Promoting the Implementation of Safe by Design

EU-US Bridging NanoEHS Reserach Efforts

EU Funding Opportunities

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Overview

ProSafe Call (planning process started)

Actual Call ideas:

- Implementation of Safe-by-Design concept(s) in industries innovation process for (specific) products
- Common data base supporting the Safe-by-Design concept(s)
- Risk Assessment along the value chain of a product
- Exposure assessment<long the value chain of a product
- ...

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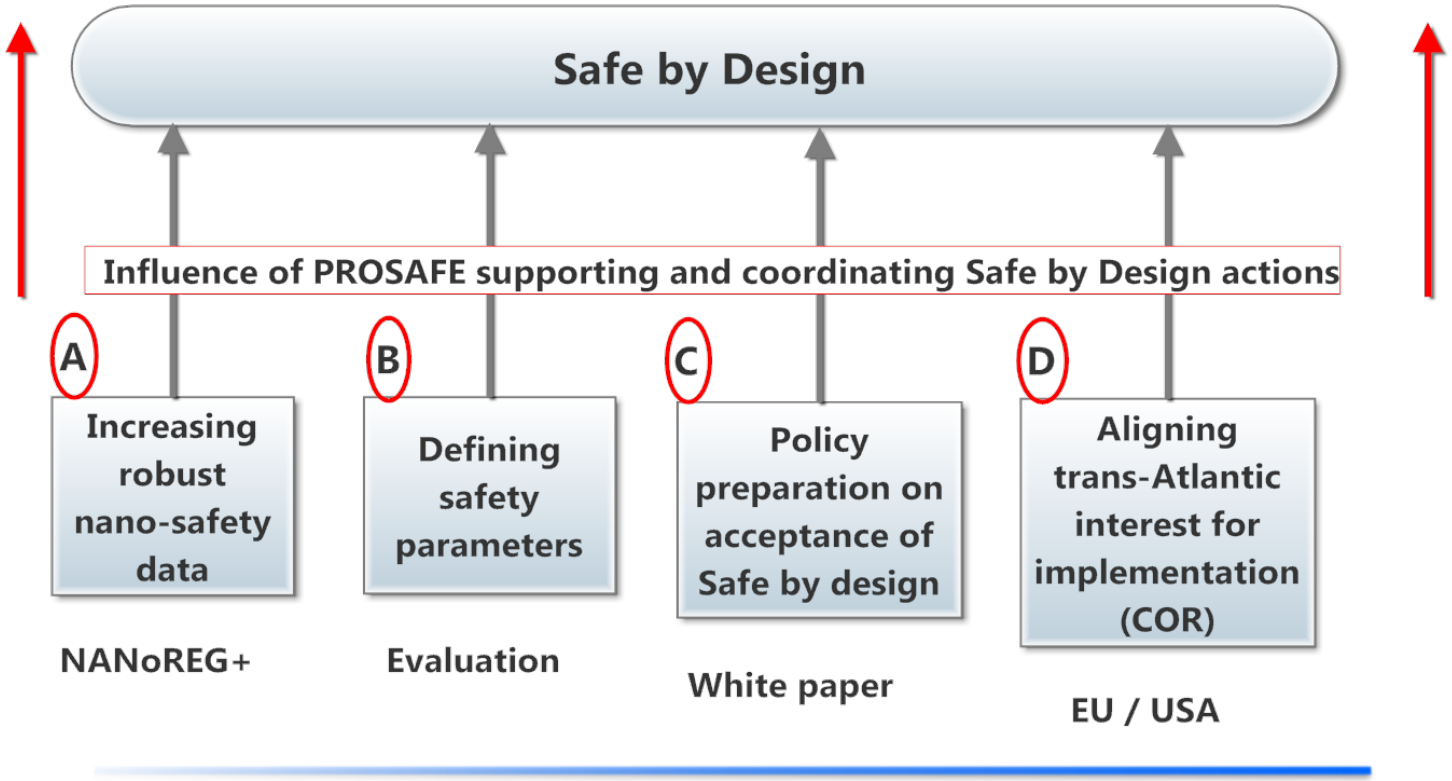
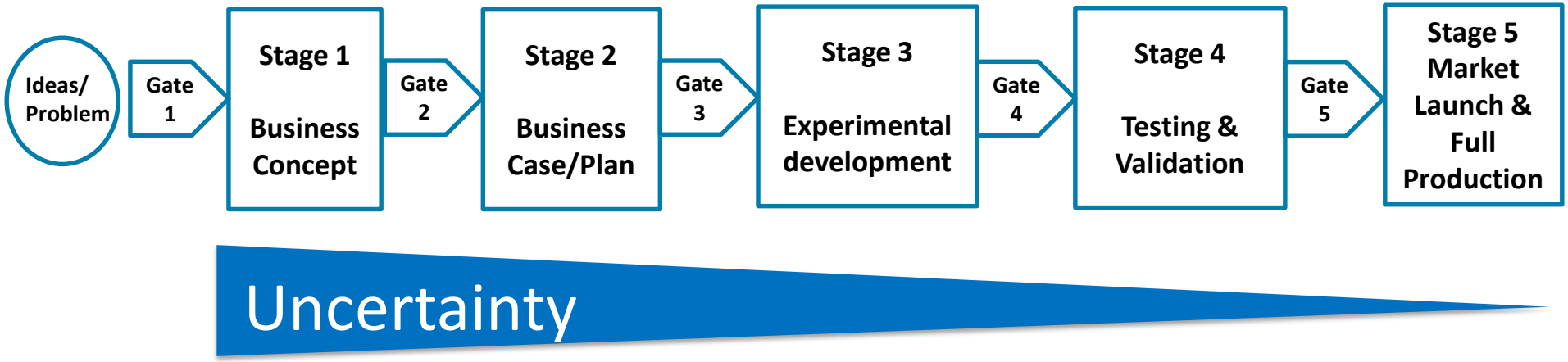
Safe-by-Design, concept and approach

