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COMMISSION RECOMMENDATION (EU) 2026/510

of 6 March 2026

on revising the European assessment framework for ‘safe and sustainable by design’ chemicals and materials

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) The Competitiveness Compass (1) emphasises the importance of closing the innovation gap in order to drive sustainable and long-term growth. It highlights the importance of innovation in boosting the competitiveness of the EU’s chemical industry, together with the protection of human health and the environment. The Competitiveness Compass also underlines the need to look at the supply of critical chemicals and to invest in technologies that will matter in tomorrow’s economy, such as advanced materials.

(2) The Clean Industrial Deal (2) presented a joint roadmap for competitiveness and decarbonisation. The roadmap aims to increase sustainable and resilient production in Europe to go beyond traditional silo solutions by taking into account the entire value chain. It also promotes lead markets, circularity and access to materials as essential drivers for competitiveness.

(3) In its ‘chemicals strategy for sustainability – towards a toxic-free environment’ (3), the Commission announced a long-term vision for EU chemicals policy, which includes the promotion of innovation for **safe and sustainable by design (SSbD) chemicals** (4) **and materials**. The strategy sets specific actions on chemicals production and use, to strengthen the protection of human health and the environment, while boosting innovation for safe and sustainable chemicals. The strategy also calls on Member States, industry and other stakeholders to prioritise innovation for substituting, as far as possible, substances of concern (5) across sectors.

(4) Europeans are concerned about the impact of chemicals and materials on health and the environment. A 2024 Eurobarometer survey (6) showed that 84 % of Europeans are worried about the impact on their health of harmful chemicals present in everyday products, and the same proportion is worried about the impact of harmful chemicals on the environment.

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(1) A Competitiveness Compass for the EU (COM(2025) 30 final).

(2) The Clean Industrial Deal: A joint Roadmap for Competitiveness and Decarbonisation (COM(2025) 85 final).

(3) Chemicals Strategy for Sustainability (COM(2020) 667 final).

(4) The term ‘chemical’ is used in several pieces of EU legislation, sometimes with important or subtle differences in meaning. Some pieces of EU chemicals legislation use more specific terms to describe subgroups of chemicals, such as ‘substances’ and ‘mixtures (of substances)’. In the context of this Recommendation, the term chemical is to be interpreted in its broadest sense. To reinforce that, the scope of the SSbD framework explicitly includes also materials, even if, for some pieces of EU legislation, materials are considered as mixtures of substances, i.e. chemicals in their own right.

(5) As defined for the purposes of the Chemicals Strategy for Sustainability (COM(2020) 667 final).

(6) Eurobarometer survey (2024) Attitudes of Europeans towards the Environment – May 2024.

(5) Several hundred substances have already been identified as substances of very high concern under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([7]). For most of these substances, the basis for identification is a harmonised classification in line with the Classification, Labelling and Packaging (CLP) Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([8]), which harmonises criteria to classify substances and mixtures that present physical, health, environmental and additional hazards. This Regulation was revised in 2024 to include new hazard categories. The Ecodesign for Sustainable Products (ESPR) Regulation (EU) 2024/1781 of the European Parliament and of the Council ([9]) also defines a larger group as substances of concern based on their harmonised classification for certain hazards with chronic effects, as well as concerns regarding their effects on recycling, reuse and other Circular Economy considerations

(6) The Ecodesign for Sustainable Products Regulation (ESPR ([10])) states that performance requirements set on product parameters, should take into consideration existing chemical safety assessments performed by the relevant Union bodies for the substances concerned, as well as safe and sustainable by design criteria for chemicals and materials, as developed by the Commission.

(7) The Communication on Advanced Materials for Industrial Leadership ([11]) refers to the safe and sustainable by design (SSbD) concept as the core of the materials transformation process.

(8) The European chemicals industry action plan ([12]) highlights the role of this Commission Recommendation revising the European assessment framework for SSbD chemicals and materials to reinforce EU chemical industry competitiveness by making the innovation process towards safer and more sustainable alternatives more efficient. The action plan announces the launching of EU innovation and substitution hubs as voluntary tools to accelerate and scale up chemical innovation and highlights the role of the SSbD concept, providing technical guidance from early-stage innovation.

(9) The life science strategy ([13]) stresses the importance of a coordinated deployment and uptake of safe and sustainable products. It highlights the role of the European assessment framework for SSbD chemicals and materials in the pursuit of the EU's sustainability and competitiveness objectives, and in the clean industrial transition, encouraging industry to replace substances of concern with safer, more sustainable alternatives.

(10) The European strategy for artificial intelligence (AI) in science ([14]) highlights how AI can facilitate breakthroughs for advanced materials design including in functionality, safety and sustainability.

([7]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

([8]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

([9]) Regulation (EU) 2024/1781 of the European Parliament and of the Council of 13 June 2024 establishing a framework for the setting of ecodesign requirements for sustainable products, amending Directive (EU) 2020/1828 and Regulation (EU) 2023/1542 and repealing Directive 2009/125/EC (OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj).

([10]) In its Annex II – product parameters described in its Annex I, especially point (f).

([11]) Communication on Advanced Materials for Industrial Leadership, (COM(2024) 98 final).

([12]) Communication on Chemicals Industry Action Plan (COM(2025) 530 final).

([13]) Communication on Choose Europe for life sciences – A strategy to position the EU as the world's most attractive place for life sciences by 2030 (COM(2025) 525 final).

([14]) Communication on A European Strategy for Artificial Intelligence in Science (COM(2025) 724 final).

(11) The Horizon Europe programme has provided dedicated support for research activities focused on operationalising the SSbD Framework as well as applying the Framework to boost innovation towards safer and more sustainable chemicals and advanced materials. Support has been provided, through specific calls from Cluster 4 of Horizon Europe ('Digital, Industry and Space'), as well as via the European partnership on advanced materials (IAM4EU), the innovative health initiative, batteries for EU, and circular bio-based Europe partnerships.

(12) As a key part in delivering on the Competitiveness Compass' call to boost innovation, the EU startup and scaleup strategy ([15]) aims to restart a virtuous innovation cycle by creating a favourable investment and business environment for young and innovative companies to start, expand and thrive. This includes reducing barriers for the translation of research into marketable products and a wider innovation uptake.

(13) Against this background, this Recommendation proposes a revised European assessment framework for SSbD chemicals and materials (the SSbD Framework). This revised Framework will act as a new point of reference for Member States, industry, higher education institutions, research and technology organisations (RTOs) to use as a methodology for assessment and decision making.

(14) The SSbD Framework aims to become a voluntary decision-making approach to steer innovation towards chemicals and materials that are safer and more sustainable over their whole life cycles. It supports decision-making throughout the innovation process and provides a common understanding of SSbD principles across value chains. It reinforces competitiveness by making the innovation process towards safer and more sustainable alternatives more efficient, while simultaneously advancing knowledge and science for safety and sustainability.

(15) This revised Recommendation builds on the Commission Recommendation (EU) 2022/2510, establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials. The 2022 Recommendation set out a framework to support the design, production, and use of safer, more sustainable chemicals and materials to protect human health and the environment, when considering their impacts all along their life cycle. The revision is largely based on the results of the two testing phases that allowed feedback from stakeholders to be taken into consideration ([16]). The aim of the testing phases was to inform an update of the SSbD Framework to improve its relevance, reliability and operability.

(16) While maintaining the elements of the initial SSbD Framework, namely a (re)design phase and an assessment phase, a newly developed scoping analysis serves as a starting point to identify and prioritise the key elements to be addressed. The scoping analysis assists in defining the system under study, considering the selected design principles and engaging with the life cycle actors. This phase allows for the implementation of the SSbD Framework to be more tailored to the needs of the innovators.

(17) In addition to the safety and the environmental sustainability aspects, the Framework now includes the social and economic dimensions of sustainability. It considers socioeconomic risks and opportunities of the system under study, with a view to support longer-term decision making.

(18) The SSbD Framework now also offers various entry points for assessment, enabling innovators to make decisions that consider both safety and sustainability aspects at different levels of innovation maturity and data availability. By reiterating the SSbD cycle as innovation matures and/or additional information becomes available, the SSbD Framework promotes comprehensive assessment as basis for robust decision-making.

(19) Introducing simplified approaches for safety and sustainability assessments, as starting points for informed decision-making, can be of particular benefits to smaller businesses when resources are limited, such as during early innovation stages.

([15]) Communication on 'The EU Startup and Scaleup Strategy. Choose Europe to start and scale' (COM(2025) 270 final).

([16]) Abbate E., Garmendia Aguirre I., Bracalente, G., et al. Safe and Sustainable by Design chemicals and materials – Methodological Guidance. Publications Office of the European Union, Luxembourg, 2024, ISBN 978-92-68-16357-3, doi:10.2760/28450.

(20) The SSbD Framework will aim to contribute to more efficient innovation processes, making business easier and faster while improving the coherence of innovation ecosystems in line with Commission's simplification efforts, outlined in the Communication on a Simpler and Faster Europe (17).

(21) In accordance with the data regulation (18), an EU common data platform on chemicals is under development. It will integrate chemicals data from multiple contributors in accordance with the findable, accessible, interoperable and reusable (FAIR) principles. The Commission will promote, on the one side, the incorporation of high-quality FAIR data on chemicals generated by the SSbD research and innovation (R&I) activities into the EU common data platform on chemicals and, on the other side, the availability of such data to implement the SSbD Framework to its fullest capacity.

(22) When considering safety and sustainability of innovation within particular value chains, specific situations might require further assumptions and deviation from some of the approaches described in the Framework. For instance, assessment of defence, aerospace, and dual-use technologies (19) need to respect the security aspects.

