Establishing the methodological basis for environmental, health and safety (EHS) impacts assessment- The SUNRISE approach

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1. Context

The SUNRISE project endeavours to formulate a comprehensive Integrated Impact Assessment Framework (IIAF), grounded in lifecycle perspective, aimed at supporting Safe and Sustainable by Design (SSbD) decision-making across the supply chains of advanced materials (AdMa) and their related products. This framework, structured into three tiers, will incorporate integrated methodologies supported by toolboxes for assessing health, environmental, social, and economic impacts. Tailored to diverse user groups and innovation stages, each tier will demand varying levels of data and expertise.

2. The SUNRISE EHS impact assessment

The SUNRISE approach for defining methodologies for environmental, health, and safety (EHS) impact assessment will include hazard and exposure considerations across the 3 tiers of the IIAF. In pursuit of this goal, we have identified potential EHS-related building blocks: tools, models, databases, and methodologies, including NAMs based on non-animal methods such as *in vitro*, *in chemico*, and *in silico* methods. These building blocks

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are evaluated for their suitability across the different tiers and are aligned with Steps 1, 2, and 3 of the EC-JRC SSbD framework. The identified building blocks encompass existing methods/tools for measuring indicators related to intrinsic physicochemical identity ('what they are'), lifecycle release, environmental fate, biodistribution, transformation by-products exposure ('where they go'), and human health and environmental effects ('what they do'). Additionally, the need to adapt existing NAMs for hazard assessment of AdMa or develop new ones in accordance with the principles of the three Rs (Replacement, Reduction, Refinement) for regulatory purposes has been identified.

3. Expected outcomes

In the upcoming months, SUNRISE aims to be able to identify the most appropriate methodologies for assessing EHS impacts across the 3 tiers of the IIAF, ultimately culminating in the development and utilization of Integrated Approaches to Testing and Assessment (IATA) built upon New Approach Methods (NAMs). These endeavours seek to facilitate the generation of reliable non-animal data for next-generation risk assessments (NGRA).

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