



UNIVERSITY OF BIRMINGHAM



NanoReg²



The Safe-by-Design Concept and its relevance across sectors

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- SbD Concept
- Output from industrial interviews

Definition and goals of NANoREG Safe-by-Design (SbD)

Methodic supporting instrument / procedure:

- For industrial research, innovation, and development projects
 - Along the whole value chain
 - Driven and motivated by regulatory requirements
 - Not a risk assessment (RA)
 - Not a life cycle assessment (LCA)
- } But: **vital part** of the SbD process

Goals of Safe-by- Design

- **Safer** nanomaterials and nano inspired products
- Application of the **precautionary principle**
- Identification of uncertainties and risk potentials **as early as possible**
- **Active management** for the reduction / elimination of risk potentials
- **Transparency** regarding safety relevant data and information

Initial position – Why safe by Design

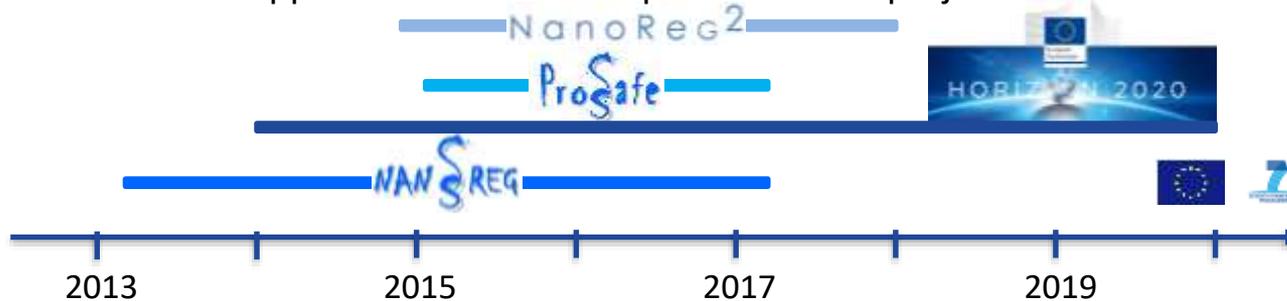
Necessity of the EU to regulate manufactured nanomaterials (MNM) → challenges:

- Well known bulk materials often behave different in the nanometer regime
- Necessity of generally accepted test methods for the characterisation of MNM
- Lack in concepts for EHS risk estimation of nano inspired innovations

Safe-by-Design ↔ **NANoREG Safe-by-Design**

→ SbD is nothing new, > 10 years applied in the engineering sector
, but

- Clear definition of an SbD concept
- Practical application of the concept in industrial projects