(23) The Commission will continue to promote the application of the SSbD Framework under Union programmes targeting relevant research objectives. This will support the roll-out of safety and sustainability considerations and decision-making over the innovation process. The Commission will continue to monitor how the SSbD Framework is incorporated in EU-funded (R&I) activities.

(24) This Recommendation respects the principle of subsidiarity, since the revised SSbD Framework serves the needs of the European Research Area and the EU single market for chemicals and materials, where there is a need for common understanding of safety and sustainability for chemicals and materials. It also respects the principle of proportionality, since it promotes the application of the framework by legally non-binding means, i.e. being voluntary without prejudging any existing Union legislation on chemicals and materials.

HAS ADOPTED THIS RECOMMENDATION:

1. PURPOSE AND SCOPE

1.1. This Recommendation promotes a European framework for 'safe and sustainable by design' (SSbD) chemicals and materials (the SSbD Framework) for R&I activities in the practice of researchers and innovators. The **details of the SSbD Framework**, based on technical reports from the Commission's Joint Research Centre (16), (20) **are set out in the Annex** to this Recommendation. This Annex explains features underpinning the SSbD Framework, which includes and brings together a set of SSbD criteria. The Annex also refers to the SSbD methodological guidance (16), (21) providing detailed guidance, templates and updated overview of relevant methods, tools and data sources.

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(17) European Commission: Secretariat-General, Making Europe simpler and faster, Publications Office of the European Union, 2025, https://data.europa.eu/doi/10.2792/5923929.

(18) Regulation (EU) 2025/2455 of the European Parliament and of the Council of 26 November 2025 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (OJ L, 2025/2455, 12.12.2025, ELI: http://data.europa.eu/eli/reg/2025/2455/oj).

(19) Dual-use technologies refer to technologies which can be used for both civilian and defence purposes.

(20) Garmendia Aguirre, I, Abbate, E, Bracalente, G, Mancini, L, Cappucci, G.M, Tosches, D, Rasmussen, K, Sokull-Kluettgen, B, Rauscher, H, Sala, S. (2025) European Commission – Joint Research Centre. Safe and Sustainable by Design Chemicals and Materials. Revised framework (2025), Publications Office of the European Union, Luxembourg, 2025, ISBN 978-92-68-30330-6, doi: 10.2760/5103785.

(21) Methodological guidance further updates: https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en.

1.2. The SSbD Framework defines a voluntary decision-making approach where safety and sustainability considerations throughout the life cycle of chemicals and advanced materials are incorporated in the development of new chemicals, innovative materials, or improved production processes. It aims to become a European reference for an innovation process in pursuit of the clean industrial transition, in parallel promoting greater Union competitiveness, which should also be promoted at the international level. It promotes the use of sustainable resources and feedstock, aims to minimise the impact of the production and use of chemicals and materials, throughout their life cycle with respect to the climate, the environment, and their effects on human health. The SSbD Framework also supports the substitution of substances of concern by finding safer and more sustainable alternatives and should accordingly guide public and private R&I investments.

1.3. While the SSbD Framework does not interfere with, nor creates new, Union legal obligations for chemicals and materials, it can guide anticipatory actions and decisions within the innovation process, including actions going beyond minimum legal compliance.

1.4. This Recommendation is addressed to Member States, industry (including small and medium-sized enterprises (SMEs), including startups and scaleups, and spin-offs) higher education institutions, organisations managing research and technology infrastructures, and research and technology organisations that contribute to or work on the design, development, production and uptake of chemicals and materials. It invites them to use the SSbD Framework in projects funded in whatever form, whether by companies' own research and development means, or for example under Union or international programmes targeting R&I and its deployment, and activities related to chemicals or materials, with the objective to apply safety and sustainability considerations systematically. The above-mentioned actors are also encouraged to refer to the SSbD Framework in relevant documents, including strategic research and innovation agendas.

1.5. Member States, industry, higher education institutions, research and technology infrastructures and research and technology organisations s should also ensure that the methods, models and data produced and used when applying the SSbD Framework align with the findable, accessible, interoperable and reusable (FAIR) guiding principles.

2. USES OF THE SSBD FRAMEWORK BY INDUSTRY

Industry actors (including SMEs, startups, scaleups and spin-offs) are encouraged to:

2.1. Use the SSbD Framework in their R&I processes for developing chemicals or materials, or improved production processes, techniques and technologies, considering safety and sustainability at each stage of the life cycle.

2.2. Make available high-quality FAIR data for assessing safety and sustainability, without prejudice to intellectual property rights and, if relevant, security considerations.

2.3. Engage with other actors when operating across the value chain to ensure comprehensive data collection and multidisciplinary approaches for a robust assessment, notably to support SMEs, including startups, scaleups and spin-offs, which may have limited resources.

2.4. Communicate regarding their use of the SSbD Framework in their corporate, safety and sustainability assessment activities, in a transparent and open way without compromising intellectual property rights and, where relevant, security considerations.

2.5. Share information that supports the application of the Framework and informs the assessment, particularly information that directly identifies potential safety and sustainability issues, while safeguarding confidentiality and competitiveness, where necessary.

3. USE OF THE SSBD FRAMEWORK BY MEMBER STATES

Member States are encouraged to:

3.1. Use and promote the SSbD Framework in their national and regional R&I programmes, thereby supporting the design and development of safe and sustainable chemicals and materials, including advanced materials, in Europe.

3.2. Use and promote the SSbD Framework in local, regional and national initiatives supporting the development of safer and more sustainable chemicals and materials, by providing guidance as from early-stage innovation.

3.3. Increase the availability of high-quality FAIR data for assessing safety and sustainability by incorporating this concept and promoting it into their national R&I programmes and related policies where relevant.

3.4. Support the improvement of assessment methods, models and tools, and make new ones available, to integrate into the SSbD Framework in order to improve the assessment of safety and sustainability.

3.5. Support the development of cross-sectoral skills and expertise required to apply the framework, and ease access to these skills and expertise, in particular for SMEs.

3.6. Support the establishment and operation of the EU Chemicals Innovation and Substitution Hub(s), as announced in the European Chemicals Industry Action Plan, and support national organisations responsible for chemical safety and sustainability assessment to collaborate with each other and with relevant EU initiatives, networks, and bodies, and to boost innovative ecosystems that accelerate the transition towards safer and more sustainable chemicals and materials.

3.7. Communicate publicly on their use of the SSbD Framework.

4. USES OF THE SSBD FRAMEWORK BY HIGHER EDUCATION INSTITUTIONS, RESEARCH AND TECHNOLOGY INFRASTRUCTURES, and RESEARCH AND TECHNOLOGY ORGANISATIONS

Higher education institutions, research and technology infrastructures, and research and technology organisations are encouraged to:

4.1. Use the SSbD Framework in their R&I activities for developing chemicals and materials, including advanced materials, or in improved production processes, techniques and technologies, taking into account safety and sustainability at each stage of the life cycle.

4.2. Make available high-quality FAIR data for assessing safety and sustainability, without prejudice to intellectual property rights and, where relevant, security considerations, in line with the Council Recommendation of 23 May 2024 on enhancing research security. Such data should be shared via the Common Data Platform for Chemicals and its services, in collaboration with relevant Union agencies (ECHA, EEA, EFSA), as appropriate.

4.3. Communicate regarding their use of the SSbD Framework in their corporate, safety and sustainability assessment activities, in a transparent and open way without prejudice to intellectual property rights and, where relevant, security considerations.

4.4. Engage in the development, promotion and uptake of new assessment methods, models and tools that can be integrated into the SSbD Framework to improve the assessment of safety and sustainability of chemicals and materials.

4.5. Support the development of professional training and educational curricula to ensure the teaching of the skills required to implement the SSbD Framework and related cooperation between wider national or EU-wide activities in this area.

5. DOCUMENTING THE IMPLEMENTATION OF THE RECOMMENDATION

5.1. The Commission will make a template available for all actors (from Member States, industry, higher education institutions, research and technology infrastructures, and research and technology organisations), accompanied also by methodological guidance to facilitate the dissemination of information across the various value chains regarding the implementation of the SSbD Framework.

5.2. By those documentation activities, the Commission will aim to ensure more transparency, whilst in parallel encouraging the reuse of data across the value chain, to reduce duplicative reporting, in line with simplification principles. The documentation activities should also provide evidence for the improvement of the SSbD Framework's tools and the progressive development of safety and sustainability of chemicals and materials' criteria.

Done at Brussels, 6 March 2026.

For the Commission
Ekaterina ZAHARIEVA
Member of the Commission

ANNEX

Contents

1. Features underpinning the SSbD framework

The revised framework ([1]) for safe and sustainable by design chemicals and materials (SSbD Framework) is a voluntary decision-making approach designed to guide innovators in developing chemicals and materials that are safer and more sustainable throughout their entire life cycle. It maintains the level of ambition of the initial 2022 SSbD Framework, while providing more support for the innovation process. This updated framework enables innovators to more efficiently identify the necessary information to support safety and sustainability decisions, while minimising at the same time inherent uncertainties.

There are several features underpinning the SSbD Framework:

- Holistic, iterative and tiered approach to assess safety and sustainability, complementing, at each innovation decision-making stage, other considerations such as functionality or cost.
- Consideration of the entire life cycle of chemicals and materials, including the processes they are involved in and the products they become part of.
- Engagement of safety and sustainability practitioners throughout the entire life cycle.
- Transparency of the fulfilment of the principles and traceability of the assessment throughout the entire innovation.

The SSbD Framework is intended to be a reference point in research and innovation activities, as well as in guiding interventions to improve the safety and sustainability of chemicals and materials. While it does not interfere with, nor creates new, Union legal obligations for chemicals and materials, the SSbD Framework can guide anticipatory actions and decisions within the innovation process, including actions going beyond minimum legal compliance.

The implementation of this revised SSbD Framework is supported by the SSbD methodological guidance (2024 version ([2]) and future updates ([3]) providing detailed guidance, templates and updated overview of relevant methods, tools and data sources.

