

REVIEW

Open Access



The European Commission's safe and sustainable by design framework: bridging innovation and legislation

Kathrin Schwirn^{1*}, Doris Völker¹, Magnus Løfstedt², Peter Fantke^{3,4}, Cecilia Bossa⁵, Anežka Sharma⁶, Leo Posthuma^{7,8} , Achilleas Karakoltzidis^{9,10}, Fotini Nikiforou^{9,10}, Alicja Mikołajczyk^{11,13}, Jaco Westra⁷, Spyros Karakitsios^{9,14}, Dimosthenis Sarigiannis^{9,14,15} and Irantzu Garmendia Aguirre¹²

Abstract

The European Commission's Safe and Sustainable by Design (EC SSbD) Framework aims to put together safety and sustainability considerations throughout the entire chemical and material innovation processes. Being a voluntary (pre-market) approach, the framework fosters the development of safe and sustainable chemicals, materials, processes, and products while drawing on existing legal frameworks. We explore the relationship between the EC SSbD Framework and current European legislation regarding safety and sustainability. We highlight commonalities and differences to deduce synergies, and identify opportunities for mutual support and benefit. By systematically evaluating each step of assessing safety and sustainability criteria, indicators, and elements in the EC SSbD Framework, we demonstrate how information generated during the innovation process can also support legal compliance while driving pro-active design improvements. Vice versa, we investigate how regulatory data and methodologies can inform SSbD assessment steps, ensuring a reciprocal flow of information between innovation and compliance efforts. Despite notable differences identified, our findings demonstrate that the voluntary EC SSbD Framework has an added value, and it fosters synergies between innovation of chemicals and materials and safety and sustainability provisions of relevant legislation.

Keywords Safe and Sustainable by Design, Chemicals management, Legal framework, Sustainability assessment, Risk assessment, Life cycle assessment

*Correspondence:

Kathrin Schwirn
kathrin.schwirn@uba.de

¹ German Environment Agency (Umweltbundesamt), Wörlitzer Platz 1, 06844 Dessau-Roßlau, Germany

² European Environment Agency (EEA), Kongens Nytorv 6, 1050 Copenhagen K, Denmark

³ substitute ApS, Graaspurvevej 55, 2400 Copenhagen, Denmark

⁴ Department for Evolutionary Ecology and Environmental Toxicology, Goethe University, 60438 Frankfurt Am Main, Germany

⁵ Environment and Health Department, Istituto Superiore Di Sanità, 00161 Rome, Italy

⁶ Research Centre for Toxic Compounds in the Environment (RECETOX), Faculty of Science, Masaryk University, 62500 Brno, Czech Republic

⁷ Dutch National Institute for Public Health and the Environment (RIVM), P.O. Box 1, 3720, BA, Bilthoven, the Netherlands

⁸ Department of Environmental Science, Radboud University, Nijmegen, the Netherlands

⁹ Department of Chemical Engineering, Environmental Engineering Laboratory, Aristotle University of Thessaloniki, University Campus, 541 24 Thessaloniki, Greece

¹⁰ Present Address: Center for Interdisciplinary Research and Innovation, HERACLES Research Center On the Exposome and Health, Balkan Center, Bldg. B, 10th km Thessaloniki–Thermi Road, 57001 Thessaloniki, Greece

¹¹ Group of Environmental Chemometrics, Faculty of Chemistry, University of Gdansk, Gdansk, Poland

¹² European Commission, Joint Research Centre (JRC), Ispra, Italy

¹³ QSAR Lab Ltd, Gdansk, Poland

¹⁴ National Hellenic Research Foundation, Athens, Greece

¹⁵ Science, Technology and Society Department, Environmental Health Engineering, School for Advanced Study (IUSS), Pavia, Italy, Piazza della Vittoria 15, 27100

Background

The current legal frameworks for assessing and managing chemicals in the European Union (EU) have evolved over several decades. Starting with the directive on dangerous substances [1] in 1967, there are today over 40 individual pieces of legislation [2] dedicated to ensure overarching chemical safety [3, 4] as well as safety of various substance groups in their applications (for e.g. cosmetics, biocidal products). In addition, there are numerous regulations and directives addressing various aspects of sustainability concerning chemical substances, processes, and products at different stages of their life cycle. A regulation is directly binding in the EU Member States as soon as published in the Official Journal of the European Union [5]. A directive defines goals of the EU and the Member States devise their own laws on how to reach these goals. Those legislation can all be seen as specifications of the Treaty on the Functioning of the European Union Title XX Articles 191 [6] (*“The European Unions (EU) environmental policy [...] aims to preserve, protect and improve the quality of the environment and to protect human health”*) [7] as well as two Articles of the Charter of Fundamental Rights of the of the European Union [8], namely Article 35 (*“A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”*) and Article 37 (*“A high level of environmental protection and the improvement of the quality of the environment must be integrated into the policies of the Union and ensured in accordance with the principle of sustainable development.”*). Furthermore, EU legislation implements international treaties (e.g. Stockholm Convention, Montreal Protocol [9, 10]) into European law. Despite these efforts, the European Commission (EC), EU agencies, and member states as well as researchers continue to identify chemicals and materials that cannot be considered as safe and/or sustainable, yet have already been placed on the market, leading to human and environmental exposure [11–13]. The European Green Deal [14] addresses this challenge through the EU Chemicals Strategy for Sustainability (CSS) [15]. The CSS calls, amongst others, for non-regulatory incentives to drive innovation, specifically from the perspective of pollution and risk prevention. These incentives- combined with a more coherent, predictable, and robust legal framework - are ought to facilitate the protection of human health and the environment. As a key action, the CSS identifies the development of a framework for safe and sustainable chemicals and materials, adopting a life cycle perspective. The idea behind this framework is to promote innovation that, starting from the conception of the innovative idea, facilitates the development of chemicals, materials, processes, and products without undesirable risks or life cycle impacts.

The most important means of achieving this is the proactive assessment of safety and sustainability right from the earliest stages of innovation. Under this initiative, the EC's Joint Research Centre (JRC) developed an SSbD Framework [16] and an associated methodological guidance [17]. In December 2022, the EC issued a recommendation to foster the implementation of the therein proposed EC SSbD Framework in innovation [18]. In addition, the EC has funded several research projects to further advance and operationalise SSbD. This includes ongoing efforts in the Partnership for the Assessment of Risks from Chemicals (PARC) [19] to operationalise SSbD by developing an SSbD toolbox [20], and establishing an SSbD knowledge sharing portal [21]. In July 2025, the EC shared a draft of the EC SSbD Framework with revisions proposed by the JRC for consultation [22]. The draft does not refer to assessment steps anymore but refers to safety and sustainability in a more holistic way. Since this draft is under consultation, this publication focuses on the framework which is presented in the EC recommendation [18].

The EC SSbD Framework is a voluntary (pre-market) approach to support and guide innovation in achieving safe and sustainable chemical and material life cycles for new chemicals, material, processes, and products and to improve those which already exist by re-design. By simultaneously assessing the safety and sustainability dimensions, the framework enables pro-active identification of hotspots and critical issues. Examples are hazards, unexpected high exposure, environmental impacts or resource inefficiencies; and the framework facilitates their identification and mitigation during the innovation process. As innovation commonly follows an iterative process, the EC SSbD Framework can be applied from the early stages of innovation to the re-assessment of existing products and technologies, considering increasing data availability. In essence, SSbD thinking focuses on driving the process of continuous improvement from the perspective of safety and sustainability.

The assessment within the EC SSbD Framework consists of five steps that follow life cycle thinking principles: Step 1 relates to hazard assessment of the chemical or material under consideration, in Step 2 human health and safety aspects (including environment) for production and processing stages are assessed, while in Step 3 the safety assessment focusses on the final application stage. Step 4 and Step 5 relate to the assessment of environmental sustainability, and socio-economic sustainability, respectively.

Under the umbrella of Treaty on the Functioning of the EU and the EU's Charter of Fundamental Rights, the EC SSbD Framework shares many of the overall aims of the existing legal frameworks. Among these are

the reduction of the impacts of chemical or material life cycles on human health and the environment, transition to a more circular economy, and fostering innovation and competitiveness of the European industry. Thus, there is a high degree of commonality between the EC SSbD Framework's safety and sustainability criteria, indicators, and elements on one side, and provisions included under various pieces of EU legislation on the other side. However, many legal frameworks are designed to ensure the safety and a certain degree of sustainability of established processes and marketed products with focus on specific substances, products or sectors. In contrast, the EC SSbD Framework provides an approach covering the innovation's entire life cycle, and which is applicable to any chemical, material, process, and product under consideration. The EC SSbD Framework supports and guides innovation towards safe and sustainable development, and ideally it would also directly facilitate compliance with legal requirements for placing innovation on the market. Despite commonalities, there are important differences between the EU legal frameworks' provisions and the EC SSbD Framework's criteria, indicators, and other elements. This article explores how the information gathered and generated during the innovation process according to the EC SSbD Framework can be of value to meet the legal provisions related to safety and sustainability across various regulatory processes. *Vice versa*, we also examine how the information and methodologies developed for legal compliance can help to inform the SSbD assessment in an iterative manner. The structure of the paper follows the EC SSbD Framework's five steps for safety and sustainability assessment. The paper describes how the information obtained under each step relates to corresponding legal provisions. Based on this analysis, relevant commonalities and differences are deduced, and the benefits and limits of overlapping concepts, content and objectives are discussed.

To identify commonalities between the EC SSbD Framework and EU legal frameworks, we performed a systematic analysis and reviewed the five steps of the EC SSbD Framework for their individual objectives, the approaches followed to address these objectives, the indicators used, and criteria applied. These were compared with criteria, obligations, and methodologies to address these obligations within some of the most prominent EU regulations and directives related to chemical safety and sustainability. Based on expert judgement, those EU regulations and directives were analysed regarding synergies to the EC SSbD Framework. This analysis includes examination of provisions regarding hazard, exposure, and risk assessment as well as reporting requirements, obligations, and provisions related to sustainability. Furthermore, guidance or publicly available information and

methodologies originating from EU legislation that can support the SSbD assessment were identified. The aim of this analysis is highlighting the relationship, and how SSbD assessment outcomes may subsequently support compliance with the EU legal frameworks. The aim is not to achieve a complete collection of legal frameworks possibly relevant to SSbD. An in-depth analysis of commonalities and differences between the EC SSbD Framework and provisions in individual EU legal framework would also require a detailed analysis of specific information and reporting requirements of each piece of legislation, and the associated regulatory guidance. It would merit its own publication. We also noted that several EU legislations are currently under review or adaptation while for new legislation the specific obligations are not yet formulated or agreed. The present study gives an overview of the general and most obvious synergies and thus it is starting point for subsequent in-depth analyses of selected synergies.