Linking of existing initiatives and approaches as well as promoting the acceptance/uptake of **Safe-by-Design** within the EU-COM its Member and Associated states and international efforts (OECD, CoR EU-US on regulatory aspects of nano).



NANoREG's Safe-by-Design concept

A common European approach to the regulatory testing of nanomaterials



Safe-by-Design (NANoREG I)

FROM POTENTIAL RISKS
TO MANAGED RISKS

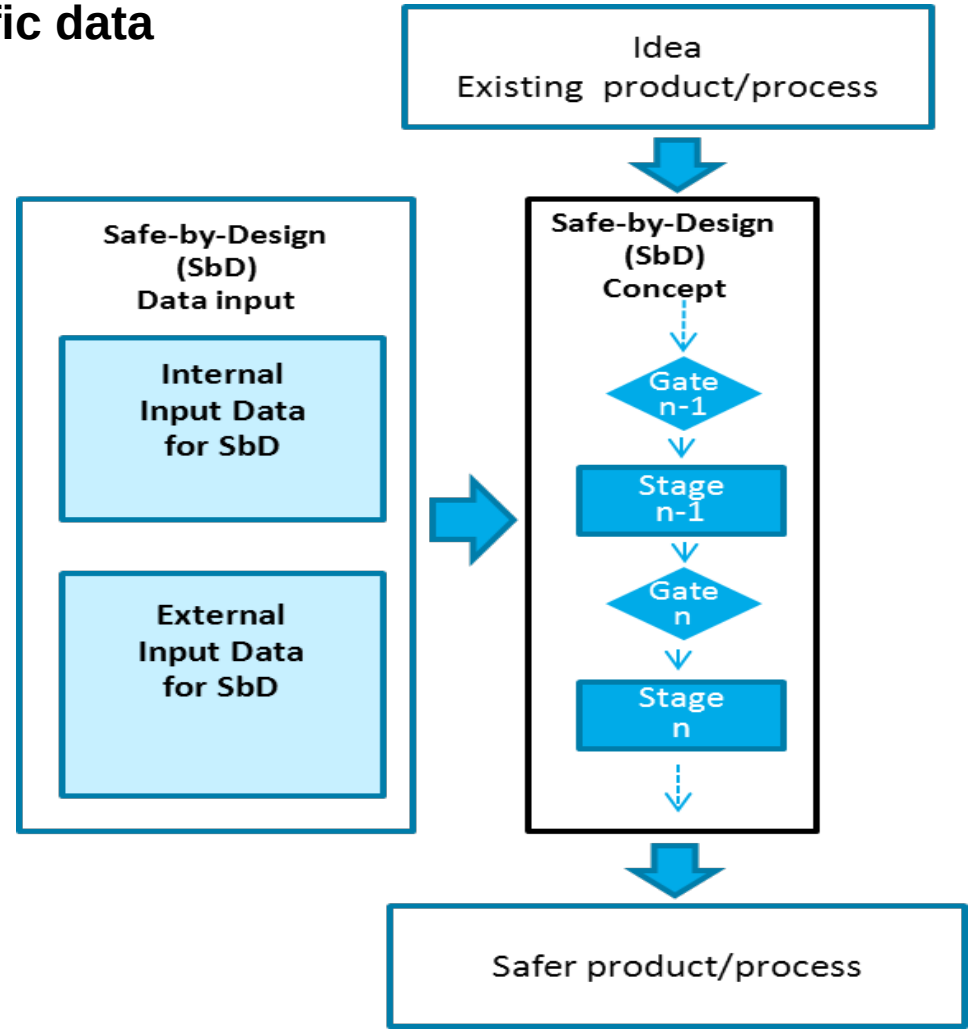
ProSafe:

Implementation of safe-by-design concept
in industrial innovation processes

NANoREG Safe-by-Design concept

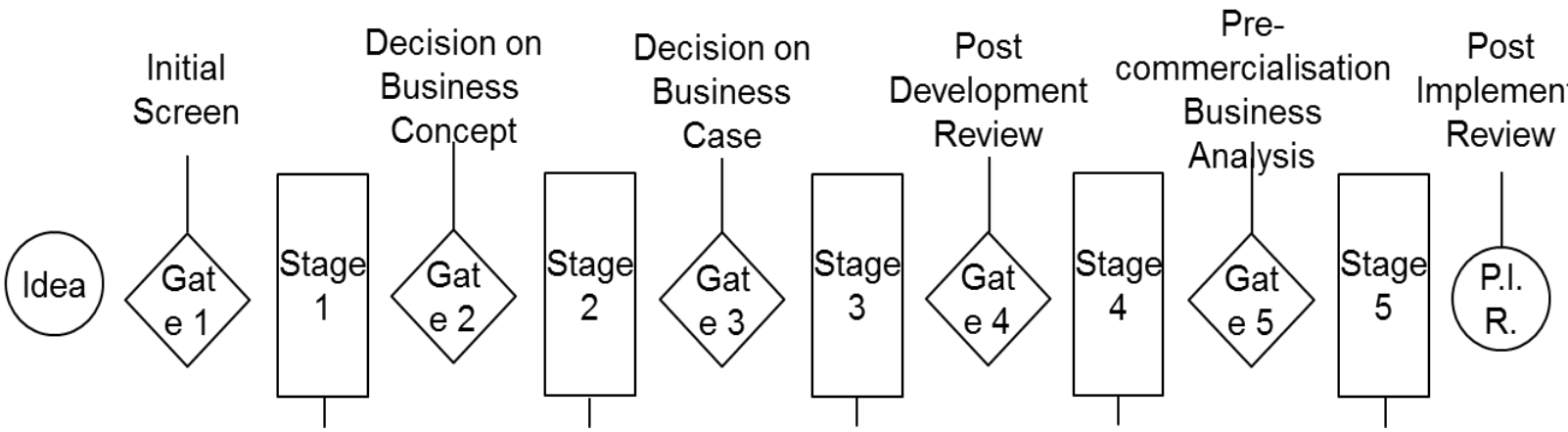
Safe-by-Design,
Concept vs. (nano-)related scientific data

There must be a strict differentiation between the Safe-by-Design innovation concept and the nano-related data the concept is using even though both are part of the NANoREG projects.



NANoREG Safe-by-Design concept for nanomaterials, etc.

A common European approach to the regulatory testing of nanomaterials



Safe-by-Design process integration in industries innovation process	No Safe-by-Design activities	- Reduction of nano related uncertainties - List of potential nano related risks - Analysis of alternatives	- Theoretical nano related risk analysis - Nano related risk mitigation - Grouping principles - Read across	Experimental nano related risk analysis	Nano related risk assessment before launch	Update nano related risk assessment after launch
		Occupational and product safety Consumer safety Environmental safety			Nano related risk management	Occupational health management during production
		Organized Dossier shared by stakeholders (Robust nano safety data) (Pre-regulatory information) Role of regulators along the GATES			Reach Dossier	

ProSafe

Action: Preparation of the first call

ProSafe is offering two main opportunities for the implementation of the Safe-by-Design concept in industrial innovation processes:

- ✓ **Common Calls:** Definition and funding of joint innovation projects addressing the development of nano material or nano products with the respective processes integrating the Safe-by-Design concept along the entire value chain.
- ✓ **Twinning of projects:** Collaboration with the innovation funding agencies on a national scale participating in calls for nanomaterials and products containing nanomaterials by supporting the Safe-by-Design concept with methods, training and other activities.