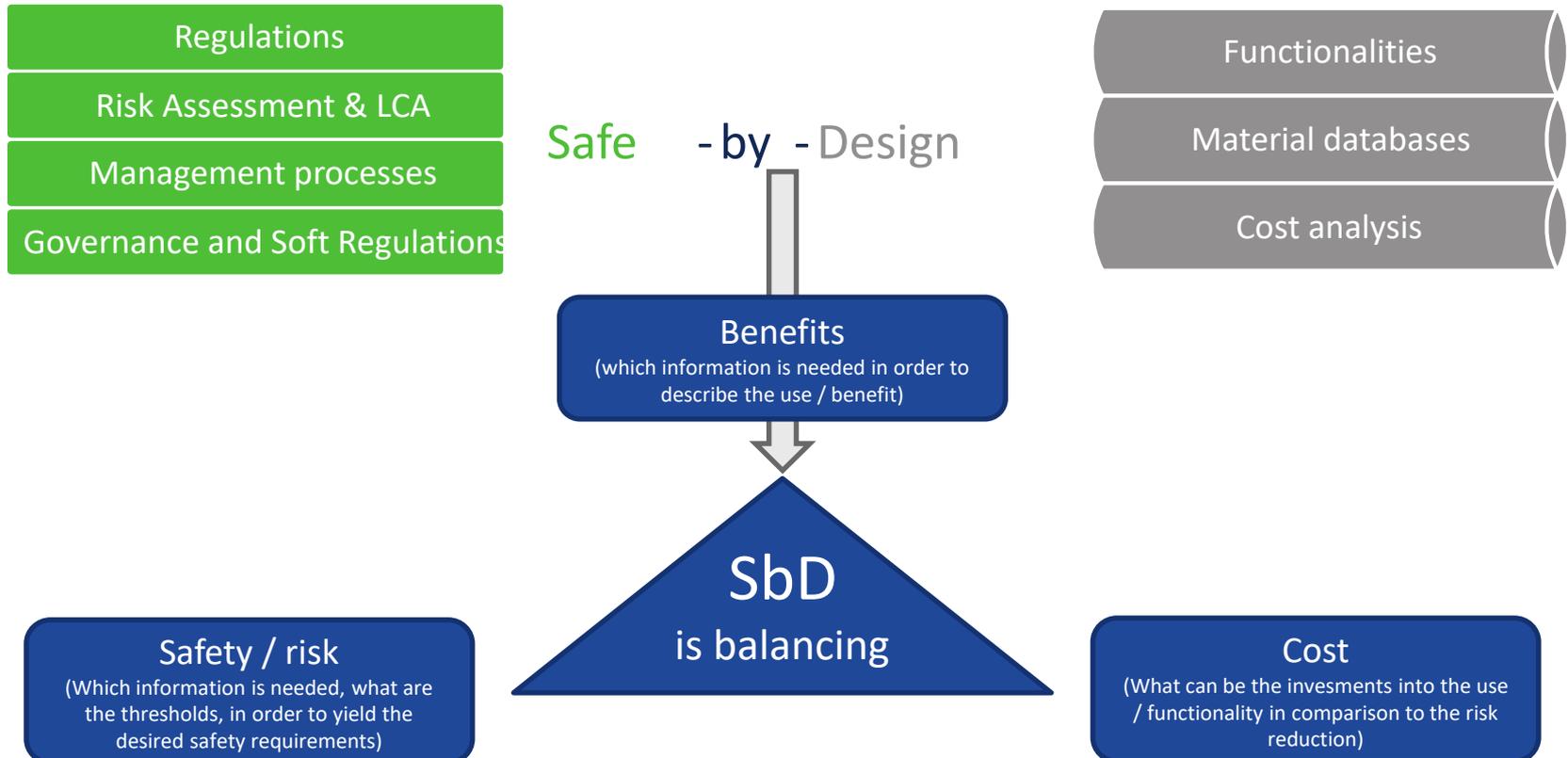
Project citations:

“Providing legislators with a set of tools for risk assessment and decision making instruments (...) including exposure monitoring and control, for (...) nanomaterials used in products”

