



Ministry of Infrastructure
and Water Management

Redesigning Chemical Innovation

Essays on Safe and Sustainable by Design



Recommendation



DG Research and Innovation, in close cooperation with the Joint Research Centre from the European Commission, is currently running a testing framework launched by a recommendation of the European Commission in December 2022. The purpose of the recommendation is the development of a ‘Safe and Sustainable by Design framework’ for chemicals and advanced materials. This triggers important discussions on how to turn this testing framework into an operational framework. Against this background, we in DG Research and Innovation welcome the engagement of the broad stakeholder community in the testing phase of the framework, including the contributions and essays in this edition. They underline the innovation potential which lies behind the application of the framework as a guidance for research and innovation, addressed not only to the European Union but also to individual Member States, individual researchers and individual innovators. The testing phase of the framework that the Commission put forward in its recommendation in 2022 has actually allowed identifying remaining challenges and the need for joining forces to find and fund solutions, thereby boosting scientific and industrial leadership in Europe.

I wish you a good read and look forward to discussing further with stakeholders on the way forward.

Jürgen Tiedje

Head of Unit E3 – Industrial Transformation, Directorate-General for Research and Innovation European Commission

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Preface



It cannot be underestimated how important the work on this revolutionary concept of Safe and Sustainable by Design is. We are on the eve of an unprecedented period of societal change, with the drastic energy transition and the raw materials transition knocking at our front door. These transitions require the application of Safe and Sustainable by Design. A brand-new concept that still faces major challenges with regard to implementation.

Safe and Sustainable by Design is an important instrument in the policy regarding chemicals for the Ministry of Infrastructure and Water Management. If we want to avoid having to deal with major costs and health damage in the future, comparable to our history with asbestos (still an important health issue more than 30 years after the complete ban in the Netherlands) and PFAS (becoming increasingly apparent), we must pay attention to safety and sustainability during the development of chemicals. But at the same time, we must keep in mind that it must remain possible for companies and our society to innovate. Policy and experience with this fundamental new approach is still in its infancy and this means that there are different ideas about what safe and sustainable design is. This collection of essays aims to make a dialectical contribution to the discussions on Safe and Sustainable by Design.

I would like to thank the authors for their willingness to contribute to this collection. All authors responded enthusiastically to the invitation. I hope that this spark of enthusiasm will resonate with you as a reader, inspire you to work on this theme, and contribute to the ongoing discussion.

Afke van Rijn

Director-General for the Environment and International Affairs
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Introduction: Facilitating the design of safe and sustainable chemicals and materials

**Kim Doornebosch, Kees Le Blanch,
Daan Schuurbiers**

The Safe and Sustainable by Design framework tells us where to go. But how to get there? Now is the time for policymakers to help shape the design of safe and sustainable chemicals and materials. The essays in this volume suggest how.

Safe and Sustainable by Design: a transition in chemical innovation

The notion of Safe and Sustainable by Design (SSbD) proposes a major rethink of chemical innovation. Prevention is now the starting point: safety and sustainability considerations should be incorporated from the earliest stages of product design to prevent chemicals and materials from harming human health and the environment.

Support for SSbD has grown significantly in recent years. Early on in the process, much emphasis was placed on the required mindset of researchers and innovators to take safety and sustainability into account. Building on preparatory ground work at European and national levels, the European Commission has established a European assessment framework for 'Safe and Sustainable by Design' chemicals and materials in December 2022¹. This framework provides an approach that can be used to minimise the impact on health, climate and the environment during sourcing, production, use and end-of-life of chemicals, materials and products.

Enabling the transition

Even though a lot of work is still ahead of us to determine how innovations can actually live up to this general framework, the question of how to 'design' in SSbD has remained largely unexplored. What does a design process that aims for safety and sustainability look like? Beyond the right mindset and a proper assessment framework, how can researchers organise and direct their work in the day-to-day practice of research and innovation? How can they involve the right disciplines, ask the right questions and overcome uncertainties, dependencies and trade-offs? Policymakers throughout Europe will have to delve into the particulars of these new interdisciplinary practices and find out what is needed to facilitate the transition to SSbD. This will involve creating incentives for innovators to adopt SSbD, stimulating demand for SSbD innovation, taking away barriers and supporting education and training.

The aim of this collection of essays is to offer insights to policymakers on how to encourage the design of SSbD chemicals and materials. The Dutch Ministry of Infrastructure and Water Management, in collaboration with the Dutch National Institute for Public Health and the Environment (RIVM), have invited prominent researchers, specialists and interest groups on SSbD to share their views on how to enable the transition to SSbD. How can it be achieved? And what can policymakers do?

Through the looking glass: 11 essays on SSbD

The essays in this volume reflect on the opportunities and pitfalls for SSbD from different perspectives. This volume does not purport to offer an alternative to the European framework. Nor does it intend to provide a complete SSbD handbook. Rather, the aim is to offer a kaleidoscopic overview of what researchers, designers, product developers and societal actors think is needed to realise SSbD from a practical perspective.

The authors suggest what they think is needed to enable the transition to SSbD in chemical innovation, pointing to gaps and omissions and identifying areas of improvement. They show how safety and sustainability assessment, product design, innovation management and economics must be integrally involved in the design of chemicals and materials. Some focus attention to the design process (as opposed to assessment). Others emphasise new forms of collaboration or deeper integration along the value chain. By highlighting the similarities and differences between the different viewpoints, the volume intends to shed light on how policymakers could encourage those who 'enact' SSbD (product developers, designers and engineers) to include safety and sustainability considerations in chemical product design and assessment.

Collectively, the essays highlight the importance of an overarching perspective when creating policies to support the transition to SSbD. SSbD requires the effective integration of chemicals assessment, sustainability science, life cycle thinking, circular design and economics. As such, the essays in this volume offer questions that policymakers should ask themselves before drafting policies.



1. Chemicals in Europe: What can Safe and Sustainable by Design deliver?

Leena Ylä-Mononen, European Environment Agency

This article describes how our current handling of chemicals—for example in textiles—has led to global crises, how Safe and Sustainable by Design can offer a promising way out and what is required from companies, policymakers and experts to achieve this.

Understanding and tackling chemical pollution

In 1967, the European Union introduced the very first directive on chemicals with the purpose of protecting human health and the environment. Since then, an extensive regulatory framework has been developed with more than 40 pieces of legislation put in place. This has resulted in massive improvements in certain areas. Europe now enjoys cleaner air. Ozone-depleting substances—a huge challenge in the 1980s—have largely been phased out. And more recently, we have seen a reduction in the use and risks of pesticides in the EU.

These improvements show that we are capable of resolving difficult challenges. However, we still have a long way to go. In the same period, the number and volume of chemicals have increased substantially. And for many of these chemicals, we have limited knowledge of their effects on human health and the environment.

On a global scale, the World Health Organization estimates that 2 million lives were lost in 2019 due to exposure to selected chemicals. And monitoring data generated under the Water Framework Directive show that only one third of the European surface water bodies is achieving ‘good chemical state’.

Recent evidence even suggests that planetary boundaries have been exceeded for chemical pollution. And when it comes to sustainability throughout product life cycles, our knowledge is even more limited. What is considered ‘safe’ today may not be considered ‘safe’ tomorrow.

Where do we go from here? Do we stay on the same path and gradually improve our responses? Or do we need to rethink how we evaluate the chemicals and materials that are a ubiquitous part of our surroundings?

Three crises, one approach

The three big planetary crises—climate change, biodiversity loss and pollution—are interlinked. These complex and multifunctional challenges can only be solved through holistic approaches. Otherwise, we will create new complications in our attempt to resolve existing problems.

Textiles are a good example of the complexities we are facing. Thousands of different chemicals are used in the textile industry. They are present in the manufactured

textile products from which we can be exposed directly, or indirectly, when they are released to the environment through washing of the textiles. Other chemicals, only used in the manufacturing process, may still end up in the environment through industrial discharges. Finally, the production of natural fibres such as cotton, hemp and linen, requires a high consumption of pesticides and water, while the production of synthetic fibres such as polyester and elastane is dependent on oil-based feedstocks which contribute to global warming—all involving chemicals at different stages of the process.

We can conduct a safety assessment of chemicals that are being used directly in textiles. But this would not be sufficient to conclude if one material is better than the other. If we want to draw such conclusions, we need to consider both the safety and the sustainability of the whole life cycle.

In 2020, textile consumption in Europe had on average the fourth highest impact on the environment and climate change from a global life cycle perspective (the top three being food, housing and transport). It was the consumption area with the third highest impact on water and land use, and the fifth highest in terms of raw material use and greenhouse gas emissions.

We therefore also need to consider the amount of water that is used, the emissions of greenhouse gases, land use, fossil fuel use and so on. And we need to consider how the textiles can be reused and recycled safely.

Safe and Sustainable by Design (SSbD), one of the key elements in the European Commission's Chemical Strategy for Sustainability, offers an alternative approach to traditional chemicals assessment. It combines and compares multiple different lines of potential impacts covering the entire life cycle. It is a voluntary instrument that can be used by companies in their R&D activities for development of new chemicals and materials or for identifying potential candidates for substitution of hazardous substances.

Chemicals in a circular economy: start with design

The presence of hazardous chemicals in products is often mentioned as a barrier for transitioning to a more circular economy. Indeed, hazardous chemicals are still present in many consumer products and building materials for many years after they

have been banned. This creates challenges when we want to reuse and recycle these materials. For example, we still have huge challenges with heavy metals and PCBs in building materials, phthalates in toys and PFOS in textiles. Instead of tackling their harmful impacts after use, can we get better at anticipating which chemicals we should avoid using in the first place?

Applying the SSbD approach is an exercise in performing holistic assessments of the potential impacts on human health and the environment early in the design phase of new chemicals and materials. It will ensure that all different aspects are considered before venturing into large-scale production.

However, applying the SSbD approach for chemicals is not going to be easy. To address the impact of a chemical on 'circularity', we would need to be able to understand or predict the potential uses of the chemical beforehand and assess if the presence of the chemical hampers reuse/recycling of the materials in which it is used.

It will undoubtedly be a very valuable tool in terms of enabling early safety and sustainability assessments

In this regard it is important to recognise the limitations. Assessment of chemicals has always been an exercise in dealing with uncertainties. In this respect, the SSbD approach is no different. It will undoubtedly be a very valuable tool in terms of enabling early safety and sustainability assessments—but it will not be able to catch everything.

Moreover, information to perform a good SSbD assessment is often lacking. Yet, we now have more predictive tools and methods available than ever before. In an ongoing European Partnership for the Assessment of Risks from Chemicals (PARC), scientists and agency experts from all over Europe are combining forces to develop a toolbox to support SSbD assessments. This toolbox will hopefully showcase how far we can go when using state-of-the-art predictive methods, new approach methods and combining the newest know-how in the different lines of assessment.

But perhaps one of the most important immediate benefits of the SSbD approach is that it will bring together chemical engineers and safety assessment experts at

early stages of the innovation process. Training the next generation of engineers and process scientists to truly embed safety and sustainability considerations can really help to change Europe's production mindset in a greener and more sustainable direction.

Can SSbD lead to real change?

To apply the SSbD approach, companies will need to invest money and time during early pre-market evaluations. And the benefits to the company should be greater than the costs, otherwise the incentives to use SSbD may be weakened. In this regard, the knowledge generated during the pre-market SSbD process may prove to be useable for the company at later stages—also for various regulatory purposes. Hence, the initial investment may later yield a valuable return.

Another important incentive for SSbD implementation can come from consumers. The demand for green products and services has increased in the last decades, with many companies adopting marketing strategies focusing on 'green' messaging. It is no longer sufficient that companies produce quality products. They also need to do it in a way that is socially responsible and does not cause harm to people and the environment. The SSbD approach can help underpin company responsibility and their green profile.

Companies need to produce in a way that is socially responsible and does not cause harm to people and the environment.

At the same time, this could create a risk for potential greenwashing. Europe has seen numerous examples of products being labelled as 'green' without sufficient documentation or labelled 'without' specific hazardous substances although they contain other substances that are equally hazardous. One example is products labelled as 'BPA free' that contain other endocrine disrupting bisphenols.

The risk of potential greenwashing also illustrates an important dilemma: the trade-off between precision and user-friendliness of the approach. The SSbD approach needs to be precise enough to deliver the broader intended benefits but it also needs to be operational (i.e. cost-effective and not overly complicated) to increase the incentives for companies to apply the approach.

Whereas the practical implementation of the SSbD approach is still being developed and tested in a number of case studies, the overall general framework has already been established. Compiling existing information, generating new information and assessing the data required for the five steps in the SSbD framework are all potentially time consuming and costly, and require a high level of expertise. Hence, companies may in many cases choose to use the framework more as (a) building block(s), rather than attempting to address all elements. This approach can nevertheless still help to reduce the number of hazardous and unsustainable chemicals that enter the market.

From a policymaker's perspective, measures that further increase incentives to use the SSbD approach will be important. After all, it is the uptake and effective implementation by the private sector that in the end will determine the success of SSbD.

Currently, a few large companies are testing the concept in several case studies. To encourage wider use, also by small and medium-sized companies, will require further efforts. This involves showcasing the value of the results generated by the approach and creating economic incentives, e.g. by embedding SSbD in the relevant EU funding programmes on research and innovation. And finally, it is important that we really prioritise the development of the sustainability part of the SSbD approach and the development of methods for weighing the different types of impacts against each other.

A step towards safe and sustainable chemicals

As the results from the ongoing case studies from private companies and research institutions emerge in the coming years, we will come to know much more about the capacity of the SSbD approach and what it can deliver. The case studies will be a key source for evaluation of the practical implementation of the SSbD approach and possible measures to improve it and will enable the sharing of good practices. The experience gained through these case studies will also help to develop methods on how to integrate the two main highly specialised elements in the SSbD approach: safety assessment and sustainability assessment, each with their own communities of experts and ways of working. Until recently, these two 'worlds' of chemical safety and sustainability experts have been separated and SSbD has already succeeded in bringing the two communities closer together. But there is still a long way to go

to develop a common understanding of the SSbD concept. When comparing the different elements in the SSbD assessment there are very likely going to be trade-offs, since it is unlikely that one chemical or material will be superior in all aspects of both safety and sustainability. To move forward we should devote time to bring the different experts together and discuss the results from the initial case studies with a strong focus on the integrative parts of the assessments.

In conclusion, the development and implementation of the SSbD approach offer significant potential for changing the way Europe evaluates chemicals and material design, use and recovery. This approach will run in parallel to the extensive regulatory framework for chemicals in the EU. The approach will lead to a growing understanding and knowledge of how the design of chemicals and materials can reduce their impacts on human health and the environment.

The future will tell if SSbD will indeed facilitate a better and more holistic assessment of chemicals and materials, and thus support Europe's transition to a circular economy with safe and sustainable chemicals.



2. Innovating based on Safe and Sustainable by Design principles: A Vision for the Chemical Industry

Eva-Kathrin Schillinger and Ann Dierckx, Cefic
Wibke Loelsberg, BASF

This essay describes Cefic's perspective on the innovation process, exploring how SSbD principles can shape and guide the industry's approach towards creating safer, more sustainable solutions based on scientific and technological know-how.

