



A common European approach to the regulatory testing of nanomaterials

NANoREG's Safe-by-Design Concept for Nanomaterials

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Context: NANoREG project



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- Full title: *A common European approach to the regulatory testing of nanomaterials*
- Uncertainty about EHS aspects
- Shrinking time to market of new MNM drives the need for urgent action by regulators
- Data are continuously generated (characterization, toxicity, exposure) but ...
- Relevance to regulators often unclear or unproven
- Need to answer questions and requirements of regulators and legislators (at both EU and National levels)

NANoREG goal



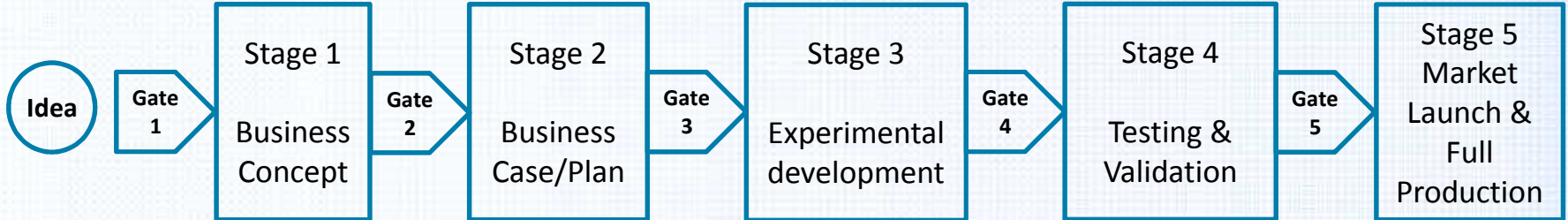
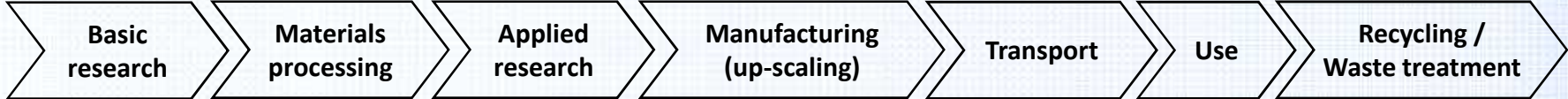
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- To provide answers and solutions from existing data, complemented with new knowledge
- To provide a tool box (NANoREG toolbox) of relevant instruments for safety assessment
- To develop new testing strategies and approaches adapted to innovation requirements
- To establish a close collaboration among authorities, industry and science leading to efficient and practically applicable risk management approaches for MNMs and products containing MNMs
- To be continued in NANoREG II and ProSafe

Safe Innovation approach: overview



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<p>Safe by Design</p>	<p>FROM UNCERTAINTIES AND POTENTIAL RISKS TOWARDS CERTAINTY AND MANAGED RISKS</p>
<p>Uncertainty and risk</p>	
<p>Regulatory Preparedness</p>	<p>FROM SHARING EXPERTISE AND KNOWLEDGE WITH INNOVATORS TO IDENTIFY UNCERTAINTIES AND POTENTIAL RISKS TOWARDS GUIDANCE FOR REGISTRATION OR MARKET APPROVAL</p>
<p>Safe Innovation Approach</p>	

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Safe-by-Design: introduction



