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Safe and Sustainable by Design

Development of safe and sustainable innovative chemicals and materials

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Summary

Innovative chemicals and materials, such as advanced materials, are increasingly used in various applications. Advanced materials, like nanomaterials or biopolymers pose new challenges for established safety and risk assessments because of their unique properties, such as their size, shape, and surface characteristics, that distinguish them from conventional materials. In recent years, concepts such as "Safe by Design" (SbD) have been developed for nanomaterials to integrate safety aspects into the early stages of design and development. This concept has been further developed, extended to other advanced materials and chemicals in general, and expanded to include the aspect of sustainability in form of "Safe and Sustainable by Design" (SSbD). In 2022, the European Commission's Joint Research Centre (JRC) presented a framework for safety and sustainability assessment aimed at helping to achieve the ambitious goals of the European Green Deal and the Chemical Strategy for Sustainability (CSS). The SSbD framework is intended to help companies and organisations assess not only safety but also environmental and socioeconomic sustainability, ensuring these factors are considered when (re)designing chemicals and materials. Application of the SSbD concept is currently voluntary. Because of the concept's complexity and frequent lack of data, practical implementation remains a significant challenge for manufacturers. To effectively promote adoption of the SSbD concept, particularly amongst small and medium-sized enterprises (SMEs), appropriate framework conditions and additional measures to develop competence, cooperation, coordination, and support are needed.

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Introduction

Chemical substances are an integral part of our everyday lives. They can be found in virtually all materials and products that surround us: in plastic products, food, cosmetics, paints and varnishes, building materials, textiles, vehicles, pharmaceuticals, and much more. Innovative materials and material combinations with new and improved properties, which can be "customised" for specific applications, are also increasingly being used. These new materials, known as advanced materials, include nanomaterials but also biopolymers, composites, novel metal alloys, and fibres.[1] These materials are used in a growing range of fields of application, such as food packaging, energy production and storage, electronics, medicine, and cosmetic products. The unique material properties of advanced materials pose particular challenges for safety and risk assessments. However, all chemicals, materials, and products classified as substances, mixtures or articles under the European Union (EU) chemicals legislation (Registration, Evaluation, Authorisation and Restriction of Chemicals [REACH] and Classification, Labelling and Packaging [CLP] regulations) must be safe to use and pose no risk to workers, consumers, and the environment. The first legally binding directive on the safety of chemical substances, the Dangerous Substances Directive (DSD), came into effect as early as 1967. Today, many regulations are in place to ensure the safety of all products on the EU market. For example, the General Product Safety Regulation (GPSR)[2] stipulates that only safe products may be placed on the market. In addition, there is comprehensive regulation for chemical substances through the REACH[3] chemicals regulation as well as sector-specific regulations covering food, cosmetics, biocides, pesticides, and pharmaceuticals, to ensure that consumers' health is not endangered, amongst other things.

In recent years, research projects have increasingly focused on developing concepts to integrate the safety of nanomaterials and other advanced materials into the innovation process. Safety considerations should be considered as early as possible, i.e. from the design and development phase. One such concept is the so-called "Safe by Design" (SbD) concept, intended to assist manufacturers of nanomaterials and nanomaterial-containing products in assessing safety and minimising risk.[4] Numerous projects and research initiatives have contributed to its development in the past (for an overview see[4,5,6]). Initially developed for nanomaterials, it has since been expanded to encompass other advanced materials and chemicals. More recently, the concept was extended to include the aspect of sustainability, building on existing concepts such as the eco-design concept and the 12 principles of green chemistry.[7] As a result, new materials should not only be safe for workers and consumers, but also pose no risk to the environment and be developed and designed with sustainability in mind. This idea is reflected in the concept of "Safe and Sustainable by Design" (SSbD). Concepts such as SSbD are necessary to meet the EU's goals towards a circular economy and the zero pollution ambition as well as the associated directives. These are outlined in strategy papers such as the European Green Deal[8], the new EU Circular Economy Action Plan (CEAP)[9], the EU Chemicals Strategy for Sustainability[10], and the 2030 Agenda[11].

Building on the previous dossier on "Safe by Design"[4], this dossier presents the evolution of the SSbD concept and explains the individual phases and assessment steps of the current SSbD framework.[12] It also critically examines the necessary conditions for implementing SSbD in practice.

The SSbD framework

In July 2022, the Joint Research Centre (JRC) released its report "Safe and sustainable by design chemicals and materials – Framework for the definition of criteria and evaluation procedure for chemicals and materials"[12], making it a significant milestone for the Europewide implementation of a concept for the safe and sustainable development of chemicals and materials. The report presents a framework that provides guidelines for the implementation of safety and sustainability aspects during the (re)design phase of chemicals and materials, along with indicators for the assessment of these aspects.