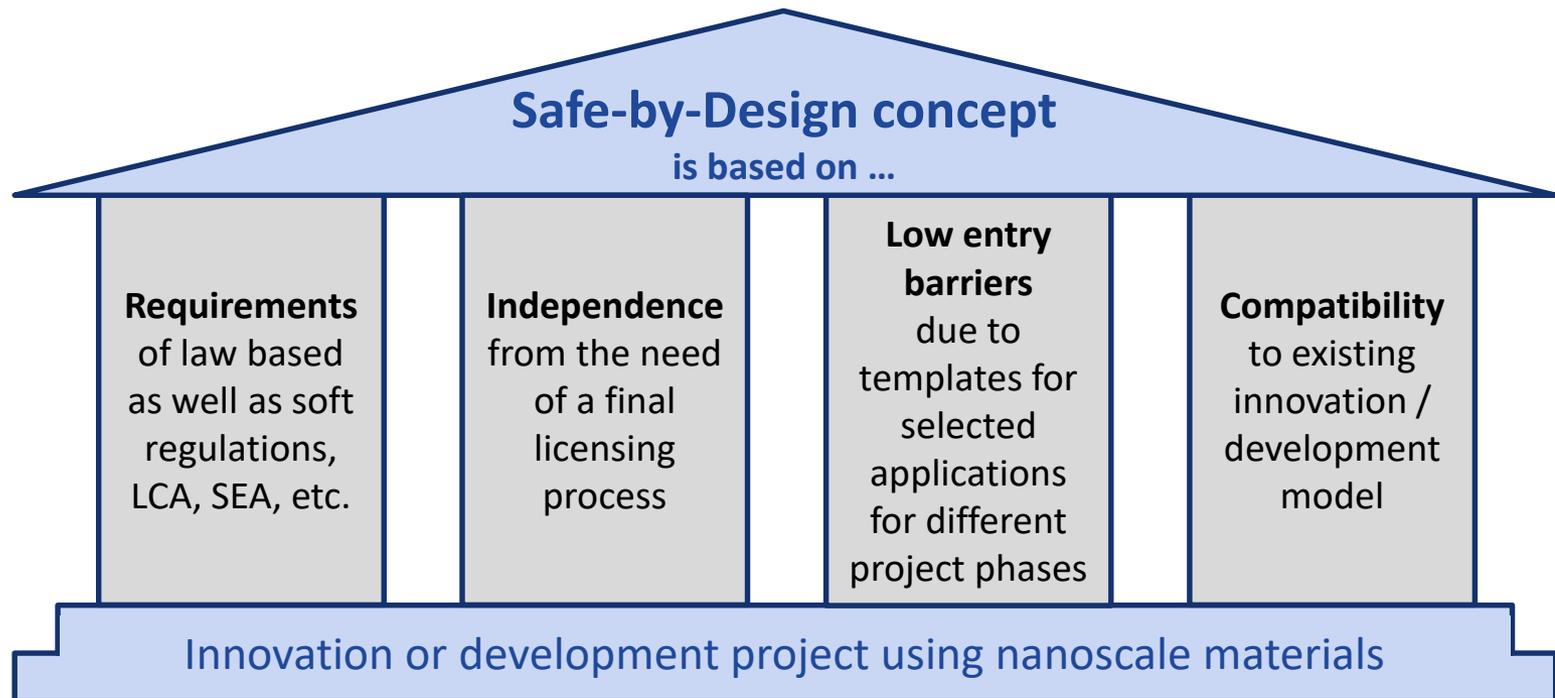
*“policy makers (...) should be stimulated and supported to take up and **implement** the results of NANoREG”*

*“**establish SbD** as a fundamental pillar in the validation of a novel manufactured nanomaterial”*

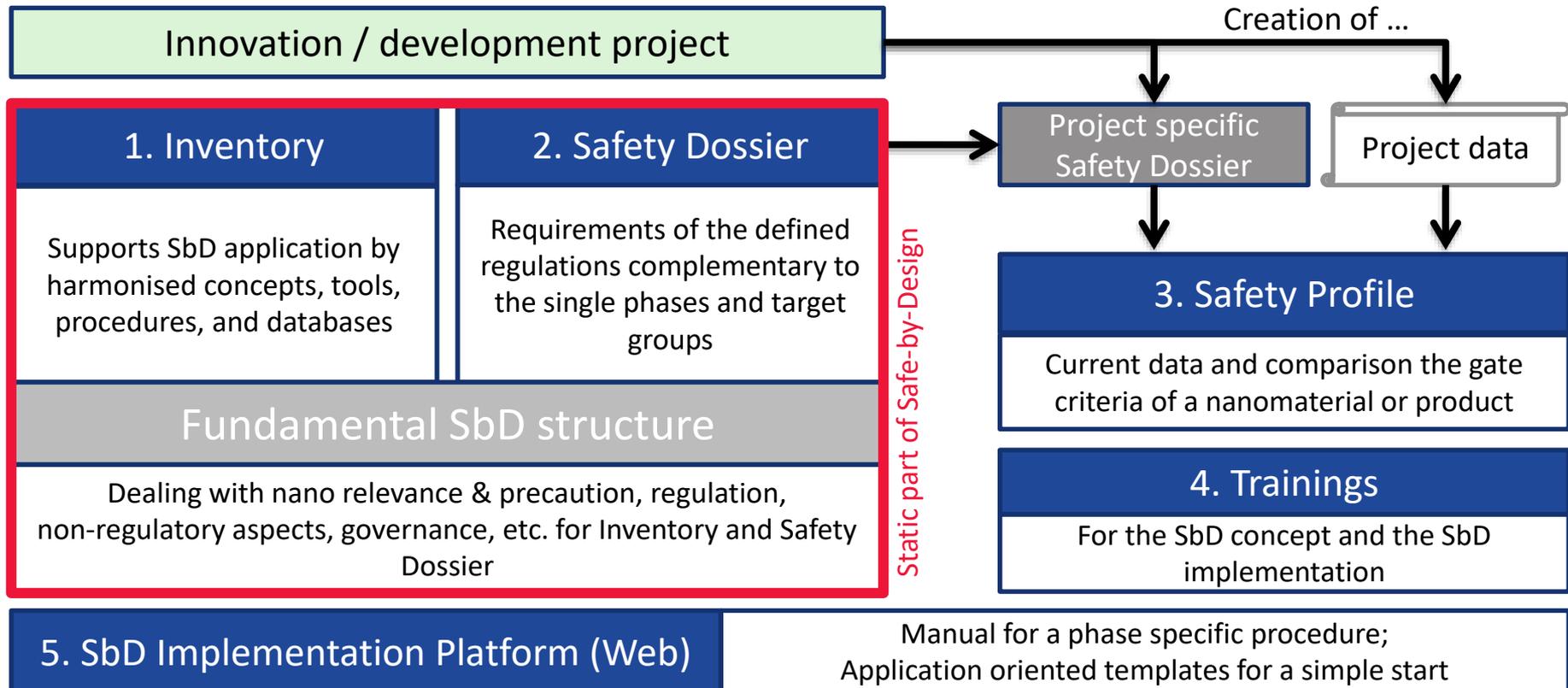
Safety aspects and design aspects of SbD leading to a balancing of use, cost, and safety / risk