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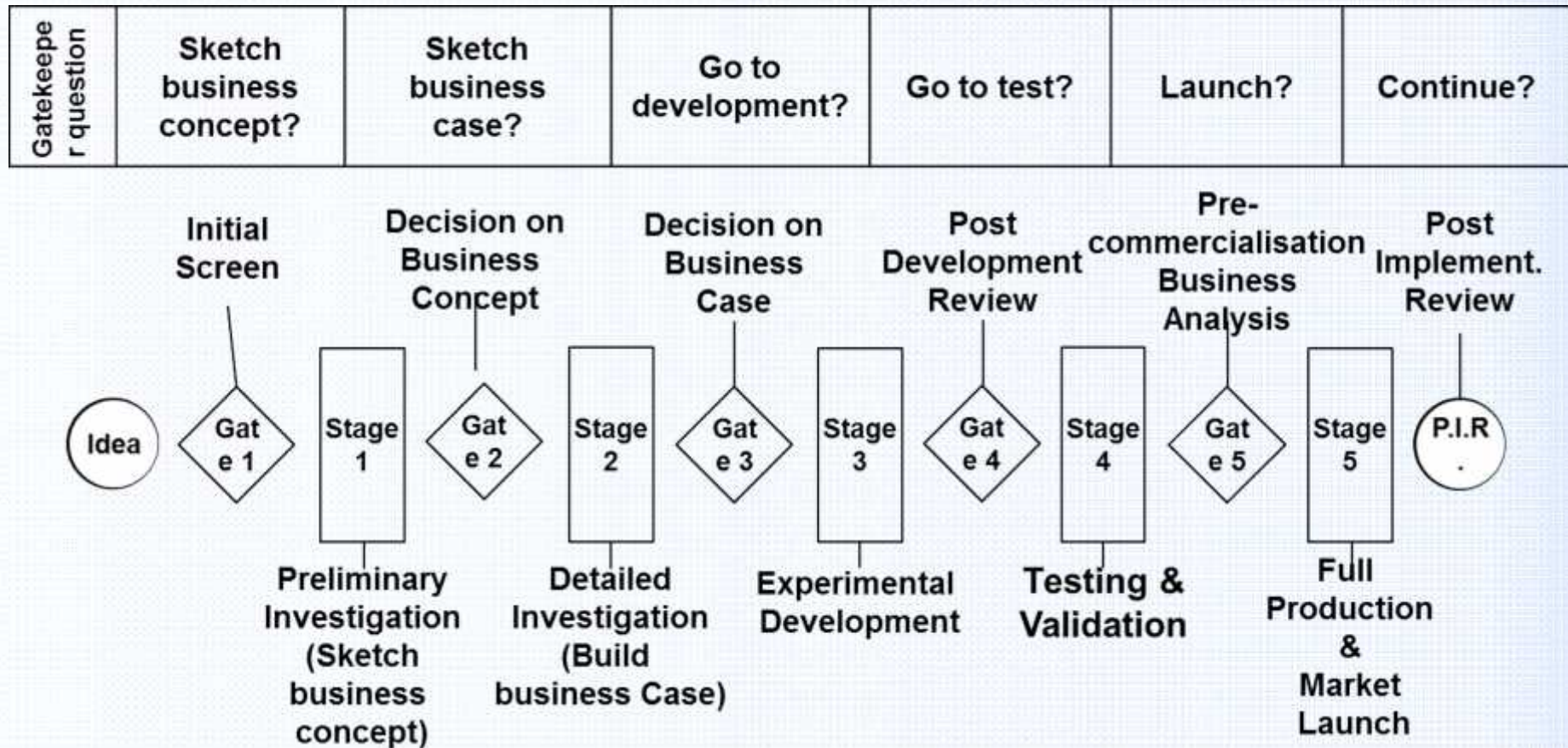
- Safe-by-design (SbD) is not new, the method has been used for years by the industry, such as QbD, ...
- There is no standard definition of SbD. The understanding about SbD is diffuse and sometimes misleading.
- NANoREG SbD is regarded as a concept covering industrial innovation processes and the entire or a partial value chain of nanomaterials, nano-products or respective processes.
- The SbD concept is tuned towards timely identification of uncertainties and potential risks as well as timely measures to reduce or eliminate these uncertainties and risks during an innovation project.
- SbD is not a stand-alone concept: it is designed so that it can be seamlessly integrated into current industrially used innovation processes.

NANoREG's Safe-by-Design concept



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NANoREG's Safe-by-Design backbone is industry's innovation process model, such as the STAGE GATE model



The STAGE GATE innovation model



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In industry, no matter the name, some sort of stage gate process is the *de facto* standard for all kinds of innovation processes and R&D projects (products, processes, technologies etc.).

Within the **STAGES** the proper work is carried out: ideation, development, tests, up-scaling, etc.

In each **GATE** so-called gatekeepers decide on the fate of an innovation project: proceed, alter (proceed through gate but minor alterations in the next phase), recycle (repeat the stage with major alterations), on-hold (wait for other projects, technologies, licenses, regulations etc.) or terminate.