The SSbD framework is divided into two phases (see Fig.1):[12]

Phase 1, the **"(re)design" phase**, incorporates various guiding principles and indicators, such as the established 12 design principles of green chemistry.[13] These indicators reflect the safety and sustainability goals during the development phase of newly developed chemicals and materials. In addition to the principles of green chemistry, other concepts such as green engineering or SbD of nanomaterials are also applied. Redesign is primarily about producing chemicals or materials already on the EU market more sustainably or replacing them with more environmentally friendly alternatives (substitutes). Once a shortlist of substitutes has been drawn up, the next phase involves a toxicological, ecological, and socioeconomic assessment of the chemicals/materials and the manufacturing processes.

Phase 2 addresses the **safety and sustainability assessment** steps, with the United Nations' Sustainable Development Goals (SDGs) playing a decisive role in this context. The SDGs can be categorised into three different dimensions, safety, environmental, and socioeconomic, which are also applied in phase 2 of the SSbD framework. The SSbD assessment steps 1, 2, and 3 address the safety dimension, step 4 the environmental dimension. The socioeconomic dimension is incorporated in step 5. As sustainability is one of the aspects assessed in phase 2, it is crucial to understand the definition of sustainability used within the SSbD framework: In the context of chemicals/materials, sustainability is defined as the ability to fulfil a desired function without exceeding defined sustainability limits throughout the entire life cycle. With an additional guarantee of socioeconomic benefits and the reduction of external effects, the socioeconomic dimension is integrated into this definition of sustainability.

For all stakeholders along the value chain of chemicals and materials, safety is already incorporated into many laws, e.g. employee protection, and implemented accordingly within companies. Within the SSbD framework, safety is defined as the absence of unacceptable risk to human health and the environment, and implemented in steps 1-3 of phase 2.[13]

The individual **SSbD assessment steps of phase 2** are explained in more detail below:

In the **first step** of the SSbD assessment, the intrinsic properties of the chemical or material are reviewed to provide knowledge and understanding of the potential hazards of the chemical/material. In published JRC case studies, hazard classification is based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) or the CLP Regulation.[14] The classification includes hazards to human health (e.g. acute toxicity via oral, dermal, inhalation ex-