How the assessment by the EC SSbD framework links to legal specifications

The starting point of the EC SSbD Framework is the scoping analysis that contextualises the assessment by defining the chemical or material under consideration, its life cycle and its function, the (re)design and innovation maturity aspects [17]. The scoping analysis is crucial for performing the SSbD assessment as the assessment is context-specific, and its scope and boundaries need to be clearly defined. It provides the basis for the subsequent assessment within steps 1 to 5.

Hazard assessment of the chemical/material (step 1)

The assessment steps of the EC SSbD Framework follow the life cycle of a chemical or material under consideration, starting with the intrinsic properties. Step 1 can be considered as the central element. It provides key information about the hazard profile of the chemical or material under consideration. Thus, it guides the entire SSbD assessment process. Indeed, the hazard profile identified in Step 1 is critical for determination of potential risks during production and processing (Step 2), application (Step 3), environmental sustainability impacts (Step 4), and potentially for the estimation on socio-economic impacts (Step 5). In addition, information gained during Step 1 assessment helps to identify potential legal implications for the substance or material under consideration when it enters the European market. Furthermore, completion of Step 1 may also highlight important information gaps that need to be addressed.

Step 1 of the EC SSbD Framework defines three groups A, B, and C (or criteria H1, H2, and H3 in [16]) based on several hazard categories which are laid down

in the Regulation on Classification, Labelling and Packaging (CLP) [4]. These groups or criteria align with hazard criteria in further chemicals legislation, as shown in Table 1. Criteria for Group A substances mirror primarily those in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation [3] to identify so-called “Substances of very high concern” (SVHC). Criteria of Group B substances include parts of criteria according to the Ecodesign for Sustainable Products Regulation (ESPR) [23] while the rest of hazard categories according to CLP are summarised in the criteria for Group C substances. This highlights the interconnection of Step 1 criteria and existing legal specification, and establishing a foundation for safety considerations. It is important to note, that in legislation predominantly the term “substance” is used, while the SSbD assessment is considered for “chemicals, materials, and products”. In this paper, the terms substance and chemicals are used simultaneously as they can be understood as synonyms. To some extent, the term “substance” also includes materials (e.g. nanomaterials). Furthermore, the terms “safety assessment” and “risk assessment” are used simultaneously in legislation and in the EC SSbD Framework, an can be understood as synonyms.

However, the link between Step 1 assessments and EU legislation is much broader. Much product-oriented EU legislation, the workplace safety legislation, and the legislation for environmental protection and on waste often refer to CLP, REACH, Persistent Organic Pollutants (POP) Regulation [25], and their substance criteria.

The goal of setting these references is to identify hazard and risks of substances, to enable a sound risk management for safe handling, use, and disposal by controlling their production, marketing, use, and disposal. Several pieces of legislation specifically restrict the use of certain hazardous substances in products and waste, including: the Regulation on Batteries and Batteries waste [26], the Directive on Restriction of Hazardous Substances in Electrical and Electronic Equipment (ROHS) [27] or the Directive on End-of-Life-Vehicles (ELV) [28] which is currently under revision [29]. Other legislative frameworks generally prohibit or regulate substances and mixtures in products or waste, particularly those classified according to CLP as: (i) carcinogenic, mutagenic, or reprotoxic (CMR), (ii) endocrine disruptors (ED), (iii) persistent, bioaccumulative and toxic (PBT), (iv) very persistent and very bioaccumulative (vPvB), or substances identified as POP. Examples include: the Toy Safety Directive [30] (currently under revision [31]), the Cosmetic Product Regulation [32] (currently under evaluation [33]), the Plant Protection Product Regulation (PPPR) [34], the Biocidal Product Regulation (BPR) [35] (currently under evaluation [36]), the Regulation on EU Ecolabel [37], or the Waste Framework Directive (WFD; currently under revision) [38] [39]. Also, REACH regulates the uses of certain substances via the restriction and authorisation of so-called Substances of Very High Concern (SVHC; criteria for SVHC see Table 1). Interconnection can also be found in legislation to other life cycle stages of a substance. Several worker safety directives

Table 1 Substance Groups of the EC SSbD Framework step 1 and their counterparts in chemicals legislation (adopted from Table 2 of [18])

EC SSbD Framework Step 1 substance Groups (detailed hazard categories can be found in Table 2 of [18])	Corresponding substance groups in specific legislation	Remark
Group A—“most harmful substances”	Substances that meet the criteria according to REACH Art. 57 (so-called “Substances of very high concern”—SVHC) as well as ED, PMT, or vPvM criteria* and substances causing respiratory sensitisation Cat. 1, or specific target organ toxicity at repeated exposure (STOT-RE) Cat. 1, including immunotoxicity and neurotoxicity	Legal consequences under the REACH are only linked to SVHC in case they have been identified in accordance with the procedure under Art. 59 REACH
Group B	Substances that meet the criteria according to ESPR Article 2, 27(b)—named as “Substances of concern”	Substance of concern according to ESPR Article 2 also includes substances that 27(a) are identified as SVHC according to the procedure under Art. 59 of REACH, 27(c) are regulated under the POP Regulation, or 27(d) negatively affects the reuse and recycling of materials in the product in which it is present
Group C	Substances that meet the criteria according to CLP Regulation Annex I part 2–5 (named as “Harmful substances”) not already covered above	

* The criteria endocrine disruptor (ED), persistent, mobile and toxic (PMT), and very persistent and very mobile (vPvM) are stated in the CSS to be taken up by REACH Art. 57 as additional criteria during the upcoming targeted REACH revision [24]

regulate the handling of hazardous substances at the workplace, including: the Directive on the protection of the health and safety of workers from the risks related to chemical agents at work (Chemicals Agents Directive, CAD) [40] or the Directive on the protection of workers from the risks related to exposure to Carcinogens, Mutagens, and Reprotoxic substances at work (CMRD) [41]. The recently revised Directive on Industrial Emissions (IED) [42] establishes rules to prevent and reduce the use and emissions of hazardous substances. It mandates an environmental management system with an inventory of hazardous substances, and an analysis of the possibilities for substituting them by safer alternatives or reducing their use or emissions. In particular, this relates to substances that fulfil the criteria of Article 57 of REACH (i.e. so-called SVHC) or that are listed as restricted substances according to REACH Annex XVII. The new ESPR requires the improvement of products in relation to various aspects including transparency about the presence of substances of concern (criteria for substances of concern see Table 1). The regulation enables the EC to set information requirements e.g. to realise the tracking of the substances of concern throughout the life cycle for specific products via delegates acts.

Conversely, many of these pieces of legislation can be used in the context of the EC SSbD Framework as information sources to retrieve data on marketed substances for the purpose of e.g. a general analysis of a substance's life cycle, re-design of products or for comparison and benchmarking with new chemicals and materials. Information on hazard classification of substances on the market can be found in the C&L Inventory [43]. However, missing entries or classifications do not necessarily indicate an absence of hazard as this may result from a lack of available data. Even for classified substances, certain endpoints can be unaddressed if related information is not available. The REACH database [44] provides tonnage dependent hazard information for registered substances placed on the EU market above one ton per year, and risk information for registered substances placed on the EU market above ten tons per year. Furthermore, REACH Annex XIV and Annex XVII list substances that require authorisation and substances that are restricted, respectively. Additionally, other legislation provides lists of prohibited or restricted substances, such as Annexes I–IV of the POP Regulation or the Annex II of the RoHS Directive. Annex II of the Cosmetic Product Regulation provides a list of prohibited substances while Annex IV–VI lists allowed colorants, preservatives, and UV filters in cosmetic products. Legislation also lists active substances approved for plant protection products [45]. Furthermore, the upcoming regulation to establish a common data platform on chemicals [46] will bring together

substance specific information from different legal sources in an easily findable, accessible, interoperable, and re-usable (FAIR) way. Information in this platform may not only support step 1. Since it will bring together also exposure relevant data (including information from human biomonitoring) and data relevant for the assessment of environmental impacts of a chemical throughout its whole life cycle, it can also support the assessment of other steps of the EC SSbD Framework. Table 2 provides an overview on provisions in EU legislation mentioned in this paper that have links to criteria, indicators, and elements of SSbD assessment as well as on information and methodologies coming from EU legislation that can assist SSbD assessment. For detailed information on a specific chemical or material—including applicable legislation and compliance obligations—the EU Chemical Legislation Finder (EUCLEF) [47], provided by the European Chemicals Agency (ECHA), can be used as a comprehensive resource.

In summary, pro-active assessment of hazardous properties during Step 1 is key to anticipate potential issues, and to avoid challenges for legal compliance related to the life cycle of a chemical, material, and product. Therefore, from the safety perspective, information on hazardous properties early on is essential to optimise the substance's life cycle, and to reduce market entry barriers. Vice versa, the wealth of information on substances on the market can be used in various ways to inform the assessment of new chemicals, materials, and products.

Human health and safety aspects in the chemical/material production and processing phase (Step2) and in the final application phase (Step 3)

Steps 2 and 3 of the EC SSbD Framework comprise the assessment of risk of chemical or material at workplace in any occupational setting, throughout the entire life cycle of the chemical or material, and the risk to consumer and the environment during the final application, respectively. These steps require combination of hazard results with exposure information about the involved life cycle steps. While hazard information was gathered in step 1, in step 2 and 3 exposure information is added to ultimately assess potential risks. The exposure potential will depend on many factors including the production processes, foreseen uses, and end of life processes.

