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How suitable is LCA for Nanotechnology assessment? Overview of current methodological pitfalls and potential solutions

Industrial perspective on nanotechnology development

Hoehener Karl
TEMAS AG

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The industrial perspective on nano technology

- Nanotechnology is one of the six “Key Enabling Technologies” (KETs) defined by the European Commission in its 2012 Communication.
- These technologies are considered by experts to be the driver for the development of new goods and services as well as the restructuring of industrial processes, needed to modernize industry.
- Given sufficient resources and support, they should play a central role in enabling the transition to an efficient, knowledge-based and low carbon economy.
- KETs are regarded as crucial for ensuring the competitiveness of European industries in the knowledge-based economy.

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The growing importance of nanotechnology (NT)

- The global NT industry is expected to grow to some US$ 76 Billion by 2020. The estimated Compound Annual Growth Rate (CAGR) of the global NT market is around 18% over 2016-2022.
- There are growing indications that the anticipated risks of some manufactures nanomaterials may not be as high as was originally thought.
- Regulatory hurdles must be minimised in order to take full advantage of the innovative and economic potential of NT, which includes their positive economic impact on environmental technologies and their use in products which help to reduce their footprints.
- The problem we are facing seems to be predominantly a matter of uncertainty due the challenge of understanding and implementing cost effective and sufficient measurement of risk/regulatory relevant parameters.

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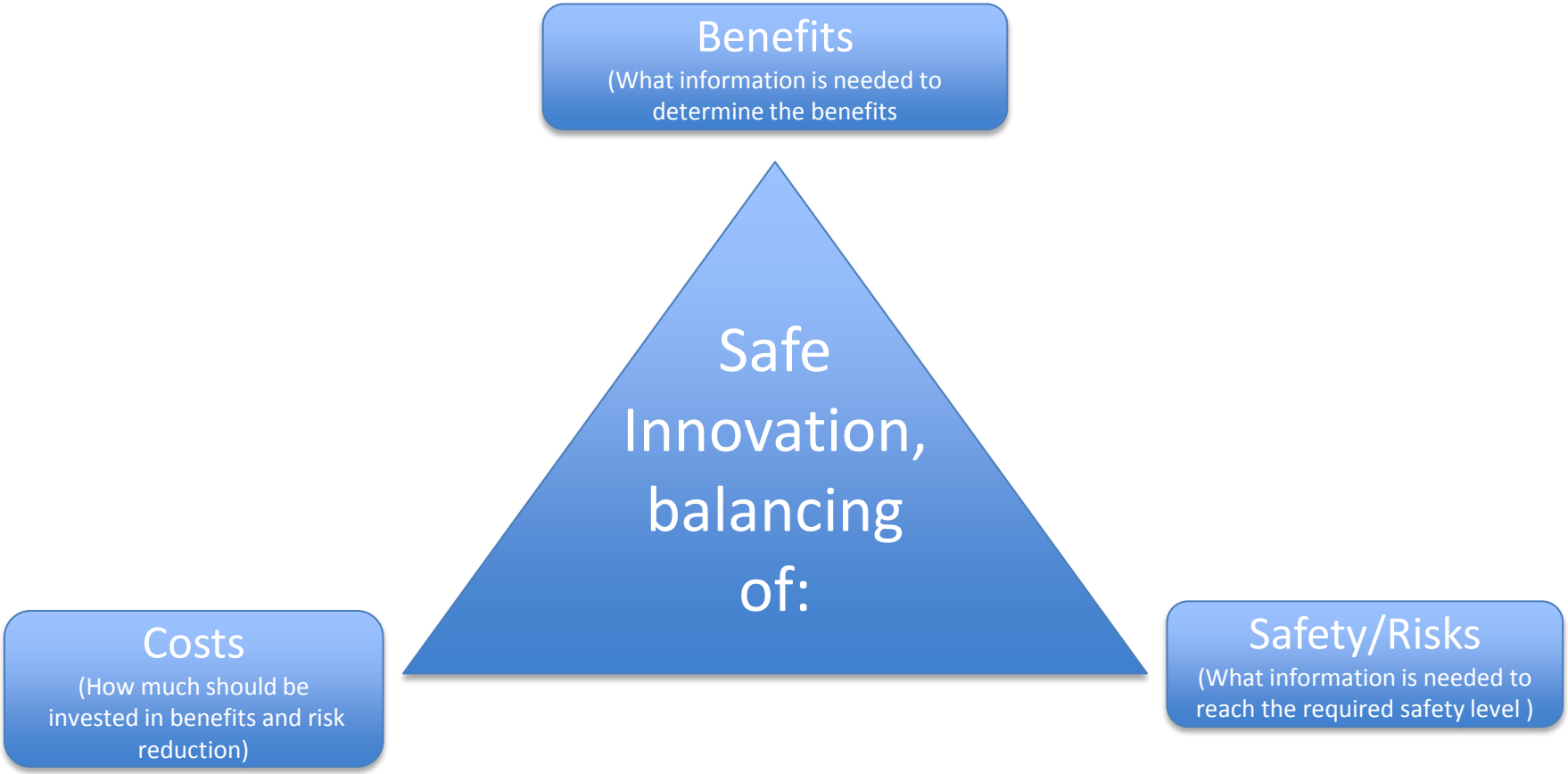
One of the industrial perspectives: Safe Innovation



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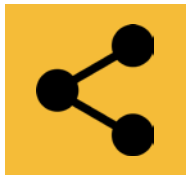
Benefits of Safe Innovation

Safer products on market

Efficient innovation process (time and costs reduction)

