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Safe-and-sustainable-by-design: State of the art approaches and lessons learned from value chain perspectives

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Abstract

Safe-and-sustainable-by-design (SSbD) is central in the European Chemicals Strategy for Sustainability, yet a common understanding of what SSbD is in concept and in practice is still needed. A comparison of current SSbD descriptions and approaches was made and lessons learned were derived from value chain discussions (packaging, textile, construction, automotive, energy materials, electronics, and fragrances value chains) to help provide input on how to implement SSbD in practice. Five important building blocks were identified: design, data, risk and sustainability governance, competencies, and social and corporate strategic needs. Other lessons learned include the identification of the biggest safety and sustainability challenges in a lifecycle-thinking approach towards the development of purpose-driven innovations, and connecting trans-disciplinary experts to the innovation process, already from the early phases. A clear understanding of what SSbD is and how to implement the SSbD framework is needed with clear procedures and incentives to support the industrial sector, especially SMEs.

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Keywords

SSbD concept, By-design, Value chain perspective, Lifecycle, Safety and sustainability, Innovation process.

Introduction

Recent policy developments such as the European Green Deal [1], the European Chemicals Strategy for Sustainability (EC-CSS) [2] and the Zero Pollution Action Plan [3] aim to support the transition towards climate neutrality and a toxic-free environment. To achieve this transition, making chemicals, materials, products, and processes safer and more sustainable by design is fundamental and both a societal urgency and a great economic opportunity for the European manufacturing industry to regain competitiveness [2].

Safe-and-Sustainable-by-Design (SSbD) focuses early in the supply chain on providing final chemicals, materials and products that fit into circular economy models while avoiding harmful properties and negative impacts on human health and the environment. It integrates the desired functionality with circularity, climate neutrality, and safety of chemicals, materials and products throughout their entire lifecycle, while at the same time promoting social responsibility and ensuring economic growth and innovation. SSbD is a central component in the EC-CSS where it is 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 minimizing the environmental footprint of chemicals in particular on climate change, resource use, ecosystems and biodiversity from a lifecycle perspective*" [2]. Although in the EC-CSS, the SSbD concept is primarily applied to chemicals, it can be extended to include materials, products/services, and processes as well.

In 2022, the Joint Research Center (JRC) of the European Commission (EC) published a SSbD framework on the definition and evaluation procedure of chemicals and materials [4] along with an EC recommendation [5] promoting this framework. The SSbD framework aims to support the design and development of safe and sustainable chemicals and materials with research and innovation (R&I) activities [4] and recommends a two-phase approach: A (re)-design phase in which eight design guiding principles are proposed to support the design of chemicals and materials and a safety and sustainability assessment phase to address chemical safety, direct toxicological/ecotoxicological impact, and aspects of environmental, social and economic sustainability in a step-wise hierarchical approach. In the assessment phase, five steps are provided for defining criteria for SSbD chemicals and materials. The first step is based on the intrinsic hazards (based on the hazard classes in the Classification, Labelling and Packaging (CLP) Regulation) which comprehensively cover the physical, health and environmental hazards. The second and third steps are based on risk considerations towards occupational safety and health aspects, as well as health and environmental impacts from the use phase based on hazard classification in accordance with the CLP Regulation and risk estimations. The fourth step is an assessment of environmental sustainability based on the impact categories that constitute the Product Environmental Footprint; this is supported by the Sustainable Product Initiative (SPI) and the Ecodesign for Sustainable Products Regulation (ESPR) [6–8]. The fifth step covers socio-economic aspects and must be seen as an exploratory phase due to limited methodological maturity but are foreseen to being supported by the Corporate Sustainability Reporting Directive (CSRD).

Also other institutions, such as the European Environment Agency (EEA) [9], the Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) Safe and Sustainable Innovations Approach (SSIA) Steering Group (SG) [10], the European Chemical Industry Council Cefic [11,12] and the non-government organisation (NGO) International Chemical Secretariat (ChemSec) [13] have published their views and recommendations on how to operationalise SSbD.

Research context and aim of this study

SSbD is a prominent part of the EC-CSS but there is limited literature on it to date because it is a relatively new concept. Previous EC work on SSbD has identified several needs in bringing SSbD to practical applicability [14]. These include: an agreed terminology, a common understanding of the principles of SSbD, criteria, assessment tools and incentives to achieve a transition from Safe-by-Design (SbD) to SSbD, and preparedness of regulators and legislation for innovative chemicals and nanomaterials [14]. Other major challenges include accounting for all the possible safety and sustainability impacts along the lifecycle and designing out these risks whilst preserving the functionality [15–17]. A common understanding of SSbD is fundamental for the development and successful implementation of SSbD itself as well as related specific guidelines and all communication activities in this field.

The first aim of this study is to align the different state of the art SSbD perspectives to move closer towards a common understanding of SSbD. The second aim is to align these perspectives with the SSbD views and practical insights from different value chains on what is needed to apply SSbD in practice. Finally, recommendations are given from the authors' view on the state-of-the-art and the needs for future SSbD activities based on the literature review and value chain discussions.

Methodology

A literature review using the key words 'Safe-and-Sustainable-by-Design' and 'SSbD', was performed for the identification of approaches, working descriptions and definitions for SSbD from policy, industrial and non-governmental organisations (NGOs) with extra focus on the applicability of SSbD in practice by industry. To identify further relevant literature on already established concepts from the fields of nanosafety and chemistry, the literature review was then extended and included the keywords 'safe-by-design', 'sustainable chemistry', and 'design for X approaches'. Although these literature articles are not focused on SSbD, they can provide ideas on how to successfully implement safety and sustainability aspects in industrial processes that could be transferred to SSbD. Literature sources were open databases: policy documents and papers as well as public reports. Some selected reports were also received via our extensive network.