Cefic's vision on SSbD

The chemical industry is at the forefront of innovating for a sustainable future, providing solutions to today's societal challenges. Cefic defines² Safe and Sustainable by Design (SSbD) as an iterative process guiding innovation and the placement on the market of solutions that are safe and deliver environmental, societal, and economical value through their applications. Cefic's members are actively engaged in testing the SSbD framework as proposed by JRC, see box 1 and box 2 for two case study examples.

To ensure SSbD fulfils this goal, it must integrate safety and sustainability principles from the very beginning of the innovation cycle. Cefic envisions innovation processes for the industry in which SSbD principles are guiding considerations for decision making. From the very beginning of the innovation project, conscious trade-off decision making has to play a crucial role, thus aligning with the broader goals of the European Green Deal and the Chemicals Strategy for Sustainability.

In scope are new chemicals, materials, products, processes, and services, as well as the potential redesign of existing ones, following e.g. Portfolio Sustainability Analysis as described by the World Business Council for Sustainable Development (WBCSD)³.

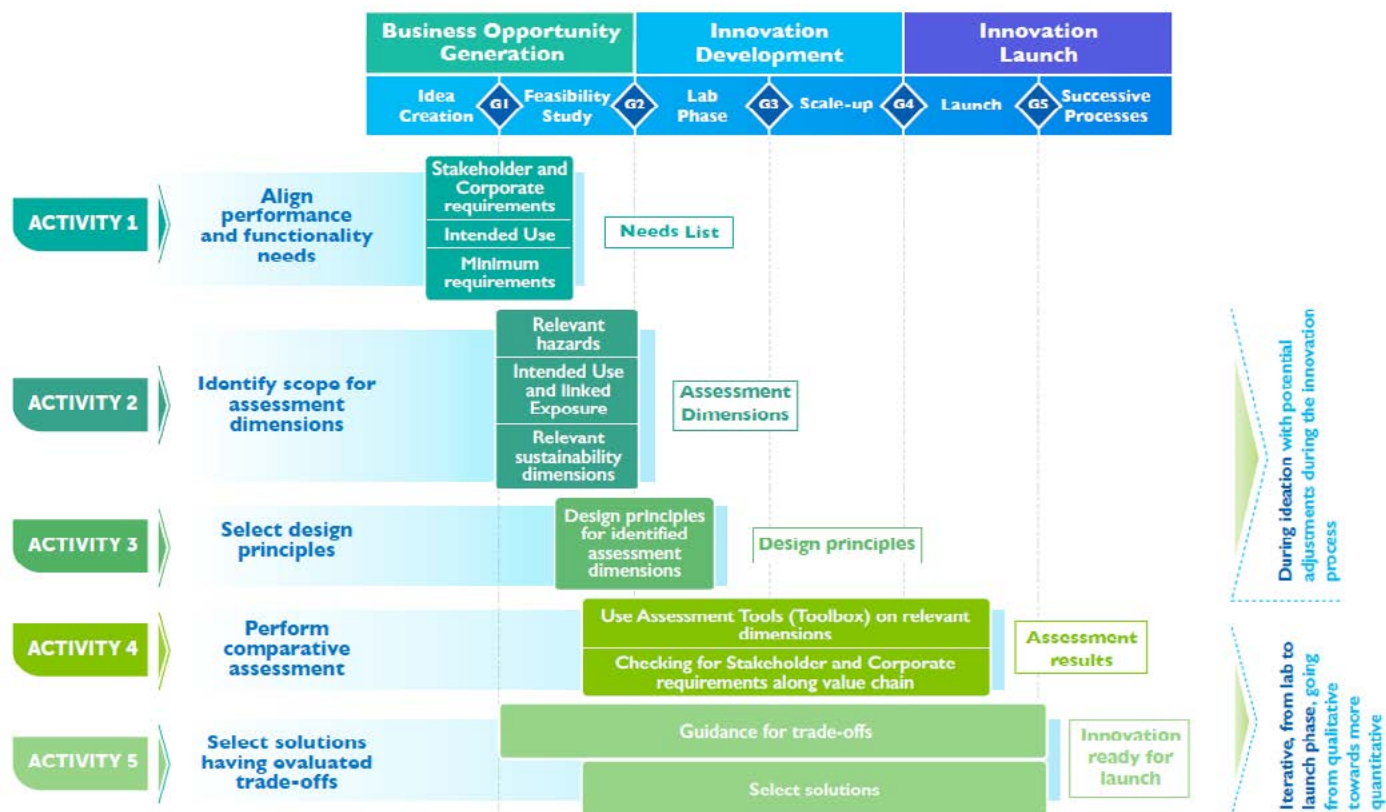
Cefic's views on implementing a Safe and Sustainable by Design approach

Cefic's 'Safe and Sustainable by Design: A Guidance to Unleash the Transformative Power of Innovation' guidance⁴ provides actionable advice for embedding SSbD throughout the research and innovation life cycle. It highlights the importance of defining use cases, managing data needs, and choosing sustainable design principles.

The guidance outlines five interdependent activities:

1. Align performance and functionality needs identify application requirements and intended uses to determine exposure scenarios and differentiate between industrial and consumer use, including professional use and end-of-life considerations.
2. Identify scope for assessment dimensions: narrow down data needs to set assessment dimensions early in the process and effectively set guiding design principles.
3. Select design principles: set principles for the most important dimensions early to facilitate market entry and identify non-viable options as fast as possible (fail fast–fail cheap).
4. Perform comparative assessment: align with EU Green Deal goals while considering additional dimensions based on their relevance to the intended use case, the stakeholder requirements or corporate strategy.
5. Select solutions having evaluated trade-offs: select viable options through continuous evaluation and trade-off decision making.

Figure 1: Cefic’s guidance on implementing a Safe and Sustainable by Design approach.



In addition, the guidance report stresses the importance of differentiating between new-to-the-world chemicals, materials, products and processes and components and processes stemming from incremental innovation processes in the assessment approach. For new-to-the-world products, the availability of relevant data will be very limited at the early stages of the innovation process—the same applies for potential knowledge and expertise based on prior innovation activities with similar compounds (in new-to-the-world cases, these will not exist). In the case of incremental innovation, certain deductions might be made from such prior innovation activities with similar compounds, hence the assessment approaches for the two cases will differ. The guidance lays out exemplary roadmaps for the SSbD assessment of both new-to-the-world and incremental innovation-based products and processes. New approach methodologies (NAMs) e.g. QSARs, in vitro and in silico tools and methods form part of these assessment roadmaps.

The way forward

Cefic considers integrating safety and sustainability aspects early in the innovation process as scientifically based common sense. The applicability of any kind of SSbD approach must be pragmatic and flexible, user-focused and incorporate assessment methodologies appropriate for each stage of innovation to generate reliable data for decision-making.

A successful SSbD implementation hinges on a collaborative synergy between first and foremost industry, academia, RTOs (Research and Technology Organisations), downstream users of the chemical sector but also policymakers, citizens and other societal stakeholders. This collaboration aims to develop a clear and practical SSbD approach that creates chemical products that are not only safer and more sustainable but also economically viable from the outset.

To ensure the economic viability and competitiveness of these innovations, the industry calls for incentives and supporting tools to foster innovation.

In order for SSbD to become a useful guidance for fast decision making:

- approaches must be lean and pragmatic;
- resource and capacity needs should be coverable by the respective existing innovation project resources.

Bringing in safety and sustainability considerations early into innovation processes relies heavily on data and assessment methodologies. Hence, the development of further flexible, adaptable (digital, e.g. predictive approaches such as modelling) methodologies, analytical methods, and toolboxes, including withgoing databases, will be needed, alongside the actual target to develop new molecules, materials, products, processes and services for substitution or new approaches.

Costs will be associated with such innovations on methodologies, toolboxes and new substances.

Given the short time left until 2050 and the complexity of investment cycles, the chemical industry needs the right funding instruments and methods, including for its academic partners.

Furthermore, data availability and accessibility along the value chain of a chemical or material plays a crucial role for the analysis throughout its entire life cycle. Here, secure approaches to data sharing and data sharing spaces need to be developed respecting the guiding principle of protection of intellectual property.

SSbD approaches should be lean and pragmatic and should be coverable by the respective existing innovation project resources.

Also, to strengthen global competitiveness of the EU chemical industry and not to create a European stand-alone solution, innovation is to be considered a crucial driver and a clear strategic link between application of any SSbD framework and the purpose of research and innovation steering and opportunities should be pointed out, including the possibility of incentivisation for industry when the assessment framework is applied (e.g. leaner registration processes).

Cefic continues to provide input such as the creation of a straightforward and easily applicable approach to SSbD innovation between the European Commission, industry, academia and RTOs and the downstream users of the chemical sector. Cefic commits to continuing facilitation of this co-creation process, bringing together all relevant stakeholders.

SSbD Test Case BASF: reformulation of a flame retardant polyamide

Siu Ting Li-Hübner, BASF

BASF applied the SSbD framework as published by JRC to the re-formulation of a flame retardant polyamide. As a baseline, few safety data are available on existing raw materials although the substances are already on the market. As the product is a multi-component, the safety and sustainability assessment of the material is a challenge. The production of a flame retardant polyamide is a multi-step value chain from extracting the raw material to monomer production, polymerisation, compounding, article manufacturing to use phase and end of life.

The SSbD assessment involved four steps:

- Step 1: Hazard assessment based on existing toxicological and ecotoxicological data, e.g. from the respective REACH dossiers.
- Step 2: Assessment of safety aspects for workers focusing on the production and processing phase involving the flame retardants based on ECETOC's Targeted Risk Assessment (TRA).
- Step 3: Assessment of safety aspects for the final consumer and the environment focusing on the use of the flame retardant polyamide product based on ECETOC's TRA.
- Step 4: Sustainability assessment through a Life Cycle Assessment according to PEFCR to compare the environmental impact of both flame retardants in an ICT connector.

Learnings

Resources: two experts from various fields of expertise were needed per step plus dedicated project management. The assessment took about 40 working days per case. Data accuracy and availability is and will remain a challenge due to the nature of the method and dynamics in value chain operations. Overall, considerable financial resources are needed to meet assessment needs. At the initial phases of the innovation process data is very limited because only limited volumes of the substance are available and uncertainties in tests are high. Also, which raw materials are used, from which supplier, as well as

which production processes will be used is not yet certain. Benchmarking in non-transparent markets will be difficult.

The feasibility of the framework largely depends on the respective stage in the value chain, i.e. whether an early precursor is evaluated, the chemical itself (here: the applied flame retardant) or the resulting material or residue. Accurate data can only be achieved for one's own production steps. Data accuracy and availability is and will remain a significant challenge throughout the assessment and a subsequent commercial product life cycle. Even though in this case data from raw materials were available through REACH dossiers, some information was missing. Sector specific performance assessments need to be considered as well: performance is a key criterium for overall sustainability and market acceptance.

Our experience and conclusion

BASF has established its portfolio sustainability assessment method TripleS, already including SSbD requirements to our R&D assessment. Our experience shows that such a framework allows to identify transformation opportunities as well as challenged products early on to further develop our product portfolio to deliver on market demands with innovative and safe solutions. At this point of time, however, considerable efforts would be required to fully integrate the SSbD framework into the innovation process without guaranteeing improved R&D results compared to today's practice and methods. The SSbD framework offers a foundation to support innovating safe and sustainable chemicals and materials, nevertheless a more practical (less time intensive) approach reflecting industry's R&D process is needed.

SSbD Test Case Clariant: Flame retardants in electronic applications

Adrian Beard, Clariant

In 2022, the JRC reached out to industry to find volunteers for running case studies on the SSbD concept. Clariant agreed to participate with a case study on its phosphinate flame retardants in consumer electronics applications. This class of halogen-free phosphorus-based flame retardants has become a common solution for engineering plastics like polyamides and polyesters as well as some special epoxy resin applications. We intended to apply the SSbD methodology to a fully commercial product—as compared to a molecule in research and development—because many data for the comprehensive sustainability assessment already existed. This approach is similar to the full-fledged JRC case study on plasticisers in food container sealants.

The case study confirmed the low hazard nature of the flame retardant. The high energy consumption for the production of elemental phosphorus and the hazard profile of other starting materials have a significant impact on the sustainability profile. In the use case of flame retarded compounds for electronics, benefits versus formulations based on brominated flame retardants in combination with antimony trioxide were demonstrated by a complete life cycle assessment (LCA) study.

Key overall learnings from our case

The JRC guidance provides a very broad and comprehensive methodology, covering the scientific literature and methods for the sustainability assessment of chemicals ('the textbook').

Consequently and unfortunately, this extensive approach requires very high efforts. Only few companies will have the necessary expertise in-house, and even then, their capacity will be limited to run SSbD assessments for all ongoing innovation projects. Outsourcing some tasks to specialised consultants or research organisations requires budgets in the range of several ten thousand Euros per analysis. The toolbox under development in the European Partnership for the Assessment of Risks from Chemicals (PARC)⁵

project will hopefully provide easily usable methods. The detailed review of our already commercialised flame retardants confirmed 'sustainability hotspots' like raw materials, which have particular hazards processes with high energy consumption and emissions life cycle stages with distinct issues. In this manner improvement potentials can be identified for incremental innovation like modification of existing products or their products processes or raw materials (sources). Such a 'baseline' study can also be a good reference point for fundamental innovation, i.e. searching for new molecules. The methods in the JRC guideline generally require quantified and validated data. Including also expert judgement and qualitative judgement (possibly with peer review) would allow for greater flexibility and filling of some data gaps. Trade-offs cannot be avoided, because it is very unlikely that a chemical will just perfectly match all criteria.

The SSbD methodology creates the necessary transparency to come to conscious decisions on certain trade-offs. The SSbD framework should be aligned with Portfolio Sustainability Assessments (PSA) based on the World Business Council for Sustainable Development's (WBCSD) framework. The chemical industry intends to standardise this tiered approach and methodology. Clariant established its 'Portfolio Value Program' (PVP) many years ago and recently updated it to include 38 sustainability criteria. This PVP is part of Clariant's innovation process.

Clariant will remain engaged in the discussions and further development of SSbD tools and methods. We believe that the approach is helpful to bring the full life cycle of chemicals and their impacts at various stages into their safety and sustainability assessment (as it is included in PSA concepts). The challenge remains to come to workable and flexible methods at each stage of the innovation process and also in retrospect for already established products.

3.

Circular chemistry

Jasper van Kuijk, Delft University of Technology

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In this essay, the author calls for the principles of 'design for disassembly' to be applied to the design of chemicals as well as to the logistics surrounding the recovery of those chemicals from products at the end of their life cycle.

With a circular product you do not only design for its assembly, but also for its return and disassembly. And in a truly circular economy we should take that principle further than we are doing now. Down to the molecular level.

