German Environment Agency

Umwelt Bundesamt

ANSI NSP Meeting on Advanced Materials, 03 and 04 May 2022

Risk Governance of Advanced Materials

Joint Perspective of the German Higher Federal Authorities

Doris Völker, German Environment Agency

Rationale for an authority perspective on Advanced Materials

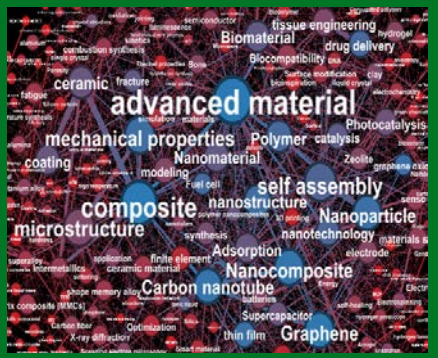
Conflict arena

Expectations towards advanced materials to foster digital and green transition

vs.

Materials of…

- high complexity,
- high heterogeneity
- broad application areas,
- potential chemical risk,
- implications for sustainability,
- challenges in regulatory coverage



Bernd Giese, BOKU

Open questions:

- What challenges do new types of materials present to us in terms of a safe and sustainable life cycle?
- What trade-offs do we encounter between the opportunities of using advanced materials and potential risks?
- What action is needed?

Thematic conferences on Advanced Materials

1	**Rationale design of Advanced Materials**	*Functionalities and Applications*	*5 -6 December 2019 UBA, Dessau, GER*
2	**Identification of action needs on chemical safety** OECD BETTER POLICIES FOR BETTER LIVES	*Approaches for structuring the field, priorisation and assessment** *Chemical safety concerns of advanced materials - advanced materials of concern*	*Online Conference 1 16 June 2020* *Online Conference 2 15 September 2020*
3	**Identification of governance needs**	*Options to act*	*Online Conference 14 June 2021*

Thematic Conferences Advanced Materials | Umweltbundesamt

Lessons learned from the TCs (very brief summary):

- Regulatory applicable definition of such a heterogenous field hard to establish, however delimitation is needed to be able to categorise and prioritise*
- Follow a targeted approach: Focus on identifying those materials/applications which may pose challenges with regard to safety, sustainability, gaps in risk assessment, gaps in regulatory coverage
- Elaborating need for action, e.g. by establishing frameworks

* Proposals available at: https://www.umweltbundesamt.de/publikationen/advanced-materials-overview-of-the-field-screening

Bundesministerium für Umwelt, Naturschutz, nukleare Sicherheit und Verbraucherschutz

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Joint perspective of BAuA, BfR and UBA on Advanced Materials

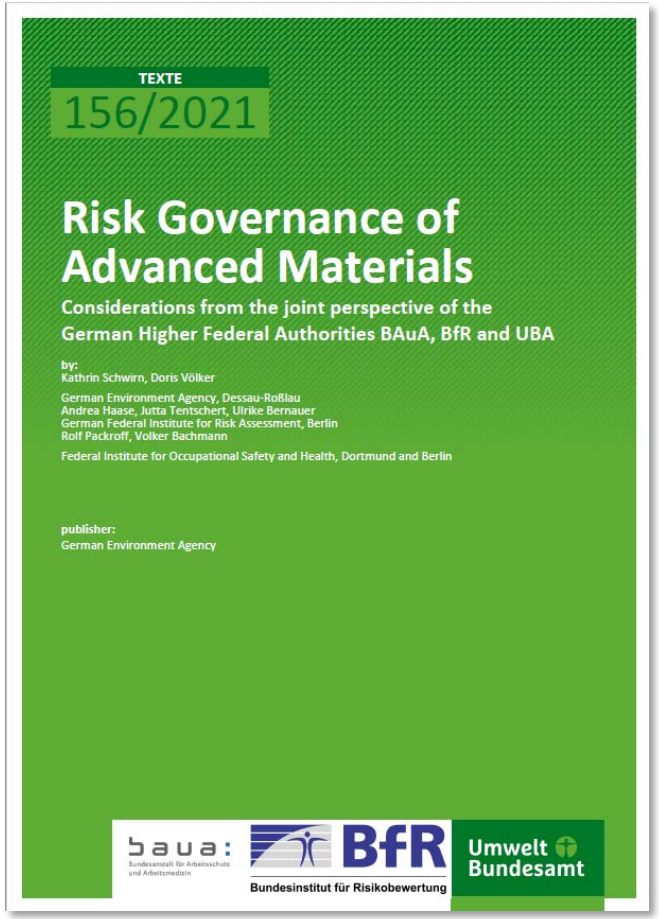
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin

German Federal Institute for Risk Assessment

Umwelt Bundesamt

Central recommendations

- Establish Early Warning System to identify „materials of concern“ and their applications
- Enable Regulatory Preparedness: Check and adapt chemical regulation and instruments of risk assessment to account for the particular challenges of (types of) Advanced Materials
- Facilitate Safe and Sustainable by Design of Advanced Materials
- Support interdisciplinary communication and network (start from the nano-community!)
- Strengthen both preparatory and regulatory research