The identified policy, industrial and NGO SSbD approaches were outlined in detail and then analysed with respect to a wide number of key aspects, including scope (chemicals, materials, products), framework structure, implementation model, starting point of the innovation process, design levels and principles, assessment dimensions, scoring/evaluation system, and trade-offs. Special focus was given to the specific safety and sustainability (environmental, social and economic) parameters and recommended tools. By analysing and combining all these elements from each perspective, commonalities and contradictions in the understanding and operationalisation of SSbD were identified, which is the first step towards a common understanding of SSbD.

Second, the different SSbD approaches were complemented by value chain perspectives on how to bring SSbD closer to practice, which were obtained during several IRISS[1] workshops in 2022 and 2023. The following value chains and representatives were interviewed: Packaging (IPC; Industrial Technical Centre for Plastics and Composites); Textiles (ETP; EU Technology Platform for the Future of Textiles & Clothing); Construction (EFCC; European Federation for Construction Chemicals); Automotive (CLEPA; European Association of Automotive Suppliers); Energy materials (EMIRI; Energy Materials Industrial Research Initiative); Electronics (INL; International Iberian Nanotechnology Laboratory); and Fragrances (IFRA, International Fragrance Association). To ensure comparability, all value chain representatives were interviewed following the same thematic procedure. Additional feedback from the value chains was obtained in a workshop held online on 25 November 2022 where 417 registrants attended. The responses were then translated to a systems approach and aligned to the main literature findings from studies applying SSbD in practice.

Finally, all the results were consolidated into recommendations for bringing SSbD closer to practical applicability.

Results

Identified SSbD approaches

Five approaches on how to operationalise SSbD were identified in the literature review, covering policy, regulatory, industry and NGO perspectives (JRC [4], EEA [9], OECD WPMN [10], Cefic [11,12] and ChemSec [13]). A detailed description of these approaches is included in the Supplementary Material 'Description of SSbD Approaches'. In addition, several SSbD-relevant articles were found for supporting the applicability of SSbD in practice by industry (Supplemental Table S1: Literature Review). There were several publications on safe-by-design in nanotechnology, sustainable-by-design, sustainable chemistry, design for X approaches, and a few on SSbD in nanotechnology/advanced materials and chemicals that are also useful in the context of SSbD. It is important to note that the five selected approaches use many of these SSbD-relevant articles as a basis to identify the safety and sustainability aspects and tools and how to put them to practice.

Comparison of policy, industrial, and NGO SSbD approaches

An overview showing the key elements of SSbD in all approaches is presented in Table 1. More detailed tables listing all compared aspects can be found in the Supplemental material (Table S2: Comparison of different SSbD approaches; Table S3: Safety and Sustainability Aspects; Table S4: Safety and Sustainability Tools). Up to date, the SSbD framework for the definition of criteria and evaluation procedure for chemicals and materials by the EC JRC [4] is by far the most detailed and comprehensive framework to bring SSbD into practice. The other approaches are more conceptual ones or working descriptions.

Scope

It must be noted that all SSbD approaches shown in Table 1 focus on chemical solutions to achieve a desired functionality. Non-chemical alternatives or the shift to service-oriented business models are not part of the analysed approaches.

The scope of the analysed SSbD approaches differs. While the broadest scopes cover chemicals, materials, products, services, and processes [10,12], the JRC framework [4] limits its scope to chemicals, materials, and associated processes. While these chemicals and materials are used *in* products, the products themselves are not covered as further assessment dimensions would be required [4].

All published SSbD perspectives agree that the highest impact of the SSbD concept can be achieved through a pre-market approach. JRC and Cefic also include existing chemicals, materials, products, and processes in their approaches as also "minor changes" like reformulations or production process optimisations, move the entire enterprise portfolio towards more safe and sustainable solutions [4,12]. Furthermore, this opens the gate to the creation of new and more

[1] http://IRISS.(iriss-ssbd.eu)).

Table 1

Bringing the SSbD key elements together from a policy/regulatory perspective (EC Joint Research Centre, JRC; European Environment Agency, EEA; Organisation for Economic Co-operation and Development (OECD) Working Party on Manufactured Nanomaterials (WPMN) Safe Innovations Approach (SIA) Steering Group), from an industrial perspective (European Chemical Industry Council, Cefic) and from an NGO perspective (International Chemical Secretariat, ChemSec).

Building Block	Policy/Regulatory Perspective			Industry Perspective	NGO Perspective
	JRC [4]	EEA [9]	OECD WPMN [10]	Cefic [12]	ChemSec [13]
Link to the innovation process?	A pre-market approach to chemicals and materials design	Design approach in product's pre-market design phase	Early phase of the innovation process	Iterative process guiding innovation and the placement on the market of chemicals, materials, products, processes and services	No
Safety?	Focuses on providing a function (or service), while avoiding volumes and chemical and material 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.	Minimising the use of hazardous chemicals	Identifying and minimising, at an early phase of the innovation process, the impacts concerning safety for humans and the environment	As an iterative process guiding innovation and the placement on the market of chemicals, materials, products, processes and services that are safe, and deliver environmental, societal, and/or economical value through their applications.	Phasing out hazardous chemicals
Sustainability?	Sustainability should be ensured by minimising the environmental footprint of chemicals and materials in particular in relation to climate change, resource use, and protecting ecosystems and biodiversity, adopting a lifecycle perspective"	Reducing greenhouse gas emissions	Minimising the environmental footprint, in particular regarding climate change and resource use and, protecting ecosystems and biodiversity, taking a lifecycle perspective.	Those chemicals, materials, products and technologies enable accelerating the transition towards a circular economy and climate-neutral society and preventing harm to human health and the environment throughout the lifecycle.	Step-wise approach starting with CO_2 emissions, and then gradually including water use, waste in production, impact on ecosystems and basic social dimensions
Circularity?	Ensuring sustainable circularity (aligned with Circular Economy Action Plan [18], Climate neutrality [19], Zero Pollution Action Plan [3], Farm to Fork Strategy [20], Bioeconomy Strategy [21])	Fostering the reuse and recycling of materials in a circular economy are built into product design	Material/chemical/product supports the waste hierarchy and circular economy	Improved circularity potential of products (Biodegradability or compatibility of products; waste prevention in the production and use phase; support of recycling opportunities in the value chain; use of recycled materials & feedstock; Recyclability, durability, repairability of the product)	Indirectly addressed (phasing out hazardous chemicals enables a circular economy)