Faster to market

Collaboration and knowledge sharing between actors along the innovation process



Property - Functionality - Safety

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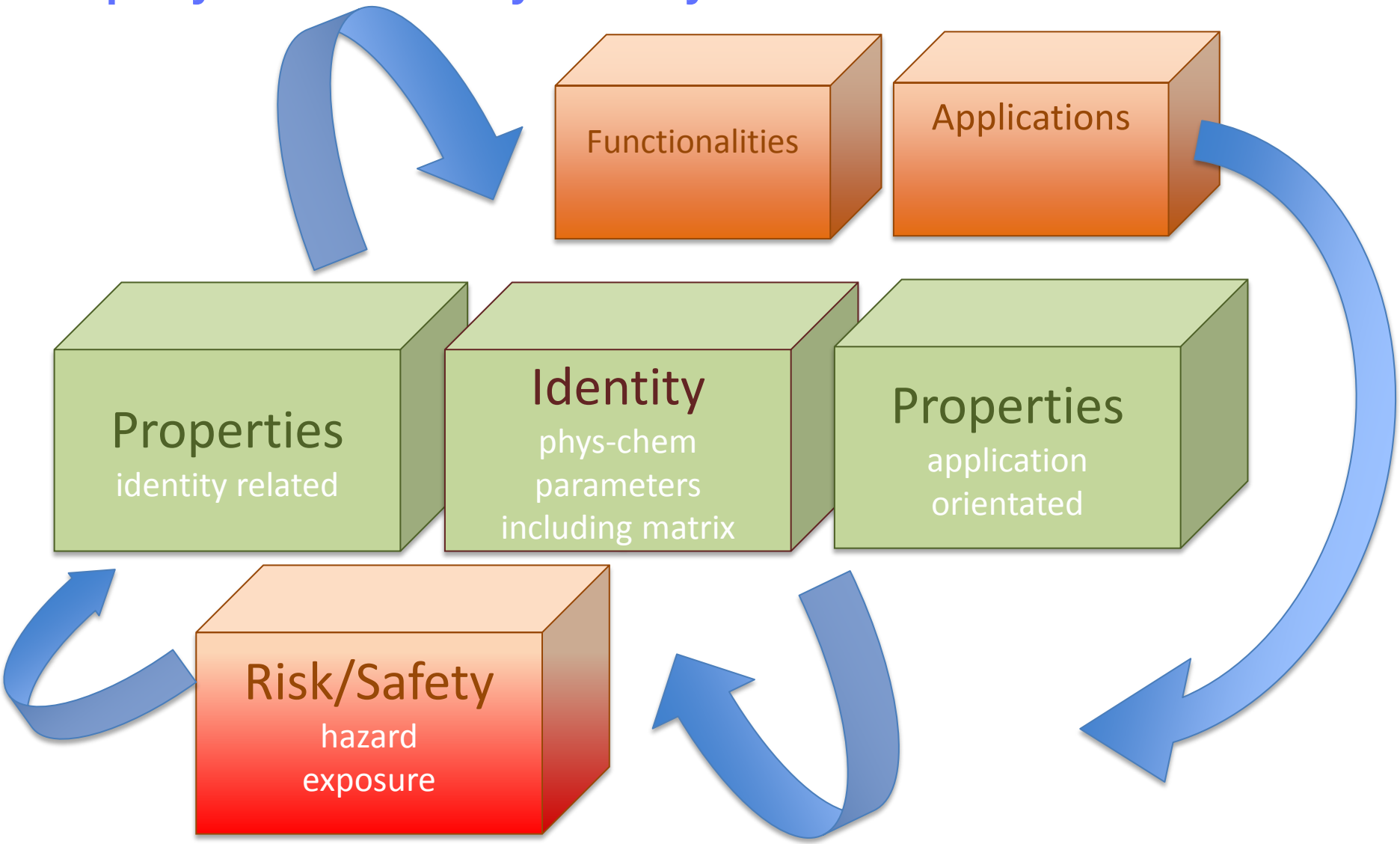

Further developed from :A. Kraegeloh
INM-Leibniz Institute for New Materials

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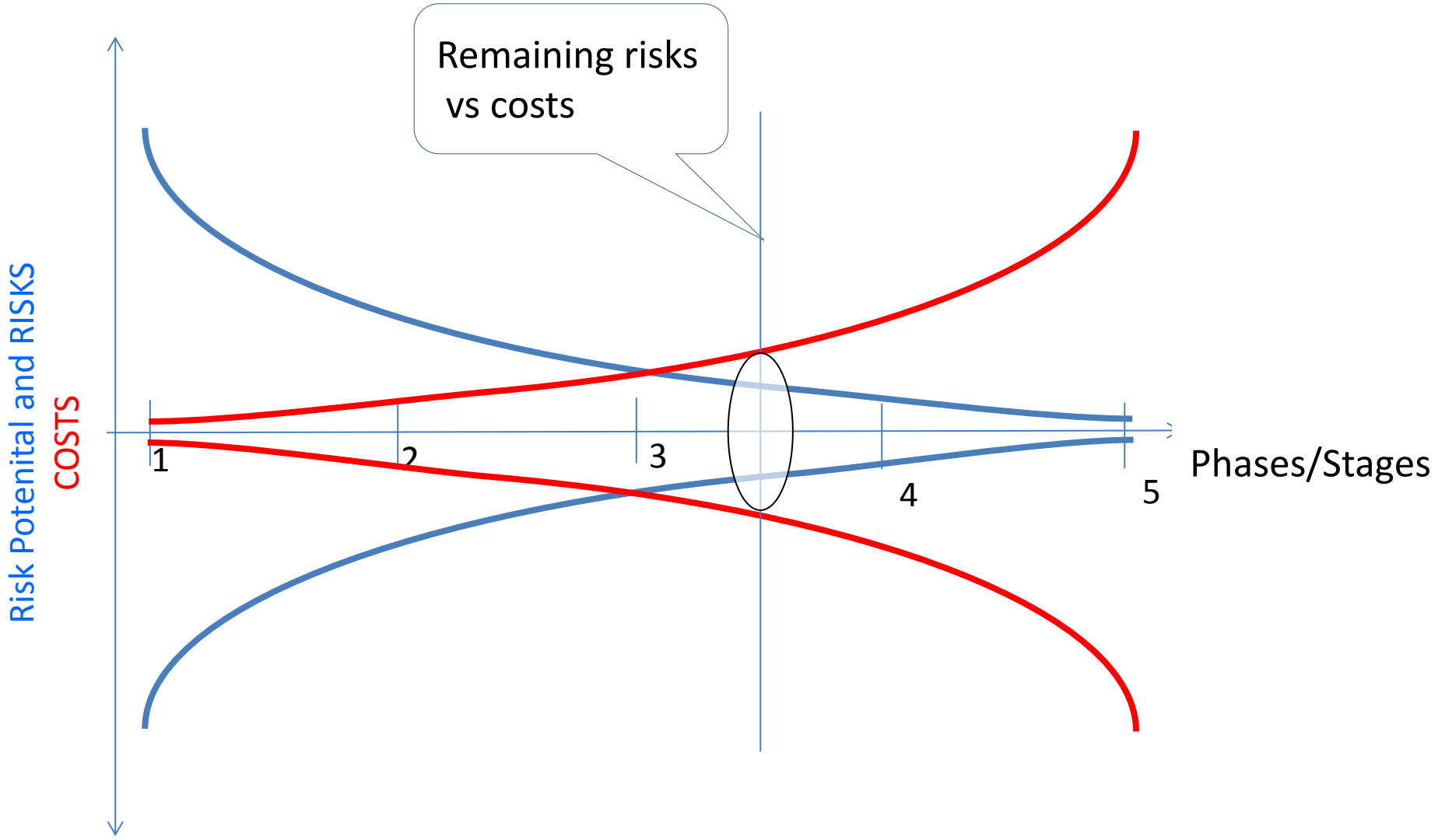
Costs to reduce risks in phases/stage