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[1] Garmendia Aguirre, I, Abbate, E, Bracalente, G, Mancini, L, Cappucci, G.M, Tosches, D, Rasmussen, K, Sokull-Kluettgen, B, Rauscher, H, Sala, S. (2025). European Commission – Joint Research Centre. Safe and Sustainable by Design Chemicals and Materials. Revised framework, Publications Office of the European Union, Luxembourg, 2025, ISBN 978-92-68-330-6, doi: 10.2760/5103785.

[2] Abbate, E., Garmendia Aguirre, I., Bracalente, G., Mancini, L., Tosches, D., Rasmussen, K., Bennett, M. J., Rauscher, H., & Sala, S. (2024). Safe and Sustainable by Design chemicals and materials – Methodological Guidance. Publications Office of the European Union, Luxembourg. https://doi.org/10.2760/28450.

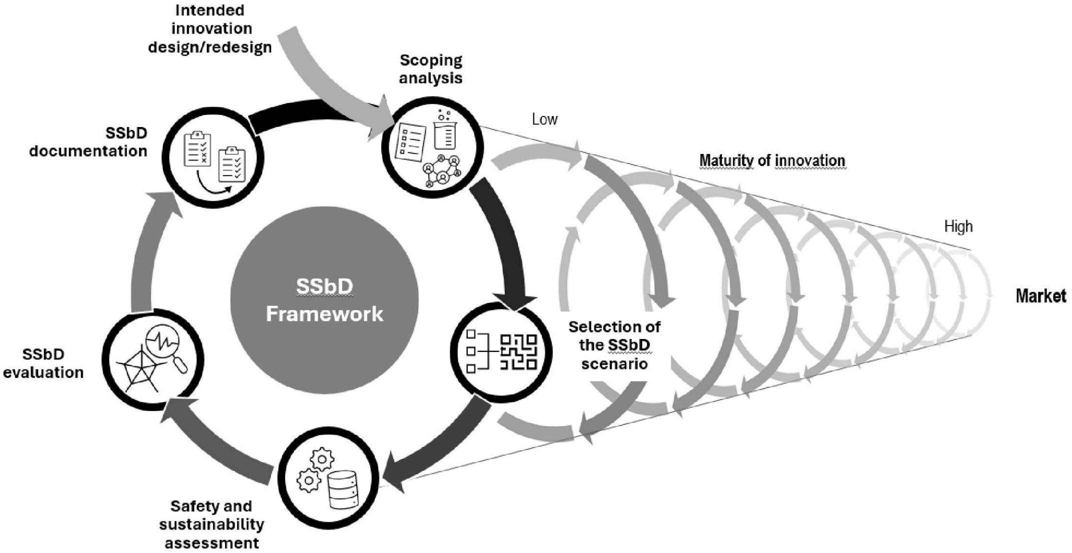
[3] https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en.

2. The overall structure of the Framework

The overall structure of the SSbD Framework is shown in Figure 1.

Figure 1

Overall structure of the SSbD Framework



The structure is a cycle which emphasises the iterative and tiered ([4]) nature of the SSbD Framework implementation throughout the innovation process for chemicals and materials.

Each iteration of the cycle considers the following elements:

- Scoping analysis: defining the objectives, principles and decision-making rules of the innovation. It includes the description of the initial SSbD system, the definition of the intended innovation including the (re)design and the engagement with the actors along the life cycle.
- SSbD scenario: representing the outcomes of the scoping analysis as well as identifying the entry point into the SSbD Framework, allowing for a tailored safety and sustainability assessment.
- Safety and sustainability assessment: the holistic assessment of aspects related to safety and sustainability, the latter including both environmental and socioeconomic, along the entire life cycle of the chemical or material.
- SSbD evaluation: presenting the outcomes of the safety and sustainability assessments, comparing them with the objectives, principles and decision rules defined in the scoping analysis.
- Documentation: recording the implementation of the SSbD Framework in a traceable and transparent manner, outlining the actions and objectives for progressive subsequent iterations.

3. Scoping analysis

Key features of the scoping analysis include:

- The **description of the initial system under study**, covering the three elements needed to define the boundaries of the system: chemical(s)/material(s), process(es) and product(s).

([4]) The iterative approach involves repeating the SSbD framework full process several times during the innovation cycle, while the tiered approach means progressing through different levels or stages of innovation.

- The definition of the targeted innovation includes:
  - the **objectives,** reflecting to what end and for what purpose(s) the SSbD Framework is being applied,
  - the **design principles**, taking into consideration the objectives, and helping to guide the direction of the innovation,
  - the **(re)design** (at molecular, process and product levels), identifying the specific actions towards the achievement of the objectives, and
  - the **decision-making rules** that define the indicators and criteria to measure the success of the actions.

The SSbD Framework refers to a **set of guiding design principles**, as set out in Table 1. These principles can be applied to steer innovation and are subject to a subsequent safety and sustainability assessment to evaluate the performance of the proposed innovation and identify any possible trade-offs. The design principles have been developed in different contexts, such as in green chemistry, green engineering, circular chemistry, sustainable chemistry, and safe by design as well as policy-related ambitions (e.g. circular economy, bioeconomy, or zero pollution). The design principles may inspire the innovation but are not equivalent to demonstrating safety and sustainability; these aspects need to be addressed via the safety and sustainability assessment and evaluation.

Table 1

Non-exhaustive list of guiding design principles, associated definitions, and examples of (re)design actions to guide safer and more sustainable innovation

Design principle	Definition	Examples of (re)design actions
Material efficiency	Pursuing the incorporation of all the chemicals/materials used in a process into the final product or full recovery inside the process, in turn reducing the use of raw materials and the generation of waste.	Maximise yield during reaction to reduce chemical or material consumption. Recover more unreacted chemicals or materials. Select materials and processes that minimise the generation of waste. Identify the occurrence of the use of critical raw materials, in order to minimise or substitute them.
Minimise the use of hazardous chemicals or materials	Preserve functionality of products while reducing or completely avoiding the use of hazardous chemicals/materials where possible.	Reduce and/or eliminate hazardous chemicals or materials in production processes. Redesign production processes to minimise the use of hazardous chemicals/materials. Reduce and/or eliminate hazardous chemicals or materials in final products.
Reduce exposure to hazardous substances	Eliminate exposure to chemical hazards from processes as much as possible.	Substances which require a high degree of risk management should be avoided where possible and the best technology should be used to avoid exposure along all the life cycle stages.
Design for energy efficiency	Minimise the overall energy used to produce a chemical/material in the manufacturing process and/or along the supply chain.	Select or develop (production) processes that: involve alternative and less energy-intensive production/separation techniques; maximise energy re-use; have fewer production steps; use catalysts, including enzymes; reduce inefficiencies and exploit available residual energy in the process or select lower temperature reaction pathways.

Design principle	Definition	Examples of (re)design actions
Use renewable sources	Target resource conservation, either via closed resource loops or using renewable material / secondary material and energy sources.	Promote the use of feedstocks that: are renewable; circular; do not create land competition; do not negatively affect biodiversity. Or promote processes that: use renewable energy resources with low-carbon emissions and without adverse effects on biodiversity.
Prevent and avoid hazardous emissions	Apply technologies to minimise and/or avoid emission of hazardous pollutants into the environment.	Select materials or processes that: minimise the generation of hazardous waste and hazardous by-products; minimise the generation of emissions (e.g. volatile organic compounds, acidifying and eutrophying pollutants, and heavy metals).
Design for end of life (EoL)	Design functional chemicals/materials that do not pose any risk to the environment/humans at their EoL. Design for preventing the hindrance of reuse, waste collection, sorting and recycling/upcycling. Design to promote circularity.	Avoid using chemicals or materials that impede end-of-life processes such as recycling. Select materials that are: more durable (longer life and less maintenance); easy to separate and sort; valuable even after being used (commercial afterlife); fully biodegradable for uses that unavoidably lead to release into the environment or wastewater. Consider: using reusable packaging for the chemical or material being assessed and for chemicals or materials in its supply chain; energy-efficient logistics (e.g. reducing transported quantities, changing the means of transport); reducing transport distances in the supply chain

The *decision-making rules* measure the success of the action towards the objectives. They set the basis for decision-making during the evaluation by defining criteria for the relevant indicators as well as weighting rules, all taking into consideration the uncertainties related to the assessment of the indicators.

— The **engagement with the actors along the life cycle** reflects the fact that the SSbD Framework goes beyond a single stakeholder and envisages the involvement and collaboration of stakeholders along the life cycle. The scoping analysis helps to understand the position of an organisation in the life cycle. It assists in identifying and engaging with actors along the life cycle early in the research and innovation process as well as in more advanced stages depending on the system under study and the targeted innovation.

4. Identification of the SSbD scenario

The SSbD scenario reflects the outcomes of the scoping analysis and determines, based on the maturity of the innovation and the availability of data, the maturity of the SSbD Framework implementation – either as a simplified/screening, intermediate, or full SSbD assessment. This approach allows innovators to tailor the safety and sustainability assessments based on the degree of maturity of the innovation and data availability related to the innovation process being considered, and then to use a tiered approach, to progressively advance toward full assessment as innovation matures.

A **set of general SSbD scenarios** are presented in Table 2. Innovators should customise these scenarios to fit the specifics identified in the scoping analysis.