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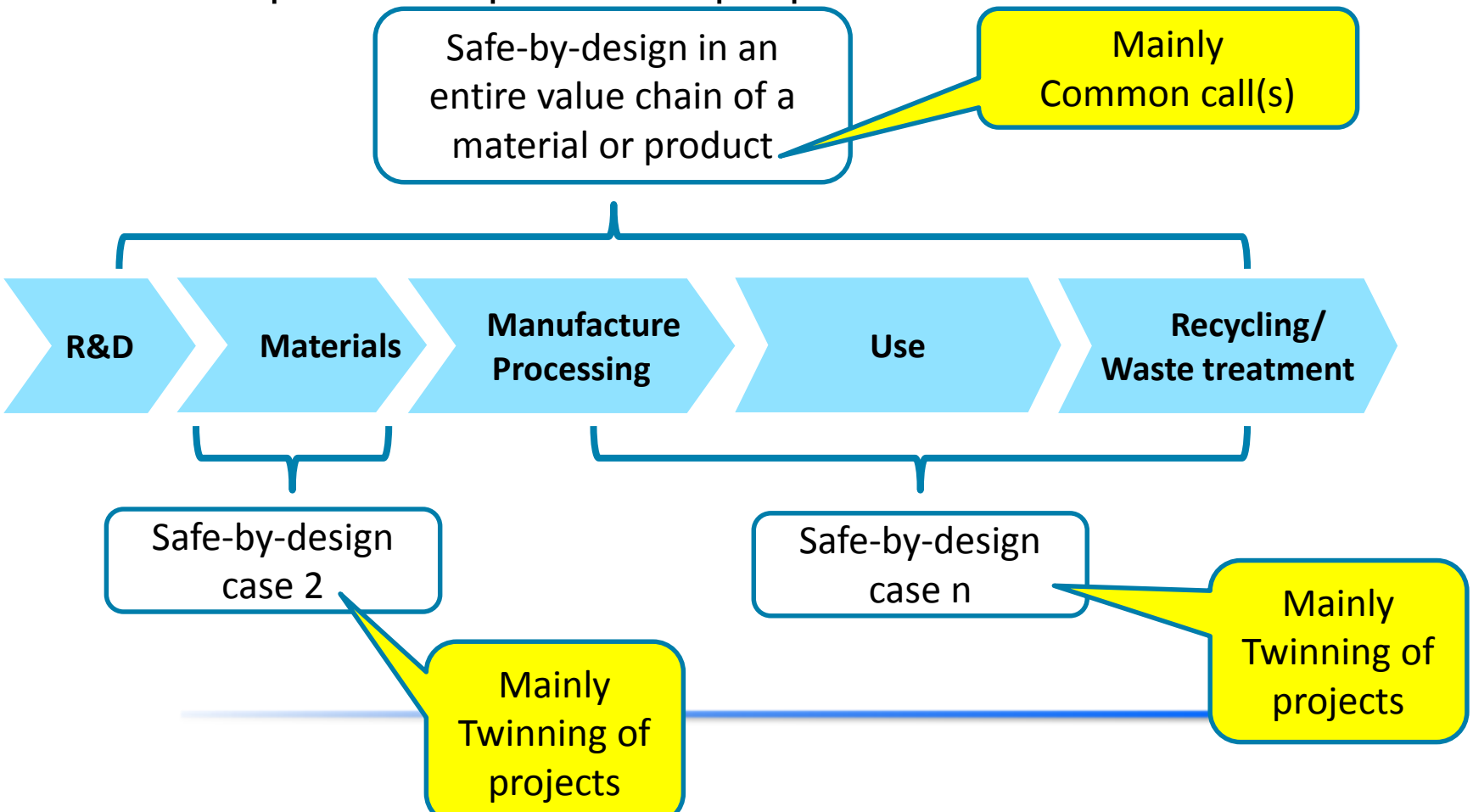
Common projects calls and twinning of projects

The adaptable Safe-by-Design concept covers:

a. the entire value chain or

b. a defined part with input and output parameters



ProSafe

Action: Preparation of the first call

ProSafe will be a supporting partner e.g. with training, implementation support, etc. in joint innovation projects on a national scale. ProSafe will support the twinning and triggering of common projects between innovation funding and regulatory agencies supporting safe innovations of nanomaterials and of products containing nanomaterials.

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NANoREG Safe-by-Design Benefits for Regulatory Authorities and Funding Agencies

- SbD delivers transparent data for all stages of the innovation process
- The SbD process delivers pre-regulatory organized dossiers and data formats shared by all stakeholders
- SbD uses ISO and OECD Standards as well as their Guidance Manuals and the NANoREG's Guidance Document
- Identification of uncertainties and risks at the earliest possible time
- Reduction of uncertainties and risks at the earliest possible time
- The strict separation of data allows an easy check and up-date of the data and thus a new risk analysis
- Be prepared to meet todays and future regulatory requirements
- SbD delivers a good balance between safety, functionality and costs

Summary: higher transparency, better process understanding

Thank you for your attention.