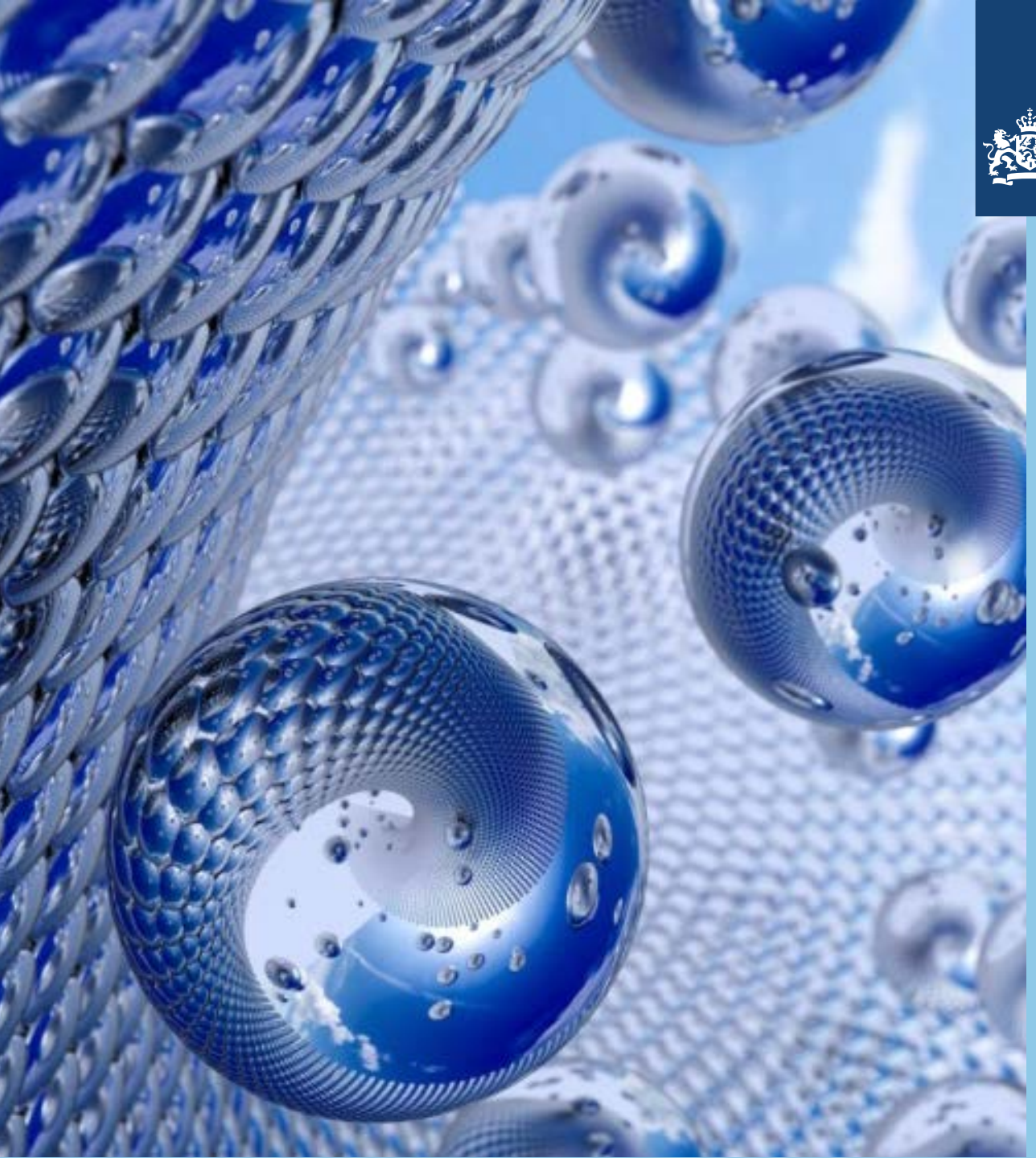

National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Activities at the RIVM (Netherlands)

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National Institute for Public Health
and the Environment (RIVM)

Governance approach

- High pace of technological developments
- Increase in complexity of (nano)materials