Table 2

General SSbD scenarios based on the maturity of the innovation and the availability of the data

SSbD scenarios	Simplified/Screening assessment	Intermediate assessment	Full assessment
Applicability	— Usually low maturity of innovation — Low data availability — High uncertainty of the assessment — Low/medium possibility to engage with the other actors of the value chain — Limited resource availability (e.g. SME) — Limited to the specific life cycle stage in which the innovation takes place	— Increasing maturity of the innovation — Medium data availability — Medium/High uncertainty of the assessment — Medium/high possibility to engage with the other actors of the value chain — Relevance of life cycle stages near to the one where innovation takes place	— High maturity of the innovation — High data availability — Low uncertainty of the assessment — High possibility to engage with the actors of the value chain — Full life cycle innovations are considered

5. **Safety and sustainability assessment**

Once the scoping analysis has been performed, the SSbD scenario has been defined, and the design principles applied, the innovator can proceed with the safety and sustainability assessment throughout the life cycle of chemical/material being considered.

- Safety assessment: evaluates *both* the hazard associated with the specific chemical or material under study and the potential of exposure in the defined scenarios. This enables to generate an estimate of risk, where possible in absolute quantitative terms, if not in qualitative or relative terms. Under the SSbD Framework, the safety of production processes including, where relevant, assessment of alternative production processes, is also assessed.

- Sustainability assessment entails an environmental and socioeconomic assessment of the chemical/material under study, from raw materials extraction to the end of life:

  - Environmental sustainability assessment: this evaluates the environmental impacts along the entire chemical or material life cycle by means of life cycle assessment (LCA), assessing several impact categories such as climate change and resource use, for, among others, the raw materials, the production processes, the final application and use of the chemical or material as well as the expected end of life stage.

  - Socioeconomic sustainability assessment: this evaluates the socioeconomic aspects along the entire chemical or material life cycle focusing on aspects related to social fairness (e.g. working conditions and human rights) and competitiveness (e.g. vulnerabilities in the supply chain, skills shortages and life cycle costs).

The safety and sustainability assessments can be tailored based on the identified SSbD scenario. Safety and sustainability assessment can be performed in parallel, in an iterative and tiered manner as information becomes available along the innovation process and could trigger the application of different design principles and the definition of (re)design actions to minimise trade-offs.

5.1. *Safety assessment*

5.1.1. *Aspects, indicators and criteria*

Different legal and regulatory frameworks have been established at national and international level to address safety of chemicals and materials. These frameworks aim to protect human health and the environment, promote safer products, and ensure transparency and accountability in chemical development, processing and use. In the Union, it brings together various legal frameworks addressing different sectors, and duty holders. The individual pieces of legislation vary in their objectives and scope, which means that also, e.g. data requirements, chemical/material life cycle stages and target populations or ecosystems vary.

Despite differences in the legal and procedural context, chemical safety assessments across sectors are underpinned by a **common scientific methodology** based on the following four elements (5):

— **Hazard identification**: determination of whether the intrinsic properties of a chemical may cause harm (e.g. carcinogenicity, reproductive toxicity, ecotoxicity).

— **Hazard characterisation** (potency or dose-response assessment): Establishment of the relationship between the dose or concentration of a chemical or material and the severity or probability of adverse effects. This includes identifying the dose at which critical effects occur, and determining reference tolerable exposure limits, where possible. Hazard characterisation builds on scientific state-of-the-art (eco)toxicological test data and dose-response descriptors (6).

— **Exposure assessment**: Estimation, for relevant routes of exposure, of the level, frequency and duration of exposure to the chemical for humans or environment, considering relevant exposure patterns and health effects under realistic and identifiable worst-case scenarios.

— **Risk characterisation**: integration of hazard and exposure information to estimate the likelihood and severity of harm under specific use conditions. Where possible, safety is expressed based on risk characterisation ratios (RCRs), which compare the estimated exposure to a chemical with the tolerable exposure limit determined in the hazard characterisation.

Each of the four elements relies on various aspects and multiple indicators. Their characterisation requires integrating diverse data streams from multiple sources (Figure 2).

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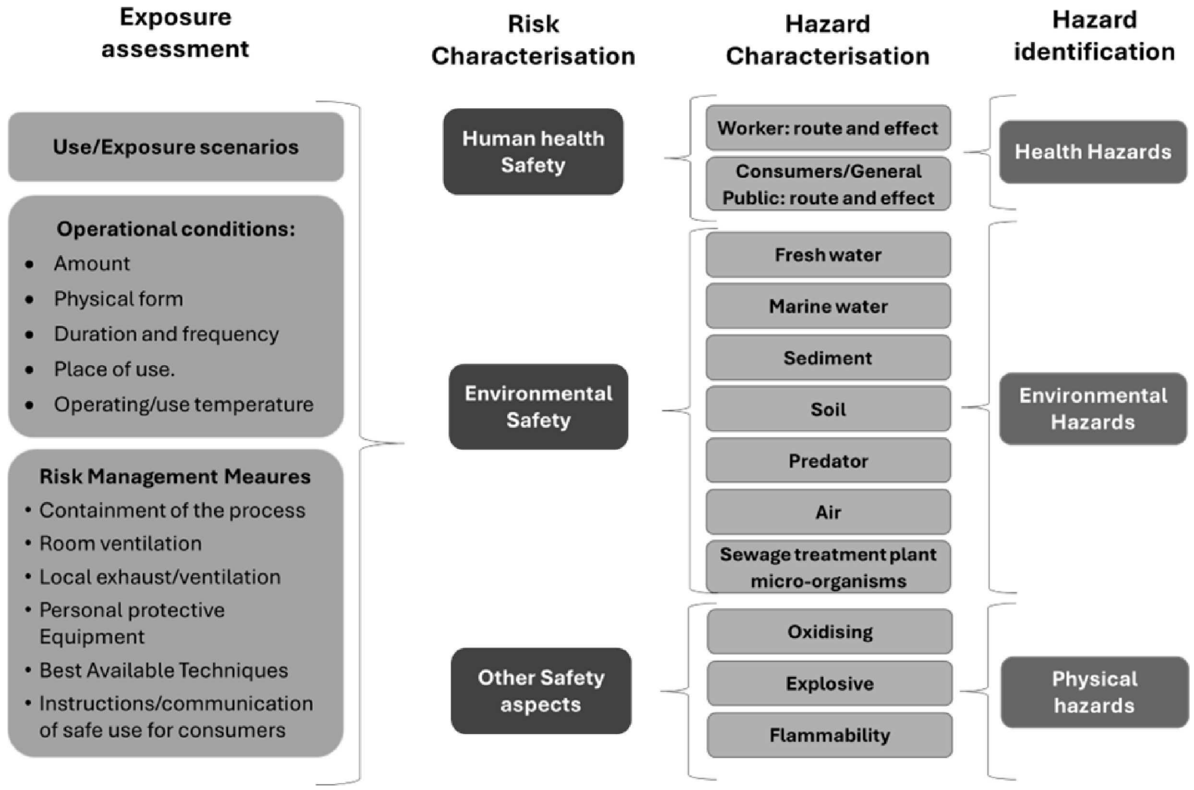
(5) Although the description under the four elements focuses on human health and environmental hazards, different and tailored approaches can be used to address specific hazard classes like 'very persistent and very bioaccumulative' or 'gas under pressure'.

(6) A toxicological dose-response descriptor is the term used to identify the relationship between a specific effect of a chemical substance and the dose at which it takes place.

Figure 2

Aspects to be considered for the hazard identification and characterisation, exposure assessment and risk characterisation



Safety criteria under the SSbD Framework can and will at least partly be based on the hazard profile of the chemicals and materials under consideration. Most hazard classes and categories are defined in part 2 to 5 of Annex I of the Classification Labelling and Packaging (CLP) Regulation (7). CLP hazard classification does not provide the specific data that are needed to support the hazard, and thus risk, characterisation. However, it is useful to screen and flag hazard related issues when deciding on the course of action at an early stage, as shown in Table 3. As this approach is not applicable to chemicals and materials for which there is no available CLP hazard classification, predictions from structurally similar substances (and/or screening New Approach Methodologies NAMs) may be a crucial analogue for the purpose.

Table 3

Hazard-based SSbD criteria and considerations in alignment with the EU policy objectives.

Hazard-based SSbD criteria	Related considerations – relevant for decision making on the role of the chemical or material in the innovation, and for the scoping analysis in the initial and subsequent iterations of the SSbD cycle
Criterium H1 that includes the most harmful substances (according to CSS (EC, 2020a)), including the substances of very high concern (SVHC) according to REACH Art. 57(a-f) (EU, 2006).	Innovators should consider impacts of the identified properties and be aware that chemicals and materials which do not pass the Criterion H1 are subject, or could become subject, to legislation that: — bans, restricts or at least discourages their use, except for derogated uses, e.g. those considered essential for society (1) — imposes conditions on safe use and requires emissions/exposure to be controlled along the whole life cycle

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(7) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

Hazard-based SSbD criteria	Related considerations – relevant for decision making on the role of the chemical or material in the innovation, and for the scoping analysis in the initial and subsequent iterations of the SSbD cycle
	— requires that activities are undertaken to identify or develop alternatives as soon as possible, so they can be substituted and their use phased out as soon as alternatives are available that are less hazardous, more sustainable and economically and technically viable — implies their use and presence has to be tracked through their life cycle — requires them to be (re-)designed to reduce their adverse effects
Criterium H2 that includes substances of concern, as described in CSS (EC, 2020a), defined in the Article 2(27) of ESPR (EC, 2024) and that are not already included in Criterion H1.	Innovators should consider the impacts of the identified properties and be aware that chemicals and materials that do not pass Criterion H2 are subject, or could become subject, to legislation that: — imposes conditions on safe use and requires emissions/exposure to be controlled along the whole life cycle — requires that they are substituted as soon as alternatives are available that are less hazardous, more sustainable and economically and technically viable — implies their use and presence has to be tracked through their life cycle — requires them to be (re-)designed to reduce their adverse effects
Criterium H3 that includes the hazard classes not covered by Criteria H1 and H2.	Innovators should consider the impacts of the identified properties and for the chemicals and materials that do not pass Criterion H3 consider: — flagging them for internal review to find methods to use them in ways that reduce their toxic effects — explaining how to ensure their safe use along the life cycle until alternatives are available that are less hazardous, more sustainable and economically and technically viable

(1) Uses are necessary for health, safety or critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health, as outlined in the Commission Communication C/2024/2849 – Guiding criteria and principles for the essential use concept in EU legislation dealing with chemicals (OJ C, C/2024/2894, 26.4.2024, ELI: http://data.europa.eu/eli/C/2024/2894/oj).

