



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

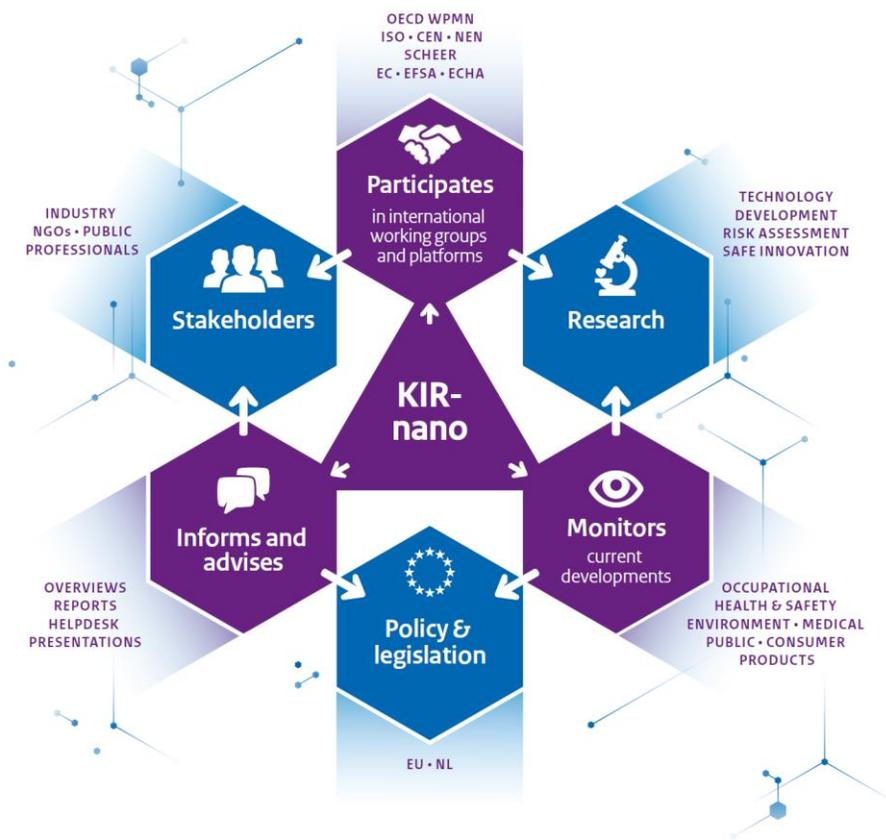
Safe & Sustainable Innovation Approach

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Knowledge and Information centre on Risks of Nanotechnology (KIR-nano)