The conceptual pillars of Safe-by-Design (SbD)



Core elements of the SbD concept



- Results from industrial interviews

- 1. Identifying potential barriers based on interviews with individually selected potential industrial companies from different industrial sectors.
- Identification of barriers from the knowledge exchange between NANoREG and Prosafe
- 3. To provide guidelines on how to prevent, reduce and overcome such barriers

Interviews - STRATEGY

Feedbacks from the SbD trainings.

- a. Concept training
- b. Implementation training

Governmental organisations on the process to prepare regulators for innovations.

Feedbacks from the application of the web based SbD implementation platform



Feedback from the Case Studies within and outside NanoReg².

Interviews with individual industrial companies for the application of SbD outside NanoReg²

Companies were either Swiss or their headquarters were located in Switzerland and are registered within the Swiss Innovation Promotion Agency under the Nanotechnology sector.



Cosmetics
Pharmaceuticals
Medical Implants
Dental
Textiles
ENM dyes
Food Packaging
Insurance



- Introduction: Q1-5 (Reference questions)
- Needs and resources of the company: Q6 – 11:
 - Declaration
 - Regulatory prerequisites
 - General safety precaution
- Desired functions and outcome of applying the SbD-IP in R&D: Q12-17
 - Scope of results
 - Flexibility
 - Support
 - Relevance

- Question (6) Is there a need for explanation about product safety towards customers/suppliers?

Generally, there is the assumption that the supplier has declared conformity about the materials; therefore there is little concern about an altered risk in the finished product

- Question (7) Is there a use of MNM databases?

Answers are highest at “MNM dye”, “Insurance”, “Dental” sectors, other sectors may opt for conventional materials

- Question (9) What kind of Risk evaluation method do you use?

Low usage of risk evaluation methods due to standardised procedures in production with the exception of the Insurance sector

- Question (10) Early detection of uncertainties and risks

Highest ranks at the Dental, Insurance and Cosmetic sectors, here the opinion of customer organizations plays a role.

- Question (11) Which kind of Project management tools do you use?

All sectors use management solutions adjusted to their needs

- Question (12) Expectations from the application of SbD?