Hazard-based SSbD criteria raise early awareness on chemical safety and associated legal aspects that the innovator/SSbD practitioner should consider when innovating, to prevent or anticipate future consequences and requirements. Hazard-based criteria need to be complemented with exposure-based safety criteria. These should consider dose-response descriptors and exposure assessment. If the exposure is known (i.e. can be estimated with confidence in the extent and control), then the required information on hazards can indeed be acquired in a more targeted way. The advantage of having the resulting, more comprehensive hazard information, as well as confidence in exposure estimations, is the ability to better support risk characterisation.

Overall safety criteria should consider risk characterisation and, where possible, be based on risk characterisation ratios (RCR); RCR> 1 indicates that the risk is not adequately controlled: the exposure levels are higher compared to the no-effect or minimal-effect levels for the relevant time and spatial scales for one or more of the health and safety protection targets (occupational, consumers and environment). Failing the RCR< 1 criteria indicates that further decisions should be made regarding the role of the chemical or material in the innovation, the scoping analysis in the initial and in subsequent iterations of the SSbD cycle and that present solution may also face challenge to comply with already existing legislation.

As the innovation progresses, and the market scenarios become clearer, innovators should also consider the broader EU – and international, where applicable – safety legal framework that needs to be applied to the specific chemical/material/product application. While the SSbD Framework does not interfere with Union legal obligations for chemicals and materials, the SSbD Framework can guide anticipatory actions going beyond minimum legal compliance by using stricter risk characterisation decision making rules and criteria during innovation.

5.1.2. *Safety assessment throughout the innovation process*

The safety assessment is performed on a tiered approach from a qualitative, semi-quantitative to a quantitative assessment as information both for the hazard and the exposure becomes available.

Hazard identification. If the chemical/material is already on the market, existing data sources may be used such as safety data sheets (SDS), regulatory classification, public databases, and QSAR models (8) or read across from structurally similar substances. The focus of hazard identification is on quickly flagging chemicals and materials with known or suspected hazardous properties. For new or modified substances, particularly at early innovation stages, data may be sparse, and in these cases the hazard identification relies on conservative assumptions and predictive tools to identify potential areas of concern.

As the innovation progresses and more information becomes available, more refined and targeted testing strategies e.g. *in vitro* methods or validated new approach methodologies (NAMs), may be used. At the later stages of innovation, hazard identification may involve integrated approaches to testing and assessment (IATAs) and, where justified and ethically permissible, *in vivo* studies.

Exposure assessment starts with the identification of the *use case* and the development of *exposure scenarios*. Methods such as the use descriptors developed in the context of REACH may be utilised to support the innovator regarding the development of exposure scenarios. In the context of the SSbD Framework, at the early stages of innovation, the exposure scenarios may be focused on a single actor. The exposure scenarios will then be expanded upstream and downstream in the value chain as the innovation progresses. Besides describing the use case itself, the exposure assessment will also consider the physicochemical properties of the chemicals or materials, the operational conditions in which the uses take place, and the risk management measures (RMM).

Risk characterisation is performed moving gradually from qualitative to quantitative assessment. Qualitative assessment (e.g. using control banding) supports early-stage decisions by assigning risk levels (e.g. high, medium and low). Quantitative assessment is often based on the risk characterisation ratios (RCR) and thus needs data of sufficient reliability. At early innovation stages and/or low data situations, exposure is assessed using intentionally conservative realistic and identifiable worst-case assumptions. As innovation moves on more realistic use conditions and risk management measures, refined models and measured or scenario-specific data will be incorporated into the assessment.

Table 4 describes the **tiered safety assessment** throughout the innovation. The core of the evaluation of the safety assessment is the interpretation of the assessment results, to understand how to proceed with the subsequent iteration. The evaluation should look at the results from two different angles: the data quality and completeness, and the identification of potential red flags or hotspots that should provide insights to the innovation.

Table 4

Summary of the tiered approach of safety assessment along the innovation

Tiered Safety assessment	Qualitative	Semi quantitative	Quantitative
Applicability	— Usually low maturity of innovation — Low data availability — High uncertainty of the assessment — Low/medium possibility to engage with the other actors of the value chain	— Increasing maturity of the innovation — Medium data availability — Medium/high uncertainty of the assessment — Medium/high possibility to engage with the other actors of the value chain	— High maturity of the innovation — High data availability — Low uncertainty of the assessment — High possibility to engage with the actors of the value chain

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(8) QSAR (Quantitative Structure-Activity Relationship): Modelling to relate safety of compound to its their physicochemical parameters.

Tiered Safety assessment	Qualitative	Semi quantitative	Quantitative
Main characteristics	— Helps to identify the priority aspects, such as exposure scenarios or hazard end points mostly guided by the identification of hot spots. — Data – it captures uncertain and unknown information. — Lifecycle coverage – can be incomplete, focussed on a specific life cycle stage. It helps identify engagement needs with life cycle actors. — Uncertainty considerations – information is limited and uncertainly high. Conservative approached mush be used to identify ‘red flags.	— Certainty on priority aspects, such as specific life cycle stages and exposure scenarios or hazard endpoints and identify those that need higher tier assessment. — Data – it captures some level of certainty based on gathered and generated knowledge mostly guided by the identified priority aspects. — Life cycle coverage – partial knowledge of the life cycle and identification of ‘uses’, engagement with the life cycle actors and collection of data for the refining of the assessment starts. — Uncertainty considerations – the lower the uncertainty e.g. higher tier, more realistic will be the assessment and less conservative methods and tools will be used.	— Helps identify the priority aspects, such as specific life cycle stages and exposure scenarios or hazard endpoints whether further action may be taken. — Data – it captures certainly and quality information. It is mostly guided by the goal of the highted quality and certainly for a robust assessment. — Lifecycle coverage – complete covering all stages of the chemical material life cycle. — Uncertainty considerations – the full set of data required for safety assessment is available.
Approach	— Information – Can be retrieved from existing sources or databases. These can support the identification of red flags or warnings indicating a need for additional data. — Evaluation – Enable early warning ‘red flags’ for hazard, exposure or overall safety. Goals, principles and decision-making rules defined in the scoping analysis. — Criteria – qualitative criteria, such as ‘red flags’ or warnings or risk characterisation levels, still supporting the identification of hotspots.	— Information – higher tier prediction tools in combination with other tests to support data generation. — Evaluation – can be made focussing on aspects that might raise concerns: Physicochemical and fate properties that might raise exposure concerns; high exposure uses; relevant hazard properties for the identified uses. The goal is to support the identification of gaps/needs for improving the different aspects of the assessment and steer innovation towards safer alternatives. — Criteria – the evaluation will consider both qualitative and quantitative criteria to identify hotspots for hazard, exposure and safety.	— Information – existing regulatory requirements and related guidance support the completeness of the assessment — Evaluation – The goal is to conclude the innovation with the safety performance of the chemical and material under assessment during it entire life cycle and steer innovation towards safer processes. — Criteria – will consider the quantitative criteria established in specific regulations for potential marketing purposes and well as any additional criteria set in the scoping analysis that will help steer innovation towards safer alternatives.

Process-related safety. The SSbD Framework includes all process-related safety considerations identified in the innovation scenario, focusing on one specific life cycle stage at the time.

The same chemical or material, thus having the same hazard profile and safety performance, may lead to a significantly different overall life cycle safety assessment depending on the process-related parameters. These parameters include aspects such as the use of precursors and auxiliary materials (e.g. solvents, catalysts) or specific operational parameters (e.g. high pressure, elevated temperature, exothermic reactions), throughout the production process, from raw material extraction, feedstock supply, synthesis and end-of-life management (recycling, waste management, etc.).

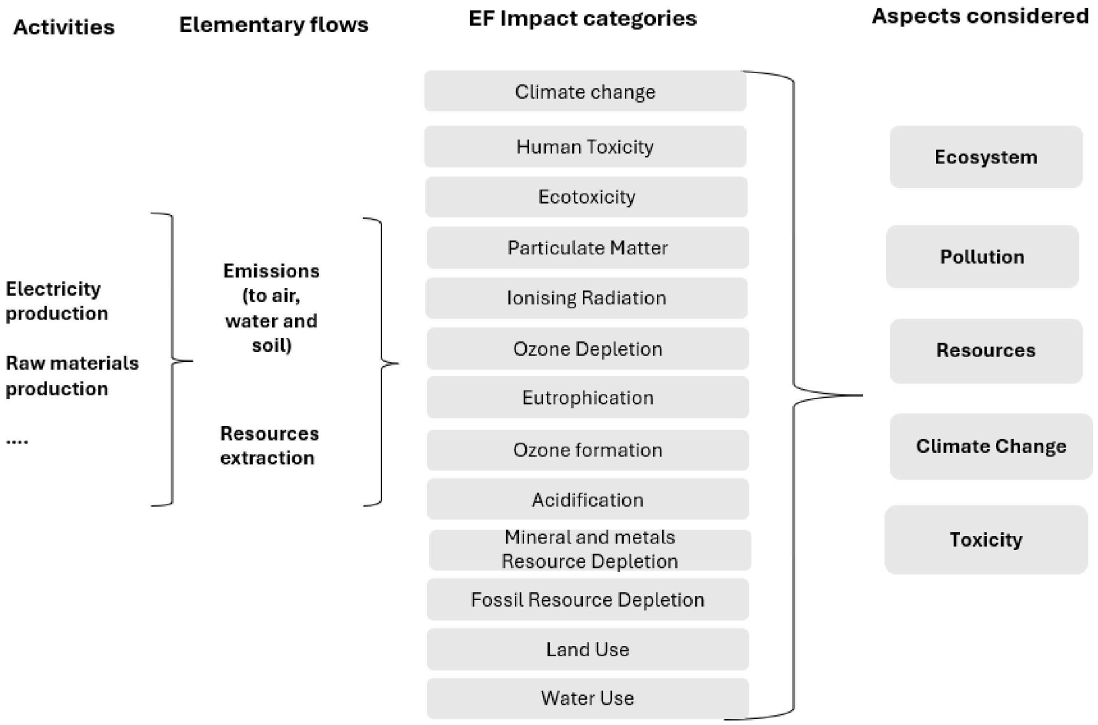
5.2. *Environmental sustainability assessment*