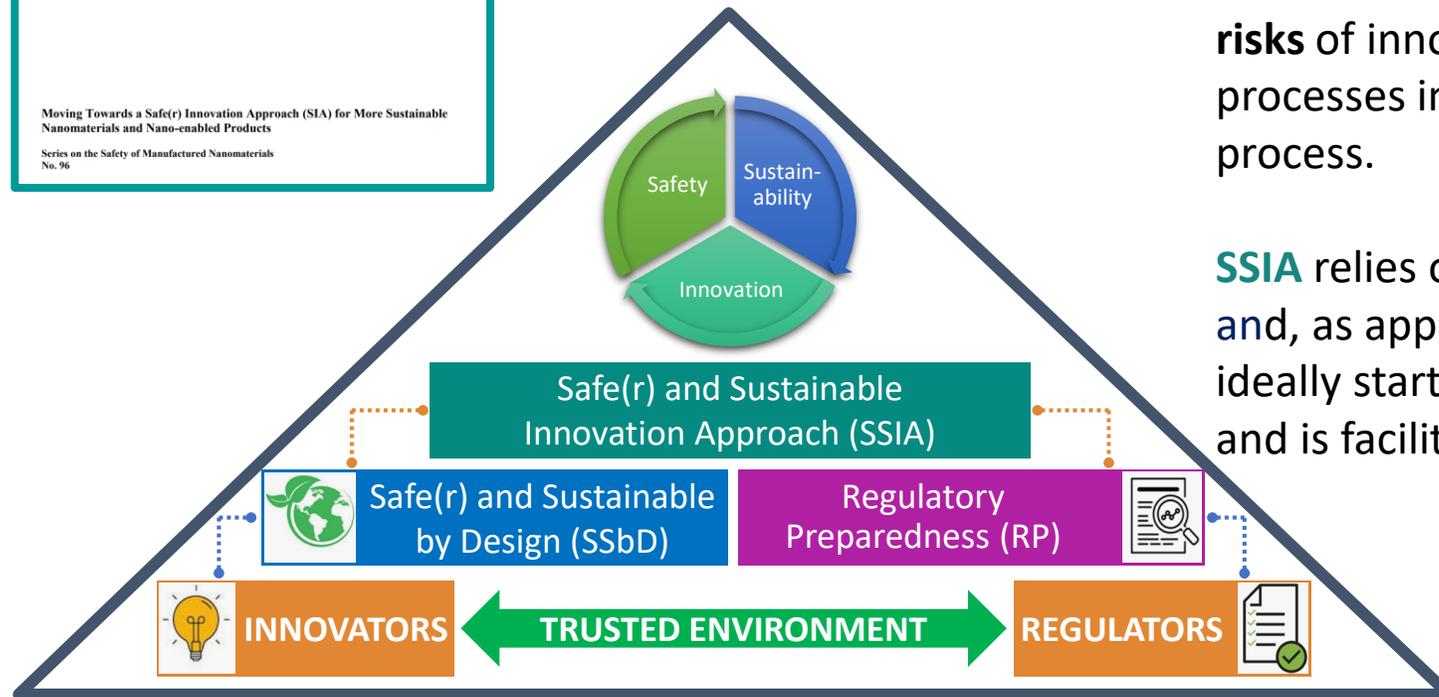
- Since 2006
- **Collects and compiles relevant knowledge** about potential nanomaterials risks for human health and the environment
- **Makes knowledge accessible & understandable and available** to professionals
 - health & safety and policy & regulation
 - occupational, environmental, and consumer
- **Connects and combines information from a wide range of fields and disciplines**
 - scientific research to legislation
 - developments in society



