



SMART4FABRY

*Smart Functional  
GLA—nanoformulation  
for Fabry disease*



**NANOSAFETY ASPECTS IN THE  
DELOS-SUSP PROCESS**

**Within the development and innovation process, clarity about the safety surrounding new technologies is one of the most important conditions for acceptance of the technology. Particularly for nanomaterials, safety is an essential point of attention due to the uncertain risks.**

Each individual process step of the DELOS-susp process was evaluated to identify possible exposure scenarios and safety issues. Occupational exposure scenarios as well as environmental exposure scenarios were registered, considering different operational conditions (i.e. physical form, concentration, quantity of chemicals, safety data sheets, risk management measures). For the risk characterisation, a risk management matrix was used as a guide to assist with quantifying the risk level. The identified possible risks are on low resp. medium risk level and are controlled. To fully cover the entire innovation process towards its final product application, it is recommended to further test immunogenicity, endotoxicity and impurities of the nano-formulation at later stage.

Project partner in Smart-4-Fabry addressing (nano-)safety issues:



**SOME FACTS ON NANOSAFETY**

- Technological innovations such as nanotechnology are being developed rapidly - thus, they present a challenge to health & environmental risk assessment.
- Because of the rapid innovation, a gap can arise between technological innovations and the development of suitable risk assessment tools / frameworks.
- A way to minimize this gap is try to reduce uncertainties and risks to human and environmental safety, starting at an early phase of the innovation process and covering the whole innovation value chain ('Safety-by-Design' concept).

PARTNERS



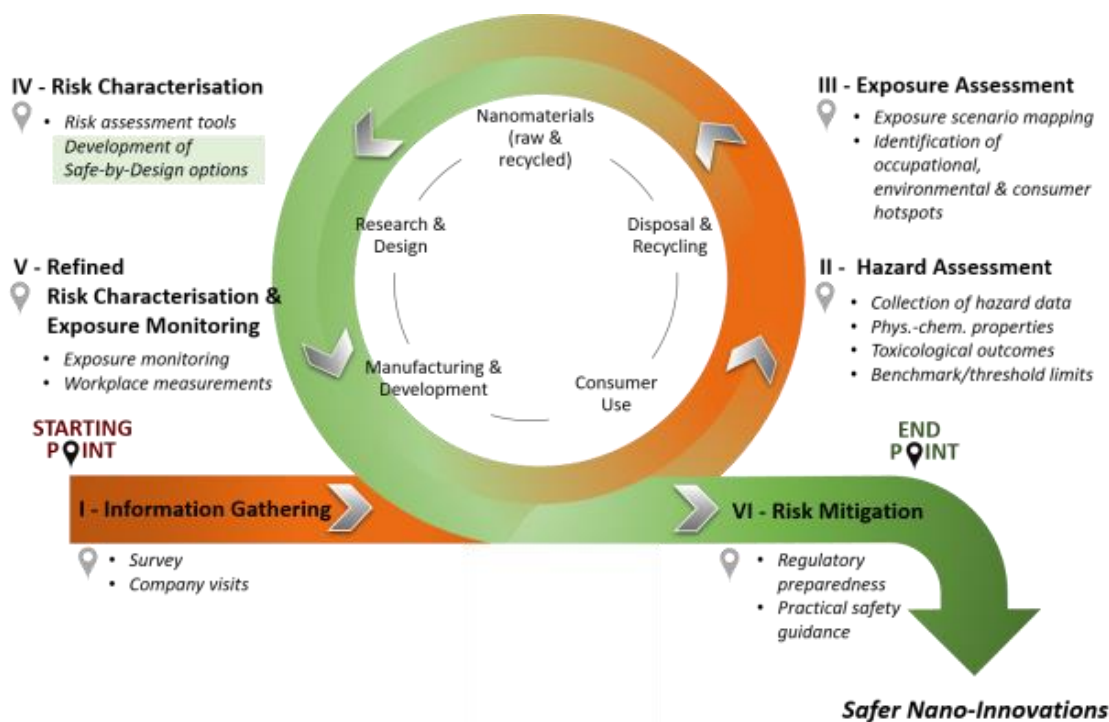
## RATIONALE DESIGN OF NANOSYSTEMS: SAFETY-BY-DESIGN

Eliminating hazards at the design stage is often easier and cheaper to achieve than making changes later when the hazards become real risks in the workplace. Thus, throughout the Smart-4-Fabry project, the so-called Safety-by-Design approach was considered. With this approach, safety aspects of materials, processes and the final product are considered and addressed from the very beginning.

The proposed safety concept follows the general REACH chemical safety assessment approach, encompassing hazard and exposure assessment as well as risk characterization and mitigation. Combining collected hazard data with identified exposure scenarios (i.e., exposure assessment step) the result obtained is a library of critical hotspots associated with initial exposure estimates (i.e., risk characterisation/prioritisation stage). This map supports the further re-design and helps to reach out to the ideal option to achieve safer nano-innovations.

To properly address possible safety issues, a sustainable safety concept with a balanced approach between design for manufacturing and design for safety was agreed, aiming to:

- Create a real-life relevant risk profile for a given material/process (identification of potential exposure scenarios);
- Reduce uncertainty related to potential hazards;
- Analyze occupational (both at lab and pilot scale) and environmental exposure using of qualitative and semi-quantitative tools to prioritize them;
- Optimize production processes and related parameters;
- Maximize safety along the entire value chain of the used nanomaterial via implementation of the Safety-by-Design concept in the innovation and development phases of the pilot plant.



### ABOUT BNN & WHAT WE OFFER



Integrating safety aspects already in the design phase of a new technology supports innovative breakthroughs in all sectors.

Especially new materials are challenging when it comes to possible risks – let's develop strategies to be as safe as possible!

Would you like to get more information? Feel free to get in touch with us & visit our website!

Contact:  
 Susanne Resch  
[susanne.resch@bnn.at](mailto:susanne.resch@bnn.at)  
[www.bnn.at](http://www.bnn.at)