5.2.1. *Aspects, indicators and criteria*

The environmental sustainability of chemicals and materials in the SSbD Framework is performed by means of life cycle assessment (LCA), to identify hotspots along their life cycle and to guide the innovation process toward feedstocks, production processes, logistic choices and uses that minimise environmental footprints. It is recommended to conduct the LCA following the existing Commission guideline i.e., product environmental footprint (PEF) method (⁹). Figure 3 shows the aspects, and the indicators (EF impact categories) included in the SSbD Framework.

Figure 3

Environment Footprint (EF) impact categories, and their link to key environmental aspects.



The impact categories included in the SSbD Framework may be subject to updates following updates incorporated into the PEF method. Other additional aspects may be integrated into future LCA practices. Any additional aspects, or updates to those currently in existence, need to be addressed on a case-by-case basis by the innovator, who can determine possible criteria, indicators and ranges.

SSbD environmental assessment based on LCA impact categories results must consider a reference against which comparisons can be made, to eventually support the decision-making process. The reference evolves throughout the implementation of the SSbD Framework, in accordance with the iterative and tiered approach.

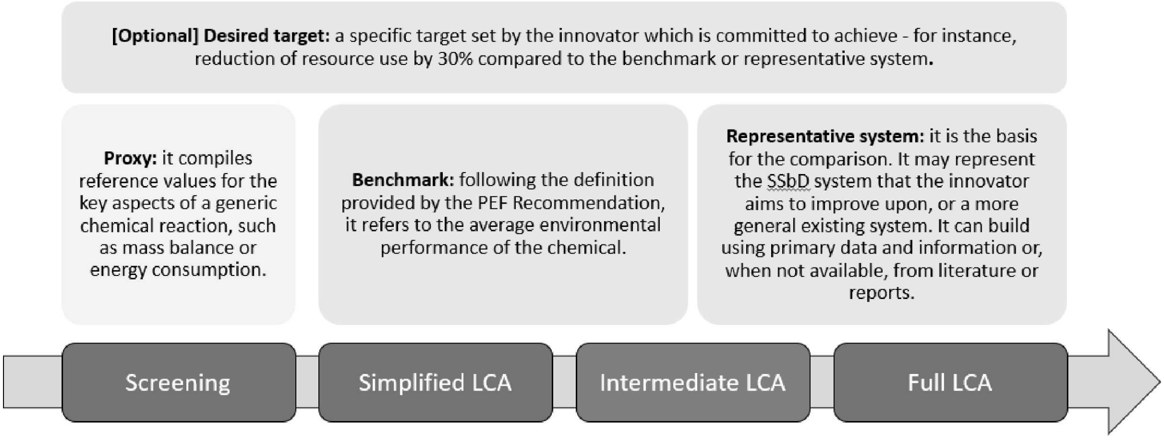
Environmental sustainability assessment in the context of the SSbD Framework has three different levels, reflecting the tiered approach of the framework: simplified, intermediate and full. In addition, a screening assessment using proxies can also be considered for very initial SSbD environmental assessment stages. The screening assessment may include a narrow set of indicators for the environmental performance of the processes involved, which might (for example) mostly reflect the energy and material resources required for the production process.

(⁹) The Commission is in the process of revising the Product Environmental Footprint (PEF) methodology based on Commission Recommendation of 16.12.2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations.

Figure 4 shows the various types of references for environmental sustainability assessment, providing related definitions and indicating the most appropriate stages for their application. For screening assessment at very early phase of innovation, the use of a 'proxy' is suggested, based on stoichiometry (e.g. mass balance of a chemical reaction) and energy consumption aspects to start understanding the main drivers of impacts.

Figure 4

References for the environmental sustainability assessment throughout the innovation process



[Optional] Desired target: a specific target set by the innovator which is committed to achieve - for instance, reduction of resource use by 30% compared to the benchmark or representative system.

Proxy: it compiles reference values for the key aspects of a generic chemical reaction, such as mass balance or energy consumption.

Benchmark: following the definition provided by the PEF Recommendation, it refers to the average environmental performance of the chemical.

Representative system: it is the basis for the comparison. It may represent the SSbD system that the innovator aims to improve upon, or a more general existing system. It can build using primary data and information or, when not available, from literature or reports.

Once the *reference* is defined, related classes of environmental sustainability performance of the innovation process can be identified. This enables the innovator to assess how good or bad the LCA results are compared to the reference system. A score can be subsequently assigned to each class of performance, to simplify the interpretation of the results and visualisation. Classes of performances can then be built. Based on the classes of performances, it is then possible to compare the obtained results against the defined reference, always taking into consideration the uncertainty of the assessment.

Table 5

Illustrative example of the classes and criteria that can be applied for each impact category

Range of values		Score	Class of performance	
Benchmark	Criteria taking as reference the representative system			
>Q4	No improvement / Worsening	0	CP5	Fail the criteria
Q3 < LCA result < Q4	Improvement + 5 %	1	CP4	
Q2 < LCA result < Q3	Improvement + 5 % to 20 %	2	CP3	Pass the criteria
Q1 < LCA result < Q2	Improvement + 20 % to 40 %	3	CP2	
< Q1	Improvement > 40 %	4	CP1	

5.2.2. *Environmental assessment throughout the innovation process*

Table 6 describes the tiered environmental assessment along the innovation, indicating applicability main characteristics. The core of the evaluation of the environmental sustainability assessment is the interpretation of the LCA results, to understand how to proceed with the next innovation stage and the associated evaluation iteration. The evaluation should look at the results from two different angles: (i) the data quality for the life cycle inventory (LCI) of the LCA model; and (ii) the identification of potential hotspots that should provide insights to the innovation stages. An analysis of the data quality to improve the life cycle inventory includes the analysis of the technological, geographical, time-related representativeness, completeness, uncertainty, and reliability of the data sources.

Table 6

Summary of the tiered approach of environmental assessment along the innovation process

Tiered environmental assessment	Simplified environmental assessment	Intermediate environmental assessment	Full environmental assessment
Applicability	— Usually low maturity of innovation — Data from laboratory most likely only from the innovator — High uncertainty of the assessment — Low/medium possibility to engage with the other actors of the value chain — Un/Defined application(s)	— Increasing maturity of the innovation — Data from industrial or pilot scale — Medium/high uncertainty of the assessment — Medium/high possibility to engage with the other actors of the value chain — Defined application(s)	— High maturity of the innovation — Data from industrial scale — Low uncertainty of the assessment — High possibility to engage with the actors of the value chain — Defined application(s)
Main characteristics	— A simplified LCA helps to identify the most important life cycle stages and processes for data refinement, and thus guide the optimal use of effort and re-sources — Knowing the product or sector application of the chemical/material under development, it is possible to create scenarios describing the possible variabilities, for instance in terms of geography or products — A very extreme initial phase to start the simplified LCA is to evaluate the indicators of the selected design principles	— This is the most iterative tier of the LCA — Continuous iterative adjustments of the simplified LCA modelling, which follows the increasing maturity of the innovation — Examples of refinement include primary data collection, filling in data gaps, inclusion of all the impact categories, and expanding the system boundaries to cradle-to-grave (as opposed to cradle-to-gate) — Effort regarding the collection of primary data for LCI via in-house data collection, enhanced engagement with suppliers and/or downstream users, making specific data requests, etc.	— Final adjustments of the intermediate LCA — The full LCA includes adjustments that allows to follow the Commission's recommendation perform the LCA — Adjustments mostly regard the refinement of the LCI, maximising the engagement of the value chain — Adjustments also regard the improvement of the modelling of the use and end-of-life phases
Approach (according to the levels of the (re)design selected)	— Molecular: the key life cycle stage is the synthesis/production of the chemical/material. Main life cycle to consider to be linked with the selected design principles, e.g. production and EoL. Note: even if the use might be unknown, consideration about the recyclability of the chemical/material is still possible	— Based on the level of the (re) design, prior effort must be given in improving the life cycle stages more linked to the level of the (re)design — The other life cycle stages must be still considered with the needed assumptions and limitations already described in 'Applicability'	— The whole life cycle of the chemical/material must be equally modelled and assessed with equal weight to conclude with the final evaluation, and so choice of the alternative – if applicable

Tiered environmental assessment	Simplified environmental assessment	Intermediate environmental assessment	Full environmental assessment
	— Process: the key life cycle stages are the production of the chemical/material, and the production of its precursors. The upstream process of the chemical/material can be prioritised in this phase — Product: the key life cycle stages are the downstream stages, such as the product (containing the chemical/material) manufacturing, the use and the EoL		

Process-related sustainability. The SSbD Framework includes all process-related sustainability considerations identified in the innovation scenario, focusing on one specific life cycle stage at the time.