Safe(r) and Sustainable Innovation Approach

OECD WPMN

Safe(r) and Sustainable Innovation Approach

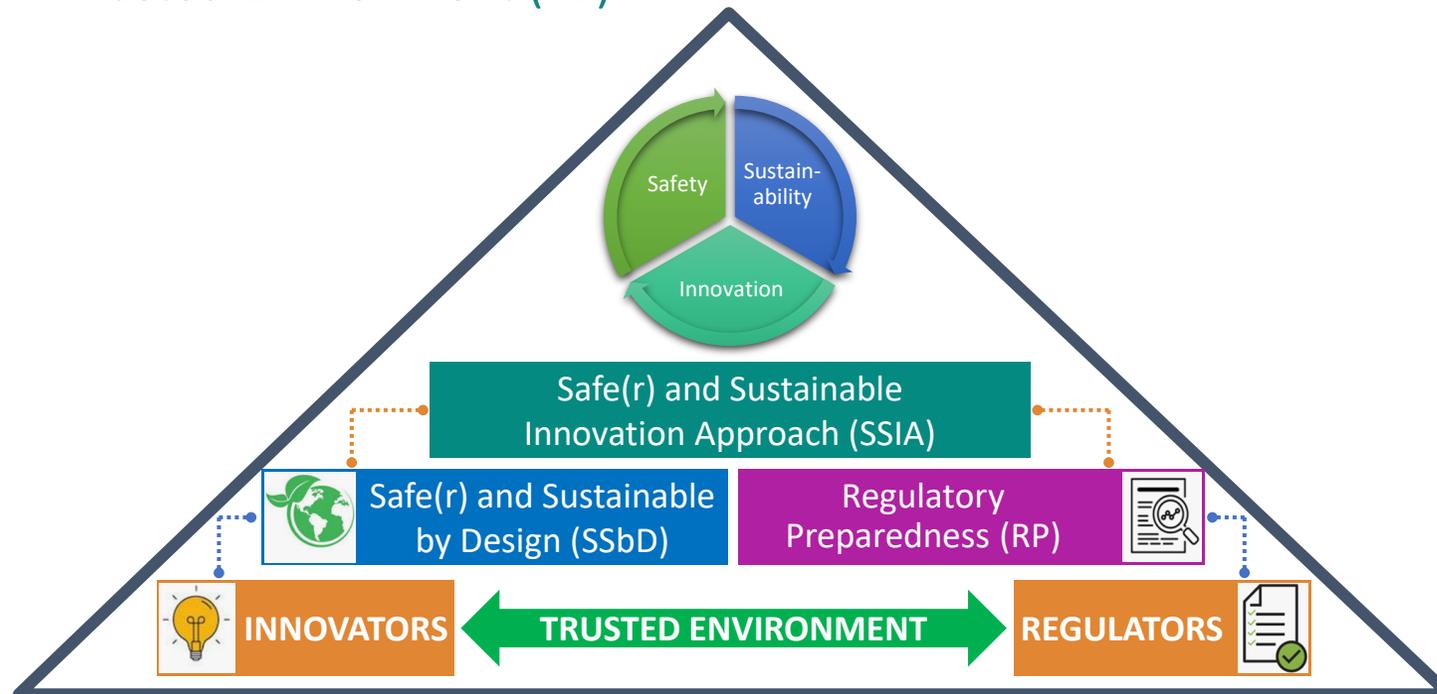


SSIA combines the **Safe-and-Sustainable-by-Design** and **Regulatory Preparedness** concepts in order to **identify and minimize** the possible **health and environmental risks** of innovative materials, products, applications, and processes in a **timely manner** during the innovation process.

SSIA relies on **dialogue between industry and regulators** and, as appropriate, other stakeholders. This dialogue ideally starts at an **early stage of the innovation process** and is facilitated by a **Trusted Environment**.

Working Descriptions

- Safe(r)-by-Design (SbD)
- Safe-and-Sustainable-by-Design (SSbD)
- Regulatory Preparedness (RP)
- Trusted Environment (TE)



Sustainability and Safe and Sustainable by Design: Working Descriptions for the Safer Innovation Approach.

Series on the Safety of Manufactured Nanomaterials
No. 105

Working Description: Safe and Sustainable by Design (SSbD)

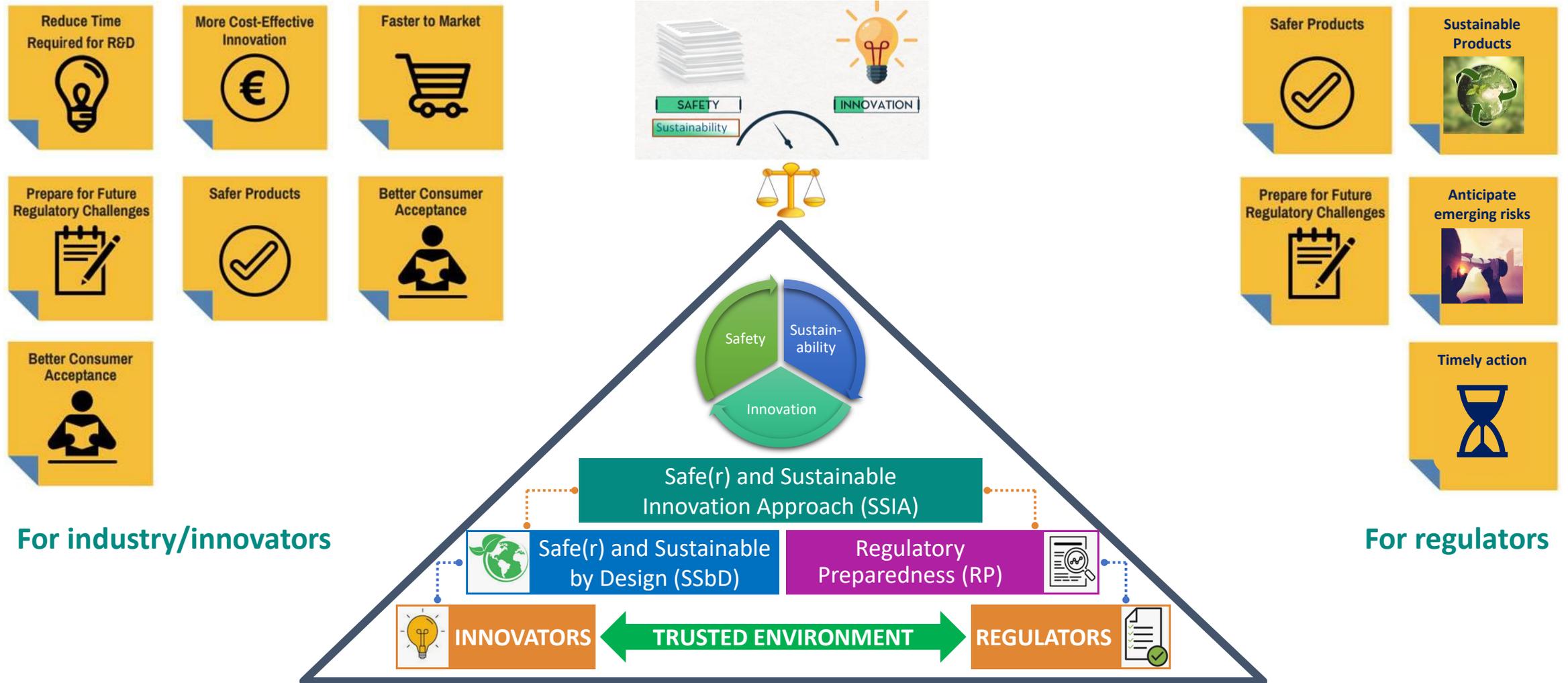
Safe and sustainable by design (SSbD) can be described as an approach that focuses on providing a function (or service), while avoiding onerous environmental footprints and chemical properties that may be harmful to human health or the environment.

