

Advancing the development of Safe-and-Sustainably-by-Design toolboxes for advanced materials: similarities between the SUNSHINE Tier 1 SSbD approach and Early4AdMa Tier 2

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1. Introduction

The European Chemicals Strategy for Sustainability (CSS) and the Zero Pollution Action Plan have called for a transition to a safe and sustainable-by-design (SSbD) approach to chemicals and materials as part of the policy ambition to achieve a toxic-free environment (EC 2020). Aiming to implement a SSbD approach, the European Commission (EC) adopted a Recommendation for establishing a European assessment framework for SSbD chemicals and materials (EC 2022), which is based on the EC's Joint Research Centre (JRC)'s SSbD framework (C. Caldeira et al. 2022). The recommendation calls for a tiered approach because for newly developed chemicals/materials, the information available can be limited in the early stages of innovation and increases along the product development process (Hristozov et al. 2023). The H2020 SUNSHINE project supports the implementation of the JRC SSbD framework for advanced materials by developing a practical screening approach integrating safety with environmental, economic, and social sustainability assessments to support innovators, and particularly SMEs (Pizzol et al. 2023), in SSbD decision making in the early stages of product development. In parallel, the Early4AdMa early awareness system for regulators and policy makers was developed by RIVM (NL), BfR (DE), BAuA (DE), and UBA (DE) (Oomen et al. 2022) to identify and address potential safety, sustainability, and regulatory concerns. Early4AdMawas later adapted by the OECD Working Party on Manufactured Nanomaterials (WPMN)'s Steering Group on Advanced Materials and subsequently adopted by the OECD WPMN(OECD 2023). This study aims to compare these two approaches in order to understand any possible overlaps and complementarities between them, and to identify potential synergies for application by different stakeholders.

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2. Materials and methods

The SSbD approach developed in the SUNSHINE project is designed to assist industries in evaluating advanced materials and products with the goal to increase their safety and sustainability without compromising their intended functional performance. This qualitative methodology involves a comparative analysis in which the material is compared to a benchmark, which could be an alternative design or a traditional material with similar functions. In parallel, the Early4AdMa system was developed as a systematic approach for early screening of safety, sustainability, and regulatory concerns related to advanced materials. While both methods consist of a series of questions for assessing environmental/health risks and sustainability, they serve different purposes and are intended for different stakeholders. To aid decision-makers from industry, policy and regulation in choosing the appropriate methodology, a comparison between the two approaches was conducted in the frame of the OECD WPMN, focusing on similarities, differences, strengths, weaknesses, and relevance for different users. A classification into common aspect categories such as safety, environmental impact, economic and social sustainability, functionality, and regulatory relevance was used for the comparison. The assessment involved comparing each approach, assigning colours (green, light green, orange, or red) to indicate similarity or variation in questions between the two methodologies, as shown in Figure 1, as well as a comparison in a joint case study. Further comparison of the two approaches has been illustrated through the assessment of a case study, a nanocomposite of graphene oxide (GO) functionalized with chitosan that is used as a substitute for classic flame retardants such as melamine cyanuric acid.