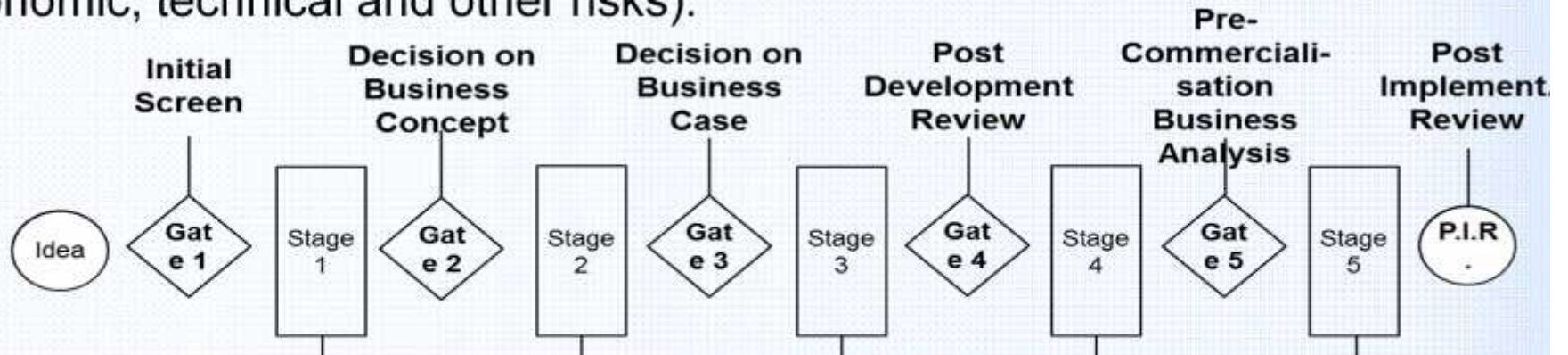
The decision is always based on balancing costs and benefits. Risks and uncertainties are included in the costs.

Risks and Risk analysis (RA) in the STAGE GATE model



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In some companies, the stage gate processes are already supplemented by some sort of risk analysis (environmental, health and safety {EHS}, economic, technical and other risks).



Industries innovation processes (Exemplarity)	Product Idea					
	Technology Idea	<ul style="list-style-type: none"> - Preliminary Investigation - Estimation of benefits and costs - Sketch business concept 	<ul style="list-style-type: none"> - Detailed Investigation - Prove of principles - Socio-economic assessments - Competitiveness benchmarking - Build business case 	<ul style="list-style-type: none"> - Product R&D - Feasibility - Prototypes 	<ul style="list-style-type: none"> - Market tests (Volume, price) - Product validation (Functionality and costs) - Business plan validation 	Market launch
	Process Idea			Applied Research and Development	Technology evaluation	Technology launch
Current non nano related industrial risk management	No risk management activities	List of potential risks	Theoretical risk analysis	Experimental Risk Analysis	Risk assessment before launch	Update Risk assessment after launch

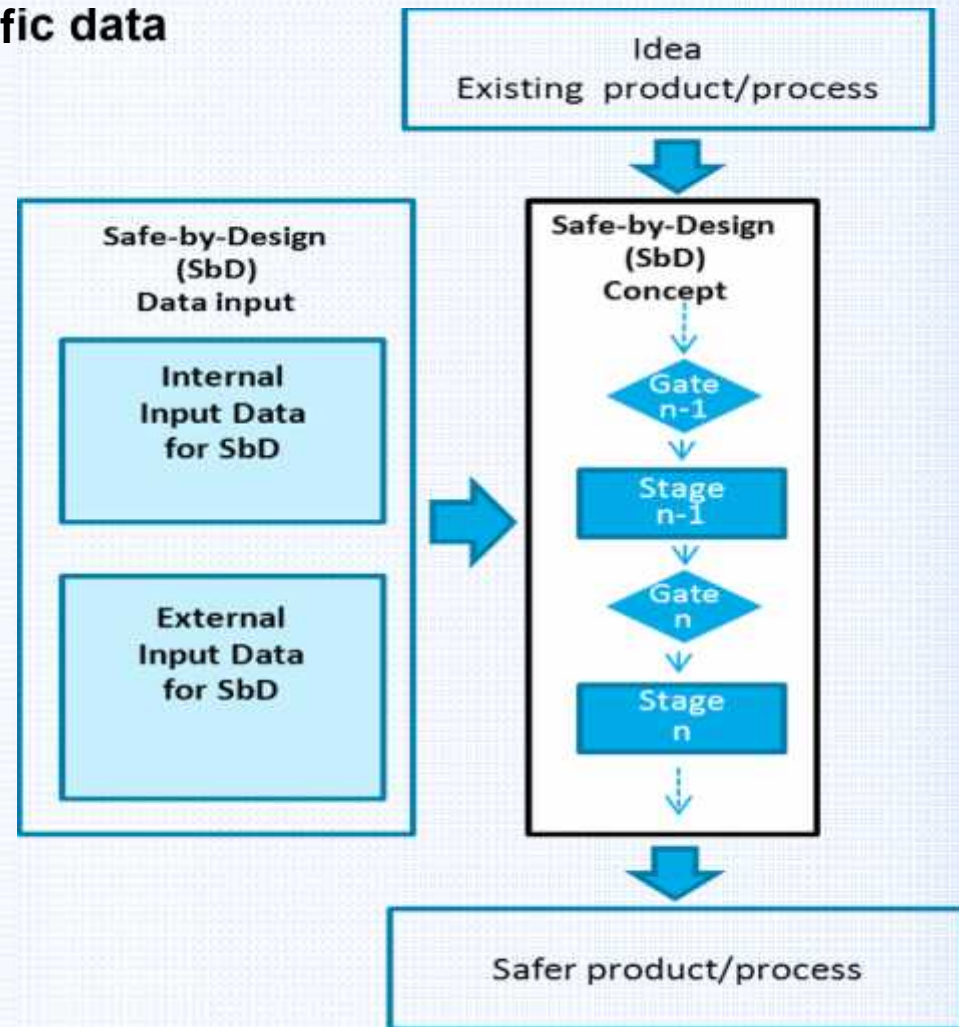
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Safe-by-Design, Concept vs. (nano-) related scientific data