Steps 2 and 3 aim to identify, quantify, and qualify the risk posed by the chemical/material under consideration throughout its entire life cycle (including end-of-life). Thus, both steps enable stakeholders to implement measures to mitigate risks, and ensure the safe use and handling of the material or chemical. Moreover, the information gathered and generated during these steps may (again, as described for Step 1) guide and support

Table 2 Piece of EU legislation mentioned in this paper

Piece of EU legislation	Provisions in pieces of EU legislation that have links to criteria, indicators, and elements of SSbD assessment	Information and methodologies coming from pieces of EU legislation that can assist SSbD assessment
Regulation (EC) 1272/2008 (CLP) [4]	Identification of hazardous substances; hazard information	C&L inventory [43]
Regulation (EC) 1907/2006 (REACH) [3] under revision	Hazard, exposure, and risk assessment along substance's life-cycle; identification, restriction, and authorisation of SVHC	List of restricted substances; list of substances subject to authorisation; REACH data base [44]; guidance for hazard, exposure, and risk assessment [49]; (Extended) Safety Data Sheet, exposure scenarios, use maps; guidance for socioeconomic analysis [81]
Regulation (EU) 2019/1021 (POP) [25]	Prohibition and restriction of production and use of POP	List of prohibited and restricted substances
Upcoming Regulation establishing a common data platform on chemicals [46]	Hazard information, exposure related information, environmental sustainability related information	Substance specific FAIR data related to safety and environmental sustainability
Regulation (EU) 2024/590 (ozone layer depleting substances) [77]	Prohibition of production and use of ozone-depleting substances	List of prohibited substances
Regulation (EU) 2024/573 (fluorinated greenhouse gases) [78]	Regulation of production and use of fluorinated greenhouse gases and of alternative substances not fluorinated	List of substances, products and equipment whose import and export needs a licence
Directive (EC) 98/24 (Chemical agents) [40]	Identification of hazardous agents at workplace; prohibition of chemical agents at workplace; determination of occupational exposure, occupational risk assessment as well as risk mitigation measures	List of prohibited chemical agents; general principles for management of risks and specific protection and prevention measures
Directive (EC) 2000/39 [55]	occupational exposure limits	List of indicative occupational exposure limit values
Directive (EC) 2004/37 (CMR) [41]	Identification of CMR substances at workplace; determination, prevention, and reduction of exposure at workplace; exposure limit values	List of occupational exposure limit values of CMR substances
Directive (EU) 2024/1785 (IED) [42]	Inventory of hazardous substances; risk assessment, exposure reduction, and prevention measures; improvement of environmental performance	BAT reference documents [80]; upcoming information from plant permits and from the environmental management system to be published
Regulation (EU) 2023/988 (General Product Safety) [48]	Product safety assessment	Upcoming EC web portal for data in the digital product passport
Regulation (EU) 2024/1781 (ESPR) [23]	Identification of substances of concern; eco-design; improvement on product aspects related to safety, sustainability and end of life processes	
Regulation (EC) 66/2010 (EU Ecolabel) [37]	Prohibition and restriction of hazardous substances depending on product group; environmental life cycle impacts	EC website on product groups and criteria [97]
Regulation (EC) 1107/2009 (Plant protection products) [34]	Identification of active substances that shall be approved for PPP; of substances that shall not be considered of low risk, and of candidates for substitution; exposure and risk assessment during use	Guidance for assessment [98]; Assessment Reports
Regulation (EU) 540/2011 [45]	Substances approved for PPP	list of substances approved active substances for PPP
Directive (EC) 2009/128 Sustainable Use of Pesticides [75]	Reduction of the risks and impacts from the use of pesticides to human end environment; integrated pest management; alternative approaches or techniques	Information on the sustainable use of pesticides via a web portal [76]
Regulation (EU) 528/2012 (Biocidal products) [35] under evaluation	Identification of active substances that shall not be approved for biocidal products; exposure and risk assessment during use; consideration of disproportionate negative societal impact of not-authorisation	Guidance on e.g. hazard, exposure, and risk assessment [99]; Assessment Reports; Database on approved active substances [54]

Table 2 (continued)

Piece of EU legislation	Provisions in pieces of EU legislation that have links to criteria, indicators, and elements of SSbD assessment	Information and methodologies coming from pieces of EU legislation that can assist SSbD assessment
Regulation (EC) 1223/2009 (Cosmetic Products) [32] <i>under revision</i>	Prohibition and restriction of hazardous substance in cosmetic products; product safety assessment	List of substances prohibited in cosmetic products; List of substances restricted in cosmetic products; List of allowed colorants, preservatives, and UV-filters; SCCS Notes of guidance for the testing of cosmetic ingredients and their safety evaluation [100]
Directive 2009/48/EC (Toy Safety) [30] <i>under revision</i>	Prohibition and restriction of hazardous substance in toys; hazard, exposure, and product safety assessment	Guidance of the EC and the Expert Group on Toy Safety [52]
Regulation (EU) 2024/3110 (Construction Product Regulation) [70]	Safety for worker and user; environmental sustainability performance	
Regulation (EU) 2023/1542 (battery/battery waste) [26]	Restriction of hazardous substances in batteries; carbon footprint declaration, recycling content; performance, durability; removability, replaceability, and safety parameters; battery due diligence	Upcoming guidance on battery due diligence
Directive (EC) 2008/98 (Waste Framework Directive) [38] <i>under revision</i>	Identification of hazardous waste; waste hierarchy; waste management; prevention and reducing adverse impacts	
Directive (EU) 2012/19 (WEEE) [69]	Design to facilitating re-use, dismantling and recovery of WEEE, its components, and materials	
Directive (EU) 2011/65 (RoHS) [27]	Restriction of hazardous substances in electrical and electronic equipment	List of restricted substance
Directive (EC) 2000/53 (ELV) [28] <i>under revision</i>	Restriction of hazardous substances in vehicles; design and production to facilitate the dismantling, reuse and recovery, in particular the recycling of ELV, their components, and materials; use of recycled vehicles and products	List of restricted substances
Directive (EU) 2022/2464 (CSRD) [63] <i>under revision</i>	Environmental, social and governance performance of a company's activity	
Directive (EU) 2024/1760 (CSDD) [64] <i>under revision</i>	Integration of sustainable due diligence into company policies and risk management systems	
Regulation (EU) 2020/852 (sustainable investment) [66]	Determination whether an economic activity qualifies as environmentally sustainable	
Regulation (EU) 2024/1252 (critical raw materials) [79]	Fostering efficiency and circularity; mitigate supply risk	List of strategic and of critical raw materials in the EU

The table provides an overview on provisions in EU legislation that have links to criteria, indicators, and elements of SSbD assessment as well as on information and methodologies coming from EU legislation that can assist SSbD assessment

later compliance with both process and product related legal requirements. In the following some examples are given. Information generated to address these steps can contribute to chemical risk assessments required under REACH, including the definition of exposure scenarios. As mentioned above, the revised IED includes obligations to assess risks, reduce emission, and apply prevention measures for hazardous substances when used in production processes. The CAD obliges the employer to perform a risk assessment for the hazardous chemical agent at the workplace, including considerations on the type and duration of exposure, work conditions, and the effectiveness of prevention measures. Additionally, the CMRD obliges the employer to assess and manage the risks associated with CMRD substances. It stipulates prevention and protection measures as well as exposure limits. Results of steps 2 and 3 can provide relevant information and indications for potential obstacles for compliance upon use. The General Product Safety Regulation [48] lays down that only safe products shall be marketed in the EU, and therefore, sets out general safety requirements for non-food consumer products while complementing sector-specific legislation. Specific obligations for assessing the risk of a product are defined in e.g. the PPPR, BPR or the Cosmetic Products Regulation. Information collected and generated during steps 2 and 3 holds significant value for regulatory purposes.

A variety of guidance documents and predictive tools, developed to support the above-mentioned legislation, may also be deployed to inform on exposure in SSbD evaluation at early stages of innovation and development. These include the identification of use cases as well as the derivation of exposure scenarios employing methods such as use descriptors that were developed in the context of REACH. Guidance for exposure and risk assessment is provided by ECHA, and by other European Agencies (e.g. European Food Safety Authority (EFSA), European Medicines Agency (EMA), and by Expert Groups that assess risks of specific products [49–52]. The Extended Safety Data Sheet, which includes Exposure Scenarios, provides information for substance's safe use along the life cycle [53]. Assessment reports of approved active substances or chemical safety assessment reports of registered substances in REACH provide safety information, and can be found e.g. at the REACH database [44] or the database for approved biocidal active substances [54]. Furthermore, in view of workplace safety, CAD provides general principles for management of risks and specific protection and prevention measures. The European Directive 2000/39/EC [55] and its amendments provide indicative occupational exposure limits. Existing legal guidance, tools, and information can give indications within SSbD assessment on the type of exposure

to be expected from a new substance, and thus points to potential risk reduction measures or even indicate limits of a chemical and material in processes and application.

Therefore, evaluation of risk during occupational settings, along with assessments of risks to consumers and the environment during use, as outlined in steps 2 and 3 of the EC SSbD Framework, enable the identification and analysis of potential risks of a chemical/material at different life cycle stages. It supports the identification of hotspots requiring improvement and risk mitigation measures. Additionally, these approaches promote safer design practices while facilitating compliance with legislation that involve risk assessments of chemicals, materials, processes, and products.

Environmental sustainability assessment (step 4)

Step 4 of the EC SSbD Framework addresses the environmental sustainability impacts of a chemical or material along their entire life cycle. This is achieved through a Life Cycle Assessment (LCA). The approach recommended by the JRC is the product environmental footprint method (PEF [56]), which consists of 16 impact categories that in the EC SSbD Framework are gathered into the four aspects mentioned by the CSS: toxicity, climate change, pollution, and resources use. The UNEP/SETAC (United Nations Environmental Programme / Society of Environmental Toxicology and Chemistry) reference model USEtox [57–59], recommended by PEF for human toxicity and ecotoxicity impacts, is well-aligned with methods also adopted in EU chemicals legislation. For example, it recommends using species sensitivity distributions derived from chronic effect test data [60] reported under, for example, REACH [61, 62].