- Working towards early awareness approach
- Enabling regulatory preparedness
- Identify potential issues, related to
  - specific advanced materials
  - current regulatory frameworks
  - Safe-and-Sustainable-by-Design
- Gain practical experience from cases
- International collaboration (e.g. OECD)

Advanced materials often are:
- complex, multiconstituent
- combining organic and inorganic
- contain or consist of nanosized materials
- 3D structure important, nanoscale

Early awareness

- Approach developed
  - RIVM, BfR, UBA, BAuA
  - Combining approaches
    - early warning system by BfR, named NESSI (Novelty, Exposure, Severity, Scope, Immediacy)
    - more detailed early warning system by RIVM
- Currently no considerations on stakeholders
- Available in brochure
  - Easily available background document
  - Thought starter => EWARN system **not finalised**

DOI: 10.21945/brochure-advanced-materials

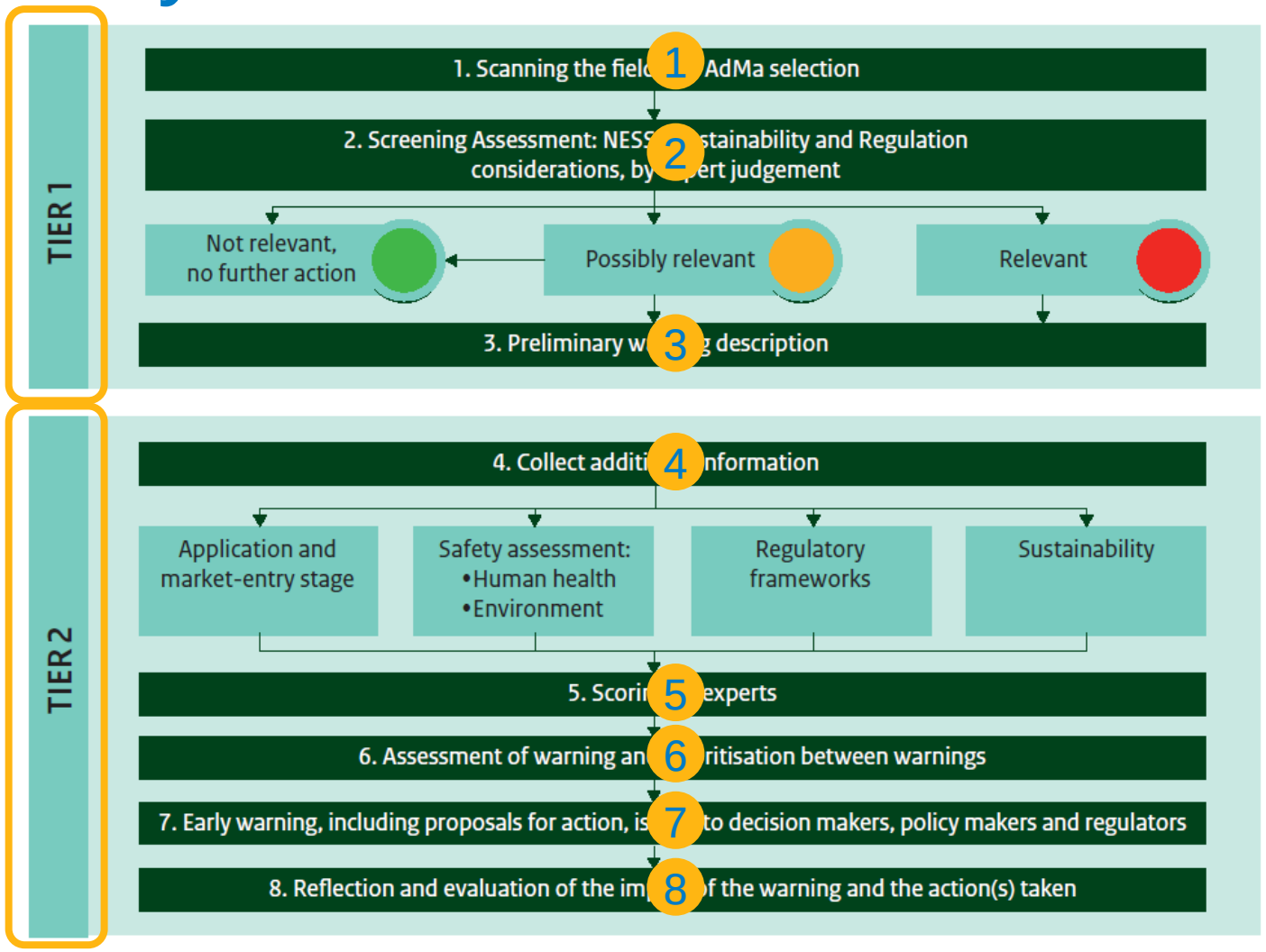
Awareness system

- Towards Safe and Sustainable Advanced (Nano)materials:
  A proposal for an Early WArning, pRioritisation and actioN system (EWARN)
  - to identify, describe and prioritise warnings a… safety and…als
  - scope curr…
  - no considerations on stakeholders
    - no details on which actors should be involved and how to organise
  - can be applied by regulators, risk assessors, as well as innovators
  - can serve as a tool in an anticipatory risk governance approach

Alternative name needed:
- ‘EWARN’ already used by WHO (Early Warning Alert and Response Network)