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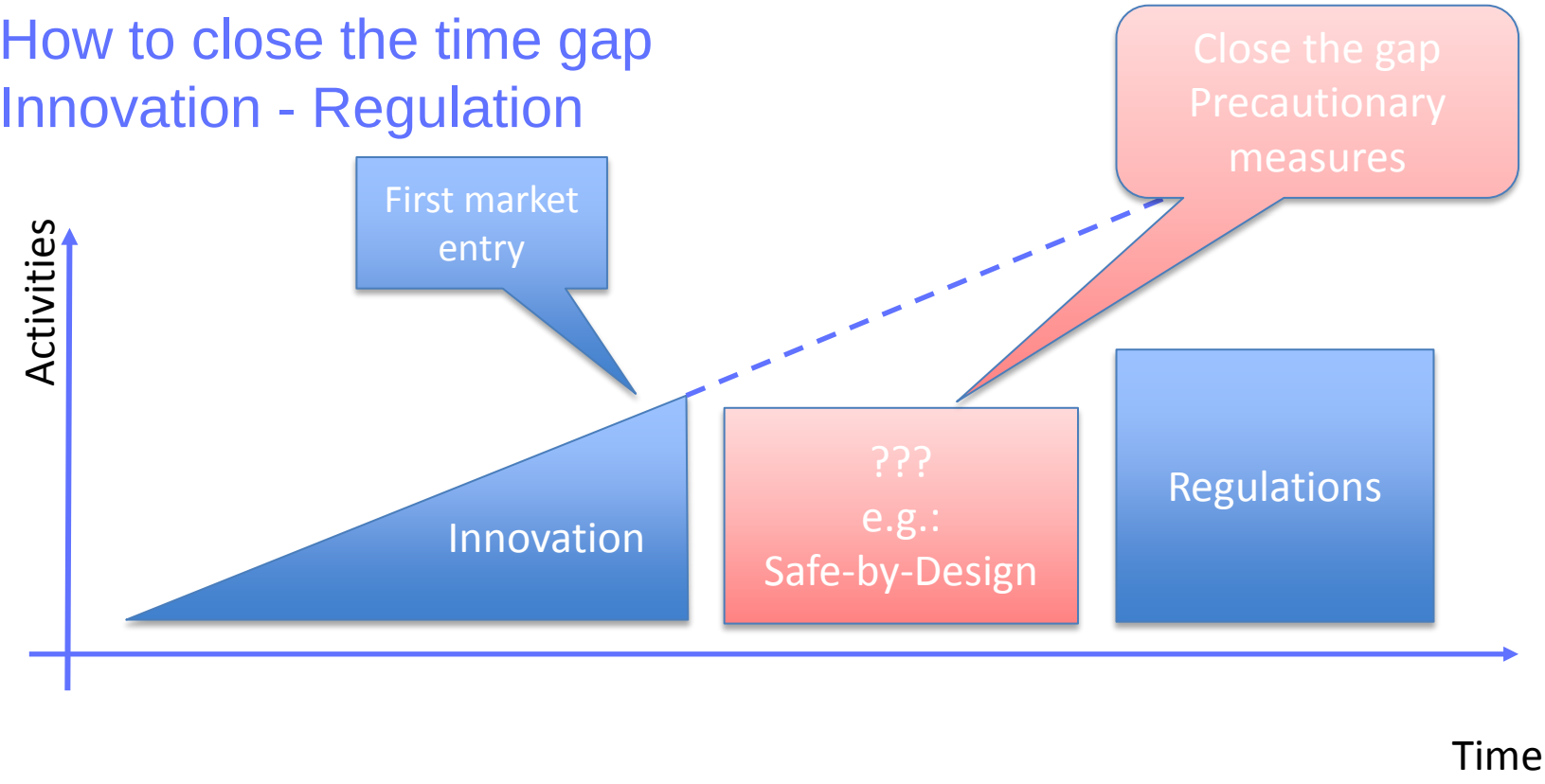
Industrial perspective on nanotechnology development

