SSbD for Regulators

IRISS

Towards a Safe and Sustainable Future

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WHAT IS SSbD?

All you need to know about SSbD for future policies

At this stage, ***safe and sustainable-by-design can be defined*** *as a* ***pre-market approach to chemicals*** *that focuses on providing a function (or service), while* ***avoiding volumes and chemical properties that may be harmful to human health or the environment, in particular groups of chemicals likely to be (eco) toxic, persistent, bio-accumulative or mobile.***

Overall sustainability should be ensured by minimising the environmental footprint of chemicals in particular on ***climate change, resource use, ecosystems and biodiversity*** *from a* ***lifecycle perspective.***

'Safe and Sustainable by Design' (SSbD) is a pre-market approach to **guide the innovation** process for chemicals, (advanced) materials, and products as announced in the **Chemicals Strategy for Sustainability**.

SSbD integrates safety as well as the three dimensions of sustainability (i.e., environmental, social, and economic) together with functionality throughout the innovation taking a lifecycle perspective.

SSbD steers the innovation process towards a green and sustainable industrial transition to:

- minimise the production and use of substances of concern, in line with, and beyond existing and upcoming regulatory obligations, and
- minimise the impact on health, climate and the environment during sourcing, production, use and end-of-life of chemicals, materials and products.

Why is SSbD important for regulators?

SSbD is important for regulators:

- To support the **European Green Deal** and the **Clean Industrial Deal** and the **EU Competitiveness Compass**.
- As SSbD is one of the three pillars of the **Safe and Sustainable Innovation Approach (SSIA)**. SSIA is a proactive approach rather than a reactive measure and requires that regulators **become aware** of and understand innovations sufficiently early to take **timely action**, and that appropriate regulatory tools are modified or developed as needed.

The SSbD Framework: Key Points

As one key action defined in the Chemicals Strategy for Sustainability, the European Commission's Joint Research Centre (EC-JRC) has published an **SSbD Framework to support the operationalization of SSbD**.

The SSbD Framework and **Methodological Guidance** consist of (1) the scoping and (2) and the assessment.

The **scoping analysis** helps the implementation of the SSbD framework according to (re)design aspects and maturity of the innovation itself. The goal, the scope and the system boundaries – which will frame the assessment of the chemical or material – are defined in this phase.

The **assessment phase** comprises of:

1. Hazard assessment,
2. Workers' exposure and safety aspects assessment during the production phase,
3. Exposure assessment during use phase of the chemical/material/product,
4. Environmental lifecycle assessment, and
5. Socio-economic lifecycle assessment. (optional step and currently under development).

It can be carried out either on newly developed chemicals and materials, or on existing chemicals and materials to improve their safety and sustainability performance during production, use, and end-of-life.

SSbD Scoping Analysis

- System Definition
- (Re)Design Definition
- Actors in the lifecycle
- Assessment Boundaries

SSbD Assessment

- Hazard assessment of the chemical/material (intrinsic properties)
- Human health and safety aspects in the chemical/material production and processing phase
- Human health and environmental aspects in the final application phase
- Environmental sustainability assessment
- Social and economic sustainability assessment

SSbD in the changing European Regulatory Landscape

For regulators, it is important to understand the regulatory developments.

SSbD is aligned with changing regulations:

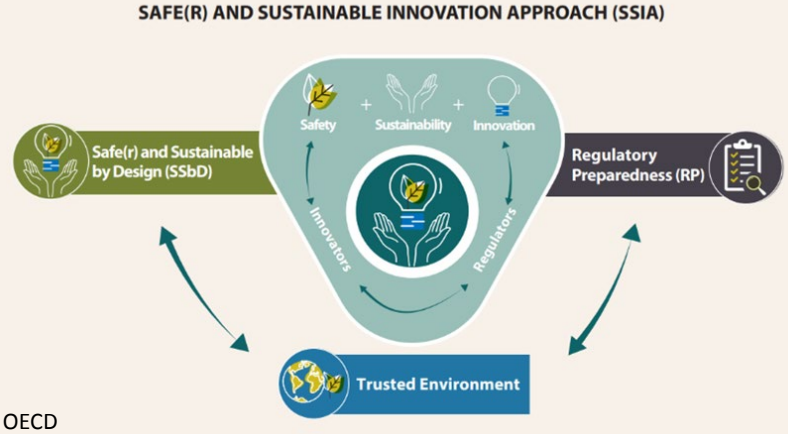
- The **'one substance, one assessment'** approach linking safety and sustainability data across EU legislation to achieve a common data platform.
- For safety, the **REACH revision** will introduce stricter EU Chemical Regulations, PFAS Restrictions, and Essential Use Criteria. The 2025 REACH revision may prioritise broader restrictions on harmful chemicals over case-by-case authorisations.
- For ***environmental sustainability***, the **Ecodesign for Sustainable Products Directive (ESPR)** is part of a package of measures that are central to achieving the aims of the **2020 Circular Economy Action Plan** and fostering the transition to a circular, sustainable, and competitive economy. The ESPR will introduce a **Digital Product Passport (DPP)**, i.e., a digital identity card for products, components, and materials, which will store relevant information to support products' sustainability, promote their circularity and strengthen legal compliance. DPP information can include:
    i. Product's technical performance
    ii. Materials included in the product and their origins
    iii. Repair activities
    iv. Recycling capabilities
    v. Lifecycle environmental impact
- For ***socio-economic sustainability***:
    - The **Critical Raw Material Act (CRM Act)** aims to ensure EU access to a secure and sustainable supply of critical raw materials, enabling Europe to meet its 2030 climate and digital objectives.
    - The **Corporate Sustainability Reporting Directive (CSRD)** modernises and strengthens the rules concerning the social and environmental information that companies have to report. Companies will now be required to report on sustainability
    - The **Corporate Sustainability Due Diligence Directive (CSDDD)** introduces the obligation for companies to conduct appropriate human rights and environmental due diligence with respect to their operations, operations of their subsidiaries, and operations of their business partners in companies' chains of activities. The due diligence process set out in the CSDDD covers the six steps defined by the OECD Due Diligence Guidance for Responsible Business Conduct:
        i. Integrating due diligence into policies and management systems,
        ii. Identifying and assessing adverse human rights and environmental impacts,
        iii. Preventing, ceasing or minimising actual and potential adverse human rights, and environmental impacts,
        iv. Assessing the effectiveness of measures,
        v. Communicating, and
        vi. Providing remediation.

SSIA – The combination of SSbD and Regulatory Preparedness

The ***Safe and Sustainable Innovation Approach (SSIA)*** seeks to enhance the ability of all stakeholders to address the safety and sustainability assessment of innovations in a robust yet agile manner. It relies on **dialogue between innovators and regulators** and combines the SSbD approach and Regulatory Preparedness:

- **SSbD**, which recommends innovators to integrate safety and sustainability considerations as early as possible into the innovation process; and
- **Regulatory Preparedness** which aims to improve the anticipation of regulators in order to facilitate the development of adaptable (safety and sustainability) regulation that can keep up with the pace of knowledge generation and innovation of chemicals, (advanced) materials and products.
- **Both SSbD and Regulatory Preparedness** concepts are supported by a process to share and exchange knowledge, information and views in a **Trusted Environment.**

The SSIA aims at reducing the time gap between the emergence of technological innovations and the development of suitable risk assessment tools and frameworks



Find more Information on SSIA on the OECD website:

Benefits of SSIA for regulators include:

- Development of regulations for safer and more sustainable chemicals, (advanced) materials, and products
- Better anticipation of emerging issues
- Preparedness for future regulatory challenges (Regulatory Preparedness)
- More efficient communication and collaboration with industry
- Timely actions
- Clear contributions to regional strategies on sustainable chemistry and thereby to the Sustainable Development Goals of the United Nations

What can regulators do to accelerate the implementation of SSbD?

Regulators should align and synergise between all Member States to:

- **Consider SSbD** in the development of upcoming innovation, safety and sustainability regulatory strategies
- Promote **the SSbD framework** in national research and innovation programmes
- Promote **the availability** of findable, accessible, interoperable, reusable **(FAIR) data** for safe and sustainable by design assessment
- Support the **improvement of assessment methods, models and tools**
- **Develop more flexible and adaptable legislation** to capture new concerns or needs in a timely manner
- **Ensure competitiveness of European companies:**
  - **Support the development of SSbD labels or certification** to incentivize industry for applying SSbD.

IRISS SSbD Community:

Visit the website www.iriss-ssbd.eu

In January 2025, the IRISS SSbD Community has launched a policy hub on their digital platform to inform about recent policy developments and facilitate a science-policy-industry dialogue

Join the Community to get access!

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Safe &
Sustainable
by Design
FOR REGULATORS