In essence, the SSbD approach aims to identifying and minimizing, at an early phase of the innovation process, the impacts concerning safety for humans and the environment and for sustainability, minimizing the environmental footprint, in particular regarding climate change and resource use and, protecting ecosystems and biodiversity, taking a lifecycle perspective. The SSbD approach addresses the safety and sustainability of the material/ chemical/ product and associated processes along the whole life cycle, including all the steps of the research and development (R&D) phase, production, use, recycling and disposal.

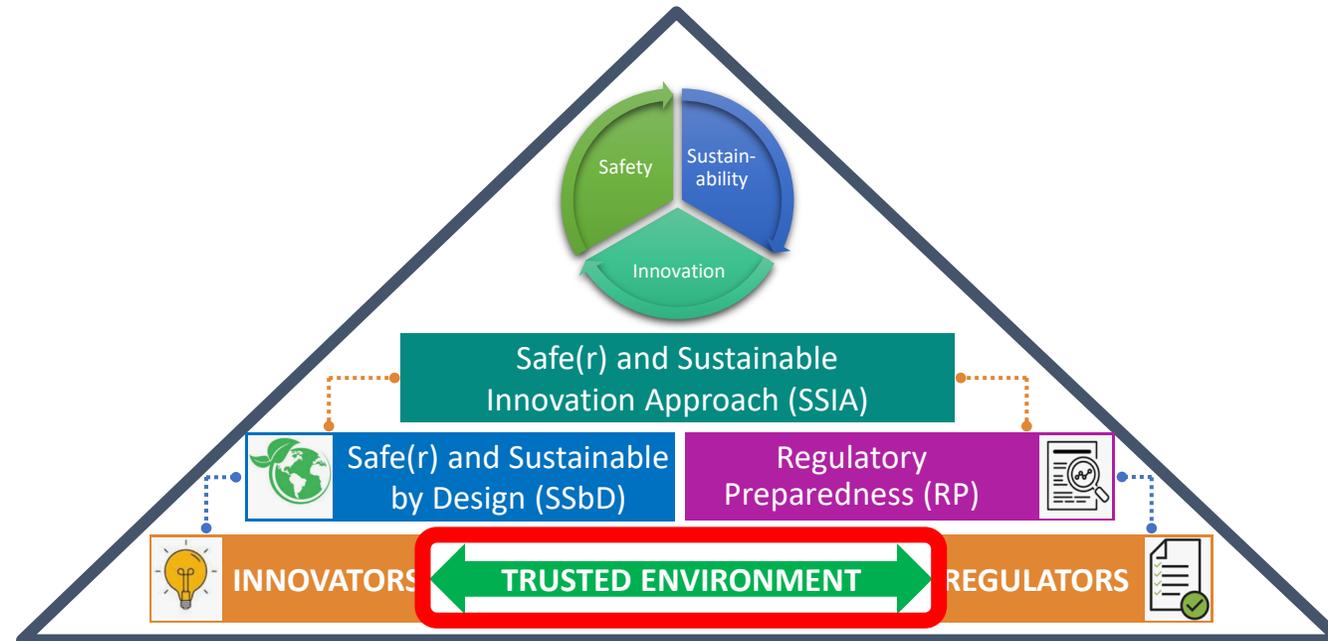
For safe and sustainable by design in nanotechnology, three pillars of design can be specified:

- I. **Safe and Sustainable material/ chemical/ product:** minimizing, in the R&D phase, possible hazardous properties and sustainability issues (promoting traceability, sustainable sources of raw materials/natural resources, minimizing resource consumption and sources, promoting social responsibility) of the designed material/ chemical/ product while maintaining its function.
- II. **Safe and Sustainable production:** ensuring industrial safety during the production of materials/ chemicals/ products, more specifically occupational, environmental and process safety aspects. The pillar should also ensure processes for the production of materials/chemicals/products minimize emissions (to air, water and soil) and resource consumption (e.g. energy, water), and optimizing waste management; and
- III. **Safe and Sustainable use and end-of-life:** minimizing exposure and associated adverse effects through the entire use life, recycling and disposal of the material/ chemical/ product. Materials/chemicals/products should be designed in a way that demand of resources is minimized during the use phase as well as during recycling, and that the material/ chemical/ product supports the waste hierarchy and circular economy.

Benefits of SSIA



Trusted environment



- early dialogue between regulators and innovators is crucial
 - share and exchange knowledge, information and views on new technologies
 - ensuring confidentiality and protecting intellectual property

SSIA is important for Advanced Materials

- To identify and present safety and sustainability issues of material innovation at an early stage, e.g. prior to market entry
- To enable regulatory preparedness by timely available adequate assessment methods and regulatory frameworks

WPMN Strategic Approach for AdMa

Development of a Strategic Approach to support RP and SSbD of AdMa and their applications

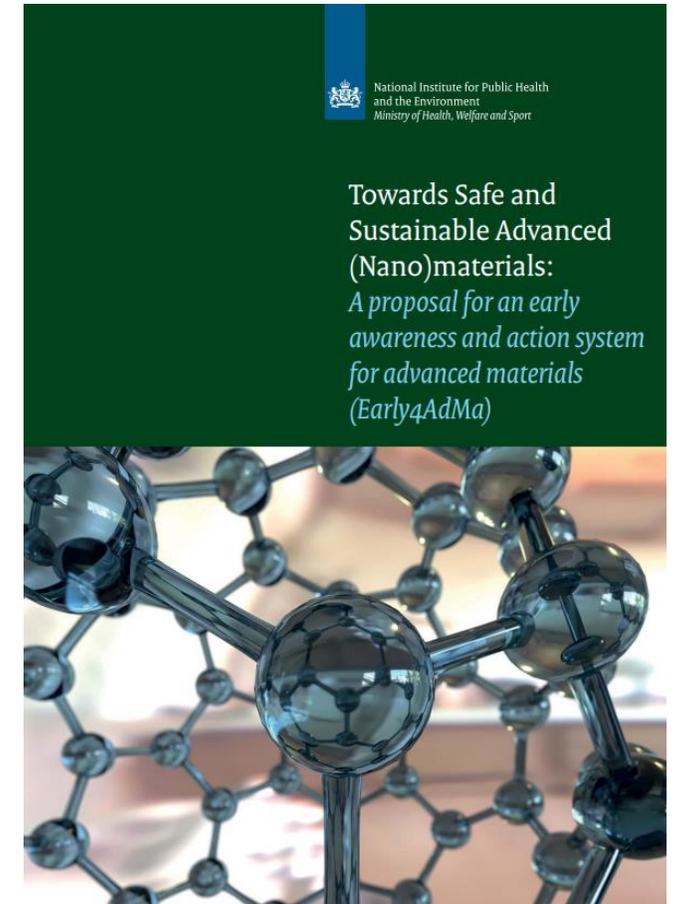
- ✓ Are regulations and methods/tools fit for AdMa?
- ✓ Identification of concerns about safety and sustainability and knowledge gaps
- ✓ Developments of recommendations and options for actions for decision makers

How will the Strategic Approach be developed?