How to close the time gap Innovation - Regulation



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A possible solution:

The NANoREG Safe-by-Design (SbD)

The drivers of SbD:

- Requirements of the law based regulations
- Needs of the sustainability (LCA, etc)
- Needs of the Soft Regulations
- Balancing Benefits-Safety-Costs

Objectives:

- Identification of uncertainties and risk potentials at early phases/stages of a projects
- Managing uncertainties and risk potentials at early stages

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Safe-by-Design (SbD) concept

NANoREG Safe-by-Design

- Safer nanomaterials and nanoproducts
- Application of the precautionary principle
- Identification of uncertainties and risk potentials at the earliest possible point in time
- Active management reducing and (if possible) eliminating uncertainties and risk potentials
- Establishing transparency for safety relevant information and data

NANoREG SbD is driven by the needs of the correlating and relevant regulation(s)

SbD as part of an industrial innovation model

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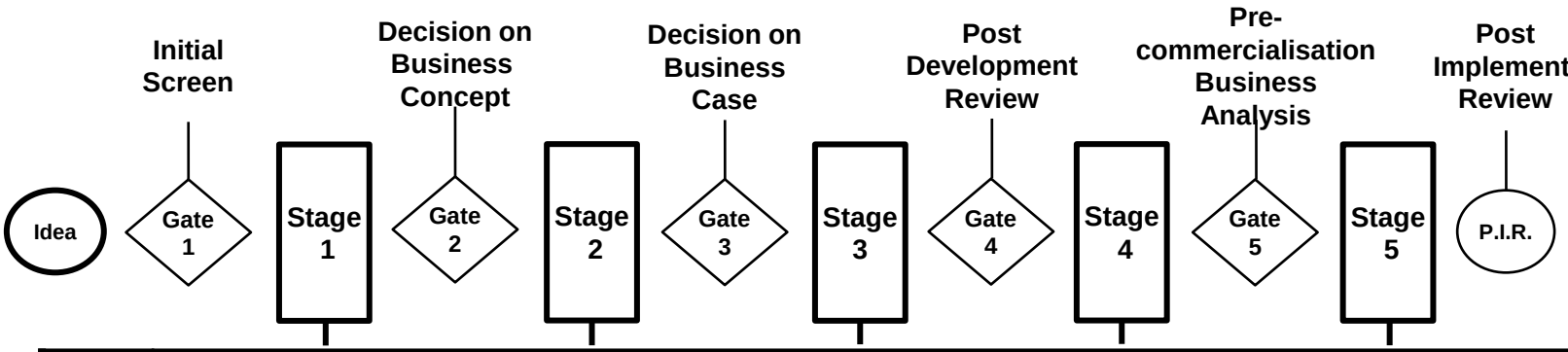

Industries innovation processes	Product Idea						
	Technology						
	Process Idea						
Industrial risk management	No risk management activities	List of potential risks	Theoretical risk analysis	Experimental Risk Analysis	Risk assessment before launch		Update Risk assessment after launch
Safe-by-Design 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 RA & RM	Nano related risk assessment before launch	Update nano related risk assessment after launch Occupational health management during production
		Occupational and product safety Consumer safety Environmental safety				Nano related risk management	
		Data for the Safety Dossiers and Safety Profile (Robust nano safety data, pre-regulatoy information)				Regulatory Dossiers	

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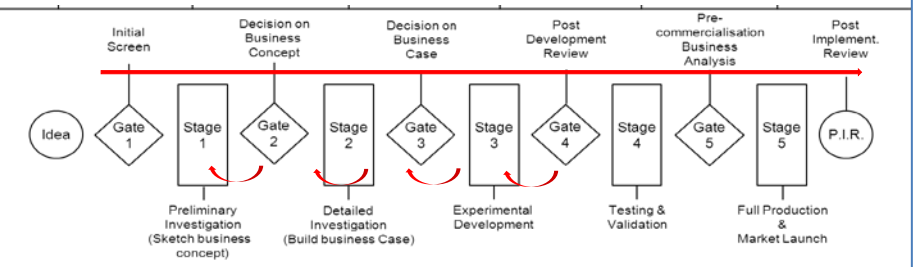
SbD concept and Risk Assessment (RA)

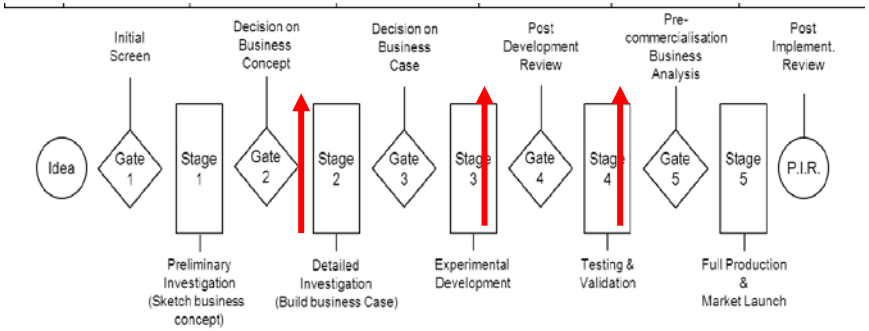
Safe-by-Design is an ongoing process within an structured innovation model



Specifics:

- SbD starts at a very early stage with the identification of uncertainties and potential risks
- SbD starts with pre-cautionary tools
- SbD is a continuous dynamic process
- Risk Assessment is a tool of the Inventory of the SbD implementation platform

A Risk Assessment (RA) will be performed at defined stages and/or triggered by a special need.