There are more and more inspiring products designed with return and disassembly in mind so that the different materials in the product can be separated. Consider the design for the modular ISPA Link shoes from Nike, as well as circular mattresses from Dutch manufacturer Auping and others. Because the different types of materials in these products are connected in a reversible manner (i.e. they are not melted or glued), the parts can be separated at the end of the lifespan of the product. Another advantage: because the parts can be disassembled more easily, it is easier to replace them, which extends the products' lifespan. You could replace the sole of the Nike shoe or the top layer of the mattress. That's much more difficult to do when everything is melted and glued together.

However, at the end of the lifespan of the components or products you are still left with the recovered materials. If you replace a part of the Nike shoe, you still have a discarded lump of rubber or cloth to deal with. You could then try to find a new use for it, either by reapplying it as new raw material for the same product or for something similar. Or you could downcycle it or even upcycle it, but that can still be quite a challenge when it comes to design, material, and logistics. And what if the need for products made from that specific material dries up?

It may sound like a ridiculously complicated challenge now, but in 40 years we will find it ridiculous that we ever released so many chemical compounds into the world without thinking about how we would break them apart and recover them.

Or what if, as with paints and coatings, the material must be bonded to the rest of the product? Good luck trying to remove the paint from the car in front of your house. Or detaching the non-stick coating from your frying pan. To reuse the metal from those designs, the paint or coating will have to be removed with an abrasive process, by thermally destroying the material or by chemically dissolving it.

But what if we would also apply the principle of designing for disassembly to chemical substances such as paints and coatings? We could design the molecular composition of a non-stick coating in such a way that at the end of the pan's life

cycle it can be exposed to a substance or process that disintegrates the components of the coating, allowing them to be 'sorted' at a substance or molecular level. When your car is at the end of its lifespan and taken back for recovery, the various parts are first dismantled at the component level. Then the entire chassis and body, with all layers of paint on it, go into the chemical recovery line. There, a combination of different sprays, heating and radiation ensures that layer by layer drips off the chassis, breaking down into the desired substances or even molecules.

Realising such an approach means that we must develop fundamentally sustainable production and circular recovery processes for chemical compounds. This also implies that chemical producers, in addition to the distribution of their substances, have to start considering reverse logistics. How do you ensure that the paint layer you sold, or the product on which the coating you supplied is applied, is returned to a place where you can 'disassemble' the coating?

Easy? No. But I think a lot of people would have been very grateful if someone had thought about PFAS in this way before putting it on everything. In a truly circular economy you recover all materials, including your chemical compounds. This is more sustainable, more circular and safer, because no overly persistent compounds are left behind in our living environment and in nature.

To achieve this, we have a huge amount of challenging scientific research to do, for all new substances and processes that need to be developed. But the first steps are already being taken. A good example is how scientists from the universities of Amsterdam and Utrecht developed an approach to create new biodegradable compounds and applied this to the development of a fire retardant. That's the kind of thinking we're looking for, but we want it to be even more ambitious. Circular chemistry also requires a transition of the chemical industry—in knowledge, in thinking, and in the arrangement of the value chains, now including recovery. Finally, there must be legislation and regulations and the right financial incentives to encourage the development of these types of substances and ensure that circular chemistry becomes the most interesting option from a business economics perspective.

It may sound like a ridiculously complicated challenge now, but in 40 years we will find it ridiculous that we ever released so many chemical compounds into the world without thinking about how we would break them apart and recover them.



4. Redefining chemistry's role: leveraging molecular design for a safe and sustainable future

Hannah Flerlage and J. Chris Sootweg,
University of Amsterdam

The authors of this essay look at Safe and Sustainable by Design (SSbD) as a critical element if chemistry is to help address various contemporary crises. In this article they argue that the pursuit of SSbD should be much more focused on promoting redesign of molecules

in a multi-dimensional, interdisciplinary approach (with the help of chemists' knowledge and computational tools including AI).

While currently undervalued in the realm of SSbD, molecular design is a powerful method that can broaden the scope of chemical substitution options beyond those available today. It has the potential to transform chemical innovation by tuning molecular properties to pre-emptively address safety and sustainability concerns.

The imperative of Safe and Sustainable by Design in chemistry

While chemistry has underpinned countless advances in health, technology and daily life, it has also propelled us into a maelstrom of ecological and public health challenges, from rampant pollution to the insidious spread of toxic substances. Modern chemistry, often criticised for its linear 'take, make, dispose' approach, faces a pivotal moment⁶. This traditional methodology is increasingly viewed as unsustainable, contributing significantly to environmental crises such as climate change and plastic pollution. The academic chemistry community in particular bears a crucial responsibility to pivot towards more sustainable thinking and practices. The concept of Safe and Sustainable by Design (SSbD) is critical in this context, challenging chemists to redesign chemicals on the molecular level to ensure safety and sustainability.

The importance and challenge of applying SSbD in academia and early innovation

Contemporary trends at many academic institutions aim to bring research to the market at an increasing pace, often motivated by the desire to address societal challenges such as environmental crises. However, this push frequently occurs without acknowledging the substantial role current chemical practices have in precipitating and escalating these environmental issues. In light of this, the acceleration from research to market not only amplifies the responsibility of scientists for the real-life effects of their innovations but also emphasises the urgent need for foresight regarding potential side effects of new chemistry. While SSbD holds promise, its application in the realm of academic and early-stage chemical innovation presents unique challenges.

The ongoing discussions on the SSbD framework published by the Joint Research Centre of the European Commission⁷ primarily focus on the assessment of safety and sustainability of chemicals (phase 2 in the framework), with less emphasis on

the initial design phase (phase 1). Although it is crucial to broadly discuss the safety and sustainability criteria for assessing chemicals, much of the methodology for achieving these goals lies in the design phase. In our view, the current interpretation of the framework tends to overlook the potential for molecular design. The design principles outlined in the framework focus on alternatives assessment—comparing chemicals rather than exploring molecular features that could inform the (re)design of chemicals for improved outcomes. While these principles are valuable for adjusting product and process designs, they fall short in guiding molecular design. This oversight limits the scope of substitution options to chemicals produced today and, moreover, restricts the framework's capacity to transform chemical innovation, where designing new molecules with tuneable properties could pre-emptively address safety and sustainability concerns.

Necessity for a multidimensional design approach

Tuning chemical structures to achieve a set of targeted properties is among the core competencies of chemistry. SSbD demands an expansion of our traditionally reductionist focus on a specific property, often aimed at marketable product performance, to encompass the chemical's interactions with the technosphere (industrial systems and society) and the biosphere (nature). This necessitates systems thinking, integrating Green and Circular Chemistry principles with advanced molecular design strategies. To fully embrace SSbD, we must leverage chemists' deep knowledge of molecular behaviour, utilising computational tools such as AI and machine learning, and drawing insights from drug design to predict environmental and health impacts with limited information.

Facilitating molecular design for SSbD

In 2022, we published a preliminary outline of what a computer-aided approach for redesigning chemicals for safety and sustainability might look like, including considerations of when molecular redesign is an appropriate strategy (see figure 1 below)⁸. To facilitate a systematic (re)design, numerous molecular structures are generated and screened *in silico*, identifying beneficial features while filtering out those with potential negative impacts. This method parallels strategies used in drug discovery, where computational models guide the selection of promising lead structures.

However, designing for non-toxicity inverts the primary aim of drug discovery. Instead of searching for a specific biological target activity, the question becomes: can we exclude harmful biological activity? With the integration of rapidly advancing computational tools, aided by AI, can we meaningfully predict properties from chemical structures in a high-throughput manner to steer toward the most benign chemical structures? These questions highlight the need for systems thinking and call for an interdisciplinary effort to integrate environmental science, toxicology, chemistry, and policy effectively.

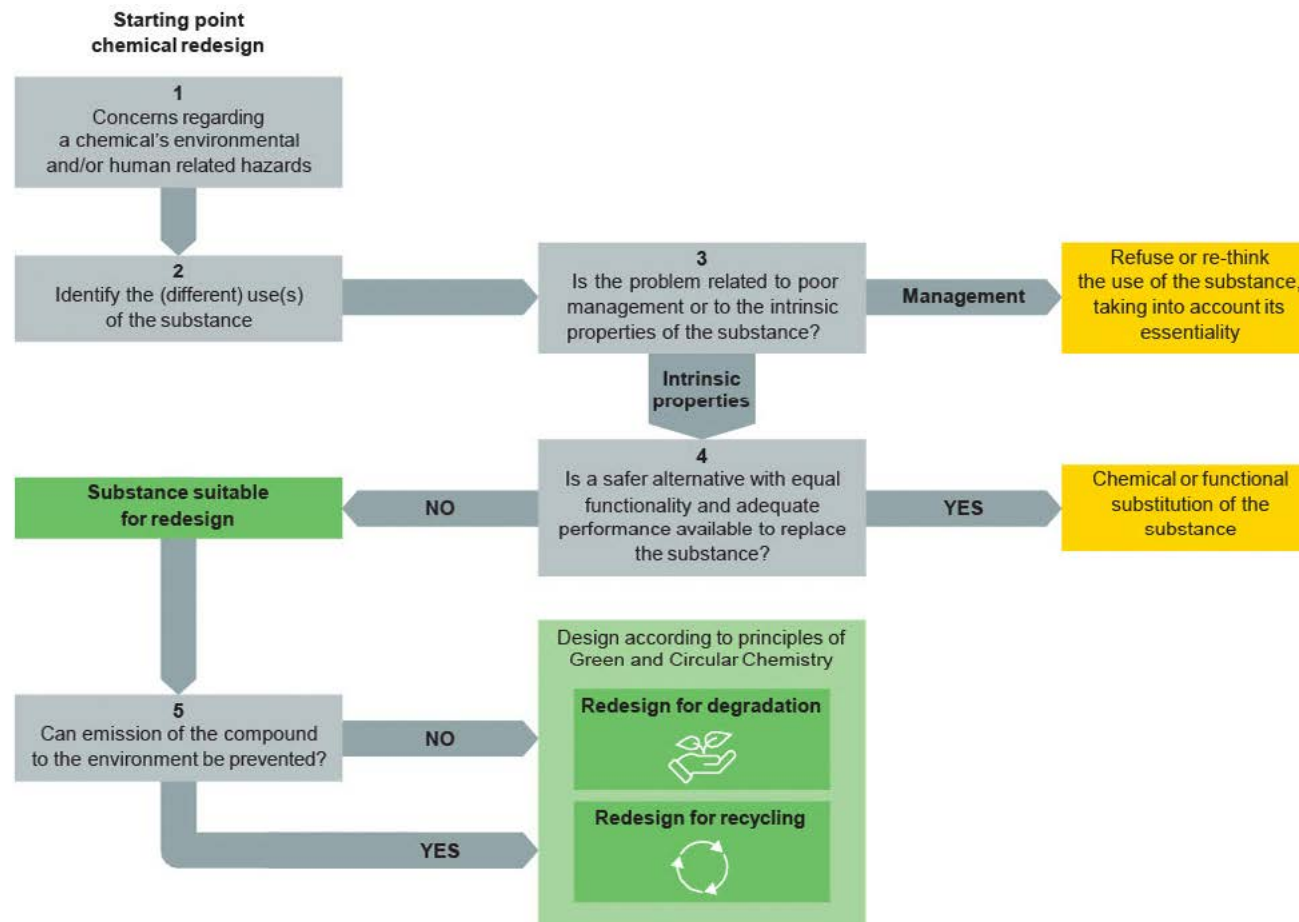
Including molecular design in SSbD to transform chemistry for a sustainable future

Realising the potential of molecular design for SSbD necessitates bridging disciplinary gaps and fostering collaboration among chemists, environmental scientists, policymakers and other key stakeholders. Establishing clear criteria for evaluating chemical properties and encouraging policy frameworks that support innovative, sustainable chemical design are essential steps. Additionally, academia's role in pioneering new chemistries underscores the importance of heightened responsibility and a proactive approach to incorporating SSbD principles at the earliest stages of innovation.

Although it is crucial to broadly discuss the safety and sustainability criteria for assessing chemicals, much of the methodology for achieving these goals lies in the design phase.

Transforming chemistry through SSbD transcends academic theory, emerging as a crucial step toward sustainability. By embracing an interdisciplinary approach, leveraging advanced computational tools and fostering policy environments conducive to innovation, the academic chemistry community with its knowledge of molecular design can play a vital role in making SSbD a success.

Figure 1: Flowchart to identify the suitability of molecular redesign. Source: Van Dijk et al (2022).



5. What is needed to move SSbD from academic to utility across industrial value chains?

Asli Tamer Vestlund, Change Chemistry
Molly Jacobs, Sustainable Chemistry Catalyst/Centre for Sustainable Production
Joel Tickner, UMass Lowell

In this essay the authors state that the underlying premise of the SSbD concept is becoming lost. Current issues such as a weaker focus on innovation and the need to move from the academic to utility across the industrial value chain are hampering efforts to operationalise SSbD. Addressing these challenges requires effective and ongoing collaboration amongst all stakeholders. Breaking down silos and aligning efforts across sectors is crucial to driving systemic change in the advancement towards safer and sustainable chemistries.

Change Chemistry and the Sustainable Chemistry Catalyst

Change Chemistry⁹ is a collaboration of over 100 members (spanning across diverse industries from leading chemical companies, brand manufacturers and large retailers to innovative startups) working to make safer and sustainable chemistry widely available in the marketplace. Our joint vision is a global economy where all chemicals, materials, and products are safe and sustainable, from creation through to disposal and reuse. The Sustainable Chemistry Catalyst¹⁰ at the University of Massachusetts Lowell in the US, a research institution that is a close partner of Change Chemistry, conducts research and policy analysis to drive a growth in safer and sustainable chemistries as a key means to reduce the impacts of toxic chemicals on public health and the environment.

Background of our involvement with the SSbD framework

Creating a supportive policy environment that incentivises commercialisation, adoption, and growth of sustainable chemistry is critical to our community vision. As such, we welcomed the inclusion of the concept of the transition to chemicals and materials that are safe and sustainable by design (SSbD) as presented in the Chemical Strategy for Sustainability (CSS).

This inclusion followed more than four years of joint efforts between the Sustainable Chemistry Catalyst and different stakeholders:

- Collaboration with the European Chemicals Agency (ECHA) to create the agency's substitution strategy and supporting materials.
- Collaboration with the consultancy Wood (now WSP) and DG Environment to develop a Chemicals Innovation Action Agenda: Transitioning to Safer Chemicals and Technologies¹¹ published in June 2019.

Both efforts were critical to building an understanding into the policy framework that it is difficult to fully address chemicals of concern without solutions at scale.

The SSbD framework, first introduced in 2022, provided a structure to implement the vision of the CSS, linking the regulatory programs for chemicals with an effort to grow solutions to chemicals of concern and avoid regrettable substitutions. Several Change Chemistry members in the chemical industry and downstream sectors have been involved as SSbD pilot testing participants and remain engaged stakeholders. With so many current and potential stakeholders that need to be engaged to

shape the development and implementation of the framework and provide much needed feedback to the European Commission, we are also engaging with a number of initiatives and organisations such as the EU-project IRISS¹² for building and connecting the SSbD community in Europe and globally, particularly with regards to value chain engagement.