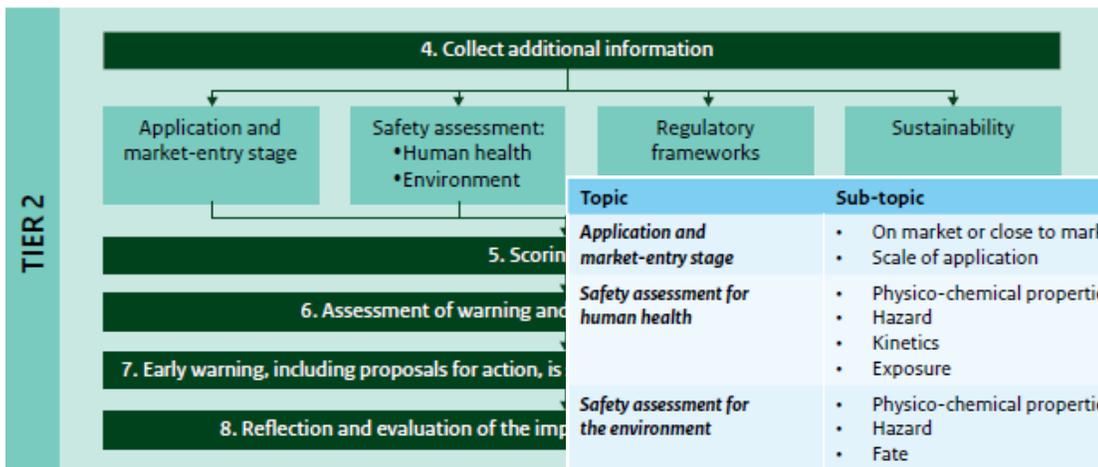
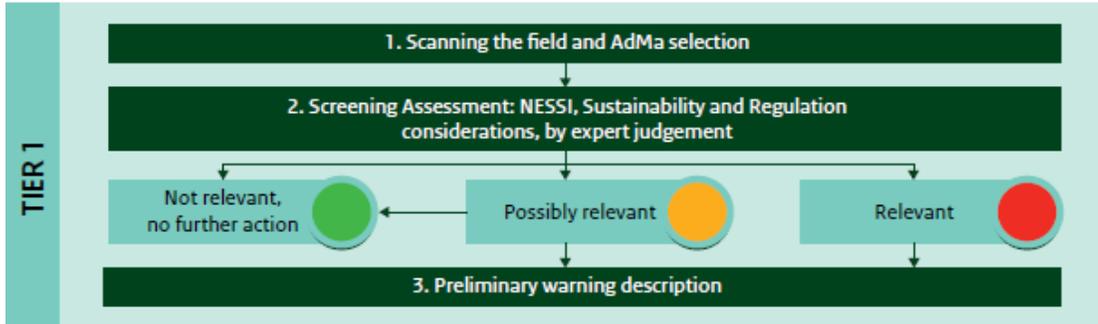
- ✓ Use Early4AdMa system as a basis for developing the Strategic Approach
- ✓ Use feedback from case studies to further improve

Early4AdMa

- ✓ Developed by German and Dutch national institutes and first tested at WPMN
 - ✓ System applied in OECD Workshop in February 2022
- ✓ 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



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 applicability assessment of underlying test methods
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

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)					



SUNSHINE

Safe and Sustainable Design for Advanced Materials

BY-DESIGN OBJECTIVES

Protect innovation by providing industries (especially SMEs) with **Safe and Sustainable by Design strategies** for multi-component (advanced) nanomaterials