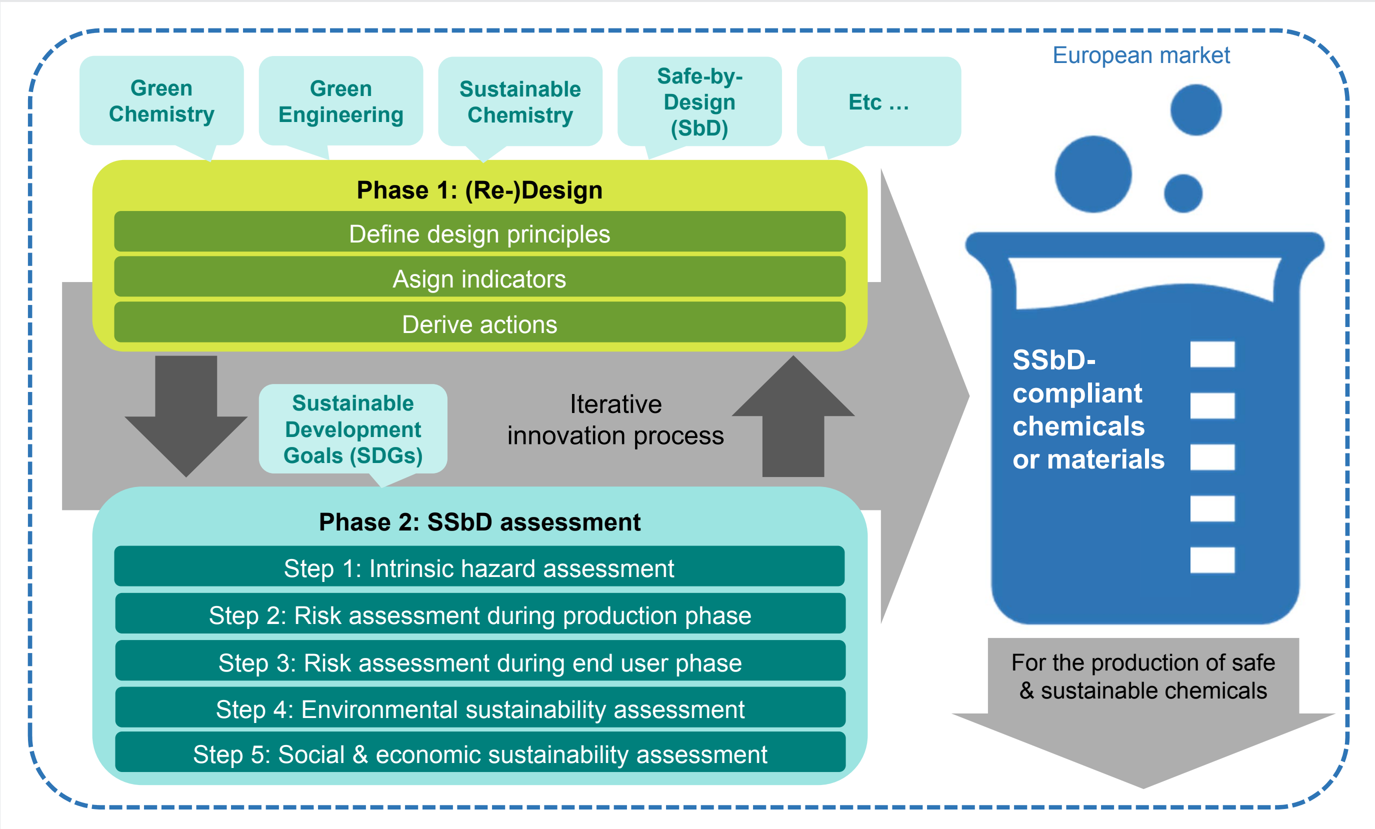

Figure 2:
The phases of the SSbD framework during the innovation process, including the underlying design principles (adapted from[12]).
The comprehensive SSbD assessment, which corresponds to the United Nations' Sustainable Development Goals (SDGs), consists of five individual steps.

posure, or skin sensitising, etc.), hazards to the environment (e.g. aquatic toxicity, harmful to the ozone layer, etc.), and physicochemical hazards (e.g. explosiveness, aerosol formation, oxidising liquid/solid, etc.). Based on this classification, the chemical/material receives a score to support the evaluation process. It is recommended to define exclusion criteria to end the evaluation and, if necessary, to stop further development at this early design phase.[12]

In **step 2**, the potential risk to human health and the environment during the production phases of the chemical or material is assessed. This requires in-depth knowledge of the specific production and processing procedures. The focus of the assessment at this stage is on the chemical/material to be assessed and how its properties influence manufacturing. In contrast, step 4 evaluates the entire life cycle using other parameters, such as material and energy flows, emissions, etc., based on a life cycle assessment. In practice, step 2 assessments divide the processes into different process steps depending on the assessment model. Using the CHEmical Safety Assessment and Reporting tool software (CHESAR 3) developed by the European Chemicals Agency (ECHA) as an example, these process steps are referred to either as Process Release Categories (PROCs) or Environmental Release Categories (ERCs). These categories outline factors such as routes of exposure and quantities under which humans or the environment could come into contact with the assessed chemical/material. In addition, parameters that influence exposure, such as workers' personal protective equipment (PPE) and process-specific safety equipment, are also considered. Using suitable software, e.g. the aforementioned CHESAR 3, the Risk Characterisation Ratio (RCR) for the respective category (PROCs or ERCs) can be calculated based on the data entered.

Step 3 assesses the potential risks during the product use phase and differs from step 2 in that all potential exposure scenarios and release categories are defined during end use (e.g. exposure through skin contact with nanomaterials in cosmetics). Apart from this, the assessment process is identical to that in step 2 and can be carried out simultaneously using the CHESAR software.

For **step 4**, a life cycle analysis or life cycle assessment (LCA) is recommended as the preferred method to assess environmental sustainability as it considers the environmental impact of the entire life cycle of the chemical/material. The EU recommends carrying out the LCA in accordance with ISO guideline 14040:2006.[15] As part of an LCA, first all energy and material flows are recorded. Using this data, summarised as a life cycle inventory, and material-specific data on carbon footprint or toxicity, the impact on specific LCA impact categories, such as global warming potential or human toxicity, can be calculated. As a result, the LCA makes it possible to compare and quantify the ecological advantages and disadvantages of the newly developed chemical in relation to conventional chemicals/materials, the so-called bulk chemicals.

In addition to the environmental dimension of sustainability, **step 5** of the SSbD framework addresses the **economic and social dimensions**. As mentioned in the definition of sustainability (see above), the SSbD framework distinguishes between environmental and socioeconomic sustainability. The SDGs represent social aspects, such as ending poverty and hunger and providing universal access to education. Economic factors, on the other hand, include, for example, improving production efficiency or the availability of raw materials (particularly critical raw materials[16]). The current version of the SSbD framework does not go into detail about which specific assessment methodologies should be used to assess social and economic factors in step 5. The reason given for this is the lack of sophisticated assessment methods. However, social life cycle analysis (s-LCA) and life cycle costing (LCC) are mentioned as potential assessment methods. The s-LCA and LCC methods still need further development and standardisation to be used successfully in practice. The respective assessment results from steps 1-5 are then intended to serve as a decisionmaking aid for companies and authorities for a comprehensive SSbD assessment.[12, 17]