Specifics:

- RA is a well established, defined and accepted process initiated at defined stages
- RA delivers well defined information about the risk of a material or product RA
- Measures to reduce risks are not part of RA

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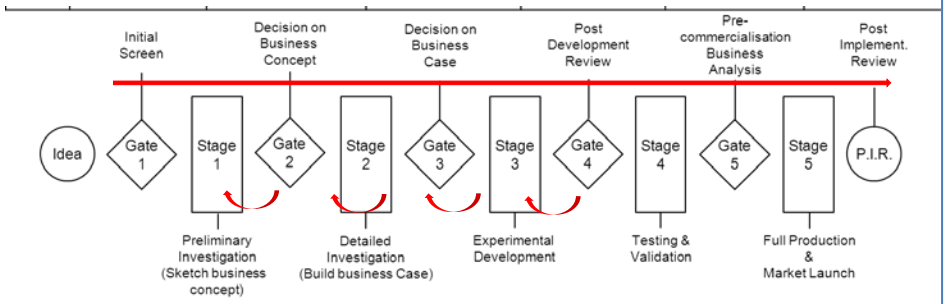
SbD concept versus Sustainability and Life Cycle Analysis

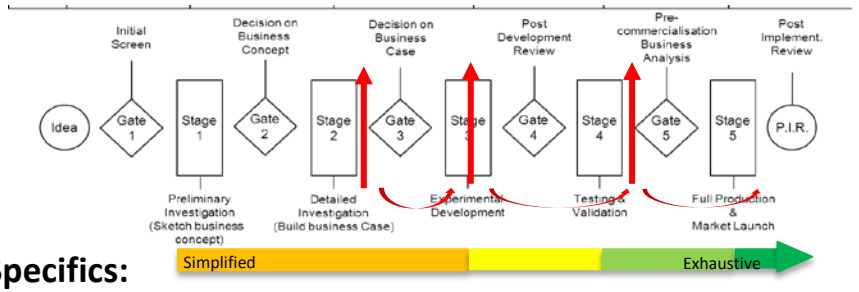
Safe-by-Design is an ongoing process within a structured innovation model



Specifics:

- SbD starts at a very early stage with the identification of uncertainties and potential risks
- SbD starts with pre-cautionary tools
- SbD is a continuous dynamic process
- Sustainability Analysis and LCA are tools of the Inventory of the SbD implementation platform.

SA & LCA will be performed at defined stages with different levels of exhaustiveness.



Specifics:

- Established & standardised method. Evaluates potential impacts on ecosystems, human health and resources.
- Limitations when applied to nanomaterials. Development needed: evaluation methodology & data on production.
- LCA can be applied ex ante to manage/ control/ mitigate the (out-coming-future) potential impacts.
- In early stages simplified LCA appro Source: LCA group of GIAKER ES Anal.)
- Sustainability Analysis and LCA, although different scenarios can be evaluated.

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Target groups of SbD

Industrial companies
(Safety dossiers and safety profiles of nano materials and nano products, corporate social responsibility, labels, code-of-conduct)

Research and development
(Inventory of safety relevant concepts, tools, and data bases)

Innovation promoting agencies
(Realisation of safety relevant requests)

Society
(Transparency ⇒ trust)

Regulation authorities and agencies
(«Regulators prepared for innovation»)

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Elements of the SbD implementation concept

Safety Dossier	Requirements of the defined regulation (s) adapted to the various phases of a project
Safety Profile	Latest data and comparison to the gate criteria of a nanomaterial / nanoproduct
Inventory	Support of the SbD application by harmonised concepts, tools, procedure, data sources and data bases
SbD Implementation Platform (Web)	Manual for the phase specific implementation of SbD, application specific templates for a low barriers to start a project
Trainings	For the SbD concept and the SbD implementation

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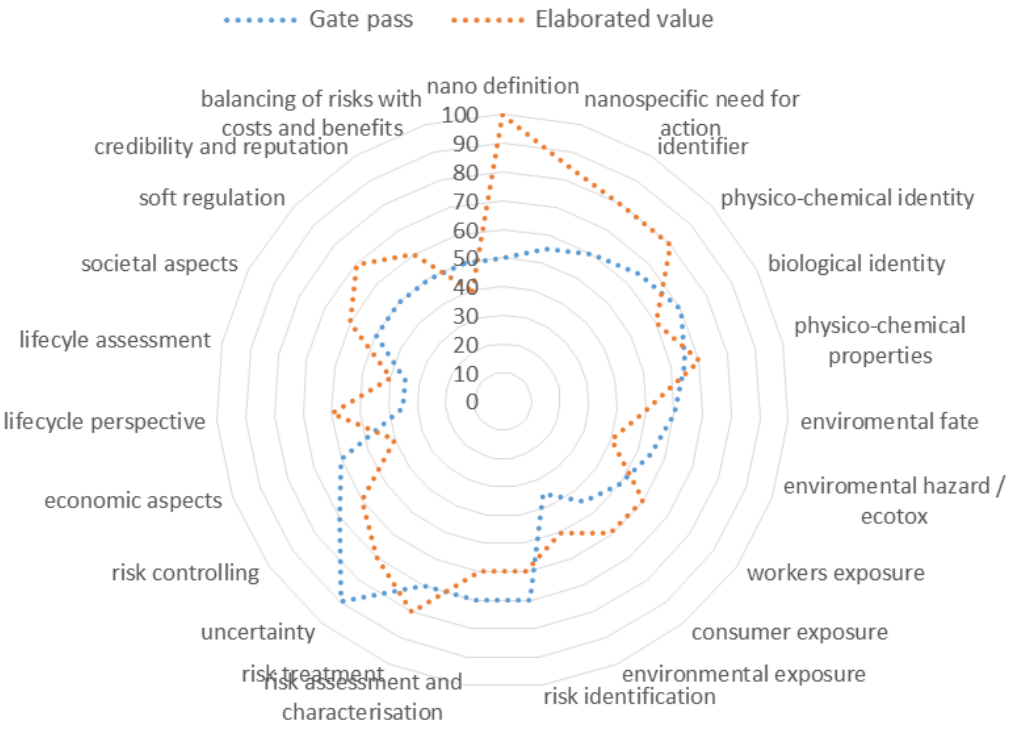
Safety Profil output of the SbD implemention process