sustainable business models within the companies and thus permitting them to get access to new market sectors, customers and/or partnerships with other companies within and outside their value chain.

Assessment dimensions

Safety and environmental sustainability dimensions are covered in all analysed SSbD approaches, while all three sustainability pillars (environmental (incl. circularity aspects), social, and economic) are only covered by JRC [4], OECD [10] and Cefic [12]. It has to be noted that the number of proposed dimensions differs and not all approaches recommend specific parameters and/or indicators for the assessment of the dimensions as they are more conceptional ones. Cefic [12] divides the recommended safety and sustainability dimensions into two minimum requirements (that have to be fulfilled), seven focus dimensions (that are needed to fulfil the European Green Deal Goals) and additional dimensions. The latter are chosen based on the intended product-application-combination. Cefic further includes *corporate requirements* and *stakeholder expectations* as additional dimensions.

Safety assessment: As the first step in the safety assessment, both JRC [4] and EEA [9] consider the human and environmental health hazards based on the intrinsic properties of the chemical or material. The intended use and the expected exposure are considered in the consecutive steps. The proposed approach from Cefic [12] is focused on risk management, taking the intended use and potential exposure into account right from the start. ChemSec [13] does not propose a certain assessment scheme, but the whole SSbD approach is hazard-based and aims to phase out hazardous chemicals. Comparing the recommended assessment parameters for human health and environmental hazards shows high commonalities between JRC [4], Cefic [12], and ChemSec [13]. This is no surprise, as safety assessments of intrinsic chemical/material properties have a high maturity level, e.g., due to the EU chemicals safety regulation REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) [22] that requires detailed information on the intrinsic properties of chemicals to enter the European market. The JRC framework [4] further includes twelve parameters to assess intrinsic physical hazards (e.g., explosives or flammable gases, liquids, and solids). Cefic [12] also includes issues arising from recycling conditions based on specific substances, that are not considered in any of the other approaches. As further safety dimensions, the JRC framework [4] covers occupational safety and health (OSH) aspects and human and environmental aspects in the application. Cefic [12] proposes exposure limitation measures covering the whole life cycle. Besides OSH aspects, further parameters are proposed by Cefic [12], like quality safety, and health (QSH), physical hazards, emission control and potential leakage are included. QSH is a critical part of any organisation as the management is responsible to ensure that employees have a safe and healthy work environment.

Sustainability assessment: For the environmental assessment, most SSbD approaches recommend using the life cycle assessment (LCA) based Product Environmental Footprint (PEF) method that assesses all aspects considered in the EC-CSS [2], which are *ecosystem & biodiversity*, *pollution*, *resources*, *climate change* and *toxicity*. The PEF is only seen as a temporary solution until a SSbD-specific guideline is available [4]. As *biodiversity loss* is only indirectly assessed in the PEF, the JRC framework [4] suggests adding it as a further parameter to be defined along with *ecotoxicology for terrestrial, marine, soil, and sediment organisms* so as not to restrict to only freshwater organisms in the assessment. In general, social and economic aspects show a low level of implementation and methodological maturity [4]. Social aspects are included in the SSbD approaches by JRC [4], OECD [10] and Cefic [12]. While all three also cover the economic dimension, Cefic [12] is the only one to propose economic parameters for the assessment. Due to this low maturity level, the JRC sees the social and economic assessment step in an exploratory phase [4].

Trade-offs

How to deal with trade-offs is an important question for the successful implementation of SSbD. In the proposed SSbD approaches, this question is only rudimentary covered or not covered at all. The hierarchical approach to the assessment dimensions recommended in the JRC framework [4] helps to avoid trade-offs on specific safety aspects due to pre-defined cut-off criteria. Cefic [12] includes a guidance on trade-off in Step 5 of the proposed workflow, but the specifics are pending.

Value chain-specific recommendations aligned to literature findings

The responses collected from the value chains on how to bring SSbD closer to practice before and after their translation into a systems approach are summarised in Supplemental Table S5 (value chain-specific recommendations) and Table 2, respectively. The input of the value chains and from the literature could be divided into five main building blocks: design, data, risk and sustainability governance, competencies and social and corporate strategy needs. There were several points that resonated with all value chains. First, there was the need for coherence with the existing legislations, especially for end-of-life and developing closed loops given that often there are restrictions in waste legislation.

From a design perspective, all value chains agreed on the importance of integrating safety and sustainability considerations as early as possible in the innovation process

Table 2

Value chain-specific recommendation on how to bring SSbD closer to practice in a systems approach and aligned with literature findings from studies applying SSbD in practice (P, packaging; T, textiles; C, construction; A, automotive; En, energy; El, electronics; F, fragrances; italics represents additional information from literature).