- ‘Warning’ not the right connotation

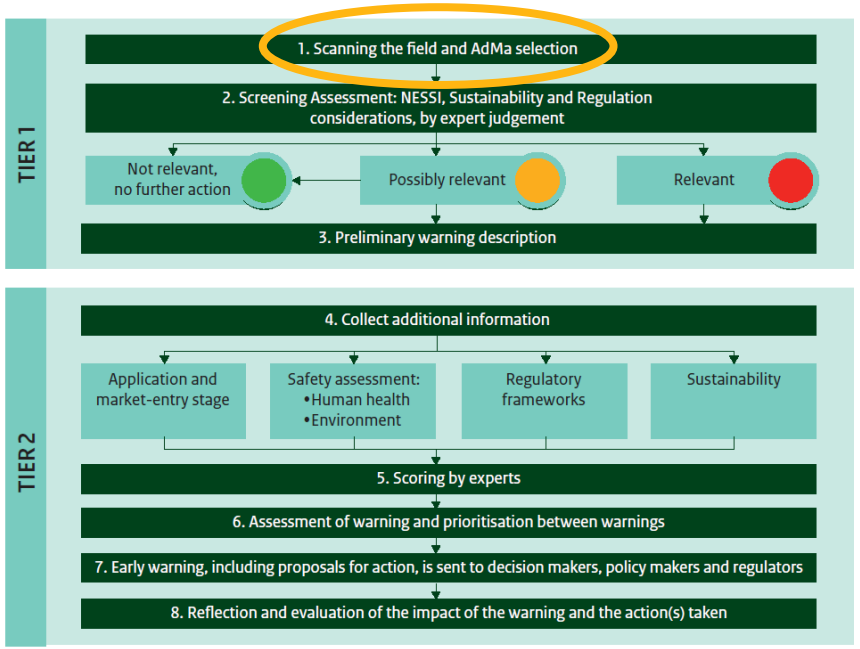
Early4AdMa: Early awareness and action system for AdMa

Awareness system



Step 1: Scanning the field and AdMa selection

- General inventory of latest developments
- Select a type or group of AdMa for further consideration
  - Broad group with multiple materials
    - May trigger more alerts, larger uncertainty
    - Further assessment of subgroups?
  - Small specific group of materials
    - Very specific, limited applicability



Step 2: Screening assessment

- NESSI (Novelty, Exposure, Severity, Scope, Immediacy)
- Sustainability
- Considerations on applicability of regulation

Step 2: Screening assessment

- NESSI assessment for advanced materials

Novelty: including all factors making the issue relevant as an emerging risk, as opposed to a known one. This can include materials that are either entirely novel or appear in new forms or new applications.

Exposure: describes the expected exposure of the AdMa or components of that material. This can relate to either the exposure levels of people coming into contact with the materials, or to environmental exposure.

Severity: describes the severity of the expected level of harm caused by the material, either regarding health concerns or environmental impact. This may relate to both acute and chronic (environmental) health issues.

Scope: describes the expected scope of the issue regarding either the number of people affected or the geographical range that may be impacted.