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 project.



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The SbD can be seen as nano-related add-on for existing industrial safe innovations processes encompassing different activities and tools.

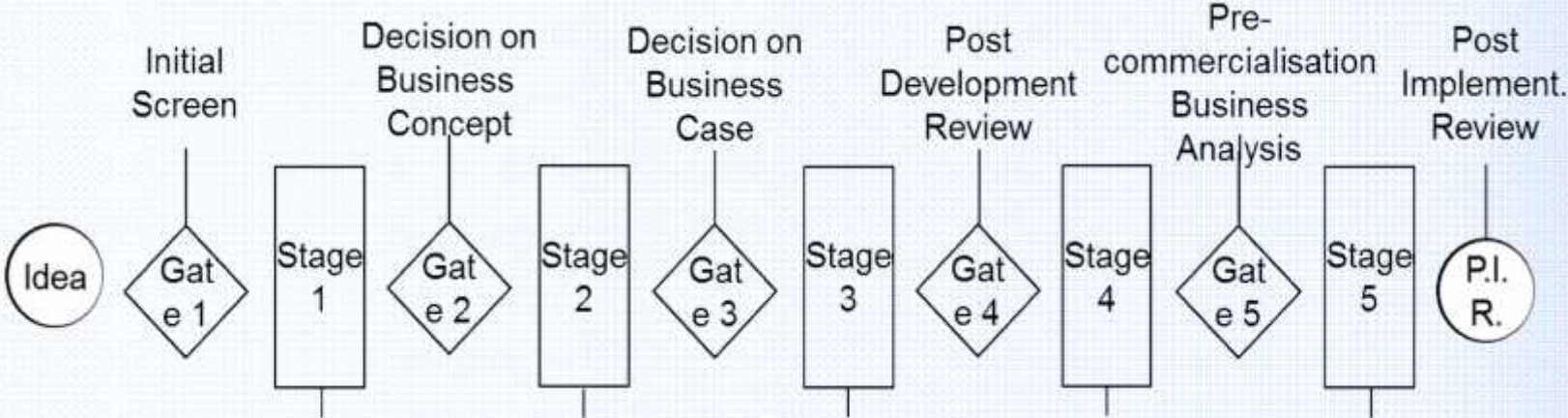
SbD supplements the risk analysis part starting in stage 1 and continuing into the risk management in stage 5.

Thus, every activity carried out during a “normal” risk analysis is also carried out within a SbD-process.

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



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Safe-by-Design process integration in industries innovation process	No Safe-by-Design activities	<ul style="list-style-type: none"> - Reduction of nano related uncertainties - List of potential nano related risks - Analysis of alternatives 	<ul style="list-style-type: none"> - 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	

Costs in the risk analysis

Costs of measures to reduce uncertainties in a stage have a direct impact on the remaining risks: the higher the costs, the lower the remaining risk. However, the costs of uncertainty and risk reduction have to be balanced with the remaining risk to find the most efficient solutions (e.g. a reduction of the remaining risk to zero is usually inefficient).