Current issues with SSbD

Weaker focus on innovation

Operationalising SSbD is undoubtedly complex and challenging. Despite the European Commission's efforts to develop and test a SSbD framework and to create toolboxes to support assessing whether a chemical substance or material can be considered SSbD, a crucial underlying premise of the concept is becoming lost: the need to focus innovation on high-performing safer and more sustainable chemistries to replace their toxic counterparts in key applications and functions.

In ECHA's substitution strategy¹³ there was an explicit focus on connecting substitution with innovation in safer chemicals, materials and technologies. Substitution in many cases is being hampered by a lack of available safer, sustainable alternatives. In 2018 the Safe Chemicals Innovation Agenda¹⁴ sponsored by the Dutch government identified seven crucial innovation areas to replace society's reliance on toxic chemicals for key functions:

- Water, grease and stain repellency
- Flame retardancy
- Preservation
- Plasticising
- Solvents
- Surfactants
- Curing agents

Sadly, chemical innovation for these functions is still critically needed. Although SSbD “aims to substitute or minimise the production and use of substances of concern”, as stated by JRC in their report¹⁵, current efforts are getting further away from this focus. Directing innovation towards these needs and pain points for companies across sectors of the value chain is critical. To date, no such attention as to how this should happen in practice has been a part of the SSbD dialogue. The limited attention to SSbD addressing key societal and industrial needs for safer

and more sustainable alternatives is not surprising given that SSbD is a concept that arose from academic efforts to design safer nanomaterials. In other words, the concept was to shape basic research and development (R&D) for new technologies. SSbD activities being centralised in DG Research, a research agency, reinforces the disconnect from societal and market priorities for solutions.

We need to focus innovation on high-performing safer and more sustainable chemistry to replace their toxic counterparts in key applications and functions.

A similar challenge has arisen in our work to advance implementation of the Sustainable Chemistry R&D Act in the United States. That law requires the White House Office of Science and Technology Policy (OSTP) to both undertake a landscape assessment of sustainable chemistry activities across the federal government and develop a strategy to more effectively coordinate and advance research, policies, financing, and incentives that grow sustainable chemistry commercialisation and adoption. The OSTP committee is co-chaired by individuals from two research agencies and the Committee's interim report was focused primarily on basic research and technology needs rather than key priorities to replace problem chemistries based on regulatory and market drivers.

Moving from academic to utility across the industrial value chain

As noted, SSbD evolved from a basic research idea of ‘Safe by Design’ nanotechnologies. However, this may not be the right approach for companies along the value chain struggling to meet market, investor and regulatory needs. SSbD as it is currently evolving, is too academic and complicated, making it very difficult for industry to use it for their sustainable chemistry design or evaluation strategies. This is even more pronounced for smaller companies or start-ups without deep scientific benches to undertake complicated multi-level assessments. Others, including the NGO ChemSec have similarly argued that as currently constructed, SSbD runs the risk of ‘paralysis by analysis’—getting stuck in endless loops of scientific analyses that are extremely difficult to put into practice¹⁶.

We are also concerned about the lack of clear definitions and wider market demand for SSbD chemicals. Currently, there is an overarching approach and assessment framework for SSbD but no clear definition on when a chemical meets the definition of SSbD, nor whether there are shades of grey in that definition. Decision rules are

different from assessment criteria—the latter of which is the basis of the SSbD framework developed by the European Commission. To date, discussions have steered away from placing a stake in the sand about the minimum criteria for declaring that a chemical meets SSbD requirements. This is necessary for its utility by downstream users and others seeking to evolve their products along both safety and sustainability dimensions.

Downstream users are also too quick to continue the use of problematic chemistries (either because of toxicity or sustainability concerns) so long as the market continues to offer cheaper incumbent chemicals. Market demand for SSbD chemicals will always be hampered by lower-cost or well-performing incumbent chemicals that are already a part of complex and established supply chains or product lines with long life cycles. Regulatory drivers that restrict or make the continued use of toxic or unsustainable incumbent chemicals extremely expensive will be crucial to the uptake of SSbD solutions among downstream users.

Innovative solutions for a given application can often take more than 10 years to commercialise at scale, and performance testing can be prohibitively expensive. Therefore, clarity on the broader system and long-term trends in the supply chain are necessary for innovative companies to consider when developing SSbD chemicals (e.g. changes in chemical feedstocks).

An important group of downstream users that face challenges due to increasing regulatory demands on chemicals are retailers. They face an increasing number of regulations in the EU but also within the states in the US, such as various PFAS restrictions or the Ecodesign for Sustainable Products Regulation (ESPR). These regulations dictate what chemicals can and cannot be in the products that they put on the market as well as requiring the retailers to consider the impact of chemicals in product circular design methods. It is quite likely that the impact of chemicals will also be a strong future consideration in other legislation such as those concerning Extended Producer Responsibility. Our own experience with the retailers in our community¹⁷ has shown that they continue to face challenges with chemicals data transparency and traceability as well as supply chain visibility. Retailers also encounter difficulties in determining whether ingredients are of potential concern to human health and the environment as well as in finding alternatives that are effective, meet customer demand and make financial sense. As a result of these,

there is clear motivation from the retail industry to increasingly demand SSbD chemicals; however, they are not clear on how to support this transition.

Changes needed in the wider policy landscape

In our experience and as mentioned above, policy mandates are a critical enabler for substitution and the uptake of SSbD solutions. R&D in alternatives as well as broad implementation of substitutes will always be held back unless there are clear policy mandates that motivate both innovation and adoption. Restrictions on hazardous chemicals will not be enough in and of themselves, as the tendency in industry is to move from a regulated option to a similar non-regulated option that can drop into existing manufacturing processes. Policy incentives are often the main enabling factor that can overcome the dominant power that incumbent products have in the market, enabling a transition to safer and feasible alternatives. In this respect, the voluntary nature of the SSbD framework could also be a clear limiting factor to its wider take up and hence, other policies that incentivise innovation and adoption of SSbD chemistries will be needed—for example recognition of chemicals and products that meet SSbD criteria or requirements for grant or contract funding.

It is unclear in the current SSbD implementation paradigm, how chemicals from outside the EU (i.e. imports) will be treated. However, chemical value chains are global in nature. Therefore, differing policies, restrictions and incentives could create a challenging playing field for SSbD solutions, particularly when a company that uses hazardous chemicals in a consumer product can still legally import these products into the EU. Therefore, the harmonisation of policy efforts globally is essential to ensure that a framework such as SSbD has the intended long-term impact of growing solutions that advance safety and sustainability as well as a circular economy and climate-neutral society.

So, what do policymakers, industry and value chains, scientific community as well as other stakeholders need to start doing concretely to put SSbD into practice?

Recommendations for ways forward

As previously mentioned, the lack of strong focus on innovation to solve specific technology challenges is a potential stumbling block. We think that an important objective of the SSbD framework as per the JRC report is (and should be) “driving innovation towards the substitution or minimisation of the production and uses of

substances of concern, in line with and beyond upcoming regulatory obligations”. This is a crucial aspect of SSbD that should be at the forefront of the framework as it becomes operationalised. As mentioned earlier, in our experience within the green and sustainable chemistry space over the past 20 years, we have seen the trend for innovating new chemistries to involve developing a new chemical and then figuring out the range of applications that it can be used for. However, innovation should be steered towards market and societal needs for safer and more sustainable substitutes. It is of utmost urgency that we focus innovation on regulatory and market priorities or for example the needs outlined above in the Safer Chemicals Innovation Agenda report published 5 years ago now, where we lack an inventory of safer and more sustainable chemicals.

For example, a chemical that has been at the forefront of focus, PFAS, will most likely be universally restricted in the near future. However, at the moment, for some functions and uses of PFAS, we simply lack suitable substitutes. Therefore, the current situation is leading to much debate on the relative degrees of harm of PFAS instead of focusing on preventing the entry of PFAS into the market altogether. This is an immediate need where SSbD can contribute by steering innovation, incentivisation and market uptake of PFAS alternatives.

We previously highlighted that there is a lack of appetite for the uptake of SSbD in the value chain due to several factors. First of all, the SSbD framework needs to represent the reality of chemical industry practices (especially considering smaller-sized companies that lack strong research bandwidth) and be pragmatic in its approach so it can have a wider uptake across the value chain. The lack of definition of SSbD also remains a stumbling block. A clear definition—a north star—and minimal and ideal criteria for measuring progress will be important. One example of a definition and criteria is the definition of sustainable chemistry developed by the multi-stakeholder Expert Committee on Sustainable Chemistry. This definition integrates health and safety along the life cycle, circularity, ecosystem impacts and importantly transparency and environmental justice¹⁸.

Policy mandates are critical enablers for chemical substitution and for the SSbD we believe that the purely voluntary nature of the framework will likely limit its wider adoption. Therefore, there need to be either market or programmatic drivers for its use. Some examples of these would be:

- Policies that restrict incumbent chemicals of concern.
- Policies that create strategic cross-agency roadmaps to grow SSbD commercialisation and adoption, for example for PFAS.
- Funding and financing for R&D, piloting and scaling of SSbD solutions.
- Incentives for manufacturing and adoption of SSbD solutions.
- Recognition, listing, and certification programs for products of SSbD.
- Procurement programs that give preferential treatment to products of SSbD.
- Programs that provide technical or convening support to companies to support SSbD transitions.

These types of policies would allow for investments and other financial incentives for innovators, first movers, and sustainable chemistry champions. Building SSbD innovation into funding and policy efforts aimed at decarbonisation, environmental justice, addressing plastic pollution and the bioeconomy are also crucial for the future. To achieve this, educating policymakers about the needs across the value chain for investments and incentives for safer, sustainable chemistries is crucial.

We believe that the purely voluntary nature of the framework will likely limit its wider adoption.

We would like to conclude by emphasising that addressing these challenges requires effective and ongoing collaboration amongst stakeholders, government bodies, policymakers, industry, scientific communities and the wider community with NGOs and business associations. A broad set of organisations play key roles in this transition to safe and sustainable chemistries. And while they may not be aligned on every aspect of policy or specific actions, it is critical to have honest conversations to identify areas of alignment and collaboration to achieve mutual goals. Breaking down silos is fundamental if we want to achieve a system change and move towards a future when safe and sustainable chemistry is simply known as ‘chemistry’.

6. Essay on the future of the Safe and Sustainable by Design framework

Henrik Edin, ChemSec

This essay states that a lot remains to be done to make SSbD an efficient tool for transformation. It should not be possible to market hazardous chemicals as safe and sustainable. The increasing complexity of the framework risks counteracting its usability in the marketplace.

Introduction

In the process of creating an efficient SSbD framework, ChemSec in this text presents its views on core principles that should be respected, on how the Commission should address the challenges ahead, and on how the SSbD framework could support reaching the goals of the Chemical Strategy for Sustainability. Three years into the process, the final form of the SSbD framework is still uncertain. A lot remains to be done. The most pressing question remains: will it be good enough?

Background

Chemical pollution and the planetary crisis

Chemical pollution is a planetary crisis that urgently needs to be addressed. It is tightly linked to other threats to our environment on a planetary level, such as the climate effect and the loss of biodiversity.

The chemical sector is the third largest industrial consumer of fossil fuels. Oil and natural gas account for 99% of the feedstock for chemical production. 70% of all chemicals that are being produced today are hazardous to human health or the environment. The number of insect species has decreased by 10% per decade since the 60's due to pesticides and 20-25% of wild bird populations have gone extinct due to persistent organic pollutants.

The current state of affairs in European chemical legislation

With this backdrop, it was a logical step for the Commission to launch the European Green Deal, the flagship initiative from 2019, striving to make the European economy more sustainable. Climate neutrality, circular economy, biodiversity protection, and a toxic-free environment are goals that were presented in it. The Commission stated that it is a priority to protect citizens and the environment against the negative impact of hazardous chemicals. To this end, it adopted the Chemicals Strategy for Sustainability in October 2020, as well as the Zero Pollution Action Plan in May 2021.

In the Chemicals Strategy for Sustainability, the Commission presented specific actions to support a transition into an economy where chemicals, materials and their use in products are safe and sustainable. One of the central points was that all new chemicals that were put on the European market must be inherently safe and

sustainable, from production to end of life. The Commission also noted that the substitution of the most harmful substances has not occurred at the expected pace and that frontrunners still encounter major economic and technical barriers.

An initial proposal by ChemSec

Based on this background and the ambitions of the Commission, ChemSec concludes that an SSbD framework should be based on three principles:

1. Safe should always mean safe; hazardous chemicals are not safe and sustainable.
2. The SSbD framework should facilitate substitution by increasing transparency and improving incentives in the market.
3. The implementation should be speedy and stepwise so that the process is not bogged down in paralysis by analysis.

Additionally, the SSbD framework should first assess parameters for safety and then parameters for sustainability.

Regarding the safety of chemicals

Hazardous chemicals are a direct threat to human health and the environment and can therefore never be identified as safe and sustainable. The negative effects of hazardous chemicals can be direct and observable, but they can also be long-lasting and more difficult to identify. Because of this, it is important to phase out and stop using hazardous chemicals.

The presence of hazardous chemicals also disrupts the emerging circular economy. It is impossible to calculate the risk of exposure as materials are being used and reused several times.

The most hazardous chemicals are the ones that fulfil the criteria for being 'Substances of Very High Concern' (SVHC). However, chemicals that are not SVHCs are not safe by default. Under the Chemical Strategy for Sustainability, there are different levels of hazards proposed. The most hazardous ones are Substances of Very High Concern (SVHCs), Most Harmful Substances (MHS), and Substances of Concern (SoC). The strategy promises that the Most Harmful Substances should not be allowed in consumer products, and a natural consequence of this should be

that substances that are SVHCs or MHS could never be called safe. The question is whether SoC could be identified as SSbD.

Another aspect of importance to safety is uncertainty about properties or data gaps. We cannot consider a substance safe on the basis that it has not been tested. Obtaining data on the many chemicals in production has been and is a main challenge, but there is no way around it. It must be done. And the promise of the SSbD concept is that in the future we should know that chemicals are safe before they enter the market.

ChemSec proposes that products should not be considered safe when including chemicals with the following properties. Also, these chemicals should not be considered safe if these properties have not been examined:

- Carcinogens, Mutagens and Reproductive toxicants, Categories 1a, 1b and 2
- Persistent, Bioaccumulative and Toxic (PBT) and Very Persistent and Very Bioaccumulative (vPvB) Substances
- Persistent, Mobile and Toxic (PMT) and Very Persistent and Very Mobile (vPvM) Substances
- Endocrine Disrupting Chemicals
- Respiratory Sensitisers, Category 1
- Skin Sensitisers, Category 1
- Specific Organ Toxicity, Categories 1, 2 (repeated exposure and single exposure) and 3 (single exposure)
- Acute Health Hazards, Category 1 and 2
- Acute Aquatic Toxicity Category 1
- Chronic Environmental Hazards, Categories 1-4
- Ozone Depleting Compounds

Implementation

For efficient implementation of the SSbD framework, it should be introduced in the market as soon as possible and on a broad scale, both with producers of chemicals and with downstream users. The parameters should be implemented in a stepwise approach, giving industry room to obtain data necessary for the assessment. Speedy implementation is necessary to keep confidence in the SSbD framework and to counteract the risk of it being postponed indefinitely.