Building Block	System Approach		
	Content (what is needed to apply SSbD?, data, knowledge)	Processes needed to apply SSbD (how?)	Organisational infrastructure (who?)
Design	Change of mindset with regard to functionality: Distinguish between vital vs. nice-to-have product performance properties (personal protection vs. fashion effect) & consumer vs. Professional products/ applications[a] (T)	Process to create SSbD awareness and compliance can be most effectively addressed in the design phase (El)	Knowledge-sharing platform to foster early dialogue between innovators and regulators (regulatory preparedness) for efficient risk and sustainability governance [23,29].
	By-design needs enablers: methodologies, digital tools, data (safety and sustainability data are often missing at the start of the innovation process) (En)		
Data	Material knowledge along the value chain needs to be improved. Producers need to work preferentially with local material producers for better data transparency (P).	Incentives to support the development of digital tools for supply chain management and more efficient end of life handling (A)	Expert platform to facilitate the access to safety and sustainability data to companies (especially SMEs) (P)
	Availability and accessibility of safety and sustainability data (C)	Exploitation of AI and robotics to improve SSbD fabrication processes (without losing performance) as well as in recycling and recovery operations (El)	
	Toolbox and Incentives: A wide deployment (especially in SMEs) needs a workable toolbox aligned with industry practices and (positive) incentives (En)	Process to share safe and sustainable practices among the different companies (El)	
Risk and sustainability governance	SSbD certification available on material safety datasheets (P)	SSbD should be based on existing chemical/material/ processes safety and sustainability legislation to simplify and support regulatory processes (T, En)	All stakeholders in the value chain (all)
	Well defined and acceptable limits for safety and sustainability criteria (A); Process of deriving acceptable limits for safety and sustainability criteria should be informed by lifecycle information from the entire value chain (A); Relevant safety factors and risk assessments (including exposure) (F); Relevant sustainability factors, not restricted to circularity and durability (F)	Process to deal with complex value chains increase burden on Lifecycle Assessments and dealing with complex (compliant) data exchange (F) Process for developing solutions in co-creation for data-sharing along complex value chain (F)	
	Treat imported materials/products in the same way and expect the same standards as EU-made ones (T)		
	Harmonised approach for certification (P)		
	Process to facilitate access to experts who can evaluate and validate SSbD materials, products and processes (P)		
	Make SSbD practically manageable for SME designers, product developers and manufacturers (T)		
	Lifecycle thinking approach including discussion on trade-offs between all safety and sustainability dimensions (En)		
	Test methods to assess the hazard of the new hazard classes in the EC CSS (endocrine disruption; persistent, mobile and toxic (PMT) properties and persistent, bioaccumulative and toxic (PBT) properties) without additional animal testing (F)		
	Strategies to reduce carbon footprint including via biogenic carbon, mass balance with renewable raw material, and process innovation (F)		

Table 2 (*continued*)

Building Block	System Approach		
	Content (what is needed to apply SSbD?, data, knowledge)	Processes needed to apply SSbD (how?)	Organisational infrastructure (who?)
Competencies	A common curriculum for education and training including standardised, structured and harmonised syllabus in SSbD and dedicated university curricula packages (All)	Training along the value chain to apply SSbD (P, T)	Dedicated training to all relevant stakeholders including but not limited to raw material suppliers, academia, scientists, engineers, designers, toxicologists, sustainability experts (environmental, social and economic), recyclers, industry, Non-Governmental Organisations (NGO's), Research and Technology Organisations (RTO's), policymakers, regulators, funding agencies, investors, consumers and brand owners (All)
		Process to facilitate increased dialogue along the value chain and across sectors to raise awareness on parallel challenges and best-practices on design for safety and sustainability (A)	Capacity building among small-to-medium enterprises (T)
		Develop accessible, easy-to-use management tools, platforms, tutorials and trainings (T)	
Social and Corporate Strategic Needs	Urgency for SSbD-supportive business models and regenerative leadership [55–57]	Processes to bring SSbD-supportive business models to practice (All)	Innovation managers, company management (All)

[a] PFAS, a very toxic and persistent chemical, is used in gear used to climb high mountains. Either a water-repellent jacket that contains PFAS but is capable to summit the world's tallest peaks with, or a water-repellent jacket that does not contain toxic chemicals and performs just fine in normal rainy conditions (Are you climbing Mount Everest, or just going to work? – ChemSec).

for safe and sustainable chemicals, materials, products and processes. Safety and sustainability assessments alone are not SSbD, design modifications are needed to ensure chemicals, materials, products and processes are safe and sustainable by design. For instance, having recyclers share their challenges with material scientists to ensure novel materials and chemicals have closed loops.

From a data perspective, all value chains shared the challenge of lack of safety and sustainability data at the early stages of the innovation process. There was also a need for improvement of safety and sustainability data accessibility along the value chain with the assurance of reliability, traceability and transparency of SSbD-related data and information along the value chain is very complex and digital methods such as Artificial Intelligence (AI) are needed to simplify the complexity. Other issues mentioned were the extra burden (cost and time) of safety and sustainability data generation. It was mentioned by several value chains that AI and robotics were being explored to improve fabrication processes (without losing performance) as well as in recycling and recovery operations.

From a competencies perspective, there is a need to develop harmonised SSbD training for all stakeholders in the value chain. In addition, accessible, easy-to-use management tools, platforms, tutorials, and trainings are needed. A common curriculum for education and training including standardised, structured and harmonised syllabus in SSbD and dedicated university curricula packages.

From a risk and sustainability governance perspective, harmonised safety and sustainability assessment methodologies are needed. A lifecycle thinking approach is needed including discussion on trade-offs between all safety and sustainability dimensions and mapping safety and sustainability needs along the innovation process.