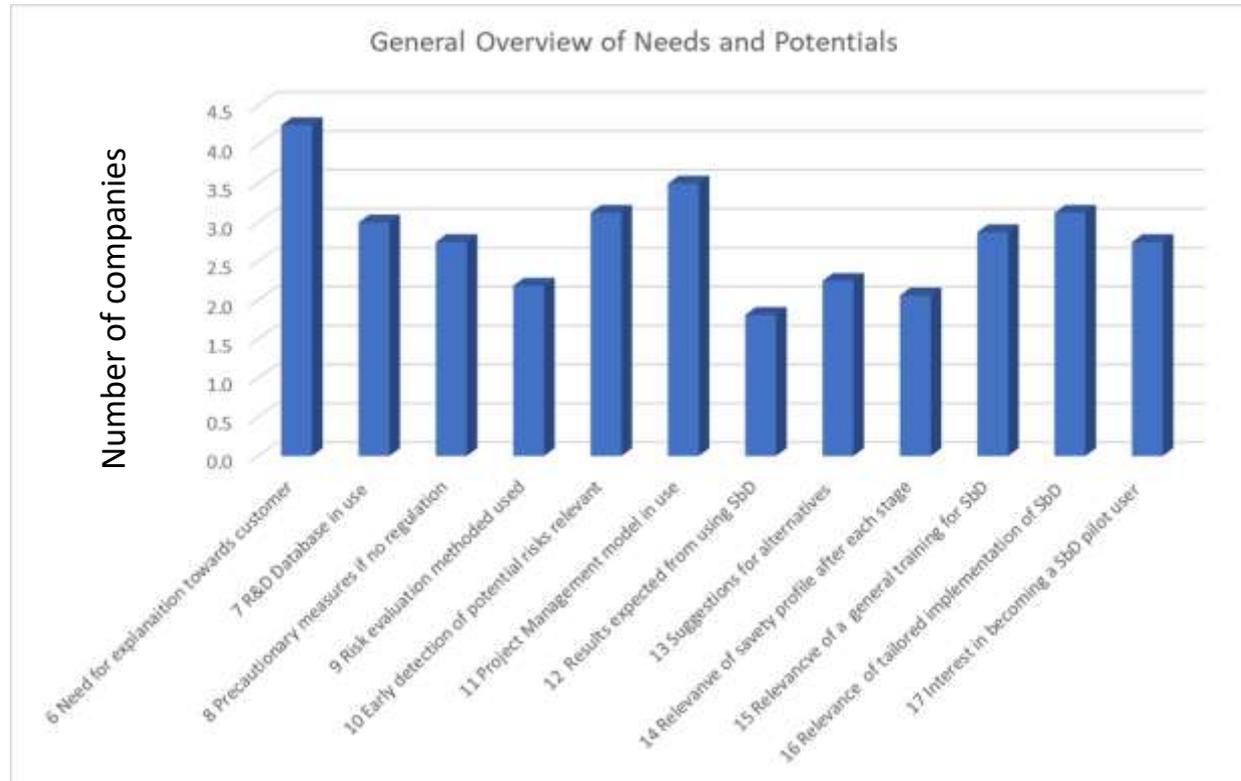
Low expectations since most companies seldom developed new materials in-house

- Question (14) Is it important to you to received a customized safety profile after each phase of your project?

This was not commonly seen as a necessary step. Only companies in the secondary economic sector have a need for a highly customized SbD implementation platform

6. Question (15,16, 17) How relevant would trainings be for you?

Most companies see it as essential, that the Safe- by- Design SbD platform is being explained and properly implemented in the R&D process. Quite a number of companies are interested in a pilot installation



Interviews – IDENTIFIED BARRIERS/SOLUTIONS

Issue	Barrier	Approach to overcome barrier
Safe-by-Design (SbD) concept from NANoREG as backbone for the implementation	The implementation of the SbD concept is too complex.	Elaboration of the Safe-by-Design implementation Platform
The implementation of the NANoREG Safe-by-Design concept is driven by the needs of the applied regulation.	Concepts, tools, procedures and databases for early Phases of a project are rare and not direct linked to the requirements and	Introducing the Safety Profile with a comparison between "Gate values" and the actual measured or estimated values.
The support of the "Safety" aspects within the implementation of Safe-by-Design is much stronger than the "Design" aspect.	Industry (mainly SMEs) sees the safety issues as an additional burden and not a benefit to save time and costs.	Complement the SbD implementation with: <ul style="list-style-type: none"> - Soft Regulation factors (supporting the marketing aspects) - a stronger support of the "Design" part with an additional focus on functionalities of materials



Lack of resources
Lack of Trust



Lack of knowledge



THANKS FOR YOUR ATTENTION!

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