Immediacy: describes the time frame until the issues become relevant and the resulting urgency to act

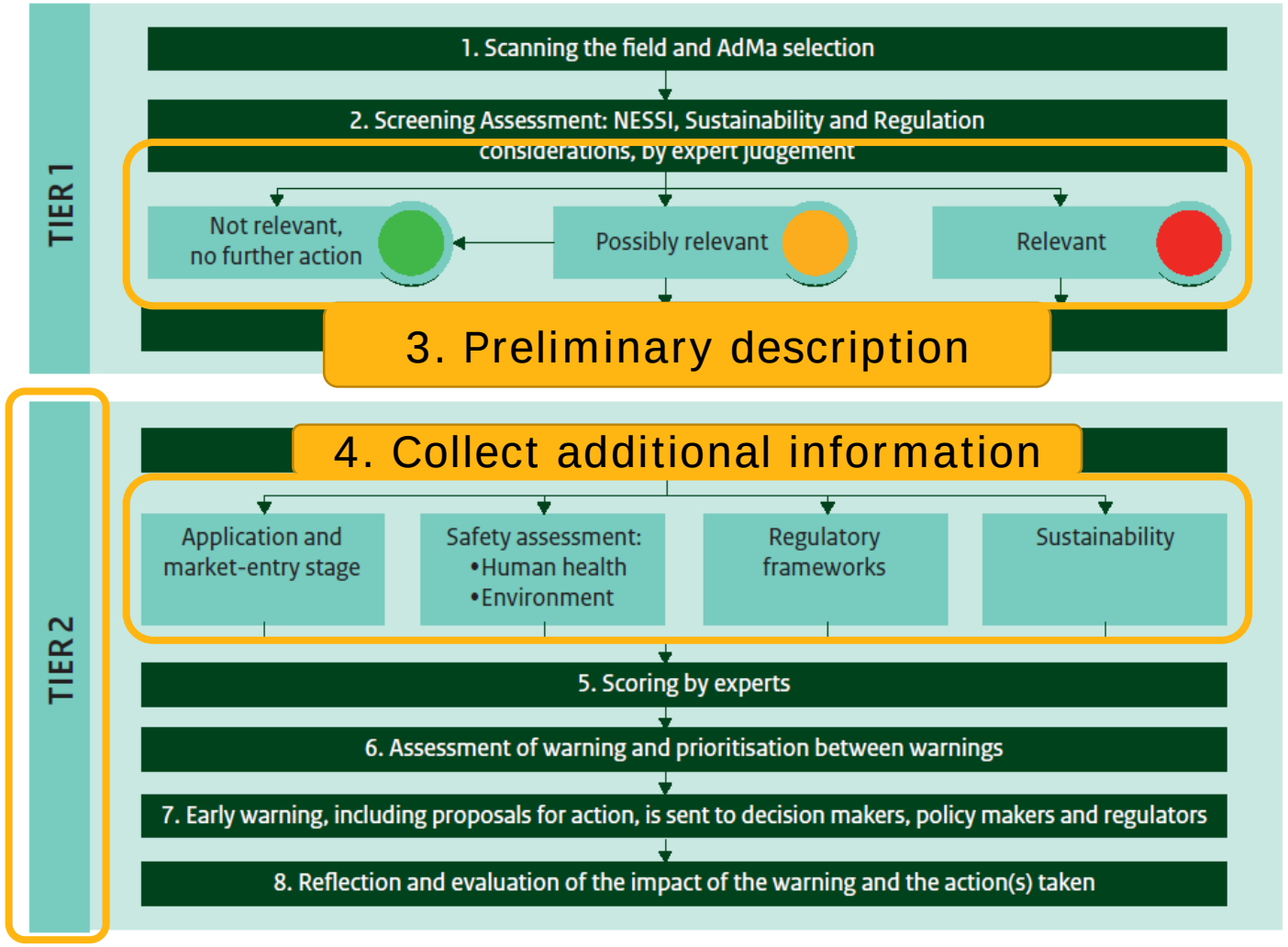
Step 2: Screening assessment

- NESSI

- Sustainability
  - Factors that may indicate sustainability issues, e.g.
    - resource use (critical raw materials)
    - environmental footprint
    - poor recyclability/reusability to support circular economy
    - during manufacturing, production, transport, use, end-of-life