Some companies would like to use the SSbD framework when procuring chemicals and want to feel confident that they are not carcinogenic, endocrine disrupting, or harmful to the environment. By making sure there are well-defined safety parameters, their work would be more efficient, and the overall conditions in the value chain would be improved. H&M Group is one company that has recognised and voiced its opinion on the importance of prioritising the safety of chemicals. For policymakers, it is important to consider that the SSbD framework could play an important role not only for chemical producers but also for downstream users.

Challenges ahead

The Joint Research Centre (JRC) published an SSbD assessment model that to a large extent corresponds with the ideas presented in the ChemSec proposal. The model has five steps where different parameters are assessed. One of them focuses on the inherent hazardous properties of the substance and it includes a cut-off criterion that specifies that chemicals with certain hazardous properties will not be considered SSbD. The other steps assess several sustainability parameters. The size of the scope for the sustainability parameters is substantial. The model contains both social and economic sustainability parameters, which makes it both large and complex. The complexity of the SSbD framework makes it, of course, less likely that there will be a speedy implementation.

The SSbD framework, an efficient tool for change

It has been clear from the beginning that the urgency for action is great; there is no time to waste in making the market for chemicals safer and more sustainable. A radical and rapid change is required, and to achieve this there are principally two viable options for the policymakers responsible for the SSbD framework.

The first option is to create legislation that forces all actors to design and create safe and sustainable chemicals. The general objection to this is that actors will try to find loopholes to avoid being affected by or reduce the impact of the law, which is often done proficiently. This is probably one of the reasons why the substitution of the most harmful substances has not occurred at the expected pace under the current regulation. This first option has, however, already been ruled out by the Commission. The SSbD framework will not be a regulation.

This leaves us with the second option, which is to harness the market forces. If enough incentives are created in the market; if the demand for SSbD chemicals is strong enough, the market actors will change their production accordingly. This requires, however, a common framework for how to assess SSbD chemicals. It also requires transparency and a free flow of information so that different products can be compared by downstream users fairly and reasonably. This is probably where the true potential of the SSbD framework lies.

However, many downstream users, who initially were very optimistic about the SSbD framework, now experience that the whole concept is turning into an academic exercise of finding the perfect data for a million data points. As the SSbD framework is becoming increasingly comprehensive, it is becoming increasingly difficult for downstream users to use it in their business. Because of this trend, there is a visible loss in confidence of downstream users, which poses a risk for the SSbD framework as a whole.

Of course, there might be a positive change coming from a very complex and comprehensive SSbD framework—from an academic and scientific standpoint, this might be true—but the pace of the change might be far too slow. And if it is, the legitimacy of the SSbD framework would easily be challenged. The change needs to start happening today, not tomorrow.

Lack of data and going beyond regulation

The SSbD framework will not be a regulation, but it should go beyond it. However, in the case studies that have been produced at the behest of the Commission to test the SSbD framework, the data that has been used has been taken from sources within the current regulatory framework, such as the registration dossiers within REACH. This is unfortunate for several reasons. The main one is that the assessment will be poorer when the wealth of information from independent peer-reviewed academic studies and other governmental reports is not used. For the substances in the case studies, high-quality information was publicly available, but not used. Additionally, information in registration dossiers is known not to be sufficient. ECHA has a target to check the quality of only 5% of the dossiers, and when they do, they very often find them lacking information.

This strange approach to data collection has created a paradoxical situation where it seems easier to get a hold of data on the long-term environmental impact of a specific substance than data on its hazardous properties. Indeed, the data on hazardous properties should already today be much more easily available and more reliable than what is being presented in the case studies. It is necessary to find a method for using all available scientific peer-reviewed data in the assessment models of the SSbD framework.

Many downstream users now experience that the whole concept is turning into an academic exercise of finding the perfect data for a million data points.

One example of where available scientific peer-reviewed data on the hazardous properties of different substances is being used at high effect is the SIN list by ChemSec. It presents a prediction for different actors for what substances will be placed on the REACH candidate list. It is highly accurate, as nearly all of the substances that are being put on the REACH candidate list have already been put on the SIN list. This kind of predictive and forward-looking function is what the SSbD framework should provide for its users by broadening the scope of the data that is being used, and this is how the SSbD framework will go beyond regulation.

The scare of the cut-off criterion

Many actors that engage in the discussion of the SSbD framework are worried about the cut-off criterion, but there is no reason to. The function of the cut-off criterion should be to guarantee that the most harmful substances cannot be marketed as safe and sustainable, not to ban the production or procurement of specific existing substances. There is no regulation or restriction connected to the cut-off criterion, and the SSbD framework in itself is no regulation either. Of course, if the market embraced the SSbD framework, it would be disadvantageous to have a product that does not pass the cut-off criterion if the competition does. But this is what is needed if we are to move towards safer alternatives. It could be argued that this is the whole point of the SSbD framework. The cut-off criterion, although at times criticised, must remain in the model.

Political interference

The Commission has during its term not delivered on all that was promised in the Chemical Strategy for Sustainability. Most notable is the failure to present a revision

of REACH. It is reasonable to assume that many of the plans changed due to external events. Both the COVID pandemic and the full-scale Russian invasion of Ukraine have been used as arguments for the change of political direction.

As the term of the Commission is ending later this year, so might the political priorities. The next Commission might have other ideas for how the problem with chemicals should be addressed. This is a considerable threat. The fact that the SSbD framework in a sense remains on the drawing board makes it very vulnerable to political change.

Assuming we are still many years away from an operational SSbD framework, we have to ensure that we consistently aim for progressive criteria. This is the only way to make the framework an efficient tool for the market to go beyond regulation.

Conclusion

It is necessary to create an SSbD framework that is appropriate and efficient, and the ultimate purpose of it must be to help reach the goals of the Chemical Strategy for Sustainability.

It will be appropriate and efficient if it can harness the power of the market by creating transparency and greater agency for downstream users. Better data is available and should be used so that the SSbD framework can go beyond regulation and guide the industry toward better chemicals. A clear cut-off criterion in the assessment of hazardous properties should be safeguarded. There is a need for a speedy implementation to retain confidence in the framework but also legitimacy. The change needs to happen today, not tomorrow, because then it might be too late.

7. Safe, sustainable and circular products: design is key

**Ruud Balkenende, Conny Bakker and Julieta Bolaños
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This essay presents a holistic design method that enables product designers and engineers to develop products that fit in a sustainable and circular economy and that are safe both in the short and long term. According to the authors, such a design method is urgently needed to prevent that hazardous substances present in products accumulate over time as a result of reuse and recycling in the circular economy.

Substances of Concern are a risk to a sustainable and circular economy

Any product that potentially harms health or the environment has no place in a sustainable society and does not meet the circular economy (CE) principles. The circular economy aims at designing out waste and keeping materials and products in use for as long as possible through reuse and recycling. In essence, a circular economy is a framework for achieving sustainability. But while the negative effects on human and ecosystem health caused by the production, use, and end-of-life of many products already pose a serious sustainability problem, the circular economy can potentially make these problems worse if, through reuse and recycling, hazardous substances present in products accumulate over time. Therefore, a holistic product design approach, aimed at professional product designers and developers, is needed that combines requirements for functionality, performance, economics, usability, recyclability, circularity, sustainability, health and safety.

Substances of Concern (SoC) are used here to indicate all substances which are (potentially) hazardous. In a sustainable and circular economy context not only the well-known and blacklisted substances should be considered, but also substances that are suspected of being hazardous, as well as potentially hazardous substances that are generated during use (e.g. microplastics). The following substances are therefore considered to classify as SoC:

- SoC present in the product—intentionally added to their composition to optimise desired properties, like phthalate plasticisers in plastics; and per—and polyfluoroalkyl substances (PFAS) in pans, clothes, and many other products.
- SoC generated by the product—byproducts unintentionally generated throughout the lifecycle, like microplastics released from e.g. packaging, and synthetic textiles.
- SoC used or added temporarily to the material or product for additional functions but not intended to be present in the final product, like formaldehyde added to textiles during manufacturing to reduce creases; and bisphenol A (BPA) in baby bottles and canned foods.

The challenges with SoC are often tackled from a chemical or technological perspective, in which one-to-one substitution of a substance of concern by a less hazardous alternative is aimed for (Syeda, 2022). Such approaches can be useful, but they sometimes lead to substitution by another harmful substance (so-called ‘regrettable substitution’).

An example of this are the cooling gases used in refrigerators. Prior to regulations about the ozone layer, the most used substances for refrigerants and blowing agents in cooling equipment were chlorofluorocarbons (CFC) and hydrochlorofluorocarbons (HCFC). These gases were replaced with hydrofluorocarbons (HFCs), which, while not depleting the ozone layer, turned out to be greenhouse gases with a high global warming potential. Therefore, in addition to substituting CFC and HCFC with HFC, additional measures had to be taken: the identification, containment, use, transportation, recovery, and destruction of the HFC fluorinated gases as well as the waste management of cooling equipment were made subject to regulation in Europe. This led to changes in the refrigerator cooling system design and the end-of-life infrastructure design. These steps were not based on a holistic product design perspective, but taken subsequently to solve newly emerging problems. And unfortunately, harmful emissions are still reported from leakage during filling, incompetent repair, and improper end-of-life treatment.

This example points to the trade-offs and potential side-effects that need to be considered over time when substituting one chemical for another. Also, a too narrow focus on substitution risks overlooking that emissions of SoC are related to the products in which they are used or formed. Emission and exposure to humans and the environment takes place throughout the life cycle of a product and depends on manufacturing, use, disposal, and potentially reuse of the product or material. In a circular economy context, with multiple life cycles of products and when using recycled materials, the risks will increase. When dealing with potential SoCs early in the design process, however, future unwanted side effects might be prevented. This is because in the early stages of product design, designers can still anticipate and address potential issues before they become entrenched in the final product or system. It does, however, require designers to tackle SoCs early in the design process, and to consider the entire life cycle of products. This is what we refer to as a holistic design approach.

Need for a holistic design approach

Potential emissions at all stages of the product life cycle thus play an important role in the design of safe and sustainable products. However, to our knowledge, holistic design methods addressing the presence of SoC in products are not available and SoCs are usually dealt with in an ad hoc way.¹⁹ The development of a Safe, Sustainable and Circular by Design method that supports product designers and engineers

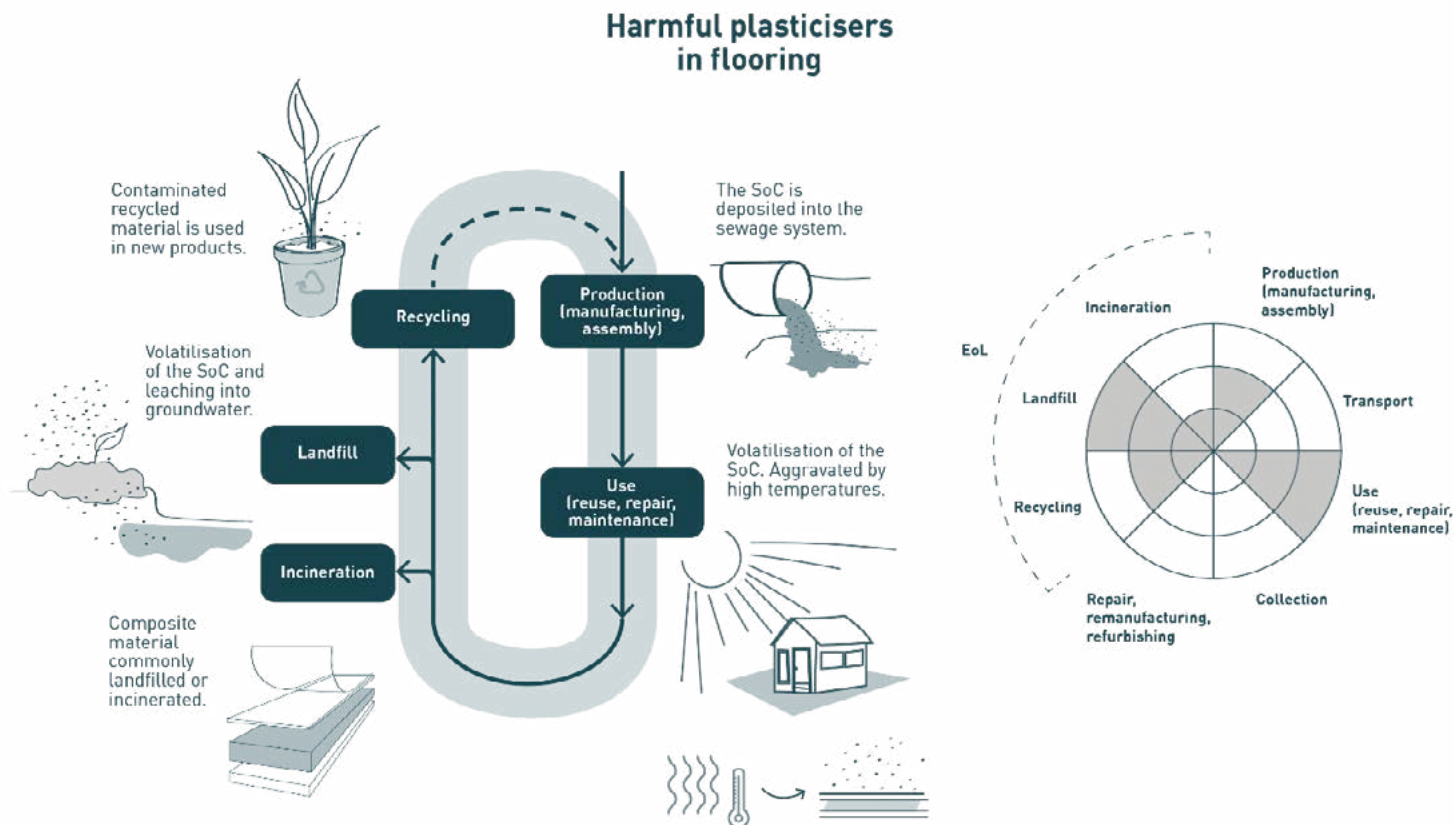
with the development of products that fit in a sustainable and circular economy and that are safe in the short and long term is therefore urgently needed.