From a social and corporate strategic needs' perspective, there is an urgency for the development of SSbD, circular and regenerative business models.

Discussion: General challenges

Linking design to the innovation process

The integration of safety and sustainability into the different stages of the innovation process is crucial for the operationalisation of SSbD [23]. The innovation process can be conceptually and operationally described from idea-to-launch and beyond, using the Cooper's Stage Gate model [24,25]. Although many perspectives (i.e., JRC, Cefic, OECD) identified material, process and product design as the key phase, what is missing is the detailed mapping of how the safety and sustainability assessment is done throughout the innovation process for stimulating the 'by-design' aspect of SSbD. Moreover, to really achieve the link between SSbD approach implementation into an innovation process it needs to be understood that innovation itself needs to move from its more traditional techno-centric mainstream, focused on economic value (i.e., as it has been during the 20th century) towards what has evolved over the last two decades due to the acceleration of global crisis and growing popularity of systems approaches to socioeconomic issues (i.e., to shape traditional innovation towards a more recent term that is sustainable innovation). Sustainable innovation has been defined as "*a new service, product, process, or practice, arising from collaboration among different actors, that contributes to operate a socio-ecological, interdisciplinary, structural and systemic transformation aimed at making society compatible with planetary limits and ensuring human well-being and societal resilience*" [26]. Thus, sustainable innovation appears to be a type of innovation that can contribute to responding simultaneously to the three dimensions of sustainable development.

Sustainable innovation in combination with responsible research in innovation [27,28] and Safe and Sustainable Innovation Approach (SSIA) [23,29] promote an interdisciplinary dialogue and is therefore an all-encompassing concept that can be mobilised by various fields of research and actions related to sustainability as well as several complementary ways of applying sustainable innovation. Circular economy (i.e., a systemic approach aiming at a more sustainable mobilisation of resources through a looping of material and energy flows within the production and consumption patterns) [30], regenerative design (i.e., set of technologies, practices, and strategies that enable the regeneration of socio-ecological systems) [31,32], and transformative social innovation that aims to radically reconfigure social systems towards increased sustainability by proposing new solutions and combinations of ways of doing, organising, learning, and designing, offering alternatives to current services [33], are a few examples that illustrate the transdisciplinary of sustainable innovation, which allows it to bridge different fields of application while generating a transformative synergy.

Sustainable innovation, in combination with responsible research in innovation are cross-cutting concepts with the potential to act as a powerful lever to accelerate a shift towards fairer and more eco-responsible modes of production and consumptions, as well as more resilient societies. Thus, only an evolved 'sustainable' and 'responsible' innovation process will be able to adopt and align to the implementation of SSbD and SSIA and both concepts enrich each other as well as help to implement each other optimally.

In order to deal with gaps and uncertainties early in the innovation process, several tips from literature can be very supportive: start with the big picture, the need for multidisciplinary experts along the value chain and with this multidisciplinary group, be practical and use common sense and expertise of the team.

Start with keeping the Big Picture in mind and shift towards purpose-driven innovation: lessons learned from a lifecycle thinking-based SSbD approach for battery technologies showed an approach to integrate the functional performance and sustainability (safety, social, environmental and economic) aspects throughout the lifecycle of materials, products and processes. In this study, different types of batteries (liquid & polymer gel, solid state, redox-flow and hybrid) were analysed for criticality, toxicity/safety, environmental and social impact, circularity, functionality and cost. This analysis showed that the big picture (lifecycle thinking) was crucial to ensure battery innovation was green and sustainable and to avoid unintended consequences [39]. Therefore, keeping the big picture in mind and identifying the biggest safety and sustainability challenges and possible gains in the lifecycle will aid in the shift towards purpose-driven innovations. Another example is the analysis of the environmental and socio-economic hotspots along the entire textile value chain, and identification of associated impacts and the different stages in the value chain where these impacts were more dominant [40]. Similar reports are available for packaging [41–44], energy [45], automotive [46,47], electronics [48], construction [49] and fragrances [50].

People, Multidisciplinary experts along the full lifecycle: In their SSbD briefing, the EEA [9] recommends a multidisciplinary design team comprising product designers, material engineers, chemists, toxicologists and sustainability experts, to consider the functionalities that a product delivers in terms of the service, safety and sustainability. This multidisciplinary design team along the value chain is the success of developing SSbD strategies in the European projects such as SUNSHINE[2] and SURPASS.[3]

Be practical and use common sense and expertise of team: Using common sense sustainability early in the innovation process can support the applicability of SSbD. Considering for instance the presence of critical materials, the use of energy, water, and solvent throughout the entire lifecycle and understanding the waste infrastructure for applying a circular economy. As with the previous point, the multidisciplinary design team along the value chain develops SSbD strategies on the basis of their expertise and 'common sense' early in the innovation process [[51], and within European Projects SUNSHINE[1] and SURPASS[2]].

Value chain and lifecycle perspective

One of the biggest challenges in applying SSbD is ensuring that it is applied from the design phase in the value chains and with a lifecycle perspective to enable safe and sustainable value chains. As noted by the EEA [9], current manufacturing systems are extensively interconnected and operate at a global level. Changing one part of the system therefore results in a number of knock-on effects and the successful implementation of SSbD will not be achievable without effective collaboration across the entire value chain: from raw material extraction through to waste management, reuse and recycling. Chemical production is especially highly interconnected, and changes in one process can jeopardise the production of feedstock for another. The infrastructure for extracting, producing and manufacturing raw materials is extremely costly, locking in polluting processes and creating barriers to technological change.

