Hazard strategy for nanoforms and nano-enabled products to implement safe-and-sustainable-by-design


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Background: The European Commission (EC) has the ambition to use chemicals and materials that are toxic-free and safe-and-sustainable-by-design (SSbD) as published in the Green Deal[1] and the Chemicals Strategy for Sustainability[2]. Within the EU-project SAbyNA[3], we aim to contribute to the implementation of SSbD of nanoforms (NF) and nano-enabled products (NEPs) by developing a user-friendly platform that supports industry in a step-wise approach to identify and implement SSbD interventions for their material, product or process.

An important part of SSbD principles involves hazard assessment. We developed a hazard assessment strategy that can be used at an early stage of product innovation.

Results: The hazard assessment strategy consists of 2 parts with increasing level of complexity. Part 1 gathers basic information on the NF or NEPs, including physicochemical (PC) properties and intended application, and aligns this with potential exposure routes and environmental compartments. Based on this information, obvious hazard concerns are identified as red flags (e.g. based on substance hazard classification or biopersistence); these can already lead to suggestions of SSbD interventions. In many cases, the level of hazards might be uncertain (orange flag), and the user will be directed to Part 2.

In Part 2 the user will be guided through a step-wise approach to gather from existing data sources and/or to generate new hazard data specific for the exposure routes of concern. The SAbyNA platform helps the user to collect PC and toxicological data available in the eNanomapper, NanoCommons and Mesocosm databases. If needed, a testing strategy is suggested to help the user to generate missing data. For human health, data on dissolution rate in physiological fluids, cytotoxicity, genotoxicity, reactivity and inflammation are gathered in a step-wise approach with guidance on which assays to use and how to interpret data. For
environmental safety, data on bioaccumulation, acute and chronic toxicity to aquatic and terrestrial organisms is gathered. All available and new generated data is integrated into a hazard category. Finally, if a hazard might exist, the SAbyNA platform guides the user to possible SSbD interventions.

Overall, the early hazard assessment strategy is a practical, user-friendly tool to identify the hazard of NFs and NEPs at an early stage of product innovation. Next steps to further refine the strategy include defining/refining thresholds for toxicity, taking into account the life-cycle of NEPs and further unraveling the link between PC properties of materials and their effect to provide practical SSbD solutions to the users.

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