

Risk assessment under REACH Regulation



Guidance on Information Requirements and Chemical Safety Assessment Part E: Risk Characterisation Version 3.0 May 2016

- In general, **under REACH registrants** need to demonstrate safe use, i.e. they **perform the risk assessments**. ECHA verifies the safe use claims, e.g., under evaluation, but mainly look at hazard side.
- **A risk assessment is performed by ECHA and member states in the following processes:**
 - Authorisations and Restriction
 - Substance evaluation, a risk-based process: if there is a concern, MSCAs can verify this risk/concern
 - Occupational Exposure Limits (OELs)
- **For biocides the evaluating competent authority evaluates and prepares an assessment report** which is then submitted for ECHA which checks that it is fit for purpose.

Hazard assessment

- Currently, the minimum data requirements for the registration of a substance are specified in Annexes VII - X of REACH.
- For each individual substance, the precise information requirements will differ, depending on tonnage, use and exposure, and the properties of the substance.
- How AdMa will fit?

Exposure assessment

For the substances fulfilling classification criteria, the registrant must provide a chemical safety assessment (CSA) to establish and document **the conditions of manufacture and use** needed to control risks to human health and the environment **throughout the life cycle of the substance.**

- All the uses for the full life cycle of the substance must be reported.
- Exposure scenarios are generated for all identified uses

How to consider different materials during the life cycle?

- Throughout the life cycle, the physical-chemical form of the advanced material may change through multiple transformation pathways.
- Major challenge to identify all possible forms throughout the life cycle
- The current chemicals' legislation (such as REACH) does not evaluate the hazard of a material throughout their life cycle
 - Where relevant, we do assess e.g. breakdown products of substances (e.g. in context of PBT/PMT assessment)

COMMISSION RECOMMENDATION (EU) 2022/2510 of 8 December 2022 established a European assessment framework for 'safe and sustainable by design' (SSbD) chemicals and materials

- **comprehensive assessment of the safety and sustainability of chemicals and materials throughout their life cycle**
- support the design, development, production and use of chemicals and materials that provide a desirable function or service while being safe and sustainable.
- tiered approach to characterise hazards as early as possible at the innovation stage (i.e. during the design of the chemical or material) by using, for example, new approach methodologies (NAMs)
- Help to take informed decisions (e.g., further assess the hazard, screen out the substance, request more data through the life cycle of the chemical or material in question).

The proposed SSbD classification of the hazardous properties is closely linked to relevant EC initiatives, such as for example the Chemicals Strategy for Sustainability.

NOT a regulatory tool!

Conclusions

- ❑ It is not clear whether the existing (inter)national legislation (e.g. REACH) and assessment methods for substances (including nanomaterials) are ‘fit-for-purpose’ to cover the potential issues posed by AdMa. Currently, ECHA doesn’t have legal mandate under REACH to extend concepts targeting substances to materials and AdMa.
- ❑ The European assessment framework for ‘safe and sustainable by design’ (SSbD) chemicals and materials could be a way to link better the life cycle assessment with the risk assessment and develop use cases for AdMa
- ❑ SSbD and ECHA: currently no formal mandate for ECHA:
 - ❑ We provide support with data and CSA methodology when asked but currently not regulatory mandate

Questions?

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