Assessing impacts of chemicals, materials, products, and processes on environmental sustainability is not a blank sheet in European legislation, and it has been become more prominent recently. Step 4 of the EC SSbD Framework can support preparedness for related obligations. The ESPR sets ambitious ecodesign requirements for specific product groups, aiming to significantly improve their circularity, energy efficiency, and other environmental sustainability aspects. Ecodesign requirements relate to product durability, reusability, upgradability and reparability, presence of substances of concern (see Table 1), energy and resource efficiency, recycled content in a product, remanufacturing and recycling, carbon and environmental footprints, and expected waste generation. Step 4 of the EC SSbD Framework might also provide information that can be utilised to address reporting requirements of the Regulation concerning batteries and waste batteries [26], the EU Corporate Sustainability Reporting Directive (CSRD) [63], and Corporate Sustainability Due Diligence Directive (CSDD) [64]

(both directives are under revision [65]). In order to be able to advertise sustainable financing, companies have to report according to the EU Taxonomy Regulation [66] whose criteria and objectives correspond to those of the EC SSbD Framework. The Regulation concerning batteries and waste batteries prescribes performance and durability requirements, carbon footprint declaration, and recycling content depending on the battery type. Furthermore, postponed to late summer 2027, economic operators have to identify, assess, and manage environmental risk categories along the supply chain [67]. The CSDD and CSRD are meant to be applied in tandem by corporate entities. While the CSDD outlines the mandatory due diligence that companies must implement regarding human rights and environmental impacts along their supply chains, the CSRD serves as the major reporting mechanism by which companies will report their relevant sustainability activities. CSRD requires large companies and listed small- and medium-sized companies, as well as parent companies of large groups, to include in a dedicated section of their management report the information necessary to understand (i) the company's performance on sustainability matters, and (ii) how sustainability matters affect the company's development and positioning. This information should provide financial market players with the necessary basis for measuring the sustainability performance of their portfolios and making sustainability-driven investment decisions. Environmental sustainability reporting obligations include aspects such information on climate protection and adaptation, water and marine resources consumption, resource protection and circular economy, environmental pollution, biodiversity and ecosystems protection. In this context, LCA provides an opportunity to identify hotspots, track impacts, and manage data in a harmonised way for auditing. Specific reporting requirements are defined in the Delegated Regulation on Sustainable Reporting Standards [68]. There is a substantial overlap of the obligations under CSRD, CSDD and the LCA-based environmental footprint impact categories recommended to consider as relevant indicators in the EC SSbD Framework at Step 4.

It is conceivable that LCA may also help to improve the environmental sustainability performance along the life cycle of chemicals, materials, and products in view of the legislation addressing circular economy and improvement of energy and resource demand. Examples of such legislation are the Directive on Waste from Electrical and Electronic Equipment (WEEE) [69], the new Construction Product Regulation (CPR) [70], the ELV Directive, the WFD, and the IED. The WEEE Directive lays down measures to protect the environment and human health by preventing or reducing the adverse impacts that is caused by WEEE, ensuring good management practices,

reducing overall impacts of resource use, and improving the efficiency of such use. The new CPR defines harmonised rules on how to express environmental and safety performance of construction products as well as environmental, functionality, and safety performance requirements for these products. In doing so, it also lists predetermined environmental essential characteristics in its Annex II. The proposed draft regulation to replace the ELV Directive aims for long-term energy savings at the manufacturing stage, reduced dependency on imported raw materials, and the promotion of sustainable and circular business models. In 2023, the Commission made a proposal for a targeted revision of the WFD which focuses on two resource-intensive sectors: textiles and food. Its objectives are to reduce environmental and climate impacts, increase environment quality, and improve public health associated with textile waste management. For the food sector, the aim is to reduce the environmental and climate impacts of food waste generation. The revised IED includes new obligations for operators to improve energy and resource efficiency, apply circular economy practices, use safer chemicals, and to establish an environmental management system that fulfils given minimum requirements. Beside measures on safety, the revised IED requires continuous improvement of the environmental performance of the installation, indicative ranges of environmental performance indicators ("benchmarks"), inclusion of an energy audit or implementation of an energy management system. It also obliges establishing a plan for the transformation of an installation during the 2030–2050 period to contribute to the emergence of a sustainable, clean, circular, and climate-neutral economy by 2050 [71].

Despite the growing number of sustainability-related legislations, no official regulatory guidance currently exists on how to conduct LCA to meet new compliance reporting requirements. Guidance for battery due diligence is expected for summer 2026. Nevertheless, the International Reference Life Cycle Data System (ILCD) Handbook by JRC [72] provides a common basis for consistent, robust, and quality-assured life cycle data and studies, complementing the ISO-standardised methodology requirements to execute an LCA and its different assessment phases (ISO 14040, ISO 14044) [73, 74]. In connection with the Directive on Sustainable Use of Pesticides [75], a web portal [76] provides key information on the sustainable use of pesticides and links to related Member States websites. Furthermore, existing substance-related lists may provide additional links to methodologies describing environmental impact benchmarks or performance assessment requirements, and that may provide valuable information for (re)design considerations beyond chemical hazard and risk information. This

includes the list of substances of the EU Regulation on substances that deplete the ozone layer [77], list of substances of the EU Regulation on fluorinated greenhouse gases [78], and the list of critical raw materials in the EU [79]. To improve the life cycle of chemicals, materials, and products, experiences can be consulted that manifested in Best Available Techniques (BAT) [80], in information that will have to be published related to environmental management based on IED obligations, in documentation from plant permits, and in the upcoming EC's web portal for data in the digital product passport.

To prepare for (future) provisions on assessing and reporting environmental sustainability impacts, Step 4 of the SSbD framework may serve as a helpful tool. It will allow the assessment of life cycle impacts regarding the relevant categories and consequently enables the identification of hot spots and informed company decisions on sustainability performance improvements. However, greater certainty about the specific (reporting) requirements on environmental sustainability impacts will be needed to understand these potential benefits of applying the EC SSbD Framework throughout the innovation. A stronger alignment of Step 4 of the EC SSbD Framework with existing and future legal provisions would ensure coherence for environmental sustainability performance.

Socio-economic sustainability assessment (step 5)

Assessment according to step 5 of the EC SSbD Framework, although not described in detail, also has synergies again with obligations of the Regulation concerning batteries and waste batteries, and reporting requirements of CSRD and CSDD. As mentioned above, topics that are covered by the reporting obligations of the CSRD include social affairs and human rights as well as governance. This includes the factors i) equality and equal opportunities, ii) working conditions, and iii) respecting human rights for social affairs, for business ethics, for business culture, iv) lobbying and v) fair business relations for the area of governance.

According to the Regulation concerning batteries and waste batteries, economic operators have to include considerations on critical raw materials use and social risk categories along the supply chain into their cooperate strategy, starting from late summer 2027. The CSDD aims to foster sustainable and responsible corporate behaviour across global value chains. Large companies (>1000 employees and >EUR 450 million turnover (net) worldwide) will be required to identify and, where necessary, prevent, end or mitigate adverse impacts of their activities on human rights (e.g. child labour, and exploitation of workers). To comply with the corporate risk-based due diligence duty, these companies need to integrate due diligence into their policies. They are obliged to take

appropriate measures to identify, prevent, and mitigate potential adverse impacts while identified actual adverse impacts have to be eliminated, minimised or remediated. Additionally, they have to establish and maintain a notification mechanism and a complaints procedure, monitor the effectiveness of the due diligence policy and measures, and publicly communicate on their due diligence efforts.

The socio-economic analysis (SEA) under REACH is a further link of SSbD assessment to legislation, and it is especially relevant to substances. The SEA serves as an information source and decision-support tool in the restriction and authorisation processes for SVHCs under REACH. In principle, there is no obligation to prepare a SEA in a specific form neither under REACH nor for socio-economic sustainability assessment. However, a typical socio-economic analysis according to REACH Annex XVI includes key elements such as the economic consequences of a restriction or authorisation for industry, impacts on consumers, benefits for human health and the environment, social implications, effects on trade, competition, and economic development, as well as information on the availability, technical feasibility, and economic reliability of alternative substances and techniques. ECHA provides guidance and further information on SEA within the authorisation process [81]. Step 5 of the EC SSbD Framework can contribute to socio-economic analysis by furthering a systematic collection of socio-economic implications of a substance, considering also possibilities for re-design, substitution or other alternative approaches. Guidance on restriction and authorisation is provided by ECHA [82, 83]. Further legislation relevant to the assessment of environmental, social, and economic sustainability of Step 4 and 5 of the EC SSbD Framework can be found in the overview of legislation in the context of the EU Green Deal provided by the Dutch network CircuLaw [84].

Thus, social and economic sustainability assessments conducted in Step 5 of the EC SSbD Framework can provide valuable information for implementing and reporting on due diligence measures. Additionally, these assessments can support the socio-economic analysis needed to decide on essential uses and viable alternatives.

In summary, the EC SSbD supports safe and sustainability innovation in two senses. First, in a proactive sense, applying the EC SSbD Framework prepares for legal safety and sustainability provisions along the life cycle of a chemical, material, and product once it comes to the market entry stage (Fig. 1). Second, and vice versa, in the efficacy-optimising sense, available information and methodologies used in the various legal frameworks can assist in assessing a (new) chemical, material, and product by the EC SSbD Framework.

Applying the EC SSbD Framework during Innovation

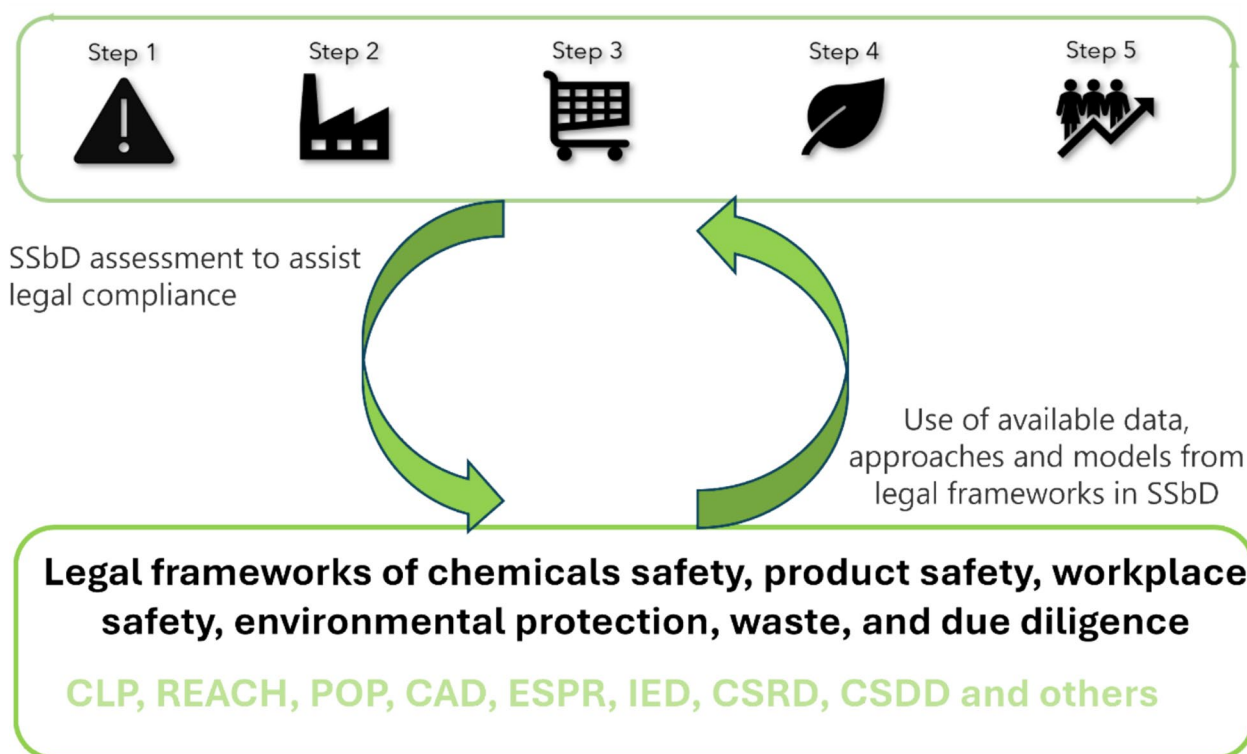


Fig. 1 Opportunities for mutual support and benefit of the EC SSbD Framework and tools of legislation. Applying the EC SSbD Framework during innovation assists the applicant to prepare for requirements of different pieces of legislation while at the same time available information and methodologies used in the legislation can provide information and strategies for assessing SSbD for a chemical or material over its entire life cycle