One of the tools which can support a value chain approach is the Extended Producer Responsibility (EPR), defined by the OECD as an environmental policy approach, in which a producer's responsibility for a product is extended to the post-consumer stage of a product's lifecycle [34]. An EPR policy is characterised by 1) the shifting of responsibility (physically and/or economically; fully or partially) upstream toward the producer and away from municipalities and 2) the provision of incentives to producers to take into account environmental considerations when designing their products [34]. As such, EPR policies shift the waste management cost or physical collection partially or fully from local governments to producers. EPR seeks to integrate signals related to the environmental characteristics of products and production processes throughout the product chain and encourage circular business models (e.g., repair, reuse, and remanufacturing) [34].

[2] https://www.h2020sunshine.eu/.

[3] https://www.surpass-project.eu/.

Less well developed and articulated within the frameworks is the Social Lifecycle Assessment (S-LCA) whose purpose is to evaluate the positive and negative impacts on communities and not just value chain actors [35]. To implement, a broad stakeholder approach is called for which addresses impact categories such as human rights, labour conditions, cultural heritage, governance and related socio-economic impacts. This focus on the social performance of the product system can allow tracking of the consequences of these S-LCA impacts similar to the Environmental Lifecycle Impact Assessments [35]. The development of a consistent view of social hotspots better directs an understanding of the intersection and interdependence of social and environmental sustainability and their alignment within a SSbD whole system.

To achieve such outcomes may require a greater democratisation of the sustainable innovation process outside of traditional narrow techno-scientific boundaries. Understandably, the protection of Intellectual Property will be crucial, and the setting up of Trusted Environments may be the answer where a culture of shared responsibility can be nurtured [36]. Social actors can comment not only on product safety, but also on the commercial applications, their social utility, and add market-laden value to the products. This engagement can lead to the development of a new social contract for the design and production of inherently safe and sustainable chemicals from inception to end of life (EoL) in pursuit of the goal for a toxic-free environment [1–3]. Thus, a sustainable value chain approach enables both business and society to better understand and address the environmental challenges associated with the lifecycle of products and services. By implementing successfully SSbD following a value chain one would expect to improve the sustainability of the value chain itself and thus creating competitive advantage for its companies in different ways: new product lines addressing market needs, improved reputation and increased brand value, better efficiency and thus lower costs as well as new business models focusing on value. By collaborating to achieve a common goal, companies can build stronger, trusted and lasting relationships with contributors along their own, as well as other value chains, including business partners, customers, consumers, nongovernmental organisations, authorities or other stakeholders.

Data

The challenges associated with data availability, reliability, and comparability for SSbD are addressed in the analysed SSbD approaches, especially in the JRC framework [4], in great detail. The lack of data is a notable issue in all value chains, both with regard to the hazard properties of chemicals and the sustainability aspects of the manufacturing processes [13]. Even for many chemicals and materials in high-volume circulation, critical information required to model environmental impacts and environmental risks is unavailable. A recent study by Wang et al. [37] substantiates the issue of data gaps for existing chemicals: from 350,000 chemicals (and mixtures) registered for production use across countries, over 110,000 do not even have a Chemical Abstracts Service (CAS) number. Significant data gaps are created due to data confidentiality practices employed by corporations to protect proprietary information and trade secrets about developments. For example, to assess the environmental impacts from a material using an LCA, the life cycle inventory (LCI) needs to be derived. To model LCI, extensive information on the production processes would be required which cannot be disclosed for commercial developments due to the risk of plagiarism. For some commercial products, LCIs are modelled but not open for review, which raises questions about the reliability of the datasets. Considering the issue that data gaps persist for many chemicals that have been on the market for years, it would be a great undertaking to obtain or model data in their design phase to apply SSbD.

Apart from the data gaps, the lack of gap-filling approaches and the comparability of existing data is also a persistent problem plaguing academia and industry. Thus, there is a need to update existing data in accordance with FAIR (findable, accessible, interoperable and reusable) data principles that allow for comparability through innovation in data science and access to data (for example, on chemicals), thus removing barriers to research while preserving intellectual property [12]. The Product Environmental Footprint (PEF) which is being developed by the EC together with the industry aims for standardised methods to be used when gathering data and, thus, encouraging data comparability. This allows companies to benchmark against each other and to create a positive movement towards more sustainable products in the long run [13].

To model relevant FAIR data, it is necessary to research and further develop quantitative methodologies, such as New Approach Methodologies (NAMs) for the prediction of toxicology, biodegradation simulation, assessment of particulates, interactions in mixtures, and future impacts estimations [12]. Such methodologies and tools would avoid animal testing and rely extensively on machine learning models to generate data for and carry out early-stage human and environmental safety, risk and sustainability assessments, thus applying the by-design approach and minimising future adverse effects when entering later stages of chemical/material/product development. It is important to distinguish these predictive tools, forming the backbone of SSbD, from the ones presently used during compliance. Aimed at pre-compliance checks and trade-off assessment during innovation, novel SSbD tools will assist in raising red flags at an early stage of chemical or material development, guiding the selections towards most promising candidates, and allowing an iterative selection of suitable materials form a large list of options. A further step would involve the compilation and harmonisation of the tools into a toolbox and its standardisation to ensure its legitimised use throughout.

Importance of digitalisation: After establishing the standardised toolbox and generating FAIR data, implementing or updating the digital strategy for the entire supply chain would be necessary. This is to ensure the traceability of SSbD chemicals and materials throughout the extended and international supply chains and support initiatives such as the Digital Product Passport proposed in the Ecodesign Sustainable Product Regulation [8]. Only after ensuring traceability of chemicals and materials would it be possible to consider the second life and overall circularity. A detailed overview of the supply chain would prevent mixing of toxic materials and chemicals at the EoL [38] and preserve the safety and sustainability profile of the recycled material in its subsequent lifecycles.