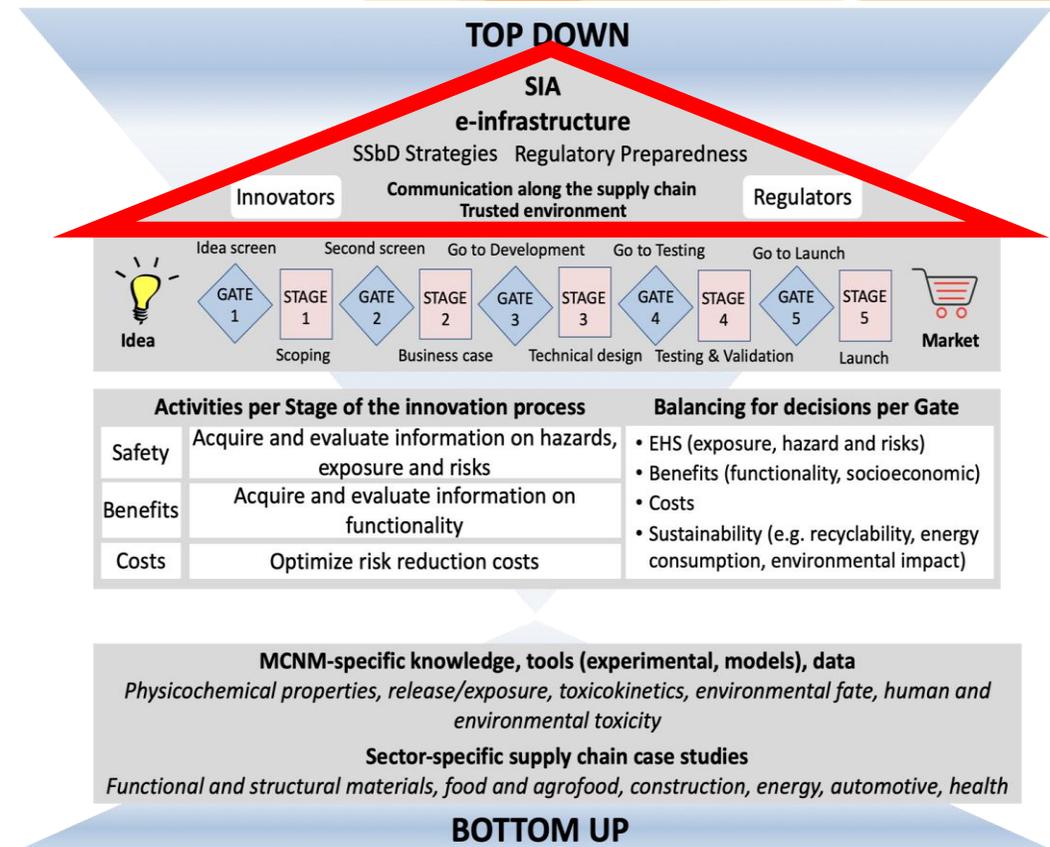
O1: Create Safe and Sustainable Innovation Approach (SSIA) e-infrastructure to facilitate the development of SSbD strategies for multi-component nanomaterials

O2: Propose experimental methods and generate data to support the development of the SSbD strategies and their validation

O3: Propose multiscale modelling approaches to support the development and testing of the SSbD strategies

O4: Employ grouping and read-across to enable use of existing information for SSbD of MCNMs

O5: Demonstrate the SSIA e-infrastructure and validate the SSbD strategies in industrial case studies