Discussion

The main objective of this paper is to show that applying the EC SSbD Framework in the innovation of chemicals, materials, and products also add value by providing information to support compliance with meeting legal obligations related to safety and sustainability. Generally, the EC SSbD Framework and legal safety and sustainability provisions share the common overall objective of minimising adverse impacts of chemicals, materials, processes and products on human health and the environment across their entire life cycle. For one thing, in innovating companies or institutions, the voluntary EC SSbD Framework can facilitate priority setting, decision making, and management largely independently of legal obligations during the innovation process. Then again, the innovation process can be pro-actively optimised, as each step of the EC SSbD Framework can be associated with a number of general (Fig. 2) and specific questions that concern legal obligations on safety and sustainability issues that will become relevant, at the latest, for market entry stage. Recognising the clear links between SSbD

aspects and current or emerging legal obligations will facilitate companies to be prepared for marketing. This, in turn, will enhance their competitiveness by building-in regulatory acceptance and avoiding investments in innovations that carry unacceptable risks or be unsustainable. However, it must be noted that individual pieces of legislation may have obligations that go beyond the safety and sustainability criteria covered by SSbD.

In particular, in the early innovation stages, stakeholders (still) unfamiliar with relevant legal obligations on safety and sustainability can familiarise themselves with legal criteria, assessment strategies, and reporting requirements via the EC SSbD Framework. At later innovation stages, the legal obligations for safety and sustainability will increasingly be apparent, and become binding when the chemical, material, and product is to be put on the market. Nevertheless, especially with regard to new and upcoming legislation, such as CSRD and CSDD, as well as newly introduced provisions on environmental and societal sustainability into existing legislation, further alignment of aspects and indicators within Step

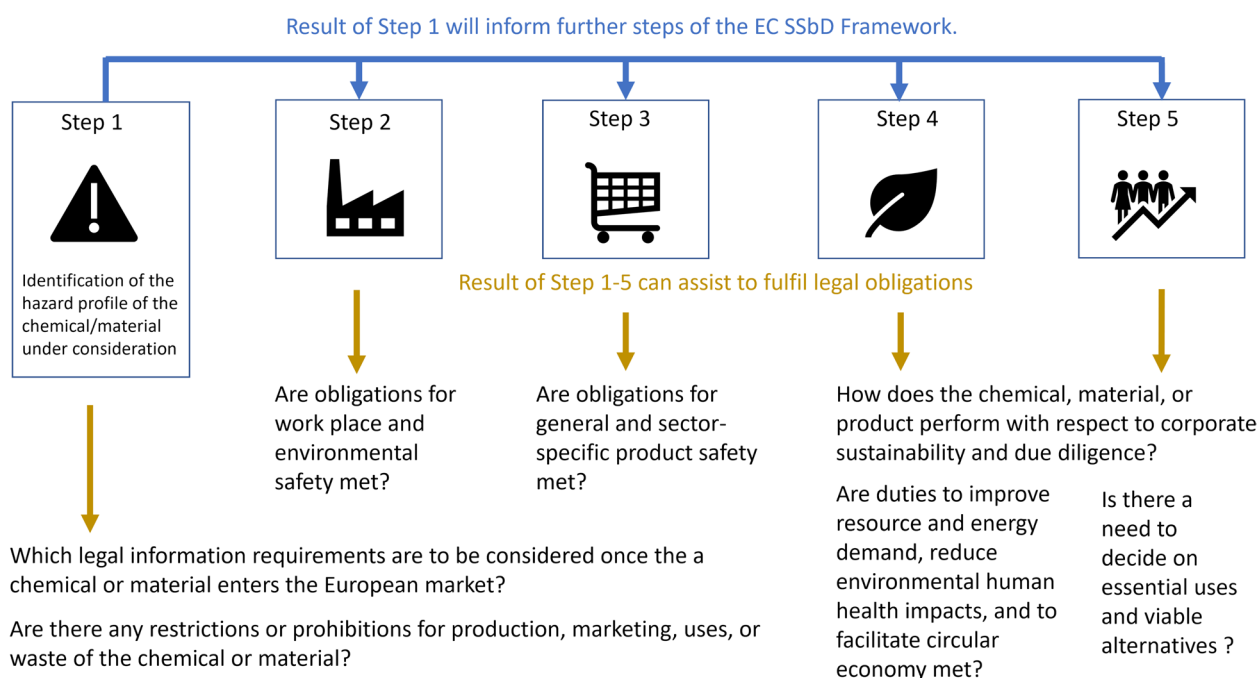


Fig. 2 Steps of the EC SSbD Framework prepare for regulatory relevant questions. Each step of the EC SSbD Framework can be associated with a number of general questions that concern to legal obligations on safety and sustainability issues. Recognising the links between SSbD aspects and current or emerging legal obligations will facilitate companies to prepare for requirements and reporting duties in the legislative landscape

4 and 5 of the EC SSbD Framework would improve its utilisation. This improvement will contribute to a better informed and more consistent decisions, and optimises compliance with (upcoming) legal obligations, while adhering to the boundary conditions of an SSbD assessment at operational, early innovation stage level (e.g. data availability constraints, broad screening of chemicals and materials).

The EC SSbD Framework is considered to be a proactive, holistic approach (i.e. considering safety and sustainability aspects together, and for the whole life cycle of a chemical or material) that requires close collaboration among value chain actors in order to perform a meaningful assessment that go beyond the collaboration currently practiced to meet legal requirements. Current practices may differ from such collaboration, as many pieces of current legislation target specific sectors or applications. As a result, value chain actors often operate in silos, leading to a lack of integration across these assessment dimensions. However, the engagement with the different value chain actors is crucial for performing an assessment according to the EC SSbD Framework, already starting with the scoping analysis. Such integration and exchange across value chain actors is, however, likewise important for fulfilling legal requirements (e.g. risk assessment under REACH). It has become increasingly

important in the light of legislation to improve sustainability, and circular economy aspects (e.g. by the digital product passport), and when calling for simplification and further alignment of assessment requirements across legislative silos [85]. In its early stages, this collaboration for an SSbD assessment necessitates creating a trusted environment [86] for sharing information and communicating transparently about innovation objectives, the principles, and decision making-processes. While this initial effort may require investment, it yields significant benefits for both SSbD assessment and legal compliance. On the one hand this will provide a broader perspective on the legislative landscape that is potentially relevant for the different actors in the life cycle, improving coherence, and avoiding unnecessary duplication of information and data. On the other hand, the established infrastructure will facilitate possible future improvement needs in the context of life cycle considerations of the chemical/material with significantly less effort.

An important difference between legal frameworks and EC SSbD Framework is that legislation predominantly addresses substances and products on the market and established processes. In contrast, the EC SSbD Framework is a pre-market approach guiding the development of new chemicals, materials, processes, and products, and the re-design of existing ones. Assessing safety and

sustainability at early stages of innovation inherently involves a high degree of uncertainty. The difference in certainty in the EC SSbD Framework compared to legislation also stems from the (un)availability of data and methods to generate the data. Legislation ensures the relevance and quality of data through standardised and harmonised test methods, along with extensive monitoring. However, these approaches are time- and resource-intensive. In contrast, the EC SSbD Framework supports and promotes, especially at the early stages of innovation, the use of new scientific and technological developments for testing and assessing chemicals and materials, including predictive tools, which sometimes come with a higher degree of uncertainty [87, 88]. As a result, information at the early stages of innovation SSbD relies to a large extent on data originating from alternative and new approaches (e.g. New Approach Methodologies (NAMs) for e.g. Step 1, and consensus approaches when different data or prediction models are available to enable high-throughput screening for potential adverse effects of substances. With possible exemptions, such data generated for SSbD assessments may not be directly used to comply with legal information and assessment requirements. In addition, the various pieces of legislation focus on different subjects and scopes. This situation leads, for example, to differences in characteristics and extent of information that can be used for an SSbD assessment. Thus, commonalities and synergies to the EC SSbD Framework vary. However, while one could argue about the quality and uncertainty of new scientific knowledge, it undeniably offers the opportunity to gain first indications of red flags and hotspots in a faster and less resource demanding manner to support priority setting and informed decision-making, as initial case studies have shown [89]. In that way, the EC SSbD Framework serves as a platform for developing scientific knowledge on new chemicals, materials, processes, and products without the constraints of legal perspectives. Significance and quality of data should be increased in an iterative way when knowledge increases during the innovation process. Furthermore, as the SSbD assessment calls for a multi-disciplinary deployment of diverse methodologies, transparency, and accessibility of information is of significant importance. FAIR methodologies [90] but also principles that demonstrate trustworthiness of digital repositories [91] can substantially contribute to these needs but possibly also advanced technologies like explainable artificial intelligence might provide applicants with e.g. insights into how conclusions from *in silico* methods (e.g., QSAR data) are derived. It is also conceivable that tools which are able to transfer and translate existing and publicly available regulatory data can be utilised within SSbD tools to promote the implementation of the EC SSbD

Framework, especially for stakeholders that are unfamiliar with the legislative landscape. For the acceptance to perform SSbD assessment, it would be beneficial if the future common data platform on chemicals considers the demands of the EC SSbD Framework.