Skills, competencies, and education needs

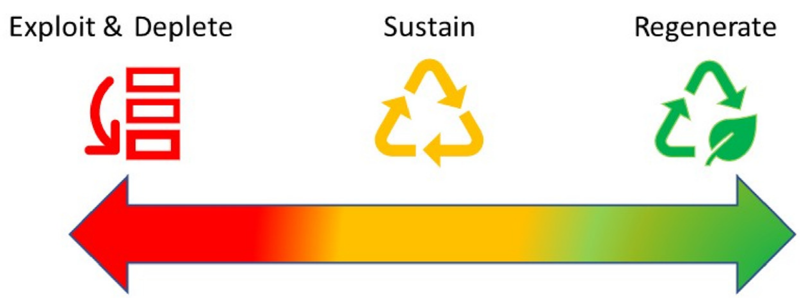
Currently, the education sector is a further source of potential inertia for SSbD as specific university curricula as well as training courses for professionals are lacking. The integration of SSbD in education is a key element to support the development and implementation of SSbD across industrial sectors [9,11] and one ‘enabling condition’ listed by the EEA [9]. Both current and future workforces need to be equipped with the necessary skill profile to incorporate safety and sustainability aspects into the product design along the whole lifecycle. This includes students of, e.g., engineering, product design, and chemistry as well as all key people in the design process, including product engineers, plant managers, chemists, sustainability experts, and decision-makers throughout the product’s supply chain [9]. To enable a life-long learning, which is an important aspect mentioned in the 1st principle of the European Pillar of Social Rights [52], diverse re- and up-skilling opportunities are required. Technical support centres [9] or the Pact for Skills [52] could support the realisation of such trainings. Additionally, societal education is needed for different stakeholders, including consumers [9,53].

Risk and sustainability governance

Harmonised safety and sustainability assessment methodologies. There are hazard-based and risk-based approaches to assess the safety of chemicals and both types are proposed by the different SSbD approaches. One important element for putting SSbD into practice is to achieve agreement on the type of assessment method and to harmonise it. One way could be to align SSbD with existing safety regulations, e.g., the EU chemicals safety regulation REACH [22], as all industrial chemicals introduced into the European market must comply with it. The data required for a successful REACH registration must include detailed information on the intrinsic properties of the chemical (Article 13 and Article 25 [22]). Additionally, the data requirement is extended also to include information on the use, exposure, and risk management of the substance. If the risk is concluded to be not controlled, the use can be restricted. Similarly, for sustainability, there is a need for harmonised approaches to support for instance the PEF.

SSbD demands more than just technical developments: SSbD demands a system approach that not only focuses on content (the what?, e.g., in terms of knowledge and data) but also on the development of processes (the how?) and the organisational infrastructure (the who?) to bring all the stakeholders together including regulators and policymakers. Within the OECD Working Party on Manufactured Nanomaterials (WPMN) SSIA Steering Group, a system approach is taken by combining SSbD with regulatory preparedness in a trusted environment. Regulatory preparedness refers to the capacity of regulators, including policymakers, to anticipate the regulatory challenges, particularly human and environmental safety and sustainability challenges. This communication and interaction help regulators to anticipate the need for new or modified regulatory tools and reduce the uncertainties for innovators and industry

Figure 1



Degeneration	Sustainability	Regeneration
Deplete, Deforest, Degrade	Reduce, Reuse, Recycle	Rethink, Restore, Replenish
Net negative	Net zero	Net positive
Shareholder centric	Partner centric	Stakeholder centric
Short term	Mid term	Long term
Business as usual green	Less harm	Restorative, regenerative
Growth at al costs	Do more with less	Do better with less
Competitive	Collaborative	Interdependent
Parts, silos	Counterparts	System, Value chain
Data hoarding	Data fragmentation	Distributed data
Laws & regulations	ESG/CSR	Beyond SDGs
Growth	Prosperity	Thrive
Organizations as a machine	Organizations as a family	Organizations as a living system (Ecosystem)
Human-centric	Human-Planet centric	Planet centric

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Illustration of traits of business models that Exploit & Deplete, Sustain, and Regenerate (Adapted from Ref. [55]). ESG, Environmental, social and corporate governance; CSR, Corporate Social Responsibility.

associated with the future development of the safety and sustainability legislation and regulations applicable to emerging technologies [23,29].

People: think of connecting all actors in the value chain and in the lifecycle together to create value chain ecosystems: The approach used in the IRISS initiative is to map the stakeholders in the value chains along with mapping the biggest safety and sustainability challenges in a lifecycle thinking approach to ensure that SSbD strategies are optimised towards maximum safety and sustainability impact. Another example is the Dutch chain approach on pharmaceutical residues in sewage water where stakeholders from both the health and water sectors were actively involved to find a solution in co-creation [54].

Social and corporate strategic needs: SSbD-supportive business models and regenerative leadership

There is an urgency for the development of SSbD-supportive business models and regenerative leadership [55–57], aiming not just for net zero sustainability, but for net positive sustainability. Regenerative leadership is stakeholder-centric, prepares for the long-term, goes beyond the Sustainability Development Goals (SDGs), aims to thrive, sees the organisation as a living system, is planet-centric and its values are to rethink, restore and replenish, instead of the traditional reduce, reuse, recycle. SSbD-supportive business models need to be developed along with a new leadership paradigm driven by new leadership practices, new business models, and new ways of collaborating and creating value [55]. This new leadership approach is holistic and has a lifecycle thinking view aiming to restore, preserve and enhance people, society, and environment. It is a purposeful and empathic leadership that focuses on fostering partnerships between people and nature [55]. Figure 1 compares the different types of business model traits including those that exploit and deplete, sustain, and regenerate. SSbD demands business models that sustain and regenerate. Therefore, a 'regenerative business' enriches all stakeholders including wider society and the environment including culture, operations, strategy and ecosystem. 'Regenerative leadership' is a way of leading that cultivates life-affirming conditions [56]. The approaches taken by leaders in this emerging field of regenerative leadership are effective ways to integrate the science-based principles of social sustainability into work teams [57].