SSbD in Austria and the EU

For years, the topic of "Environment, Health and Safety" (EHS) of materials has been recognised as highly relevant in Austria. In 2011, a specific funding programme for nanotechnology topics (Nano EHS Programme[17]) was established. These Nano EHS-funded projects have enabled Austria to secure a leading position in safety research of nanomaterials in Europe. One focus of these projects was analysing the applicability of the SbD concept and developing recommendations to expand the scope of the concept.[18] The knowledge gained from these projects has positioned Austrian stakeholders as pioneers and key contributors to the field of SSbD. For instance, this is reflected in their participation in forward-looking international plans and projects. In retrospect, projects such as NANoREG already contributed to fundamental developments to shape the field: Austrian stakeholders were involved in establishing the SbD concept for nanomaterials and applying it for the first time in a case study. Currently, European projects such as IRISS[19] and the Partnership for the Assessment of Risks from Chemicals (PARC)[20] are significantly influencing the implementation of SSbD in Europe, with Austria well represented in these flagship initiatives, demonstrating its leading role at European level. The IRISS project serves as an SSbD coordination and knowledge transfer project, whereas the European partnership programme PARC has dedicated a separate work package to the development of SSbD. PARC pursues the overarching goal of improving knowledge about the safety of chemical substances to better protect human health and the environment. This includes developing and refining scientifically sound methods and instruments to assess chemical risks, investigating various exposure pathways, toxicological effects, and the environmental impact of chemicals. In addition to assessing risks, PARC also supports the development of strategies and measures to manage these risks, including necessary regulations, guidelines or best practices for the safe use and disposal of chemicals. PARC is also focussing on the operationalisation of the SSbD framework, for which a separate SSbD toolbox is currently being developed. This toolbox is primarily designed to support small and medium-sized enterprises (SMEs) in the practical implementation of SSbD. The toolbox will integrate various software solutions that address and analyse various aspects of the SSbD framework, allowing the SSbD toolbox user to apply the extensive SSbD framework as holistically and comprehensively as possible and carry out all assessment steps. However, developing this toolbox presents several challenges: on the one hand, existing tools vary in in their complexity, specificity, user-friendliness, availability, and technical support. On the other hand, combining the data generated by the various tools into a holistic SSbD assessment remains challenging.

The next steps

The expansion of the range of sustainability-related knowledge, which is absolutely necessary for SSbD in Austria, and the integration of the established safety research expertise developed for the future implementation of the SSbD framework are currently being discussed at ministerial level. The scope of the SSbD framework makes it clear that additional measures to develop and finance competence, cooperation, and coordination are needed to enable the operational implementation of SSbD in Austria, particularly for SMEs.

The SSbD roadmap[21] serves as a basis for the implementation of national measures to establish the SSbD framework. It outlines the following fields of action: (i) structural development and networking, (ii) international communication and networking/collabration, (iii) creation of suitable framework conditions, (iv) knowledge development and transfer, and (v) supporting measures and research.

At European level, the JRC is revising the SSbD framework's current version. The further development is supported by ongoing consultations with European stakeholders and measures for international communication and networking. The next steps leading up to the planned publication of a revised framework in 2025 will include gathering experience reports from various stakeholders, which serve as the basis to revise the framework. Relevant information can be found on the European Commission's SSbD website.[22]

Conclusion

The complexity of the SSbD framework shows the need for a broad range of data, expertise, and information for a comprehensive assessment. As a result, an effective exchange of information between the relevant players along the entire value chain is needed. Particularly in the case of innovative material or substance classes, such as advanced materials, it is to be expected that specific data will be lacking, difficult to obtain or strictly confidential. The reasons for this are the absence or complexity of suitable test methods or software for particular steps within the SSbD assessment because of incompatibility with the respective material or substance classes. Even where data is available, it is not always possible to use it or check its quality because of data protection and trade secrets. Therefore, a data management system is required that allows for the quality of the data to be checked and data protection and trade secrets to be upheld.[23]

Although the European Commission supports the application of the SSbD framework through its recommendation on establishing a European assessment framework for inherently safe and sustainable chemicals and materials[24], there is currently no legal basis for the framework's implementation, making SSbD implementation voluntary. Coupled with the aforementioned complexity and efforts required, relevant stakeholders have rarely applied the SSbD framework to date. This problem has already been addressed during SSbD stakeholder workshops and will continue to be discussed at European and international levels to help improve the framework.

From a scientific, regulatory, and business perspective, the SSbD framework holds great potential to improve the safety and sustainability of chemicals and materials, and act as a driver of innovation. However, targeted measures are needed at both national and international levels to gain support from relevant stakeholders (e.g. chambers of commerce) for its introduction and implementation, thus making the SSbD framework feasible for companies of all sizes.

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