The development and use of innovative methods and approaches enable SSbD to act as a testing ground to test, and assess chemicals, materials, and products in a predictive manner, which in turn helps to enhance the maturity and promote the regulatory acceptance of these methods. Subsequently, testing innovative methods and approaches within SSbD assessments will increase their maturity, and improve the data quality which is relevant for their potential later use in addressing legal obligations, as for instance by providing basis for the development of harmonised OECD (Organisation for Economic Co-operation and Development) test methods. The utilisation of sufficiently predictive or, later on, regulatory accepted methods in turn will support the acceptance and implementation of SSbD by industry. Thus, the EC SSbD Framework in its core acts as a crucial tool that bridges innovation of chemicals, materials, processes, and products with legal obligations related to safety and sustainability.

Conclusion

The aim of this study was to highlight the link between the EC SSbD Framework and current EU legislation frameworks with relation to safety and sustainability. The present analysis systematically showcases interlinks between criteria, indicators, and elements in SSbD assessments and provisions laid down in legislation. These interlinks presented offer mutual benefits (1) to support addressing legal compliance based on early anticipation of safety and sustainability issues in innovation, and (2) to ease SSbD assessments by deploying information and methodologies originating from legal obligations. This analysis can serve as an overview on the general and most obvious synergies, and as a basis for more in-depth comparisons of synergies, e.g. at the level of requirements of individual legislations.

The EC SSbD Framework is a voluntary (pre-market) approach to be applied to chemicals, materials, processes, and products in innovation activities. It supports the identification of red flags and areas for improvement related to safety and sustainability as well as the informed decision making along the innovation process. In that respect, it refers to new chemicals, materials and products but also to evaluation and re-design of the existing portfolio. The EC SSbD Framework represents an opportunity for applicants to future-proof their innovations by not only improving product performance but also gaining competitive advantage in a market that increasingly

values safer and more sustainable solutions. The application of SSbD will support the transition of industries manufacturing and using chemicals towards improved energy, resource efficiency and safer products in alignment with the objectives of the European Green Deal on climate neutrality, biodiversity protection, circular economy and zero-pollution ambition. On a more fundamental note, current European policy initiatives such as the Clean Industrial Deal and the upcoming Chemical Industry package put an additional and stronger focus on competitiveness and the innovation power of the EU (chemical) industry. This is exactly where the SSbD paradigm can and should play an important role, as at its core SSbD guides and fosters innovation in such a way that it supports competitiveness and incorporates fundamental and longstanding societal benefits such as safety and sustainability. From this perspective, the EU SSbD Framework clearly fits into the current policy agenda.

As a voluntary approach, industry is invited but not obliged to implement the EC SSbD Framework in their innovation processes. The SSbD Framework offers clear benefits to support the continuous improvement towards safer and more sustainable chemicals, materials, and product over their life cycles. Importantly, in doing so it supports becoming pro-actively prepared for related legal obligations. Thus, improving safety and sustainability via applying the EC SSbD Framework can facilitate regulatory acceptance and market readiness of innovative chemicals, materials, and products, and help to avoiding investments in unacceptable risks or unsustainable innovation. Furthermore, the EC SSbD Framework helps to identify and addresses safety and sustainability challenges, such as those related to e.g. workplace safety, resource demands, and circularity. In this way, the EC SSbD Framework can address barriers to trade, economic inefficiencies or aspects of due diligence.

However, data acquisition, and assessments within the EC SSbD Framework is complex, time-consuming and resource demanding, and faces numerous challenges [92]. In response to these challenges, the EC is currently undertaking guiding and supporting activities, such as collecting best practices from its application, promoting stakeholder exchange [93], and funding research and innovation projects related to SSbD and to NAMs development, validation, and application [94]. The SSbD toolbox developed in the PARC project provides a structured collection of tools to operationalise SSbD. Next to this, an SSbD knowledge sharing portal provides access to information, guidance, and case studies, and which gives access to a user community for SSbD within PARCopedia [95]. At the same time, a growing research community for SSbD has been established in Europe, e.g. [96]. Further development of the

framework, including clearer guidance, as started in 2024 with the methodological guidance, more cases studies as well as flexible, versatile, and integrated tools will boost its ease of use. In the long-term, integrating the SSbD thinking into corporate innovation management, together with education and training will be key to establish the relevant skills and foster an SSbD mindset. Consequently, it will facilitate moving toward the goals of the European Green Deal, Clean Industry Deal, and the United Nations 2030 Agenda.

Disclaimer

The views expressed in this manuscript are those of the authors and may not necessarily reflect the official position of the European Union, the granting authority (e.g. HADEA), or the institutions the authors are affiliated with.

Abbreviations

BAT	Best available techniques
BPR	Biocidal products regulation
CAD	Chemical agents directive
C&L	Classification and labelling
CLP	Classification, labelling and packaging (regulation)
CMR	Carcinogenic, mutagenic, and mutagenic
CMRD	Carcinogens, mutagens and reprotoxic substances directive
CPR	Construction product regulation
CSDD	Corporate sustainability due diligence directive
CSRD	Corporate sustainability reporting directive
CSS	Chemicals strategy for sustainability
EC	European Commission
ECHA	European Chemicals Agency
ED	Endocrine disrupter
EFSA	European Food Safety Authority
ELV	End-of-life vehicles (directive)
EMA	European medicines agency
ESPR	Ecodesign for sustainable products regulation
EU	European Union
EUCLEF	European Union Chemicals Legislation Finder
IED	Industrial emission directive
ILCD	International life cycle data system
ISO	International Organization for Standardization
JRC	Joint Research Centre (of the European Commission)
LCA	Life cycle assessment
NAM	New approach methodology
PARC	Partnership for the assessment of risks from chemicals
PBT	Persistent, bioaccumulative, and toxic
PEF	Product Environmental Footprint
PMT	Persistent, mobile, and toxic
POP	Persistent organic pollutants (regulation)
PPPR	Plant protection product regulation
QSAR	Quantitative structure–activity relationship
REACH	Registration, evaluation, authorisation and restriction of chemicals (regulation)
ROHS	Restriction of hazardous substances in electrical and electronic equipment (directive)
SCCS	Scientific committee on consumer safety
SEA	Socio-economic analysis
SHVC	Substance of very high concern
SSbD	Safe and sustainable by design
vPvB	Very persistent and very bioaccumulative
vPvM	Very persistent and very mobile
WEEE	Waste from electrical and electronic equipment (directive)
WFD	Waste framework directive

Acknowledgements

The work was supported by the PARC project (Horizon Europe Grant Agreement No 101057014) within the framework of the EU Horizon Europe research and innovation programme, and by the European Union's Horizon 2020 research and innovation programme under grant agreement 857560 (CETOEN Excellence). A.S. thank the RECETOX Research Infrastructure (No LM2023069) financed by the Czech Ministry of Education, Youth and Sports for supportive background, and the Grant Agency of Masaryk University within the project MUNI/R/1381/2023.

Author contributions

KS, DV, ML and IGA wrote the main text. LP, NF and AK prepared draft Fig. 1. KS prepared Fig. 2, Tables 1, and 2. All authors were involved in the discussion and reviewed the manuscript.

Funding

Open Access funding enabled and organized by Projekt DEAL. The work was supported by the PARC project (Horizon Europe Grant Agreement No 101057014) within the framework of the EU Horizon Europe research and innovation programme, and by the European Union's Horizon 2020 research and innovation programme under grant agreement 857560 (CETOEN Excellence). Authors thank the RECETOX Research Infrastructure (No LM2023069) financed by the Czech Ministry of Education, Youth and Sports for supportive background, and the Grant Agency of Masaryk University within the project MUNI/R/1381/2023.

Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Received: 25 April 2025 Accepted: 19 October 2025

Published online: 07 November 2025

References

- Council of the European Union (1967) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196. <http://data.europa.eu/eli/dir/1967/548/oj>
- European Commission (2019) Commission staff working document: Fitness check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries. SWD/2019/199 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52019SC0199>
- European Commission (2006) 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 (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2006/1907/2024-10-10>
- European Parliament, Council of the European Union (2008) 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 (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2008/1272/oj>
- European Union (2025) Official Journal of the European Union. <https://eur-lex.europa.eu/oj/direct-access.html>. Accessed 9 Sep 2025
- European Union (2016) Treaty on the Functioning of the European Union—Part Three—Union policies and internal actions Title XX—Environment Article 191 (ex Article 174 TEC). OJ C 202. https://eur-lex.europa.eu/eli/treaty/tfeu_2016/art_191/oj
- European Union (2025) EU environmental policy. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:environment>. Accessed 22 April 2025
- European Union (2012) Charter of fundamental rights of the European Union. 2012/C 326/02. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:OC_2012_326_R_0391_01
- Secretariat of the Stockholm Convention (2001) Stockholm Convention on Persistent Organic Pollutants (POPs). <https://www.pops.int/TheConvention/Overview/tabid/3351/Default.aspx>. Accessed 15 Sep 2025
- UNEP Ozone Secretariat (1987) The Montreal Protocol on Substances that Deplete the Ozone Layer. <https://ozone.unep.org/treaties/montreal-protocol>. Accessed 15 Sep 2025
- Landrigan PJ, Fuller R, Acosta NJR, Adeyi O, Arnold R, Basu N, Baldé AB, Bertollini R, Bose-O'Reilly S, Boufford JL, Breyse PN, Chiles T, Mahidol C, Coll-Seck AM, Cropper ML, Fobil J, Fuster V, Greenstone M, Haines A, Hanrahan D, Hunter D, Khare M, Krupnick A, Lanphear B, Lohani B, Martin K, Mathiasen KV, McTeer MA, Murray CJL, Ndahimananjara JD, Perera F, Potočnik J, Preker AS, Ramesh J, Rockström J, Salinas C, Samson LD, Sandilya K, Sly PD, Smith KR, Steiner A, Stewart RB, Suk WA, van Schayck OCP, Yadama GN, Yumkella K, Zhong M (2018) The lancet commission on pollution and health. The Lancet 391(10119):462–512. [https://doi.org/10.1016/S0140-6736\(17\)32345-0](https://doi.org/10.1016/S0140-6736(17)32345-0)
- Aurisano N, Huang L, Milà i Canals L, Joliet O, Fantke P (2021) Chemicals of concern in plastic toys. Environ Int 146:106194. <https://doi.org/10.1016/j.envint.2020.106194>
- Trasande L, Zoeller RT, Hass U, Kortenkamp A, Grandjean P, Myers JP, DiGangi J, Hunt PM, Rudel R, Sathyanarayana S, Bellanger M, Hauser R, Legler J, Skakkebaek NE, Heindel JJ (2016) Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis. Andrology 4(4):565–572. <https://doi.org/10.1111/andr.12178>
- European Commission (2019) Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: The European Green Deal. COM/2019/640 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52019DC0640>
- European Commission (2020) Communication from the Commission to the European Parliament, the Council, The European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM/2020/667 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52020DC0667>
- European Commission: Joint Research Centre, Caldeira C, Farcas R, Garmendia Aguirre I, Mancini L, Tosches D, Amelio A, Rasmussen K, Rauscher H, Riego Sintes J, Sala S (2022) Safe and Sustainable by Design chemicals and materials—Framework for the definition of criteria and evaluation procedure for chemicals and materials. Publications Office of the European Union. <https://doi.org/10.2760/487955>
- European Commission: Joint Research Centre, 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. JRC138035. <https://doi.org/10.2760/28450>
- European Commission (2022) Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for 'safe and sustainable by design' chemicals and materials. OJ L 325. <https://eur-lex.europa.eu/eli/reco/2022/2510/oj>
- Marx-Stoelting P, Rivière G, Luijten M, Aiello-Holden K, Bandow N, Baken K, Cañas A, Castano A, Denys S, Fillol C, Herzler M, Iavicoli I, Karakitsios S, Klanova J, Kolossa-Gehring M, Koutsodimou A, Vicente JL, Lynch I, Namorado S, Norager S, Pittman A, Rotter S, Sarigiannis D, Silva MJ,