Essential for a method to guide designers to safe and sustainable by design circular products is insight in the mitigation strategies that can be used in the design process. As a starting point to develop such a method, we studied a range of cases to identify what interventions were used to deal with SoC across the product life cycle. The cases demonstrate different products, substances, use situations and end-of-life treatment: e.g. household refrigerators containing refrigerant gases, DEHP (Bis(2-ethylhexyl) phthalate) in both cables and flooring (illustrated in [Figure 1](#)), emission of microplastics from agricultural mulch films, and synthetic textiles, such as outdoor garments, containing PFAS. We analysed the mitigation strategies and classified them into five major levels of intervention, i.e. chemical, material, component, product, and system level. This expands the usual approach that is purely aimed at chemicals and materials and incorporates the functionality and use context of the SoC. Our results show three groups of mitigation strategies (depicted in [Figure 2](#)) that are specifically relevant to product design: Avoid, which entails any modification to the product that eliminates the SoC from the product, Control in which the SoC remains in use, but its emissions are prevented, and Reduce which includes any modification that results in the reduction of the volume of the SoC or its emissions. In all cases we assessed the environmental impact and we did a risk assessment, which is not commonly considered when dealing with SoC in the design process.

A new safe, sustainable and circular by design method for product designers

Safe, sustainable and circular by design problems are very complex. Solutions are often context sensitive; they may involve compromises between different societal values, like human health, ecosystem health, safety, justice, and prosperity. A systemic design approach requires insight in the functionality of the SoC in a specific product, its effect throughout the product's life cycle, ways to eliminate or manage risks throughout the life cycle, and guidance to deal with potential trade-offs between sustainability, safety, performance, and cost.


Figure 1: Emission risks associated with phthalates plasticisers in flooring over the product life cycle. The pie chart provides a qualitative assessment of toxicity risks and environmental impact.



We are currently developing a method through which designers can buttress the mitigation of risks caused by SoC through a systemic (holistic) approach which makes possible trade-offs and unintended side effects visible. We will also outline the prerequisites for effective implementation of such a method.

We propose a three-step approach, aimed at professional designers and developers:

Figure 2: Main strategies used to mitigate the risks of SoC in products, illustrated with examples.

 Avoid		
Avoid	Alternative value proposition or function	Waterproofing weaving techniques
Substitute	With substances or materials known to be safe	Natural rubber for flooring
	With less harmful substances or materials	Non ozone depleting refrigerants
Phase out	Re-evaluate essentiality	No PFAS in non-essential uses



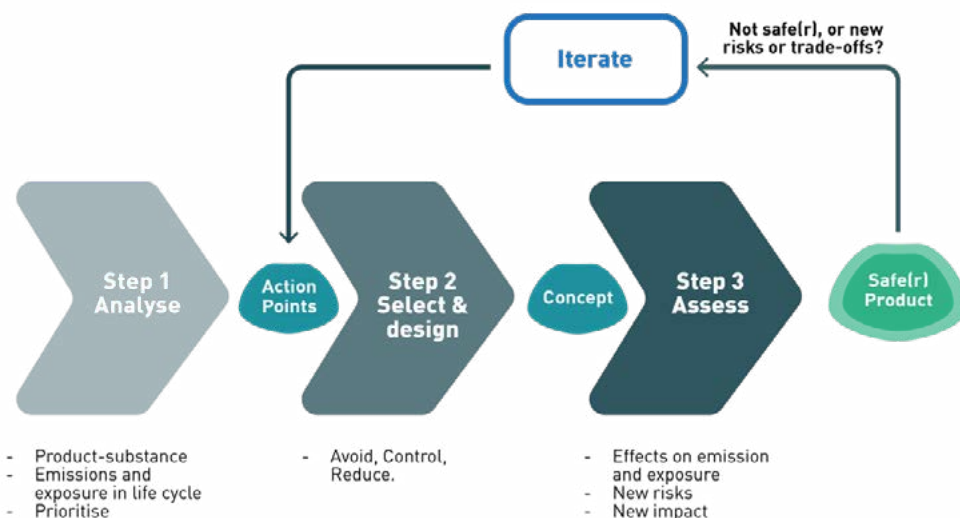
 Reduce			 Control		
Reduce content (lower volumes = lower exposure)	Reduce content of the SoC in the product or limit use to certain components	Reduced amount of refrigerant	Contain / isolate	Prevent emissions or exposure by isolating the SoC in the product.	Hermetic cooling systems
	Durability	Increase quality		Redefine production/ manufacturing processes	Controlled chambers in manufacturing
Increase useful life / Keep in use longer (to avoid accumulation at end of life)	Maintenance and repair	Reinforcing cable sleeves	Control collection / recovery	Separate collection	Collection of refrigerants
	Alternative business models	Reusable food packaging		Monitor materials to avoid SoC	Monitoring flooring waste
		To protect vulnerable groups		Risk information	SoC can be easily separated
Inform / customise	To avoid mechanisms that aggravate emissions	Washing information on label	Maintain control over the product	Maintain influence in case unforeseen negative effects arise.	Design for disassembly

Figure 3: Design approach to deal with SoC in products. The steps are described in the text.

Prior to the analysis step, in the case of a redesign, the presence of potential SoC and the environmental impact of the materials used should be established. Preferably this is done by reviewing a full material declaration using available sources (like ECHA and SIN list). For a new design, common SoC associated with the intended materials should be considered. Unfortunately, in many cases material suppliers are unwilling to share a full material declaration. In the case of a lack of data, the presence of SoC might be derived from the material specification and a more qualitative assessment can be pursued.



Step 1: Analysis and prioritisation of product-substance combinations

Analysis of the product throughout its different life cycle stages is needed to identify if it might generate and release SoC that were not originally added to its composition. In this stage potential emission and exposure scenarios need to be developed that consider the manufacturing, use and disposal context, as well as explicitly addressing reuse (potentially after mixing with other materials in recycling). The scenarios can subsequently be prioritised according to severity of their effects on human health and the environment by comparing the identified emission and exposure scenarios corresponding to each product life cycle stage,

preferably using (semi-)quantitative methods like life cycle assessment and risk assessment. Unfortunately, as toxicity and environmental data on many substances are missing, we may have to resort to a more qualitative approach.

Step 2: Selection of strategy and (re-)design of product

Executing ideation and conceptualisation as common in product design, solutions are generated following the identified mitigation strategies. The method prioritises strategies to Avoid the use of the substance over Control or Reduce strategies. Note that also combinations of strategies can be considered (as in the refrigerator example where both Avoid and Control were applied). In this stage also potential effects of new solutions on different system aspects are considered, ranging from safety and sustainability trade-offs to performance and cost. The method does not prescribe specific actions, but stimulates designers to consciously consider, and even prioritise, dealing with SoC as integral part of the creative design process.

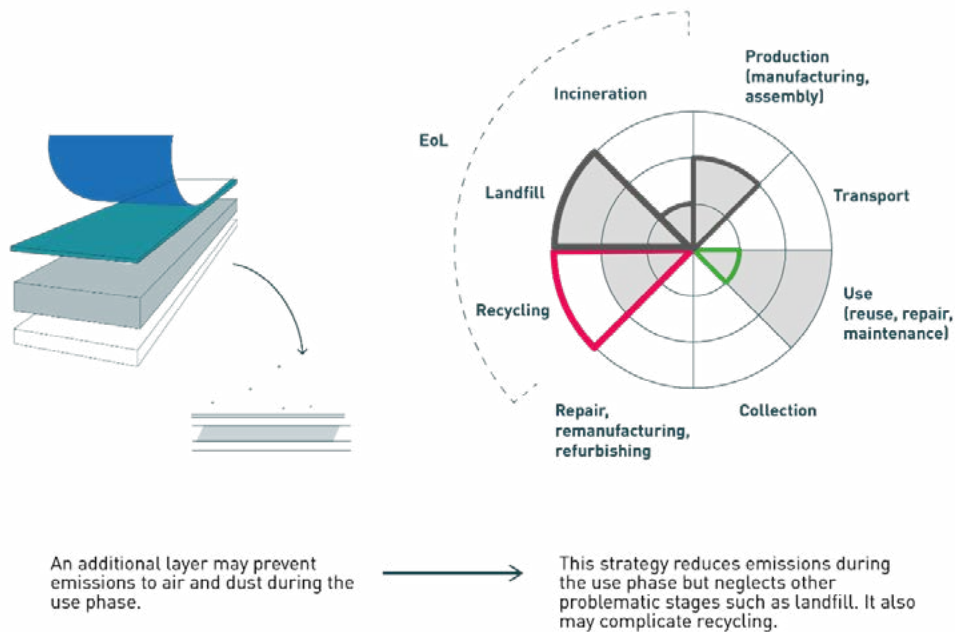
Step 3: Assess the developed product-substance-strategy combination

As in the analysis phase, the effects of the newly developed concepts are evaluated for all life cycle stages of a product to establish whether the level of concern of the related emission-exposure scenarios is reduced, maintained, or increased. This way the designer can observe improvements as well as further points of attention. This evaluation is holistic, i.e. addresses effects on a broad range of sustainability impacts, safety, performance, and cost. In this way the designer reflects on the potential trade-offs of the strategy, which can include the balance between sustainability and safety, but also reduced performance and increased manufacturing costs, amongst others. An example of a qualitative evaluation is shown in Figure 4.

The reflection as part of the third step already indicates that going through steps one-to-three is an iterative process. This fits the design process as commonly carried out but is also a necessity given the level of complexity, combined with the uncertainties surrounding the current state as well as potential solutions.

Figure 4: Example of qualitative risk and sustainability assessment of the emission of phthalates from flooring (indicated in grey in the figure) and a redesign intended to decrease these risks.

The grey area in the radar diagram shows the assessment of the original risk and impact. The outlines show the risk and impact of the modified design: improvement relative to the original product is shown in green, increased risk is indicated in red, a grey outline indicates no significant change. Possible trade-offs in other life cycle stages are easily identified. In the example, the redesign has decreased the risk during use due to encapsulation, however the risk during recycling increases, while other stages remained the similar.



Requirements for implementation

The primary barrier to effectively dealing with SoC from a product design perspective is the lack of information on the composition of materials used. For substances mentioned on the lists of Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) or Restriction of Hazardous Substances (RoHS) often only a compliance statement is provided. For other substances (like plasticisers, flame retardants, and color agents) usually no information is provided at all. This is already cumbersome when looking into a single product, but becomes unmanageable when considering next life cycles, e.g. mixing with other materials and use for different purposes in a next life cycle (leaving for instance almost all recycled plastics unsuited for food-grade applications). This strongly calls for an obligation to full transparency on the composition of materials used in products. Product passports with full material declarations would be a possibility.

The lack of reliable data on the impacts and risks of potential SoC forms another major barrier. Contrary to performance and cost data, for most SoC present in products, data on toxicity are at best incomplete, if not absent. Data on sustainability impact categories are even harder to find. While qualitative analysis might provide a first estimation, the integration of quantitative methods such as risk assessment and life cycle assessment will deliver more accurate results. Here additional steps in REACH might be needed. Although these barriers are well-known,²⁰ we want to stress that effectiveness of any method stands or falls by transparency of data regarding effects, risks, and impacts, even if the method allows for some level of qualitative assessment.

Bringing the method to product design practice has additional challenges. It requires an interdisciplinary approach with collaboration between designers, assessment experts, and stakeholders in the value chain. To incentivise companies to consciously deal with safety and sustainability related to SoC, product-oriented directives like the Ecodesign directive for electrical and electronic products might need an expanded scope, e.g. with respect to data provision (product passports with full material declarations). Ethical considerations, such as balancing performance losses with safety concerns and environmental impacts, need to be more specifically addressed in a next iteration of the method, which we are currently developing in collaboration with design agencies and industrial partners.

8. Enabling a mindset change: the Safer and Sustainable Innovation Approach

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This essay argues for the need for a Safe and Sustainable Innovation Approach (SSIA) to enable the transition to Safe and Sustainable by Design (SSbD). It highlights OECD activities on integrating functionality with safety and sustainability to boost innovation at the design stage.

The Safer and Sustainable Innovation Approach (SSIA): a mindset change to enable the transition to Safe and Sustainable by Design (SSbD)

To protect humans and the environment from the potential risks of novel chemicals and materials, a preventive life cycle thinking approach is needed that integrates innovation with safety and sustainability considerations. Indeed, the demand for nanomaterials and other advanced materials is expected to increase significantly in the coming years (think of the production of renewable energy, batteries, zero-emission buildings, semiconductors, medicines, medical devices, satellites, space launchers, planes or defence equipment).²¹ The challenge is to keep abreast with the fast pace of technological innovations and adapt safety and sustainability testing and assessment methods, policy and regulations accordingly. For instance, are the newly developed test methods including new approach methodologies for chemicals adequate for nanomaterials or advanced materials? Are safety and sustainability issues identified in a timely manner? Are policymakers and regulators aware of innovations early enough to take appropriate action and ensure that appropriate policy and regulatory tools are modified or developed as needed?

Keeping pace with innovation remains a challenge for policy implementation. Some lessons can be learned from the work of the Organisation for Economic Co-operation and Development (OECD) on developing science-based, rigorous and comprehensive systems for assessing and managing the potential risks of chemicals, including 'emerging risks' of innovations.

Combining state-of-the-art science and regulatory approaches with innovation for future-proof policy making

Policymakers demand a holistic approach to chemicals safety and sustainability that can speed up the green transition. This would include the integration of safety and sustainability considerations at the design phase of chemicals and materials and requires proactive and preventive approaches that anticipate safety and sustainability impacts before they emerge, reducing the need for costly and time-consuming risk mitigation efforts.

The OECD develops reliable methods for the identification of potential risks from new and innovative chemicals and materials (including nanomaterials and nano-enabled products), but work is still needed for the development of sustainability tools and methods that can be applied early in the innovation process. The OECD

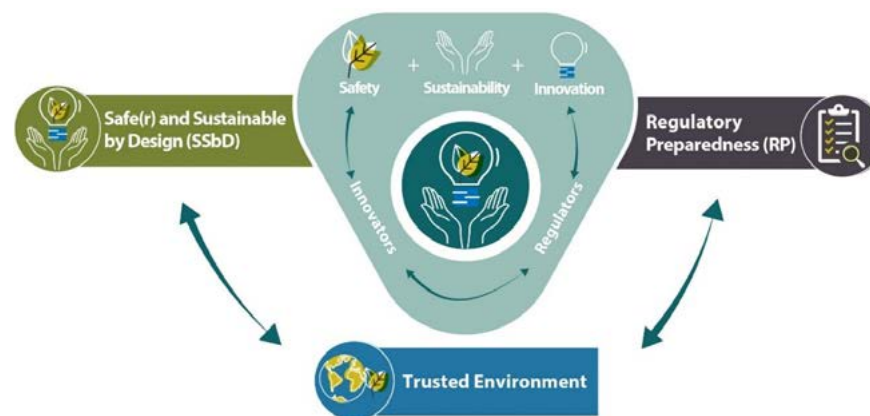
Working Party on Manufactured Nanomaterials (WPMN) therefore developed the Safer and Sustainable Innovation Approach (SSIA)²² to promote a shift from remediation to prevention. It recognises that early safety and sustainability assessment can prevent long-term negative impacts of innovations. It is a commitment to prioritise safety and sustainability, ensuring that materials, products, processes, and technologies do not pose risks to people or the environment or a burden to the planet. Accordingly, SSIA aims to: i) enhance the ability of all stakeholders to assess the safety and sustainability of innovations in a robust yet agile manner; and ii) reduce the time gap between the emergence of technological innovations and the development of suitable risk assessment tools and frameworks.