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Recommendation: Establish horizon scanning and early warning system

Proposal for an identification of "Materials of Concern"

A "Material of Concern (MoC)" is

- (i) a material meeting the criteria for classification as a "hazardous substance" or "hazardous mixture" within the meaning of the criteria set out in Annex I to Regulation (EC) 1272/2008, or
- (ii) a material from which hazardous substances or mixtures according to (i) can arise or be released during its production or over its life cycle, or
- (iii) a material which does not meet the criteria (i) or (ii) but which, because of its morphological, physico-chemical, chemical, (eco)toxicological or release properties, could pose a risk to human or environment during its production or over its life cycle, or
- (iv) a material which could pose a concern regarding additional sustainability aspects.

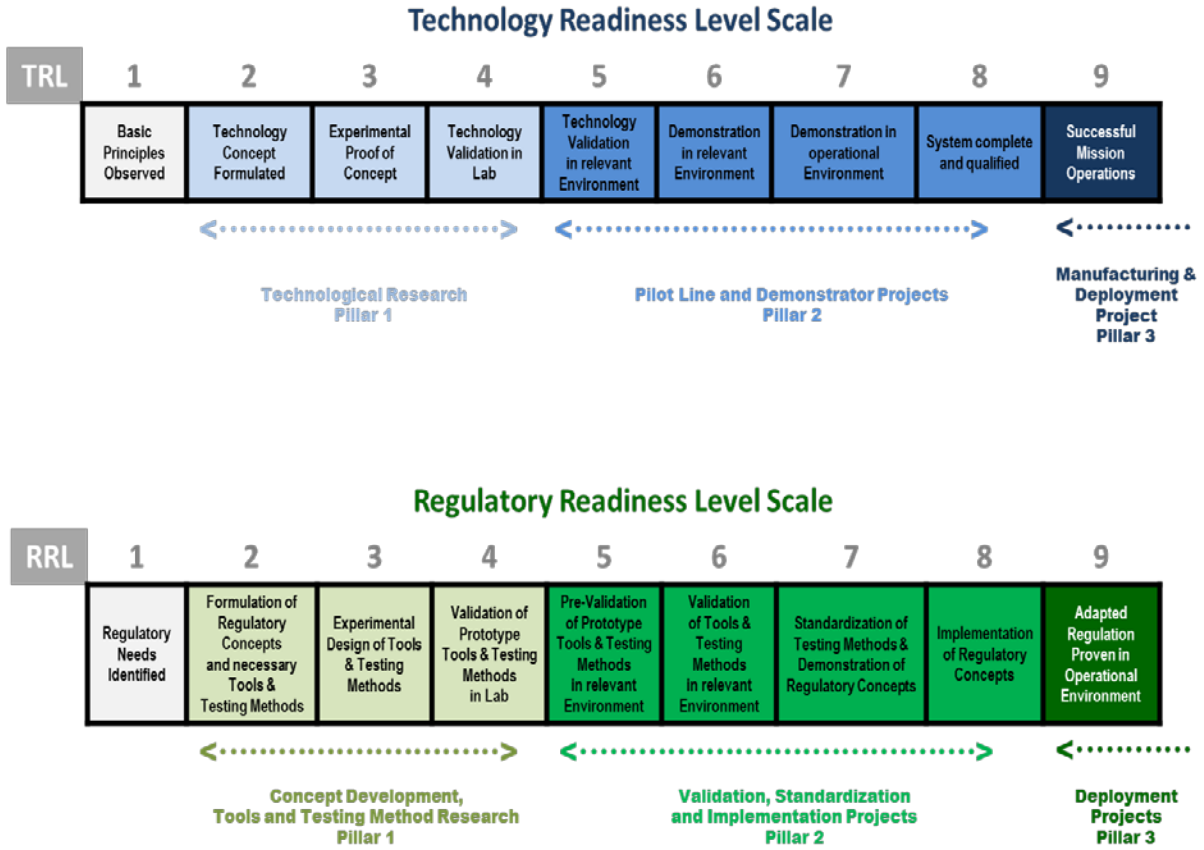
Identification of „MoC" as screening step of an Early Warning System

- should allow to identify from the variety of all materials those that give rise for specific concerns and/or pose challenges for chemical safety or other aspects of sustainability
- Importantly, the definition covers all materials and is not limited to AdMa!