- Theunis J, Tralau T, Uhl M, van Klaveren J, Wendt-Rasch L, Westerholm E, Rousselle C, Sanders P (2023) A walk in the PARC: developing and implementing 21st century chemical risk assessment in Europe. *Arch Toxicol* 97(3):893–908. <https://doi.org/10.1007/s00204-022-03435-7>
20. Sarigiannis S, Nikiforou F, Karakoltzidis A, Rydberg T, Halling M, Battistelli C L, E. B, Bossa C, Bouman E, Bourgé É, Brouwer-Milovanovic M, Hill A, Iacovidou E, Iavicoli I, Kanerva T, Kärnman T, Leso V, Lindén J, Lofstedt M, Nowack B, Sánchez Jiménez B, Resch S, Selvestrel G, K. S, Sharma A, Subramanian V, Telaretti Leggieri R, van Bodegraven M, Van Dijk J, Westra J, Zheng Z, Gypakis A, Karakitsios S (2024) A Computational Toolbox Supporting the Development of Safe and Sustainable By Design Chemicals and Materials (Conference contribution at AIChE Annual Meeting 2024). <https://aiche.confex.com/aiche/2024/meetingapp.cgi/Paper/691473> and <https://www.parc-ssbd.eu/>
 21. PARC (2025) SSbD Knowledge Sharing Portal. <https://www.eu-parc.eu/ssbd>. Accessed 21 Aug 2025
 22. Garmendia Aguirre I, Abbate E, Bracalente G, Mancini L, Cappucci G M, Tosches D, Rasmussen K, Sokull-Klüttgen B, Rauscher H, Sala S (2025) Draft for consultation: Safe and sustainable by design chemicals and materials: Revised framework 2025. https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en#revision-of-the-ssbd-framework. Accessed 28 Oct 2025
 23. European Parliament, Council of the European Union (2024) 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 (Text with EEA relevance). OJ L, 2024/1781. <https://eur-lex.europa.eu/eli/reg/2024/1781/oj>
 24. European Commission (2025) 2025 Commission work programme and annexes. https://commission.europa.eu/publications/2025-commission-work-programme-and-annexes_en. Accessed 22 Apr 2025
 25. European Parliament, Council of the European Union (2019) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (recast) (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2019/1021/2024-10-17>
 26. European Parliament, Council of the European Union (2023) Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2023/1542/2024-07-18>
 27. European Parliament, Council of the European Union (2011) Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (Text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2011/65/2025-01-01>
 28. European Parliament, Council of the European Union (2020) Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles. <https://eur-lex.europa.eu/eli/dir/2000/53/2023-03-30>
 29. European Commission (2023) Proposal for a regulation of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulations (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC. COM/2023/451 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2023%3A451%3AFIN&qid=1689318552193>
 30. European Parliament, Council of the European Union (2009) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (Text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2009/48/2022-12-05>
 31. European Commission (2025) Protecting children from unsafe toys and strengthening the Single Market: revision of the Toy Safety Directive. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13164-Protecting-children-from-unsafe-toys-and-strengthening-the-Single-Market-revision-of-the-Toy-Safety-Directive_en. Accessed 28 Feb 2025
 32. European Parliament, Council of the European Union (2009) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2009/1223/2024-04-24>
 33. European Commission (2025) EU chemicals strategy for sustainability: Cosmetic Products Regulation (revision). https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13197-EU-chemicals-strategy-for-sustainability-Cosmetic-Products-Regulation-revision_en. Accessed 28 Feb 2025
 34. European Parliament, Council of the European Union (2009) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. <https://eur-lex.europa.eu/eli/reg/2009/1107/2022-11-21>
 35. European Parliament, Council of the European Union (2012) Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2012/528/2024-06-11>
 36. European Commission (2025) Biocidal Products Regulation: evaluation. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14527-Biocidal-Products-Regulation-evaluation_en. Accessed 02 Sep 2025
 37. European Parliament, Council of the European Union (2009) Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2010/66/2017-11-14>
 38. European Parliament, Council of the European Union (2008) directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain directives (text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2008/98/2024-02-18>
 39. European Commission (2023) Proposal for a targeted revision of the Waste Framework Directive. https://environment.ec.europa.eu/publications/proposal-targeted-revision-waste-framework-directive_en. Accessed 22 April 2025
 40. Council of the European Union (1998) Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). <https://eur-lex.europa.eu/eli/dir/1998/24/2024-04-08>
 41. European Parliament, Council of the European Union (2004) Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version). OJ L 158. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004L0037-20240408>
 42. European Parliament, Council of the European Union (2024) Directive (EU) 2024/1785 of the European Parliament and of the Council of 24 April 2024 amending Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC on the landfill of waste (Text with EEA relevance). OJ L, 2024/1785. <https://eur-lex.europa.eu/eli/dir/2024/1785/oj>
 43. ECHA (2025) C&L Inventory. <https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database>. Accessed 28 Feb 2025
 44. ECHA (2025) ECHA Chemicals Database - ECHA CHEM. <https://chem.echa.europa.eu/>. Accessed 09 Sep 2025
 45. European Commission (2011) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (Text with EEA relevance). OJ L 153. https://eur-lex.europa.eu/eli/reg_impl/2011/540/2025-05-28
 46. Council of the European Union (2025) Proposal for a Regulation of the European Parliament and of the Council 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, Interinstitutional File: 2023/0453 (COD) from 26 June 2025. <https://data.consilium.europa.eu/doc/document/ST-10883-2025-ADD-1/en/pdf>
 47. ECHA (2025) EU Chemical Legislation Finder (EUCLEF). <https://echa.europa.eu/en/information-on-chemicals/euclef>. Accessed 28 Feb 2025