Conclusions and recommendations

SSbD is a design approach that integrates the desired functionality with safety and sustainability considerations in the innovation process of chemicals, materials, products, and processes while avoiding harmful impacts on people, climate and the environment from a lifecycle perspective. While there are many perspectives on SSbD, a common understanding is still missing, and its implementation currently faces many challenges. This study contributed to finding a common understanding by comparing different SSbD approaches and by aligning these with value chain views and inputs. In the author's view, the following recommendations to bring SSbD closer to practical applicability could be derived from this study.

In terms of design, there is an urgent need for establishing criteria and guiding principles for SSbD driven by the application of life cycle thinking in chemicals, materials and product design. For SSbD, it is essential to integrate functionality, circularity, climate neutrality, and safety of chemicals, materials, products, and processes throughout their entire lifecycle in an iterative way, while at the same time promoting social responsibility and ensuring economic growth and innovation. Communications channels along and across value chain and an information-sharing ecosystem is needed to share and discuss challenges on safety and sustainability issues of chemicals, materials, products and processes. Industry-driven knowledge-sharing hubs might connect the value chain and provide a value chain-specific SSbD ecosystem that is supportive for the uptake and utilisation of SSbD strategies by industry, especially small and medium-sized enterprises. There is a need for an EU-led SSbD international network of experts to share their knowledge and expertise to support industry in the operationalisation of SSbD in practice. The Digital Product Passport under development under the EU Ecodesign Sustainable Product Regulation [8] might also be one way to accelerate the traceability issue. It is also important to start with the big picture in mind, be practical and use common sense and the expertise of multidisciplinary design teams. The corporate strategy of industry should allow for dialogue between R&D and regulatory and sustainability affairs to drive towards safe and sustainable innovations.

In terms of data, the development of ontologies for safety and sustainability data is needed to ensure the data is FAIR and maximise data valorisation for machine learning analysis. Given the many data gaps in chemical safety and sustainability assessment, it is essential to obtain or generate data (e.g., through modelling) in the design phase. Funding agencies should demand dissemination using FAIR data. Industry R&D should also include FAIR data as a good practice. The research community can support the development of SSbD tools which will assist in identification of red flags at an early stage of chemical, material or product development, guiding the selections towards most safe and sustainable candidate. A further step would be the compilation and harmonisation of the tools into a toolbox and its standardisation to ensure its legitimised use throughout.

In terms of risk and sustainability governance, harmonised and validated safety and sustainability assessment methodologies are needed, as well as integrative tools combining LCA approaches and risk assessment for analysis early in the innovation process and throughout. This lifecycle thinking approach is urgently needed in order to minimise safety and sustainability impacts and avoid unintended consequences. Incentives such as certification schemes and SSbD label should be created to support marketing and consumer choice.

In terms of skills, competencies, and educations, SSbD aspects need to be integrated into vocational training and university programmes to equip future SSbD actors with the necessary skill profile to apply SSbD in practice. Just as important are training courses for professionals, that need to be open to everyone (e.g., free-of-charge online courses or training schools). An SSbD directory compiling all SSbD courses and events could support the visibility and accessibility of such education offers. As consumer acceptance was identified as an important aspect to accelerate the transition to SSbD, societal education and awareness raising are equally important aspects (e.g., consumer education through product marketing).

In terms of social and corporate strategic needs, SSbD-supportive business models and regenerative leadership are needed to embed SSbD thinking in business strategies for the development of safe, sustainable, and circular chemicals, materials, products, and processes. This could be through the support and facilitation of safety and sustainability assessment during R&D, or by looking at services as a business model. CEOs and innovation managers need to embrace SSbD in their daily corporate activities and enable the company culture to become supportive of SSbD and therefore, driving the industry towards a more sustainable future.

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Data availability

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.cogsc.2023.100876.

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* of special interest
* * of outstanding interest

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The zero pollution action plan sets a vision for 2050 for air, water and soil pollution to be reduced to levels no longer considered harmful to health and natural ecosystems, that respect the boundaries with which our planet can cope, thereby creating a toxic-free environment.

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The 'safe and sustainable by design' (SSbD framework) is a voluntary approach to guide the innovation process for chemicals and materials. It aims to steer the innovation process towards the green and sustainable industrial transition, substitute or 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.

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The Recommendation is addressed to EU countries, industry, research and technology organisations (RTOs) and academia with each stakeholder group giving feedback on different actions including using the framework when developing chemicals and materials, making available FAIR data for safe and sustainable by design assessment, supporting the improvement of assessment methods, models and tools, and supporting the development of professional training and educational curricula on skills related to safety and sustainability of chemicals and materials.

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This article discusses regenerative business and regenerative leadership to support all aspects of sustainability. Regenerative means to renew, replenish, heal, and revitalise. In practice, 'regenerative' means to understand and work with the living-system dynamics of the organisation and its wider ecosystem; to work in ways that allow the business to become life-affirming. Three levels of learning from living-systems are highlighted: 1) Living Systems Design (analogous to SSbD); 2) Living Systems Culture (a shift in organisational culture from organisation-as-machine to organisation-as-living-system); and 3) Living Systems Being (leaders that are more systemic, empathic, integrated and balanced).

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