Recommendation: Be regulatory prepared for emering technologies

- **Shape appropriate regulation for AdMat**
  - review relevant legislation and corresponding risk assessment instruments if they are fit for purpose
  - close identified gaps swiftly
  - whether such materials are considered as article or a substance/mixture should not lead to a reduced level of protection

    ⟹ sufficient risk assessment data should be available
  - same requirements should be met, regardless of whether a material is manufactured within or outside of EU
- **Develop appropriate assessment methods in a timely manner**
  - continuous development of required test methods should be guaranteed



Packroff 2019

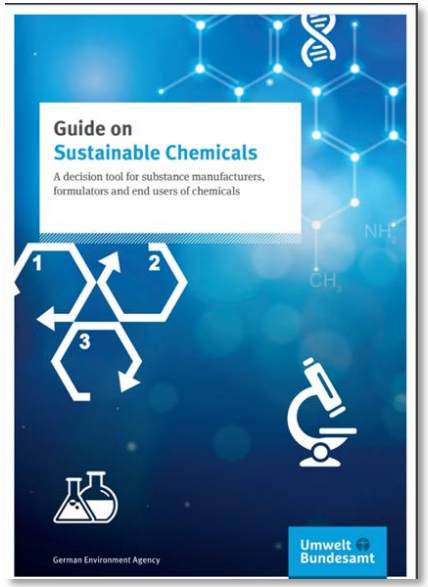
„Regulatory Readiness Level“ of measurement, testing and risk evaluation methods and tools to assess the regulatory fitness to deal with (material) innovation

Recommendation: Promote Safe and Sustainable by Design

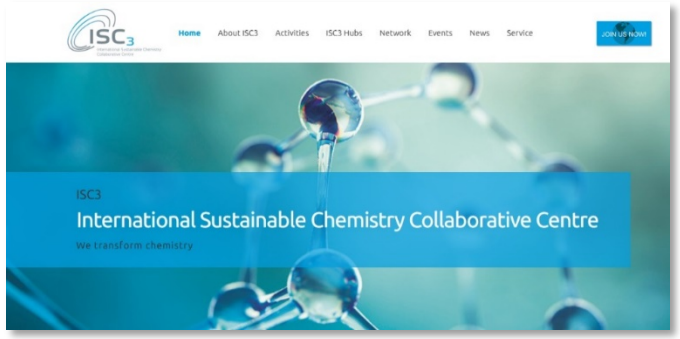
- **Take advantage** from existing tools & approaches from research on SbD for nanomaterials
- **Involve** ongoing/upcoming projects (e.g. H2020 Sunshine, Harmless, Diagonal, Horizon Europe PARC, national projects)
- **Take into account**
  - related approaches for chemicals & applications → e.g. sustainable chemistry, LCA
  - regulatory environment (e.g. chemical legislation, product regulations)
- **Interdisciplinary cooperation** and **networking** on national, EU and international level (IND, F+E, NGO and authorities) for common understanding on the meaning of S&SbD and to agree on criteria and indicators
- **Research efforts** considering safety & sustainability from the start of innovation

EU COM (2021)

EU COM (2022)



UBA (2016)



www.isc3.org

Recommendation: Enhance preparatory research and strengthen regulatory research

Preparatory research: Keep pace with innovation
Provide basic data which can be used to deduce regulatory needs for action
Initiate research to identify adequate alternative testing and assessment strategies
Develop and evaluate principles and options (incl. criteria) to ensure safe and sustainable development of advanced materials
Approach the implications of advanced materials for the objectives of a circular economy
Research investments to improve recovery, recycling and high quality recyclate use

Regulatory research: Support good governance with scientific evidence
Broad research possibilities and scientific freedom with sufficient funding to allow the investigation of materials which are suspected to be of safety concern or pose a regulatory gap
Identify needs and development of standardised testing and evaluation methods
Evaluation of the effectiveness of governance strategies

Follow up to the thematic conferences

National: **German Interagency Working Group on Advanced Materials (led by BfR): Governance strategy to tackle emerging risks of AdMa**

with 11 participating authorities/institutes, 5 observing ministries

Objective:

- Establishing an Early Warning System
  - Regulatory preparedness for materials innovations
  - Identify potentially critical materials/applications early on
  - Identify data gaps, needs for research and method development
  - Check existing legislation and guidance documents for needs of adaptation
- Establish regular communication and open exchange
  - Make use of complimentary expertise, develop approaches together
- Discuss and support development of concepts such as SbD, SSbD, RP

International: **OECD Working Party on Manufactured Nanomaterials (WPMN): Steering Group on Advanced Materials (SG AdMa)**

since WPMN-21 (Summer 2021), Lead DE and NL, 18 delegations

detailed information in following presentations (Eric Bleeker, Mar Gonzalez)

How can standardisation contribute to good governance of Advanced Materials?

Terminology:
- Definition (of categories) of what can be understood as Advanced Material

Risk characterisation:
- Methods to identify specific properties and features (e.g. multicomponent character, …)
- Methods for chemical-morphological characterisation of materials (e.g. aspect-ratio of particles)
- Methods to determine (eco)toxicity and fate
- *in-vivo* and *in-vitro* methods for determination of biopersistance (e.g. particles in the lung after inhalation)

Measurement:
- Methods to eluciate dustiness and release of chemical substances from Advanced Materials under life-cycle conditions
- Methods to monitor exposure at workplaces, in biological samples, environmental compartments and biota

Reference materials:
- Measurement standards for those (categories of) Advanced Materials which were identified as of concern

Thanks for your attention

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https://www.umweltbundesamt.de/en/topics/chemicals/nanotechnology/advanced-materials