	Investment to reduce uncertainties	Benefit of investment	Remaining risk potential	Remark
Stage 1	small	large	small	Small investments have large benefits
Stage 2	medium	medium	medium	
Stage 3	large	small	large	Large investments have small benefits

NANoREG Safe-by-Design benefits for Entrepreneurs



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- SbD can be integrated into existing industrial innovation processes
- Early and easier identification of uncertainties and risks
- Reduction of uncertainties and risk
- Projects with unacceptable risks can be timely recycled or terminated
- Less “surprises” (i.e. unforeseen events) during the development process and market introduction
- Be prepared to meet today's and future regulatory requirements
- Well balanced Safety, Functionality and Costs
- Consumers view: Supports confidence through the transparent process and between the stakeholders agreed "organized data collection".
- The strict separation of data allows an easy check and up-date data and thus to perform new risk analysis
- Ensures better design of products and better business models

Summary: money, time, and resources can be saved

NANoREG Safe-by-Design Benefits for

Regulatory Authorities and Funding Agencies

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- 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 today's and future regulatory requirements
- SbD delivers a good balance between safety, functionality and costs

Summary: higher transparency, better process understanding

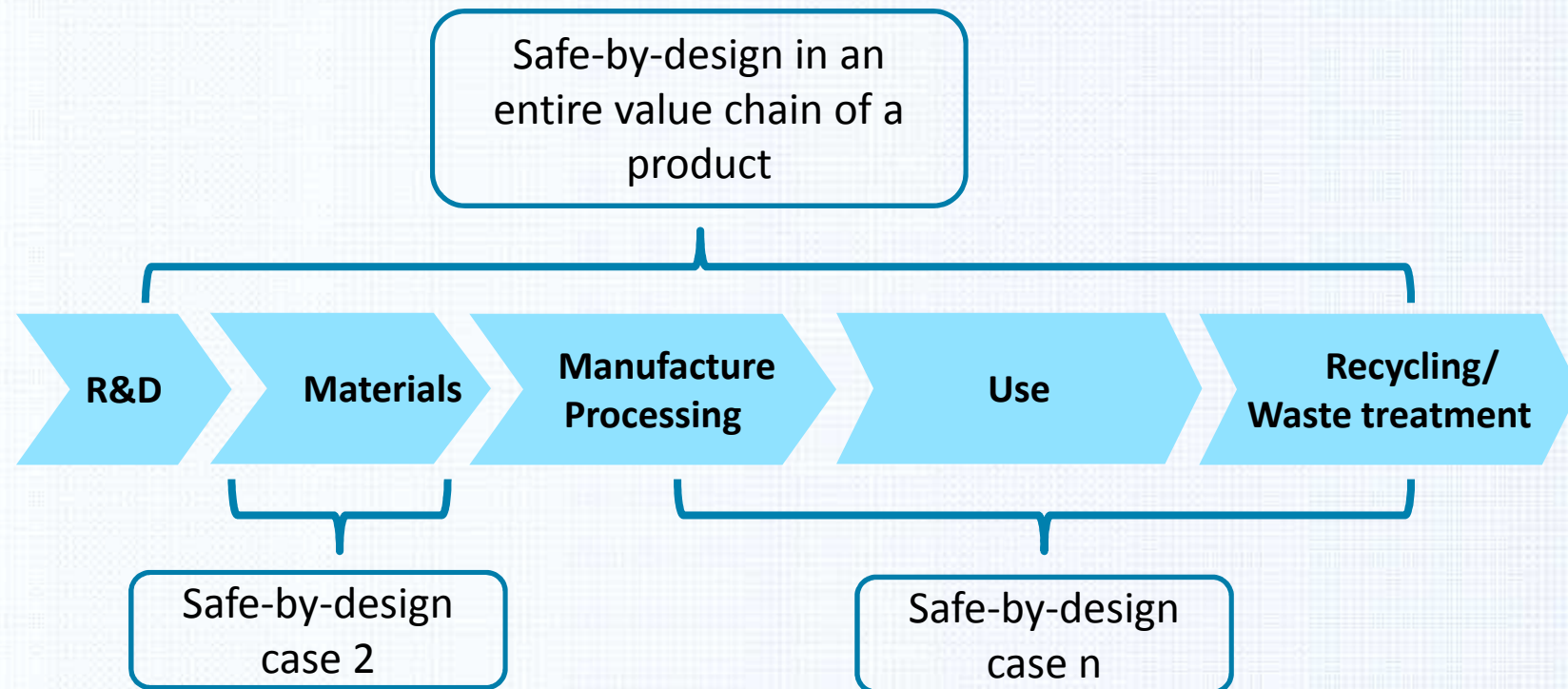
Application of NANoREG's Safe-by-Design



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The modular Safe-by-Design concept covers:

- a. the entire value chain or
- b. a defined part with defined input and output parameters



Thank you for your attention