Content:

- Creation of **project-specific documents** for selected target groups
- Structuring of all safety relevant data and information

Goal and purpose:

- **Support** of the management processes
- **Exchange** of information
- Standardised overview of the “gate-pass” criteria **compared** to the elaborated values



Exemplarily graph, under development

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Safe-by-Design and the GLOBAL RESPONSIBLE CARE CORE PRINCIPLES

1. Continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles so as to avoid harm to people and the environment
   → NANoREG Safe-by-Design (SbD) concept
2. Use resources efficiently and minimise waste
   → Identification of uncertainties and potential risks at early stage
3. Report openly on performance, achievements and shortcomings
   → The safety profile is an effective tool thereto
4. Listen, engage and work with people to understand and address their concerns and expectations
   → SbD creates transparency, as a basis for dialogue
5. Cooperate with governments and organisations in the development and implementation of effective regulations and standards, and to meet or go beyond them.
   → Innovators prepared for regulation is an instrument thereto
6. Provide help and advice to foster the responsible management of chemicals by all those who manage and use them.
   → SbD is such instruments

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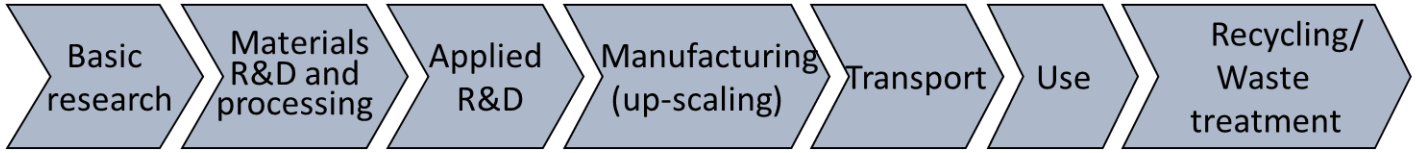
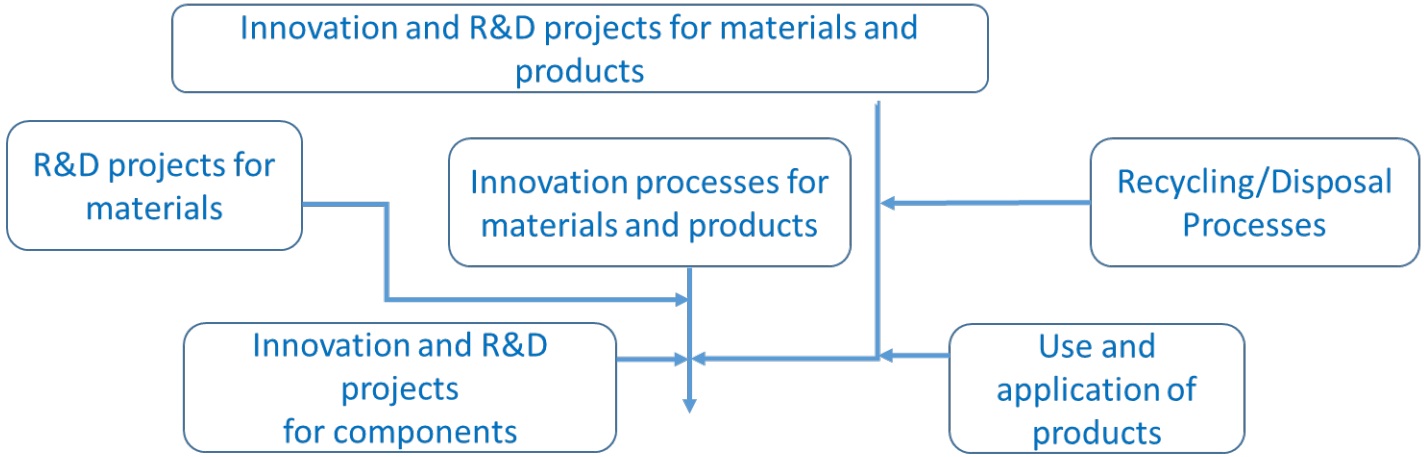
Implementation of SbD along the Value Chain

The entire Value Chain



Applied industrial innovation and R&D projects



SbD as part of individual projects

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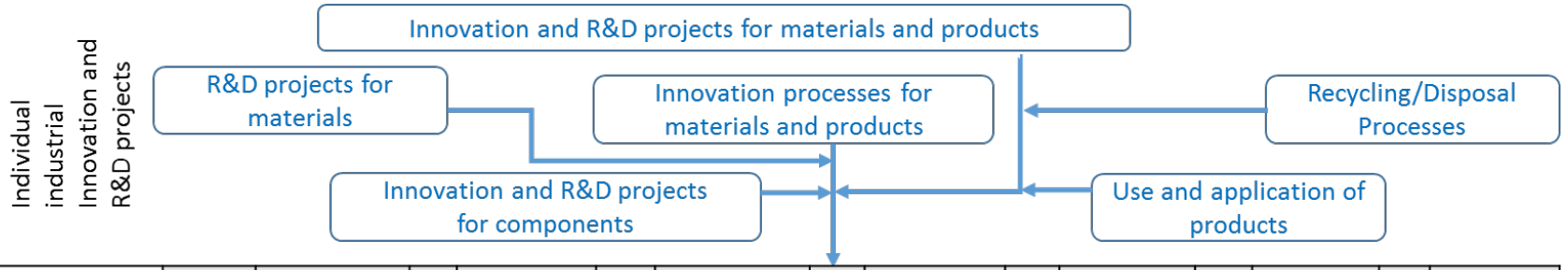