By assessing the chemical processes in their entirety, the SSbD Framework can help to identify environmental pressures and potential impacts that might otherwise be missed. Environmental hotspots could be identified in the early stages of the technological and process innovation; moving toward further stages, the identification of environmental pressures and impacts associated with the industrial plants will be also possible.

5.3. ***Socioeconomic sustainability assessment***

5.3.1. *Aspects, indicators and criteria*

Under the SSbD Framework, the socioeconomic sustainability assessment aims to identify and, where possible, quantify the socioeconomic risks and opportunities in the innovation process. Its goal is to assist innovators in selecting relevant indicators to:

- boost innovation and competitiveness by developing more resilient and sustainable value chains,
- promote social fairness and to minimise the risk of human rights abuses and poor working conditions in the value chains,
- support risk management and risk mitigation throughout the life cycle, addressing ethical and reputational risks, degree of autonomy / risk of supply chain disruptions, and financial risks from accidents and hazardous processes,
- identify opportunities and socioeconomic benefits as well as costs and externalities associated with the different innovation strategies.

A list of socioeconomic aspects and impact categories applicable in the context of the SSbD Framework, along with examples of indicators, is shown in Table 7.

Table 7

List of socioeconomic impact categories and aspects including examples of indicators

Impact category	Socioeconomic aspect	Examples of indicators
Human rights	Risk of child labour in the supply chain	% of children in employment (age 7-14)
	Risk of forced labour in the supply chain	Risk of forced labour in the country (cases per 1 000 inhabitants)
Working conditions and quality of jobs	Fair salary	Living wage, per month Minimum wage, per month Sector average wage, per month
	Working time	Hours of work per employee, per week
	Equal opportunity and discrimination	Gender wage gap (%)
	Freedom of association and collective bargaining	Trade union density (% of employees organised in trade unions) Right of association (ordinal scale) Right of collective bargaining (ordinal scale) Right to strike (ordinal scale)
Health and safety	Presence of safety measures	Preventive measures and emergency protocols exist for: (i) accidents and injuries; (ii) pesticide and chemical exposure Adequate general occupational safety measures Hours of injuries per employee
	Accidents at work	Rate of fatal and non-fatal accidents at the workplace (cases per 100 000 employees and year)
	Safe and healthy living conditions	Organisation efforts to strengthen community health (e.g. through shared community access to organisation health resources) Management efforts to minimise use of hazardous substances and control of structural integrity
Contribution to economic development	Contribution to macroeconomic development	Contribution of the product/service/organisation to economic progress (e.g. annual growth rate of real GDP per employee)
	Creation of knowledge-intensive employment	Knowledge intensive jobs (% high-skilled employees / total employees required for a unit of production)
Supply chain vulnerabilities	Supply chain vulnerabilities	No of flags related to the presence of critical raw material as material inputs, based on the Commission methodology. Mass of critical raw materials/total material input; and additional qualitative assessment of supply chain vulnerability
Skills and technology innovation potential	Technology potential	Patent growth rate in % of this technology for a defined period of time
	Skill shortages risk	Ratio of training investment per employee v industry benchmarks
Life cycle costs	Life cycle costs	Internal costs (incl., e.g. material acquisition, labour, energy, etc.) Externalities (including, e.g. through monetisation of LCA impacts)

- The *supply chain vulnerabilities* impact category includes but is not limited to critical raw materials (CRM) related risks. Other factors such as energy supply disruptions, water scarcity, and the general availability of raw materials, catalysts, feedstocks, chemical molecules may significantly affect the competitiveness, sustainability and security of value chains. These broader dimensions of vulnerability are particularly relevant in the context of international competitiveness, climate change, shifting global trade dynamics, and resource competition.

- On the *life cycle costs* impact category, the role of the socioeconomic assessment in the SSbD Framework is not to duplicate in-house corporate financial analysis. Rather, it is to support and complement the assessment of internal costs with additional economic considerations, helping innovators and companies to consider the socioeconomic risks and opportunities of their designs. This includes potential risks, costs, and benefits that extend beyond the company level. At company level, implications related to access to credits, insurance premium, etc. could be considered as well.

- In addition, the socioeconomic sustainability assessment aims to steer innovation towards strengthening competitiveness by assessing aspects such as technology potential, skills shortages risks, and the creation of knowledge-intensive employment. In doing so, it helps companies not only to comply with safety and sustainability principles, but also to position themselves strategically in evolving markets and policy landscapes.

Social life cycle assessment (S-LCA) provides a foundation for evaluating social risks and benefits across the life cycle of a product or process. Reference scales, often used in S-LCA, enable the classification of performance across a continuum – from very low to very high risk/benefit – based on predefined benchmarks such as international norms (e.g. International Labour Organisation (ILO) standards, International Conventions, etc.). In the context of the SSbD Framework, the reference scales can serve as either exclusion or prioritisation criteria. S-LCA integrates ethical boundaries into the design process, steering innovation away from socially harmful practices.

On the other hand, societal life cycle cost (S-LCC) allows alternative chemicals or materials to be ranked based on total cost throughout and along the life cycle. This includes societal costs, for example, damage costs due to environmental and health impacts, or the reduced energy bills for the consumer due to a more energy efficient product. The highest ranked option will be that which entails the lowest total cost (i.e. including both internal and societal costs), while maintaining an equal level of technical and functional performance.

5.3.2. *Socioeconomic assessment throughout the innovation process*

The socioeconomic assessment in the SSbD Framework builds on the previously undertaken scoping exercise and building of the environmental life cycle inventory. Therefore, the integration of socioeconomic indicators is streamlined and simplified, via using the same SSbD system boundaries.

The scoping analysis is critical in shaping the socioeconomic assessment, because the design principles that are chosen, e.g. a company’s commitment to source only certified, ethical, and sustainable raw materials, will play a foundational role in determining which socioeconomic aspects and indicators should be included, how these indicators should be addressed. The design principles and related actions and commitments should be transparently documented, to allow for traceability and consistency across iterations of the assessment that can be fully audited.

The assessment may use both primary data, i.e. quantitative or qualitative values obtained by or based on direct measurement or observations, and secondary data, from literature and databases. The use of primary data strengthens the robustness of the assessment at the highest level of innovation maturity. However, secondary data are very useful to perform simulations of potential value chains at low and medium innovation levels.

Whilst the integration of the socioeconomic analysis into the SSbD Framework provides valuable insights, some limitations should be acknowledged. This includes (i) data availability and granularity; (ii) trade-offs and aggregation; (iii) statistical nature of risk data; (iv) limited causality; (v) feasibility of robust socioeconomic assessment and uncertainty of cost estimates at low maturity of innovation; (vi) challenges in tracing supply vulnerabilities; as well as (vii) uncertainties in the monetisation factors for externalities. These limitations suggest the need for iterative use of the assessment supporting early decision-making. However, they also suggest the need to recognise when deeper engagement is necessary, continuously revisiting and refining the socioeconomic analysis as more data becomes available, conditions change, or the innovation matures.

6. **Evaluation and decision-making**

The aim of the SSbD evaluation as a whole is to support the decision-making process throughout the innovation within the frame defined by the scoping analysis. The evaluation compares the outcomes of the assessment of safety and sustainability aspects, with the objectives and the innovators' self-determined decision-making rules (and/or with reference to established external norms, minimum performance levels or standards) for the safety and sustainability dimensions.

The evaluation, informed by the safety and sustainability assessment, may lead to different decisions, e.g. regarding selection of a chemical, material or process, adjusting the (re)design principles being applied, etc. These insights and choices are then integrated into a new development cycle, where lessons learned guide future innovation efforts, ensuring continuous improvement towards safer and more sustainable solutions.

While the SSbD Framework allows for the visualisation and possible evaluation of trade-offs as well as identification and exploitation of synergies within and between the different aspects of the safety and sustainability dimensions, considerations go beyond these. Other important aspects, such as the functionality of the chemical or material and market considerations, e.g. penetration, consumer price, etc., need to be considered.

The use of decision-making rules, defined early in the scoping analysis and tailored to the specific case, is an important approach to formalising and systematising decisions made during the innovation process. It is also important to obtain engagement with the actors in the value chain and to make clear documentation of the strategic decisions made during the SSbD implementation.

Uncertainty considerations are an integral part of the SSbD Framework and should be considered in the evaluation and decision-making. Sources of uncertainty can range from the lack of information about the life cycle, to the level of data quality and its availability. The level of detail of the uncertainty analysis should be coherent with the tiered approach and consistent with the overall scope and purpose of the assessment. The refinement of the assessment in each iteration will involve the incorporation of new data, information and possibly methods to better characterise the system and thus reduce the uncertainty.

Example of a dashboard to visualise the SSbD results

The safety and sustainability assessment of the life cycle of chemicals and materials entails many aspects that need to be considered individually and then be integrated to support decision-making. To this end, dashboards are provided as examples. They show elements and information that should be considered for a comprehensive evaluation of the safety and sustainability aspects and to monitor the progress of the innovation process. The dashboards give the practitioner the flexibility to adapt the visualisation of the framework to the maturity of the innovation and to the availability of data. A dashboard approach also allows the inclusion of both qualitative and quantitative outcomes of the assessment (moving from simplified, toward intermediate and full SSbD assessment).

The **scoping dashboard** should enable to visualise the scoping elements that feed into the subsequent assessment phase. The scoping dashboard enables practitioners to track the evolution of the SSbD implementation (and related completeness of the required information and data), as well as preparing for a more focused safety and sustainability assessment.

The **assessment dashboard**. An assessment dashboard offers a comprehensive view of the results derived from the safety and sustainability assessment. It should be designed to be tailored to the maturity level of the innovation – such as TRL (n) – following a tiered approach. The assessment dashboard helps to identify major hotspots and areas for improvement, while also visualising potential trade-offs within and across the safety and sustainability dimensions.

