Safe-by-Design: Engineered prerequisites for ensuring inherent safety

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Abstract

Fighting global problems such as pollution by Per- and polyfluoroalkyl substances (PFAS) requires new types of chemistry, to which biotechnology and synthetic biology could contribute. However, like with every new technology or application, new risks might emerge and we must ensure that these new alternatives are no less harmful than those they replace (i.e. regrettable substitution) (Bouchaut et al., 2022; Sweetman, 2020; Zimmerman & Anastas, 2015). In literature, the Safe-by-Design (SbD) approach is argued to be a way to prevent such from happening as it provides guidelines and an iterative approach to identify possible emerging risks and develop anticipatory strategies to lower or mitigate these, during early stages of development (Bouchaut & Asveld, 2021; Robaey, 2018). Thereby, SbD relies heavily on knowledge of properties and characteristics of materials and chemicals to be able to identify potential emerging risks and to define appropriate risk-lowering strategies – thereby creating *inherent safety*.

In this paper, we have researched the monitoring and regulation of PFAS in the Netherlands and Europe. It is known now that PFAS degrade extremely slowly due to their stability and persistence in the environment, and that these chemicals accumulate in humans, resulting in adverse health effects (Schrenk et al., 2020). This evidence is strongest for long-chain PFAS, and most are restricted under the Stockholm Convention (UN Environment Programme, n.d.). In response, industry has developed and produced short-chain PFAS as a safer alternative. However, new studies are showing that these too have adverse effects on human health, but this is difficult to measure as there appears to be no suitable analytical equipment to do so.

This illustrates a prerequisite for successfully implementing SbD: we need to have equipment (e.g. analytical tools for monitoring and measuring) that generates knowledge needed for SbD to be successfully incorporated. Without such, potential risks cannot be estimated during early stages of development, nor can anticipatory strategies be developed which is crucial for new types of (synthetic) chemicals and biotechnologies to be developed safely and responsibly.

Key words: Regrettable Substitution, Safety, Risks, PFAS, Synthetic Chemicals

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