	Innov. Modell	Ideas	Gate 1	Phase/ Stage 1	Gate 2	Phase/ Stage 2	Gate 3	Phase/ Stage 3	Gate 4	Phase/ Stage 4	Gate 5	Phase/ Stage 5	Gate 6	Results
Industrial innovation models	innovation management processes	Product idea	Product Development											Product
		Technology idea	Technology Development											Technology
		Material idea	Material Development											Material
		Production process idea	Production process Development											Production process
Safe-by-Design complements	Innovation risk mgmt. processes	No risk management activities	Establish context for innovation risk mgmt. process, risk screening		Coarse risk assessment with theoretical data		Risk assessment refined with experimental data		Risk assessment refined with market tests data		Risk assessment refined with market launch data			Risk monitoring over rest of PLC,
	EHS mgmt. processes	No EHS management activities	1.Establish context for EHS management process 2.Safety screening		Occupational HS mgmt. for R&D personnel, occupational HS mgmt. for production/ application, use and of consumer				Occupational HS mgmt. for R&D personnel, during production, application or use, and consumer					
					Environmental impact consideration over sustainability analysis (LCA)				Management of environmental impact over PLC along VC					
	Regulatory mgmt. processes	No regulatory management activities	1.Establish context for regulatory management 2.Regulatory screening		Activities to fulfil application specific regulations (e.g. GLP)				Application specific regulations (pharma, food, cosmetics, toys, medicinal products etc.)					
					SRD if there are activities		SRD or PPORD		PPORD or REACH		REACH, etc.			
	Safety data mgmt. processes	No safety data management activities	Definition Safety Dossiers, screening of safety data		Elaboration of the data for the Safety Profile, coordinate and consolidate the data, create the Safety Profile							Elaborate the regulatory specific dossiers		

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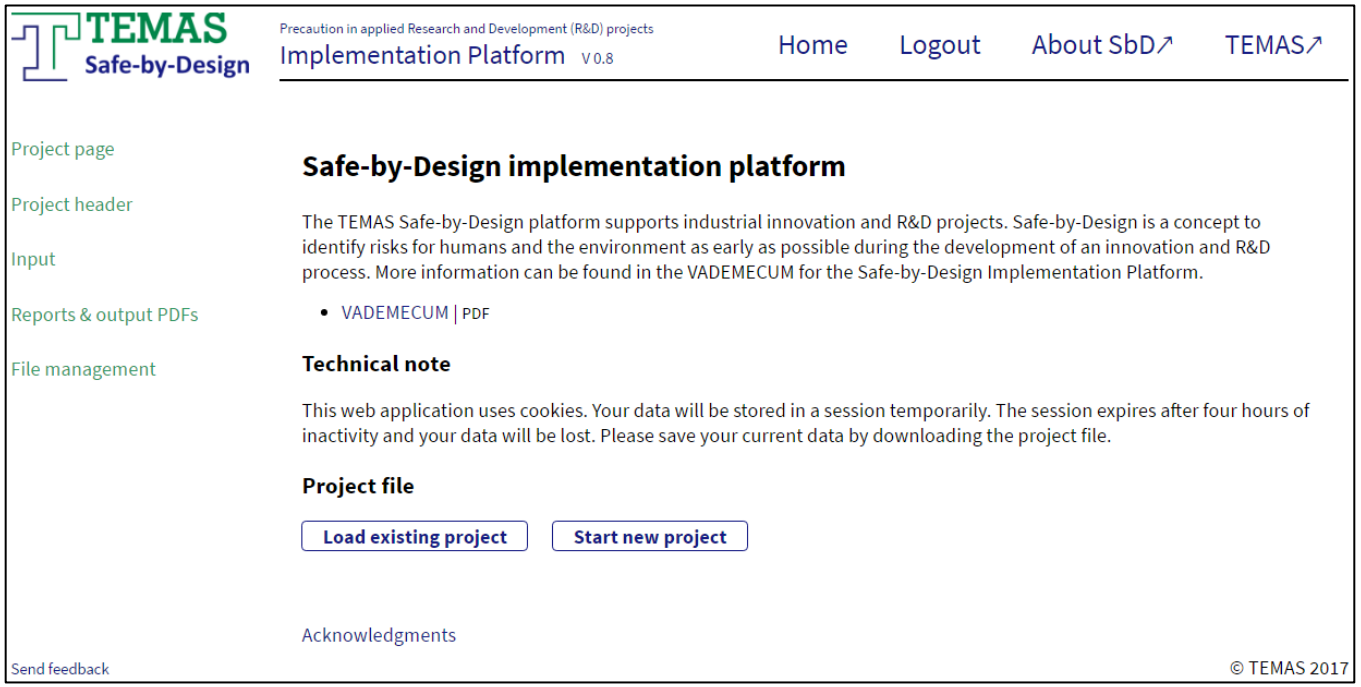
Access the Safe-by-Design implementation platform (Web application)