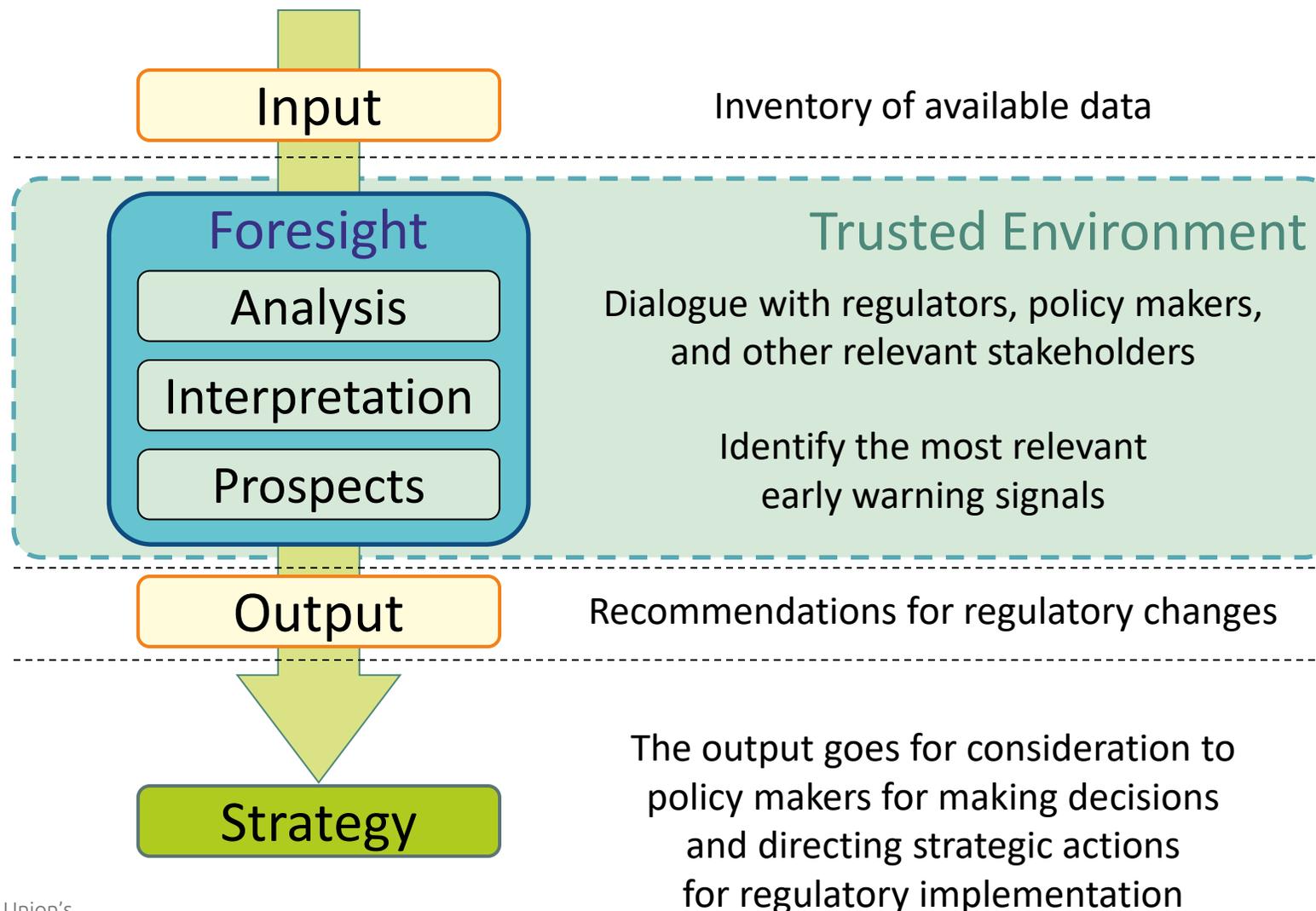


Foresight Framework

Explicit foresight studies are needed to inform and guide Regulatory Preparedness

The SUNSHINE Foresight Framework will act as a diagnostic tool

The exact form that the SUNSHINE Foresight Framework will take is under development in the project



Menti Questions

1. Can you indicate your interest (1 = low interest to 5 = high) in Safe and Sustainable by Design approaches?
2. How interested might you be (1 = low interest to 5 = high) in having a dialogue with regulatory bodies to share your innovations before market launch (so early in the innovation process) in order to better anticipate to potential safety and sustainability issues?
3. Could you list at least three “ barriers ” to having a dialogue with regulatory bodies at an early stage of the innovation process of your new products?
4. Could you list at least three “benefits” to having a dialogue with regulatory bodies at early stages of the innovation process of your new products





More information

- > OECD – Nanosafety

<https://www.oecd.org/science/nanosafety/>

- > OECD Series on Safety of Manufactured Nanomaterials

<https://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm>

– Includes recording on “OECD Webinar on Safer and Sustainable Innovation Approach for More Sustainable Nanomaterials and Nano-enabled Products” (3Nov22)

- > SUNSHINE project

<https://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm>

- > National Institute for Public Health and the Environment (RIVM)

<https://www.rivm.nl/en/nanotechnology>