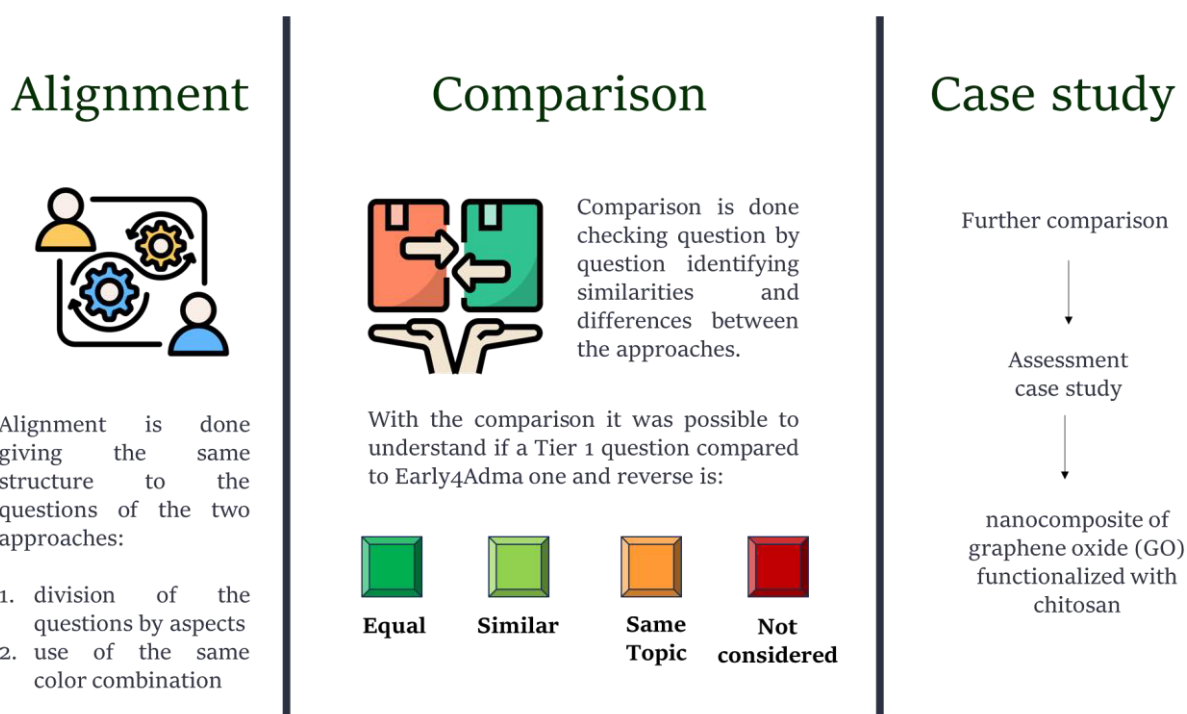


Figure 1: Alignment and comparison method between Early4AdMa and SUNSHINE Tier 1 approach and application to a case study

3. Results

The findings indicated that while both approaches share similarities, they also have distinct differences in the key issues and aspects they address, so we concluded that both ultimately complement each other. The comparison revealed that Early4AdMa

focuses on identifying safety and sustainability concerns and regulatory challenges, while the SUNSHINE approach aims to assess specific impacts on a case-by-case basis to assist companies in creating safer and more sustainable materials or applications. Specifically, SUNSHINE evaluates safety, environmental, social, and economic sustainability, as well as functionality, while Early4AdMa assesses questions about safety, environmental sustainability, and coverage by regulation and regulatory tools. SUNSHINE is designed as a self-assessment tool for industries, especially SMEs, while Early4AdMa assists policy makers in anticipating emerging challenges related to advanced materials, regulators in increasing their preparedness to tackle these challenges, and industrial companies in preparing for regulatory relevant questions when a product is approaching readiness to be placed on the market. Furthermore, SUNSHINE provides a comparative analysis of alternatives, whereas Early4AdMa does not. The comparison of results from applying the approaches to the same case study is challenging due to differences in aspects covered and the way results are presented. However, when comparing safety and environmental sustainability aspects, the results from the two approaches show similar percentages of positive contributions or potential avoided issues.

4. Conclusion

This study compares the Tier 1 SSbD approach from the SUNSHINE project with the Early4AdMa early awareness system within the framework of the OECD WPMN. Both methodologies aim to address early stages of materials development and to support the implementation of the EC's SSbD framework. While similarities and differences were identified between the two approaches, it is clear that Early4AdMa is useful for identifying safety and sustainability issues and regulatory challenges, making it ideal for regulators and policy makers. On the other hand, the SUNSHINE approach focuses on pinpointing safety and sustainability concerns for specific materials/products to aid SSbD decision making by industries, particularly SMEs. We conclude that the two approaches support stakeholders in different ways to apply the SSbD approach described in the EC's SSbD framework.

5. References

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