https://temas.taglab.ch/SbDimplementation/index.php?p=home

Live demonstration of the beta version (V0.8) based on a case study



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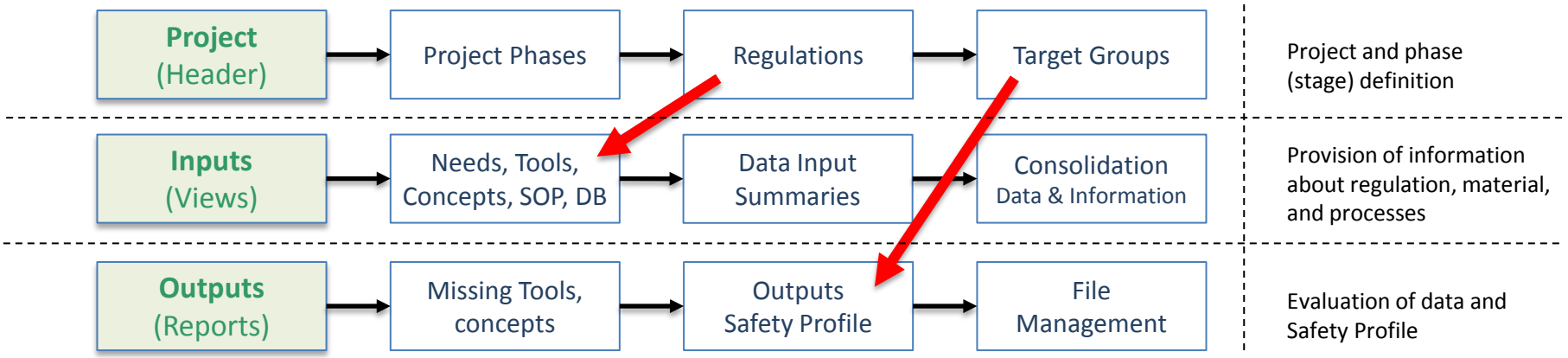
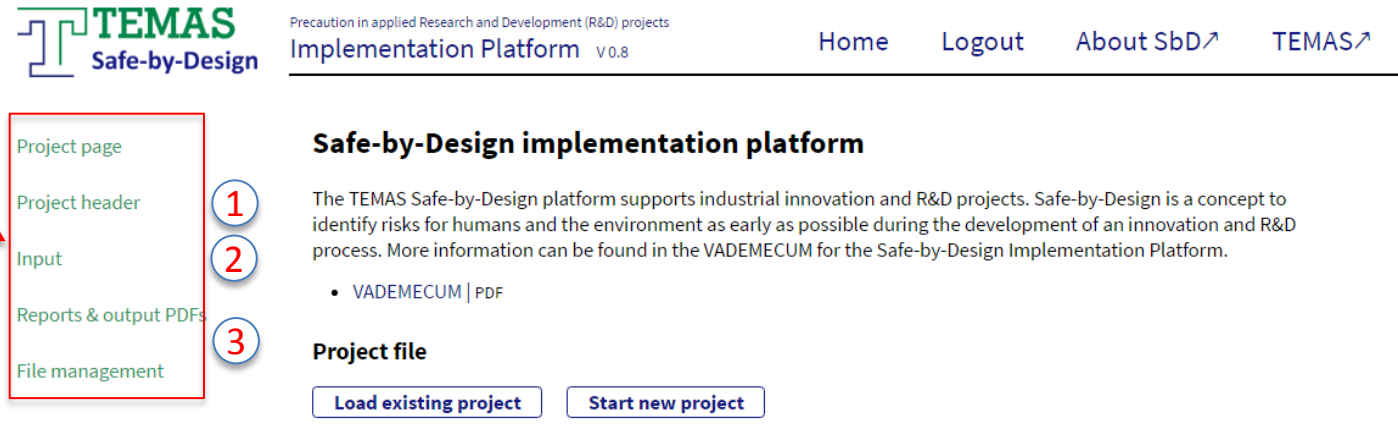
Structure of the Safe-by-Design Implementation Platform



SbD Implementation Platform (Web application)



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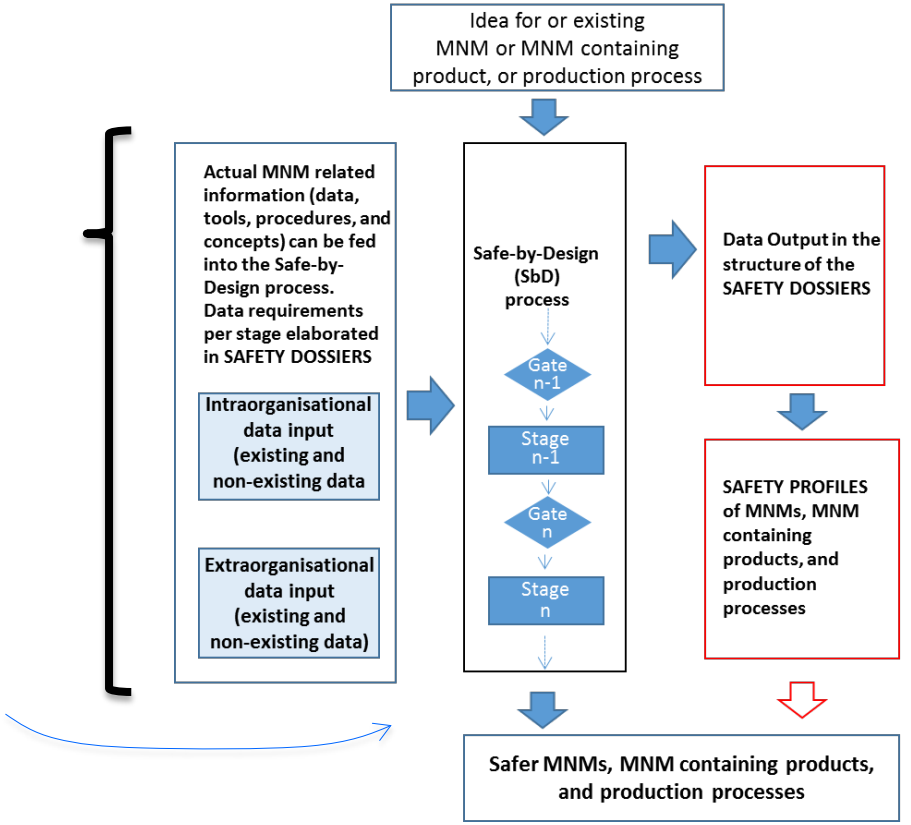
SbD Implementation

The NANoREG Safe-by-Design concept consists of the following elements:

1. Procedures adapted to the latest scientific knowledge, information and data
2. Stable SbD implementation process
3. The safety profile, developed from the "requirements" of the project-specific "Safety Dossier

This SbD concept makes it possible create an actual Safety Profile when new findings and data are available



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Many thanks for your attention