48. European Parliament, Council of the European Union (2023) Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2023/988/oj>
49. ECHA (2025) ECHA website on Guidance. <https://echa.europa.eu/en/support/guidance>. Accessed 28 Feb 2025
50. EFSA (2025) Guidance and other assessment methodology documents. <https://www.efsa.europa.eu/en/methodology/guidance>. Accessed 28 Feb 2025
51. EMA (2025) Scientific guidelines. <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines>. Accessed 28 Feb 2025
52. European Commission (2025) Guidance on Toy Safety. https://single-market-economy.ec.europa.eu/sectors/toys/toy-safety/guidance_en. Accessed 28 Feb 2025
53. ECHA (2025) Extended safety data sheets. <https://echa.europa.eu/safety-data-sheets>. Accessed 1 April 2025
54. ECHA (2025) Information on biocides. <https://echa.europa.eu/information-on-chemicals/biocidal-active-substances>. Accessed 2 Sep 2025
55. European Commission (2000) Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (Text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2000/39/2021-05-20>
56. European Commission (2021) Commission recommendation on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations. C/2021/9332 final. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=intcom:C%282021%299332>
57. Rosenbaum RK, Bachmann TM, Gold LS, Huijbregts MAJ, Jolliet O, Juraske R, Koehler A, Larsen HF, MacLeod M, Margni M, McKone TE, Payet J, Schuhmacher M, van de Meent D, Hauschild MZ (2008) USEtox—the UNEP-SETAC toxicity model: recommended characterisation factors for human toxicity and freshwater ecotoxicity in life cycle impact assessment. *Int J Life Cycle Assess* 13(7):532–546. <https://doi.org/10.1007/s11367-008-0038-4>
58. Sala S, Biganzoli F, Mengual ES, Saouter E (2022) Toxicity impacts in the environmental footprint method: calculation principles. *Int J Life Cycle Assess* 27(4):587–602. <https://doi.org/10.1007/s11367-022-02033-0>
59. Fantke P, Chiu WA, Aylward L, Judson R, Huang L, Jang S, Gouin T, Rhomberg L, Aurisano N, McKone T, Jolliet O (2021) Exposure and toxicity characterization of chemical emissions and chemicals in products: global recommendations and implementation in USEtox. *Int J Life Cycle Assess* 26(5):899–915. <https://doi.org/10.1007/s11367-021-01889-y>
60. Owsianiak M, Hauschild MZ, Posthuma L, Saouter E, Vijver MG, Backhaus T, Douziech M, Schlekat T, Fantke P (2023) Ecotoxicity characterization of chemicals: Global recommendations and implementation in USEtox. *Chemosphere* 310:136807. <https://doi.org/10.1016/j.chemosphere.2022.136807>
61. Fantke P, Aurisano N, Provoost J, Karamertzanis PG, Hauschild M (2020) Toward effective use of REACH data for science and policy. *Environ Int* 135:105336. <https://doi.org/10.1016/j.envint.2019.105336>
62. Saouter E, Aschberger K, Fantke P, Hauschild MZ, Bopp SK, Kienzler A, Paini A, Pant R, Secchi M, Sala S (2017) Improving substance information in USEtox®, part 1: discussion on data and approaches for estimating freshwater ecotoxicity effect factors. *Environ Toxicol Chem* 36(12):3450–3462. <https://doi.org/10.1002/etc.3889>
63. European Parliament, Council of the European Union (2022) Directive (EU) 2022/2464 of the European Parliament and of the Council of 14 December 2022 amending Regulation (EU) No 537/2014, Directive 2004/109/EC, Directive 2006/43/EC and Directive 2013/34/EU, as regards corporate sustainability reporting (text with EEA relevance). OJ L 322. <https://eur-lex.europa.eu/eli/dir/2022/2464/oj>
64. European Parliament, Council of the European Union (2024) Directive (EU) 2024/1760 of the European Parliament and of the Council of 13 June 2024 on corporate sustainability due diligence and amending Directive (EU) 2019/1937 and Regulation (EU) 2023/2859 (Text with EEA relevance). OJ L, 2024/1760. <https://eur-lex.europa.eu/eli/dir/2024/1760/oj>
65. European Commission (2025) Proposal for a directive: Commission simplifies rules on sustainability and EU investments, delivering over €6 billion in administrative relief. https://finance.ec.europa.eu/publications/commission-simplifies-rules-sustainability-and-eu-investments-delivering-over-eu6-billion_en. Accessed 22 April 2025
66. European Parliament, Council of the European Union (2020) Regulation (EU) 2020/852 of the European Parliament and of the Council of 18 June 2020 on the establishment of a framework to facilitate sustainable investment, and amending Regulation (EU) 2019/2088 (Text with EEA relevance). OJ L 198. <https://eur-lex.europa.eu/eli/reg/2020/852/oj/eng>
67. European Parliament, Council of the European Union (2025) Regulation (EU) 2025/1561 of the European Parliament and of the Council of 18 July 2025 amending Regulation (EU) 2023/1542 as regards obligations of economic operators concerning battery due diligence policies (text with EEA relevance). <https://eur-lex.europa.eu/eli/reg/2025/1561/oj>
68. European Commission (2023) Commission Delegated Regulation (EU) 2023/2772 of 31 July 2023 supplementing Directive 2013/34/EU of the European Parliament and of the Council as regards sustainability reporting standards (Text with EEA relevance). https://eur-lex.europa.eu/eli/reg_del/2023/2772/2023-12-22
69. European Parliament, Council of the European Union (2012) Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast) (text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2012/19/2018-07-04>
70. European Parliament, Council of the European Union (2024) Regulation (EU) 2024/3110 of the European Parliament and of the Council of 27 November 2024 laying down harmonised rules for the marketing of construction products and repealing Regulation (EU) No 305/2011 (text with EEA relevance). OJ L, 2024/3110. <https://eur-lex.europa.eu/eli/reg/2024/3110/oj>
71. European Commission (2025) 2050 long-term strategy. https://climate.ec.europa.eu/eu-action/climate-strategies-targets/2050-long-term-strategy_en. Accessed 28 Feb 2025
72. European Commission, Joint Research Centre (2010) International Reference Life Cycle Data System (ILCD) handbook—general guide for life cycle assessment—provisions and action steps. EUR 24378 EN. <https://publications.jrc.ec.europa.eu/repository/handle/JRC58190>
73. ISO (2006) ISO 14040:2006—Environmental management—Life cycle assessment—Principles and framework. <https://www.iso.org/standard/37456.html>
74. ISO (2006) ISO 14044:2006—Environmental management—Life cycle assessment—Requirements and guidelines. <https://www.iso.org/standard/38498.html>
75. European Parliament, Council of the European Union (2009) Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for community action to achieve the sustainable use of pesticides (text with EEA relevance). <https://eur-lex.europa.eu/eli/dir/2009/128/2019-07-26>
76. European Commission (2009) Sustainable use of pesticides. <https://webgate.ec.europa.eu/dyna2/sud/>. Accessed 24 April 2024
77. European Parliament, Council of the European Union (2024) Regulation (EU) 2024/590 of the European Parliament and of the Council of 7 February 2024 on substances that deplete the ozone layer, and repealing Regulation (EC) No 1005/2009 (text with EEA relevance). OJ L, 2024/590. <https://eur-lex.europa.eu/eli/reg/2024/590/oj/eng>
78. European Parliament, Council of the European Union (2024) Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (Text with EEA relevance). OJ L, 2024/573. <https://eur-lex.europa.eu/eli/reg/2024/573/oj/eng>
79. European Parliament, Council of the European Union (2024) Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020 (Text

- with EEA relevance). OJ L, 2024/1252. <https://eur-lex.europa.eu/eli/reg/2024/1252/oj>
80. European Commission (2025) European Bureau for Research on Industrial Transformation and Emissions: BAT reference documents. <https://bureau-industrial-transformation.jrc.ec.europa.eu/reference>. Accessed 2 Sep 2025
 81. ECHA (2011) Guidance on the preparation of socio-economic analysis as part of an application for authorisation. ECHA-11-G-02-EN. https://echa.europa.eu/documents/10162/2324906/sea_authorisation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e
 82. ECHA (2025) How to prepare an Annex XV report. <https://echa.europa.eu/en/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions>. Accessed 28 Feb 2025
 83. ECHA (2025) How to apply for authorisation. <https://echa.europa.eu/en/applying-for-authorisation>. Accessed 28 Feb 2025
 84. CircuLaw (2024) EU legislation and regulations for a circular economy. <https://www.circulaw.nl/eu-wetgeving>. Accessed 28 Feb 2025
 85. Bruinen de Bruin Y, Franco A, Ahrens A, Morris A, Verhagen H, Kephelopoulous S, Dulio V, Slobodnik J, Sijm DTHM, Vermeire T, Ito T, Takaki K, De Mello J, Bessens J, Zare Jeddi M, Tanarro Gozalo C, Pollard K, McCourt J, Fantke P (2022) Enhancing the use of exposure science across EU chemical policies as part of the European exposure science strategy 2020–2030. *J Expo Sci Environ Epidemiol* 32(4):513–525. <https://doi.org/10.1038/s41370-021-00388-4>
 86. Soeteman-Hernández LG, Sutcliffe HR, Sluijters T, van Geuns J, Noorlander CW, Sips AJAM (2021) Modernizing innovation governance to meet policy ambitions through trusted environments. *NanolImpact* 21:100301. <https://doi.org/10.1016/j.nanimp.2021.100301>
 87. von Borries K, Holmquist H, Kosnik M, Beckwith KV, Jolliet O, Goodman JM, Fantke P (2023) Potential for machine learning to address data gaps in human toxicity and ecotoxicity characterization. *Environ Sci Technol* 57(46):18259–18270. <https://doi.org/10.1021/acs.est.3c05300>
 88. Fantke P, Cinquemani C, Yaseneva P, De Mello J, Schwabe H, Ebeling B, Lapkin AA (2021) Transition to sustainable chemistry through digitalization. *Chem* 7(11):2866–2882. <https://doi.org/10.1016/j.chempr.2021.09.012>
 89. Söderberg E, von Borries K, Norinder U, Petchey M, Ranjani G, Chavan S, Holmquist H, Johansson M, Cotgreave I, Hayes MA, Fantke P, Syrén P-O (2024) Toward safer and more sustainable by design biocatalytic amide-bond coupling. *Green Chem* 26(22):11147–11163. <https://doi.org/10.1039/D4GC03665D>
 90. Karakoltzidis A, Battistelli CL, Bossa C, Bouman EA, Garmendia Aguirre I, Iavicoli I, Jeddi MZ, Karakitsios S, Leso V, Løfstedt M, Magagna B, Sarigiannis D, Schultes E, Soeteman-Hernández LG, Subramanian V, Nymark P (2024) The FAIR principles as a key enabler to operationalize safe and sustainable by design approaches. *RSC Sustainability* 2(11):3464–3477. <https://doi.org/10.1039/D4SU00171K>
 91. Lin D, Crabtree J, Dillo I, Downs RR, Edmunds R, Giaretta D, De Giusti M, L'Hours H, Hugo W, Jenkyns R, Khodiyar V, Martone ME, Mokrane M, Navale V, Petters J, Sierman B, Sokolova DV, Stockhausen M, Westbrook J (2020) The TRUST principles for digital repositories. *Sci Data* 7(1):144. <https://doi.org/10.1038/s41597-020-0486-7>
 92. Abbate E, Ragas AMJ, Caldeira C, Posthuma L, Garmendia Aguirre I, Devic AC, Soeteman-Hernández LG, Huijbregts MAJ, Sala S (2025) Operationalization of the safe and sustainable by design framework for chemicals and materials: challenges and proposed actions. *Integr Environ Assess Manag* 21(2):245–262. <https://doi.org/10.1093/inteam/vjae031>
 93. European Commission (2024) Safe and sustainable by design—What the framework is, how to get involved, test the framework, download documents. https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/chemicals-and-advanced-materials/safe-and-sustainable-design_en#workshops. Accessed 28 March 2025
 94. Fantke P (2025) Safe and sustainable-by-design (SSbD): calling for efficient metrics, biophysical benchmarks, and broader application. *Sustain Chem Pharm* 45:101986. <https://doi.org/10.1016/j.scp.2025.101986>
 95. PARCopedia SSbD user community group (2025). <https://www.parcopedia.eu/groups/ssbd-user-community/>. Accessed 23 April 2025
 96. Network for Safety and sustainability of Chemicals and materials (2025) Working Group Safe and Sustainable by Design (SSbD), Innovatio & Regulation. <https://www.nanosafetycluster.eu/nsc-overview/nsc-structure/working-groups/wge/>. Accessed 31 March 2025
 97. European Commission (2025) EU Ecolabel: Product Groups and Criteria. https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel/product-groups-and-criteria_en. Accessed 3 Sep 2025
 98. EFSA (2025) Pesticide evaluations: regulations and guidance. <https://www.efsa.europa.eu/en/applications/pesticides/regulationsandguidance>. Accessed 17 Sep 2025
 99. ECHA (2025) Guidance on biocides legislation. <https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>. Accessed 17 Sep 2025
 100. European Commission, Directorate - General for Health and Food Safety (2024) The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation: 12th revision. <https://doi.org/10.2875/19428>

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.