- Considerations on applicability of regulation
  - Initial screening on whether or not
    - the material or product is covered in current (EU) chemical legislation
    - any potential concerns can be assessed
      (based on the information that is required in a regulatory dossier)

Awareness system



Step 5: scoring by experts

Topic	Sub-topic
Application and market-entry stage	• On market or close to market • Scale of application
Safety assessment for human health	• Physico-chemical properties • Hazard • Kinetics • Exposure
Safety assessment for the environment	• Physico-chemical properties • Hazard • Fate • Exposure
Applicability of regulatory frameworks	• Identification of the adequacy of relevant regulatory frameworks, including applicability assessment of underlying test methods and assessment strategies
Sustainability	• Raw materials and resources • Manufacturing, production, transport and use • End-of life (recyclability and reusability)

Step 5: scoring by experts

- Detailed questions
- Numbered scoring

Application and market-entry stage

Descriptor	Question[a]	Answer (score)	
		Yes (9,6 or 3)	*No (0)*
Scale of application *(max. 12 points)*	Is (one of) the (intended) application(s) of the AdMa for use at large (e.g. used		

Applicability of regulatory frameworks

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			

Safety assessment for human health

Descriptor	Question[a]	Answer (score)			Comment/ clarification
		Yes (3 or 6)	*No (0)*	*? (1)*	
Physico-chemical properties	Is there an indication of new or enhanced properties (e.g. electric, electromagnetic)				

Safety assessment for environment

		(3 or 6)			
Physico-chemical properties	Is there an indication of new or enhanced properties (e.g. electric, electromagnetic) /multicomponent/advanced aterial that may have an				

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				

Step 5: scoring by experts

Uncertainty in scoring

- Different types of expertise needed
  - Group of experts
- Cases with little information would receive a low final score
  - When no information: score is 1
  - Lack of expertise may lead to “no information”
- Need to address uncertainty:
  - Potential maximum score
  - Potential minimum score
- Automatically calculated in spreadsheet digital scoring system

Step 6: Assessment / prioritisation of warnings

- Questions in Step 5
  - help structure to identify important issues for safety and sustainability for AdMa
- Answers in Step 5 serve as starting point
  - to assess need for warning
  - to formulate warning
    - which topic / sub-topic raises concerns
  - to rank/prioritise different warnings

Step 7: Early warning & proposal for follow-up

Topic	Potential actions
Application and market entry stage	• 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)	• 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	• 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	• Encourage improved sustainability based on identified areas of most relevance, e.g. - 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	• Encourage Safe-and-Sustainable by Design, circular economy, substitution. • Facilitate interaction between relevant stakeholders. • Regularly monitor developments of innovations.

Examples

Step 8. Reflection and evaluation

- After some time, reflect and evaluate on:
  - the warning identification (steps 1 to 6)
  - the actual action(s) taken
  - the impact of the actions

- To showcase improvements and learn from earlier actions

Initial feedback collected

- Meeting OECD WPMN SG AdMa
- Written comments

- Provide further guidance/clarity
  - Terminology (‘warning’, ‘EWARN’)
  - Improve differentiation between missing expertise and uncertainty
  - Provide guidance to qualitative questions
  - Questions on application and market-entry stage provide input to importance of warning, do not lead to warning
- Include information on benefits and intended use of AdMa
  - To be included as part of general information on case?
- Discuss if and how to evaluate the system

Options for further development

From feedback

- Allow for comparisons between materials
  - Useful in SSbD, but not so much as an awareness system
- Further enhance scoring system
  - Option to apply different weighting
  - Consider yes/no instead of numeric answers
  - Informed by experience from more case studies
- Make user friendly via web platform
- Broaden beyond nanomaterials

Next steps

- Further develop system
  - Based on feedback
  - How to identify relevant cases?
  - Further develop step 1 - scanning the field
    - Engage industry/industrial organisations
    - Engage horizon scanning organizations
  - Invite others to contribute

- Further case-studies
  - Invite others to use the system and provide feedback

More information

- Risks of Nanotechnology Knowledge and Information Centre (KIR nano)
  - https://www.rivm.nl/en/nanotechnology/risks-of-nanotechnology-knowledge-and-information-centre-kir-nano