SSIA combines three components (see Figure 1):

- **Safe and Sustainable by Design (SSbD)**, which recommends that innovators integrate safety and sustainability considerations as early as possible into the innovation process;
- **Regulatory Preparedness**, which aims to improve the anticipation of regulators in order to facilitate the development of adaptable (safety and sustainability) regulation that can keep up with the pace of knowledge generation and innovation; and
- A **Trusted Environment** which provides a safe place for stakeholders (including regulators and innovators) to collaborate, co-create, share information and make decisions based on a common understanding of risks and benefits. By fostering communication and collaboration, better informed decisions can be made that prioritise both safety and sustainability, without compromising functionality.

Figure 1: OECD's Safer and Sustainable Innovation Approach. Source: OECD (2023).

Overall, the OECD's SSIA is a mindset that requires a comprehensive approach to promote innovation that is not only economically viable but also safe and sustainable. The development of tools and resources to support SSIA implementation is a crucial aspect of this effort, helping stakeholders navigate the complexities of innovation in a responsible manner.



Towards a common understanding of SSbD

In order to have a common understanding of the SSIA elements, the OECD developed working descriptions for Sustainability (see Box 1) and for Safe and Sustainable by Design (see Box 2). These working descriptions support the process of identifying and prioritising the elements to be considered for safety and sustainability (OECD, 2022) and of developing standardised and harmonised SSbD practices that can facilitate their application by stakeholders and regulators, ensuring a consistent and effective approach for SSbD implementation.

Box 1:**Working description Sustainability [extract OECD (2022)]**

Sustainability supports societal, economical, and environmental UN Sustainable Development Goals (SDG's) for our planet and for present and future generations. It refers to the use of the biosphere by present generations while maintaining its potential yield (benefit) for future generations.

Sustainability is about minimising the environmental footprint, in particular regarding climate change, pollution and resource use, protecting ecosystems and biodiversity. It entails a life cycle perspective (from raw material extraction, production, use, and end of life) where research and development (R&D) are aligned to a holistic approach by integrating human and environmental safety and promoting circularity and innovation.

Sustainability should prevent waste in the first place (zero waste) and includes material loops and processes that support the “waste hierarchy” which ranks waste management options according to what is best for the environment, giving top priority to durability and repairability. When a material, product or process is developed, efforts should be made for re-use, recycling, recovery, waste reduction, and lastly ensure minimal disposal. Circular economy and industrial responsibility are means that contribute to sustainability.

In summary, sustainability could be described as the ability of a material or chemical to provide products or services with desired functionalities without exceeding planetary boundaries, while ensuring well-being and other socio-economic benefits.

Box 2:**Working description Safe and Sustainable by Design (SSbD) [extract OECD (2022)]**

Safe and Sustainable by Design (SSbD) can be described as an approach that focuses on providing a function (or service), while avoiding onerous environmental footprints and chemical properties that may be harmful to human health or the environment.

In essence, the SSbD approach aims to identify and minimise, at an early phase of the innovation process, the impacts on safety for humans and the environment and on sustainability. The aim is to minimise the environmental footprint, in particular regarding climate change and resource use and taking a life cycle perspective to protect ecosystems and biodiversity. The SSbD approach addresses the safety and sustainability of the material, chemical or product and associated processes along the whole life cycle, including all the steps of the research and development (R&D) phase, production, use, recycling and disposal.

Empowering regulators and innovators: tools, methods and guidance to enhance SSbD implementation and regulatory preparedness.

The SSbD landscape is fast evolving with a proliferation of tools and proposed methodologies for facilitating its implementation. Advanced materials play a crucial role in advancing SSbD implementation due to their unique properties and potential to enable safer and more sustainable products and technologies. They have the potential to offer innovative solutions to complex challenges, such as pollution, climate change and resource scarcity. They have enhanced performance compared to traditional materials (i.e., strength, durability, and conductivity) and longevity, which together reduce the need for frequent replacements and minimise waste. SSbD can therefore promote advanced materials that are safer, more environmentally friendly and have sustainable life cycles (think of reduced energy consumption or improved recyclability). Nevertheless, for SSbD to be applied early in the innovation process, risk and sustainability assessments need to be performed in a cost- and time-effective manner.

As a starting point, the OECD has mapped out tools, systems, and platforms²³ developed to date, focusing on the selection of integrative tools (by integrative tool we refer to those covering more than one SSbD element as included in the OECD's working description on SSbD, see Box 2). Tools are identified with regards to design aspects (type of material, manufacturing process, final product and use, end-of-life), and whether elements such as resource use, human health risks, environmental impacts, life cycle considerations, circularity, climate change, social and economic indicators can be evaluated. This will enable the development of an SSbD Decision Framework that should assist innovators to select the most appropriate tool based on their needs.

At the same time, new material, chemical, or product developments come with uncertainties regarding their safety and sustainability and whether existing regulation is sufficient to cover potential risks. Regulators (and innovators) need to anticipate information gaps, concerns, and regulatory needs to be addressed (e.g., development of guidance, harmonised testing methods, and adaptation of legislation to prevent possible negative impacts of newly developed chemicals and materials). This process can be facilitated by early dialogue between innovators and regulators in a trusted environment. In order to achieve regulatory preparedness,²⁴ SSIA encourages broadening the scope of the assessment from a hazard-based approach (focusing on specific properties such as mass, size) to applications and functionalities, including considerations on the end use exposure scenario and sustainability throughout the life cycle.

To reinforce regulatory preparedness, the OECD is developing pragmatic approaches for anticipatory risk governance. An example is the Early Awareness and Action System for Advanced Materials (Early4AdMa)^{25 26}. This pre-regulatory tool can flag potential safety, sustainability, and regulatory warnings of advanced materials, assisting regulators to anticipate the areas to tackle in a fast-moving technological field (the elements of SSbD according to the working description in Box 1 provide the basis for this tool).

Overall, the OECD's SSIA is a comprehensive approach that aims to promote innovation that is not only economically viable but also safe and sustainable.

A system approach: what is needed to transition from SSbD to SSIA?

In order to overcome the triple planetary crisis (climate change, pollution and biodiversity loss) at a faster pace, we need a transition from SSbD to SSIA. Hence, there is a need for an organisational infrastructure to bring stakeholders together:

- **For early dialogue between innovators and regulators**

Under SSIA, the role of regulators will need to shift to a more pro-active, anticipatory, and preventative role. This dialogue early in the innovation process will reinforce regulatory preparedness and the timely adaption of assessment methodologies and regulation.²⁷

- **For interdisciplinary dialogue on safety and sustainability**

Integrating safety and sustainability in the innovation process means combining these two sets of expertise, each with their own priorities. This cannot be achieved without a multi-disciplinary dialogue and co-creation for the development of this new SSbD paradigm and way of working. To date, most of the dialogue is primarily focused on the safety perspective and then sustainability elements are added. Yet there is still a need for an integrated approach applicable early in the innovation process. A balance should be sought between innovation, safety, and sustainability through the application of existing scientifically sound approaches.

- **For bringing all stakeholders in the life cycle together**

There is a need to continue building a multidisciplinary group, combining not only safety experts with sustainability experts, but also with actors of the entire life cycle.²⁸

The transition from SSbD to SSIA also requires new approaches to data management, tools, methods and harmonisation and standardisation, especially:

- **A data management plan following FAIR guiding principles²⁹**

Current tools aiming to assist the implementation of combined safety and sustainability, like any other analytical or decision-making tools, are most effective when they have access to sufficient and reliable Findable, Accessible, Interoperable and Reusable (FAIR) data. The quality and quantity of data available can significantly impact their accuracy and usefulness. It is important to note that many of the currently available tools and methods require a lot of data and might not be suitable in the design phase for SSbD application.

- **Integrated safety and sustainability tools and methods, taking into account the entire life cycle**

Boosting innovation through the development of reliable hazard/risk assessment tools and standards that can support the generation and management of reliable FAIR data is crucial for the maximum valorisation of data and to accelerate the use of in silico tools. Exposure-oriented approaches need to consider the entire life cycle of the materials, product, and processes from manufacturing to disposal. It requires life cycle thinking to include the environmental and social impacts of the product at each stage. This anticipatory approach will result in safety and sustainability considerations at an early phase of the innovation, the ‘design phase’, before initiating the development of the products, when no data for the specific product is yet available. There is a need to develop a guiding decision framework to support innovators, especially in SMEs, to anticipate these exposure scenarios throughout the life cycle of a new product, while integrating sustainability considerations right from the design phase.

- **Harmonisation and standardisation** of SSbD-supportive tools and methods, as well as guidance on how to bring SSbD to practice.
- **Integration of safety and sustainability into innovation** to ensure that products and emerging technologies do not pose risks to people or the environment thereby creating solutions that are not just efficient but also ethical, safer, sustainable, and circular.

Conclusion

The OECD’s work is guided by its commitment to promote innovation, economic growth, and sustainable development while ensuring that these efforts are aligned with the highest standards of safety and environmental protection. SSIA promotes the implementation of SSbD through the development of harmonised and scientifically sound tools for the safety and sustainability assessment of materials, chemicals, products, and processes, including guidance on how to use existing tools and methods. By applying a prevention-based approach and by developing guidance, the OECD strengthens regulatory preparedness and supports international chemical strategies in developing policies for the implementation of SSbD principles across its member countries and beyond. As such, it complements the EU Chemicals Strategy for Sustainability and the Strategic Research and Innovation Plan for safe and sustainable chemicals and materials.

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9. SSbD is a learning process

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This essay argues that the implementation of SSbD requires a radically different view on innovation. SSbD calls for a cyclic, transparent, hands-on and cooperative learning process. It should build on existing knowledge and expertise while drawing in new disciplines and promoting out-of-the-box solutions.

Abstract

Safe and Sustainable by Design (SSbD) is a notion that is undisputed, direly needed, and attainable, but it still faces major challenges. This essay outlines some guiding principles and considerations for action. It starts on the premise that SSbD implementation calls for a radically different view on innovation, and that SSbD is a learning process rather than an endpoint. This process should build on existing knowledge and expertise, while drawing in new disciplines (such as behavioural and data sciences) and promoting out-of-the-box solutions. This calls for a cyclic, transparent, hands-on and cooperative learning process that focuses on proven solutions and best practices. A new centre of expertise could play the role of focal point, inspirator, knowledge-broker, counsellor and driver of change. The challenge at hand is complex, but doable if we take small, concrete steps, learn by doing, share experiences, and learn together—across science, industry as well as policy disciplines. Now is the time to start.

A common understanding

SSbD as a fundamental approach has gained significant ground in various sectors, including in the global chemistry arena. Relevant sectors, ranging from academia and scientific institutions to industry, policy and governance, have all recognised the need to integrate safety and sustainability considerations into the design and development of compounds, products and processes from their inception. In this context, ‘innovating the process of innovation’ has been underlined as a cross-cutting theme. Stakeholders share the notion that safety and sustainability are interconnected, and solutions not only minimise risks to human health and the environment but also promote long-term viability and resilience in the face of pressing global challenges such as pollution, environmental degradation, resource depletion, and climate change. Against this background, SSbD has been widely accepted as the way forward, underlining economic necessity in addition to human health and environmental sustainability.

From supply- to demand-driven

Despite this common understanding, implementation of SSbD is not up-to-standard. Several challenges remain. A main barrier to transition is the fact that chemical products are usually designed from a supply-based perspective: industry presents a solution to a (perceived) need or problem, and this solution is tested against legal safety and sustainability requirements first after the substance was synthesised.

However, in order to be truly preventive, any innovation and introduction of new compounds, products or processes should start from a demand-based perspective—not in the commonly used market sense, but in the sense of the long-term interest of global society as a whole. This requires a radical shift in the way of looking at, and working on, innovation. In other words, innovations should arise from a need, and they should not be designed just in view of their functionality, but also meet long-term societal interests, including safety and sustainability standards.

Beyond criteria and indicators...

Rather than developing chemistry that is as safe and sustainable as is required, we should strive for chemistry that is as safe and sustainable as possible. Some criteria and indicators along those lines have already been developed within international contexts, including various UN conventions, the Organisation for Economic Co-operation and Development (OECD), the World Business Council for Sustainable Development (WBCSD), and the EU Chemicals Strategy for Sustainability. However, criteria and indicators are not enough. After all, they assess compounds, products and processes first after they have been developed. A more preventive approach is needed—which, by definition, is one of the premises of SSbD. This approach should build on existing knowledge and expertise with regard to current products and processes. These insights should be incorporated in the development of new products and processes in explicit and innovative ways.

... and beyond current risk-based approaches

One major, underlying challenge lies ahead: moving from intention to action. This aspect of SSbD has received little attention, both in academia, industry and policy arenas. Too often, there is paralysis by analysis: a wish to study, test, understand and contemplate everything, and to weigh all pros and cons, before starting implementation. A far more productive approach is learning by doing. In addition to boldness, transparency and trust, this requires a clear discourse, within and among the various arenas, on a process to evaluate progress and transform new insights into new theory, design and practice. What works well and what does not? Which areas of the chemistry sector—e.g. bulk versus specialised markets—are moving towards SSbD, which are not, why is this, and what is needed to ensure progress where it is lacking? This cyclic, cooperative learning process is the essence of SSbD.

Gathering and disseminating experiences

In order to facilitate such a cycle of theory, design, implementation and evaluation, a platform or structure is needed to support and promote this in practical terms. There is currently no data collection or data sharing facility in this regard, nor a clearinghouse mechanism or 'brokering' platform that can gather and disseminate best practices and lessons learned. Such a structure, however, is needed for SSbD to be effectively implemented, and for the underlying science, policy and governance theory to be developed in a centralised manner. Like SSbD itself, this platform should encompass the entire value chain, from initial exploration to societal and environmental impact.

A centre of expertise could function not just as a clearinghouse, but also as a motor and a trusted environment for testing ideas.

How to avoid an added burden

Many have argued, and rightly so, that SSbD calls for a holistic approach. The same is true for any mechanism for evaluation and collection and sharing of data, knowledge and experiences. However, there is a significant risk that such a holistic approach becomes so complex that it becomes unworkable. Above all, throughout this journey, we need to ensure that SSbD evaluation, carried out through monitoring and reporting frameworks, does not become yet another burden, on top of existing reporting schemes such as Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Ecodesign for Sustainable Products Regulation (ESPR), and corporate sustainability reporting (CSR).

Centre of expertise as a driver of change

One option would be to create a centre of expertise dedicated to enabling and speeding up the implementation of SSbD. This should be an interdisciplinary endeavour, uniting data, knowledge and experiences from scientific, industry and policy arenas, from the safety and sustainability communities, and from chemical sciences as well as social, behavioural, legal and economic sciences, plus data and information technology. This centre of expertise could function not just as a clearinghouse, but also as an information centre or 'counsellor' that assists businesses in their transition towards SSbD, as a trusted environment for testing ideas and soliciting feedback, and as a motor that generates ideas and drives innovation with regard to the process of major transitions.