The key elements to be included in the assessment dashboard are:

- safety assessment: the outcome of the safety assessment, as reported for the different elements considered, i.e. intrinsic properties, and risk based on exposure during the manufacturing, processing, use and end of life,
- environmental sustainability assessment: the results are reported for the 16 environmental impact categories, to unveil trade-offs if any,
- process-related safety and sustainability: to visualise the outcome of the safety and sustainability process-related considerations, focusing of a specific life cycle stage of the chemical or material,
- socioeconomic sustainability assessment: the results are reported for the different impact categories selected, as appropriate and feasible to the case at hand.

For each of the assessment dashboard key elements, the following should be reported:

- level of uncertainty: each result is associated with an uncertainty level that can be assessed via a qualitative or a quantitative approach,
- life cycle stages: the results of the assessment should include information on the life cycle stage(s) considered in the assessment.

The iterative nature of the SSbD Framework allows the progressive inclusion and integration of data, resulting in progressively increasing completeness of the assessment at each iteration. Figures 5 and 6 show examples of how the key safety and the environmental sustainability assessment elements may be depicted.

Figure 5

Example of safety assessment results to be included in the dashboard

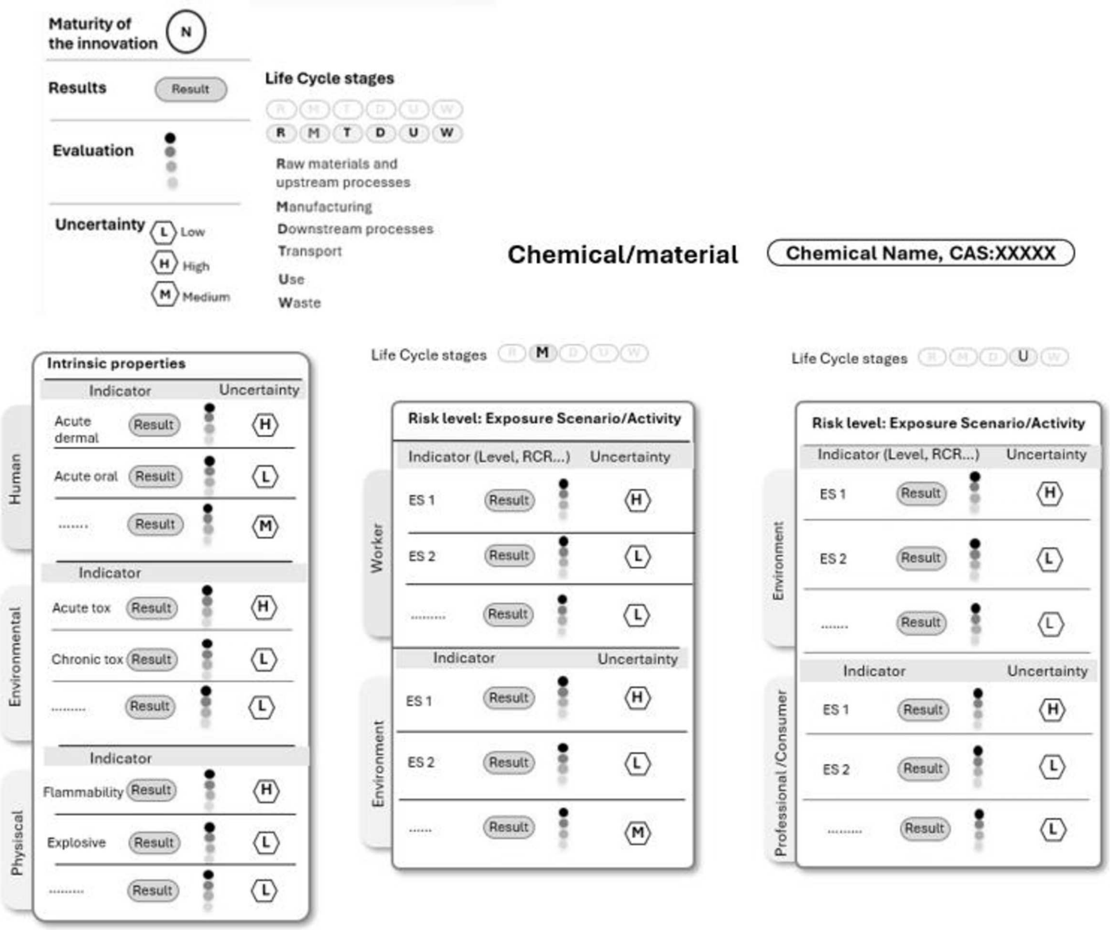
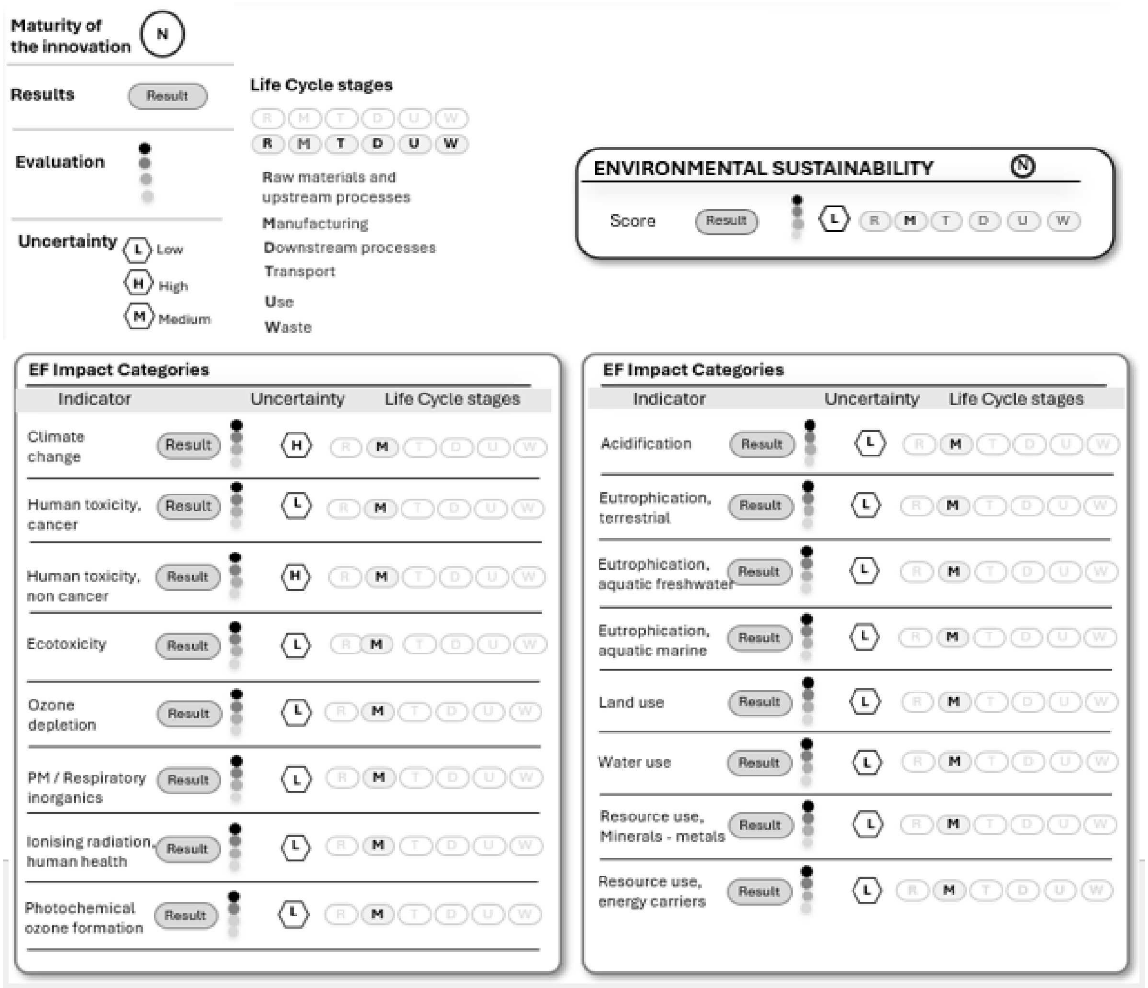


Figure 6

Example of environmental sustainability assessment dashboard



Visualising results from both the safety and sustainability assessments can act as an aid to inform decision-making. However, it is very important in the context of the SSbD Framework to supplement this with detailed information of the assessments that have been undertaken. Presenting comprehensive data helps reveal strengths and weaknesses that aggregate results might obscure, making it an essential component of the evaluation.

7. **Documentation**

Documentation gives greater transparency regarding the way the SSbD Framework has been implemented. It sheds more light on the traceability and consistency of tiered safety and sustainability assessments and reveals the identification of hot spots and data gaps along the progressive stages of the innovation process being undertaken.

Uncertainty considerations for the assessment should be documented fully and systematically in a transparent manner. This should include both qualitative and quantitative aspects relating to data, methods, scenarios, inputs, models, outputs, sensitivity analysis and interpretation of results.

The documentation produced represents a useful repository and summary of the evolution of the innovation process to be resourced already during the iterations as it gets complemented by improved scoping, generated data, and innovation decision made. It can be used both for internal communication purposes, e.g. between the in-house different functions and hierarchical levels involved in the R&I process of an organisation, and for external communication purposes, e.g. with different actors in the life cycle, or with external interested parties.

Templates for the documentation are available in the SSbD methodological guidance (2024 version (10) and future updates (11), including examples of the main elements to include.

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(10) Abbate, E., Garmendia Aguirre, I., Bracalente, G., Mancini, L., Tosches, D., Rasmussen, K., Bennett, M. J., Rauscher, H., & Sala, S. (2024). Safe and Sustainable by Design chemicals and materials – Methodological Guidance. Publications Office of the European Union, Luxembourg. https://doi.org/10.2760/28450.

(11) https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en.