Manageable, and focused on functionality

Importantly, all such efforts should build upon what businesses already do. They should lessen their burden, rather than aggravating it. They should result in concrete, manageable elements of support that culminate in transition at business, sector and global levels. They should be instituted based on bottom-up motivations and interests, rather than on top-down regulations or requirements. Through their interdisciplinary nature, they should provide ideas and solutions that are out-of-the-box, and that focus on ultimate functionality rather than proximate practicality. Perhaps a certain toxic chemical, for instance, should not be swapped with a less toxic one, but by an IT solution that circumvents using any chemicals at all. At the same time, however, through a whole-cycle analysis, other impacts of such solutions should also be considered, for instance requirements relating to energy, resource availability, equitable access, and circularity.

The main objective along the way is to innovate the process of innovation, both at the science, industry and policy levels.

An iterative learning process

Importantly, the transition towards SSbD should be an iterative learning process—a process that is continually evaluated and adjusted to emerging data, insights and experiences. This should take place at all levels, from hardcore chemistry to evaluation, governance and communication processes. Shaping this multi-level process calls for involvement of experts in change management. Here, too, interdisciplinarity is key.

Various points of attention

Importantly, this learning process calls for a clear policy theory: what exactly is the problem, how will SSbD contribute to solutions, what are the policy requirements for this? And how does SSbD fit into existing policies and frameworks that address chemicals' safety and sustainability and the division of responsibilities?

In addition to these policy-related questions, there are issues that are more application-oriented, such as:

- communications (who are the various actors along the value chain, and even within companies, what are their views and needs, how do we collect those, how do we get these actors around the table, and how do we get them to speak a common language?);
- financial and legal aspects (how do we find investors to help us make these changes, and how can we establish a 'trusted environment' that sufficiently addresses confidentiality and IP concerns);
- governance aspects (how do we divide responsibilities, how do we ensure transparency and accountability);
- data aspects (how do we standardise data collection and ensure that data are FAIR—i.e., findable, accessible, interoperable and reusable); and
- instruments needed for implementation, including hardware (such as computer facilities), novel models and tools for assessment of risk and sustainability, methods for weighing various risks and interests, and novel ICT solutions.

A landscape that provides clarity...

This learning process is hugely complex, but, supported by the suggested centre of expertise, it will help shape the landscape that shows stakeholders' interests and strengths, as well as risks and limitations, and ways to address those. It makes it easier to see how challenges can be compartmentalized and tackled in small steps, allowing for visible progress and victories along the way. These success stories can then inform and inspire stakeholders who are still hesitant, or who still lack the knowledge, experience or resources to apply SSbD.

... supported by data and best practices

The main objective along the way is to innovate the process of innovation, both at the science, industry and policy levels. Stakeholders in all arenas, and at all levels, should undertake this endeavour together, take ownership of the learning cycle, and share the responsibilities that come with it. This cooperative, cyclic approach is new and hence calls for new approaches, tools and mechanisms. One new tool, for instance, could be experiments that measure the effects of SSbD practices against conventional practices, looking not just at safety and sustainability endpoints but also at aspects such as costs, return on investment, hardware and software needed, expertise and time needed, effective pathways, and market access.

The outcomes could find a place in a databank of knowledge and experiences, under the umbrella of the centre of expertise.

Rolling up the sleeves

More than anything, the road to effective SSbD implementation is one of trial and error—not an armchair exercise, but a question of rolling up the sleeves, getting started, reaching out to others beside ‘the usual suspects’, and not being afraid of making mistakes. After all, mistakes are often what guides improvement.

The very first step, however, is the realisation that SSbD is a process, rather than an endpoint.



10. Dutch Design Molecules – Vision of the Royal Association of the Dutch Chemical Industry (VNCI) on Safe and Sustainable by Design

Michiel van Kuppevelt, VNCI

In this essay the VNCI pledges its allegiance to the concept and ideal of Safe and Sustainable by Design, which it sees as a golden trademark opportunity for the Dutch chemical industry provided that Dutch and European policymakers also play their role.

Once perhaps a layer of pfas in pizza boxes may have seemed like a good idea, but we now know better: it is not a safe and sustainable solution in the long term. There are more examples of the enthusiastic application of substances with useful properties, without sufficient consideration of the possible consequences for human health and the environment over the entire life cycle of the substance. Safe and Sustainable by Design (SSbD) aims to incorporate this progressive insight into a methodology. This methodology is primarily aimed at the chemical sector but can be applied more broadly.

SSbD means that the safety and sustainability of substances, materials, products and processes are taken into account as much as possible in the design phase. And that these are included as central values for the entire life cycle. This requires a different mindset from scientists, process and product developers, business management and all other stakeholders, such as the government and ultimately the consumer. The goal is to achieve a clean(er) and safe(r) living environment through a systematic and interdisciplinary approach, in which the material flows by design are truly sustainable and circular.

The knowledge and input of the chemical industry are indispensable. Not only is the chemical industry the starting point of almost all (95 percent) production chains. Chemistry also offers the solutions and innovations needed for the transition to SSbD.

The VNCI regards SSbD as the direction for innovation within chemistry that leads to a better future.

SSbD framework

The chemical industry is at the basis of just about everything that we as a society need every day for our prosperity and well-being, from food and medicine to cars, clothing and computers. How can the chemistry needed to make these products be used as safely and sustainably as possible? SSbD helps to make this decision. This is done by taking a system-approach, looking at both sustainability and material, process and occupational safety. This multidisciplinary approach leads to transparent considerations that then provide better system solutions.

Looking at the entire value chain of a product is essential for this. Chemical reactions, for example, require reactive molecules. This means that most basic chemicals have dangerous properties, otherwise chemical reactions cannot take place. These basic chemicals are no longer present in the end product. An SSbD analysis must make clear what the most safe and sustainable options are and what considerations play a role.

We consider the transition to safe and sustainable chemistry as the way to regain society's trust in the chemical sector and strengthen its license to operate.

A strong focus on eliminating hazards at the start of the process greatly limits the number of options and says nothing about the chemical safety of the end product or its circular suitability. That is why, in that better future, hazardous substances can still be used in the production process, if that ultimately provides the best overall solutions. But of course, this must be done in a way that has the smallest possible negative impact on human health and the environment. This can be achieved by way of the following considerations:

- Emissions and exposure are prevented as much as possible throughout the entire life cycle. For example, through production in closed loop processes.
- Where the chemical process makes this possible, hazardous substances are replaced by less hazardous substances (substitution).
- Compounds are produced as much as possible from sustainable or renewable raw materials (including biobased).
- Waste does not exist. In a circular value chain, substances are used again and again as raw materials as much as possible.
- Substances that still have a chance of ending up in the environment are made biodegradable where possible. In such a way that they break down in the environment into substances that are not harmful or persistent.

Innovation plays a crucial role in achieving the above points. And it is important that (chemical) innovation is given the necessary leeway in the SSbD method. To make SSbD a success, it is also important that chemical companies and subsequent value chains work together. To achieve this, the SSbD framework must be lean and pragmatic, and must provide room for considerations based on different forms of expertise.

Barriers

Many Dutch chemical companies and companies further down the value chain have already taken the path to sustainable and safe substances and have taken major steps in these fields. To illustrate the current state of affairs, we draw on findings from two recent studies initiated by the Ministry of Infrastructure and Water Management, carried out by Bureau KLB and Royal HaskoningDHV. These studies are about safe and sustainable innovation with a focus on chemical SMEs. These companies are particularly interesting for research into innovation, because especially in small markets, they can distinguish themselves with innovation. Family businesses, for example, appear to have a strong focus on the long, sustainable term. These companies are often affiliated with partnerships or consortia, because of the exchange of knowledge and access to subsidies.

One of the companies in Bureau KLB's research sees the future this way: 'Ultimately, we want to supply customers with the safest possible product with the lowest possible carbon footprint, as easily traceable as possible and with the highest possible share of renewable carbon.'

On the way to that future, companies appear to encounter a number of serious limitations. In general, they argue that the government's focus is still too much on the energy transition and not enough on the materials transition, while a focus on both—at the same time—is necessary.

More specifically, the companies that participated in the two above-mentioned studies face the following obstacles:

- To achieve innovations, cooperation throughout the value chain is necessary, with raw material knowledge of producers (or suppliers) and application knowledge of customers being mutually exchanged. However, it is not always easy to find innovative partners who are willing to share the necessary data, especially in the recycling chain. In the field of safety, REACH still provides the necessary transparency, but in the field of sustainability this transparency is often lacking. This should be more regulated or encouraged by the government, the companies believe. A European (or global) digital materials passport is a possible tool for more transparency in the chain.
- Current chemistry is mainly based on fossil raw materials and has been optimised in efficiency and cost optimisation for more than a century. Conversely, the market

for alternative carbon sources, such as bio-raw materials, is still quite inefficient and opaque. There are many different sources and varying players. This stands in the way of scaling up. The new SSbD-based chemistry can only compete with fossil chemistry if society (and the value chain) is prepared to (partly) bear the costs of innovation. “Sustainability that is driven by changing laws and regulations can be sold to customers to a certain extent,” says one company in the study.

“This is not possible for sustainability initiatives that lead to higher costs and are not legally required,” says another company. In other words: groundbreaking innovation is not possible without stimulation and support from the (European) government. Although it should be noted that legislation alone does not provide alternatives. Innovation is not a fixed linear process in which the outcome is certain to be positive. Legislation actually works best when the right direction has already been found, but the market still needs a push.

- The safe and sustainable substances not only have to compete with cheaper fossil-based substances, but also with substances that are produced outside the EU under less strict environmental regulations (and therefore do not comply with European rules). More support for sustainable raw materials from the government and better enforcement at European external borders would help in this regard.
- Getting SSbD off the ground requires a lot of groundbreaking innovation. This often involves investments that do not pay for themselves in a few years. Government subsidies not only help reduce risky and sometimes unaffordable development costs, but they also promote acceptance within the company and help to ‘sell’ a project to management. Moreover, subsidies are often essential for the involvement of knowledge institutions. Even though companies say they can easily find their way to subsidies, the high costs of scaling up production are a barrier, partly due to the high compliance costs for new processes and competition with (cheaper) fossil-based products.
- SSbD is about innovation in the value chain. Subsidy structures must be tailored to this. This might require that resources are available to bring parties together and facilitate collaboration and innovation process. As an example, see the scheme for circular chain projects (Circular chain projects, more subsidies and new focus on textiles; rvo.nl).
- The transition to SSbD is a broad challenge. New research methods, new business operations, new ways of collaboration and new assessment frameworks are needed. This includes more than just the business community, which is particularly good at technical innovations. Trust is essential to enable

collaboration between all stakeholders, and ways must be found to do that well.

- Particularly small players in the market encounter a large bureaucratic and administrative burden. The various departments of these companies must fulfil the same roles as those in larger ones, but with less manpower. That demands a lot from the organisation and its employees. “There is a huge underestimation of what the raw materials transition requires from chemical companies, and there is too much of a controlling and not enough of a supportive attitude from the government,” said one company. “The government is also quick to assume that the market will do its work here.”
- The high entry costs to get sustainable alternative substances approved in REACH can be an obstacle to putting them on the market (“REACH costs can run into hundreds of thousands, which is a lot of money for the average SME.”)

Strong trademark

The Netherlands is a small, densely populated country with many industrial activities (heavy industry, chemicals, agriculture, transport), which puts pressure on the living environment. Partly because of this, the (chemical) industry in the Netherlands is faced with critical public opinion. The VNCI considers the transition to safe and sustainable chemistry as the way to regain society’s trust in the chemical sector and strengthen its license to operate. The innovative SSbD approach also provides opportunities to remain competitive on the global market. For example, by marketing the substances, materials and technologies inspired by the SSbD methodology. In this way, Safe and Sustainable by Design can become the *trademark* of Dutch chemistry.

Dutch chemistry has the advantage of being a large, strong, and highly innovative sector that is well integrated into the ecosystem with education, knowledge institutions and government. All knowledge, skills, and facilities are available (just think of the excellent technical universities, the highly integrated chemical clusters, and the port of Rotterdam) to take a leading position in safe and sustainable chemistry in Europe, both in research and production and in shaping a circular economy. SSbD is a very suitable methodology for this because it includes sustainability as well as substance, process and occupational safety. This multidisciplinary approach leads to transparent considerations that then provide better system solutions.

The VNCI sees opportunities to become a leading country within the EU and in the world with Safe and Sustainable by Design. If it were up to the VNCI, SSbD will become the new normal for the portfolio of chemical companies. If we don't do it, who will? Dutch chemistry now has the opportunity to direct the mindset towards SSbD and develop SSbD into a strong trademark: Dutch Design Molecules!

Recommendations

SSbD is still in development. To make the methodology successful, the following recommendations for the (European) government are made, based on the two studies mentioned above:

- Continue to collaborate with the chemical companies in the development of the SSbD methodology and incorporate their experiences to arrive at an applicable framework. Link safety and sustainability of substances and materials, circularity (materials transition) and product functionality in the methodology.
- Ensure that everyone can continue to learn from each other about SSbD and that this knowledge is safeguarded. A good knowledge infrastructure between governments, scientists, knowledge institutions and the business community is essential for this.
- Stimulate sustainable innovations in chemistry. Look at what is already happening, build on it and strengthen it. For example, in the field of biobased raw materials. And stimulate local initiatives. It is therefore important that the SSbD methodology can fit in with current innovation processes.
- Developments in digitalisation are moving rapidly. Use these options for SSbD. For example, artificial intelligence can support the search for SSbD molecules by generating better data (without the use of laboratory animals) and performing system analyses. Digitalisation can also help to simplify and improve communication in the chain.
- SSbD is also a social challenge. How and why certain considerations are made is partly culturally and socially determined. And these considerations can change over time due to major events. Trust in each other is important

to have a good discussion about shared values. Governments can help by drawing up assessment frameworks in a democratic manner.

- Consult individual companies about the impact of plans and measures. They can indicate where (well-intended) policies can hinder sustainability. Due to low energy costs and government subsidies in the US and China for example, the business climate in the EU is relatively poor and raw materials often come from far away (which is not sustainable). All the more reason to focus European policy on rewarding sustainability.
- Clarify how the (often complex) regulations should be implemented, so that not every company has to reinvent the wheel. And ensure that companies do not have to report on the same matters in a different way for every European (and Dutch) government regulation. Companies that voluntarily submit all their portfolios to sustainability criteria with external parties should be able to easily use that data to comply with government reporting requirements.
- Provide clear, long-term milestones and don't constantly adjust them. Companies are perfectly capable of innovating accordingly. This also includes predictability of regulations in chemistry. And do not make regulations an obstacle to bringing sustainable substances to the market.
- For imports from outside the EU, correct not only for CO₂-emissions released during the production of goods, but also for other sustainability aspects of raw materials and end products.
- Ensure better enforcement of non-compliant products, produced both within and outside the EU.

Contribution of the VNCI to SSbD

- Encourage the chemical industry to get started with SSbD and share its experiences, such as through the VNCI platform Chemie Magazine. SSbD can be applied via the EU framework, but also via the Cefic methodology, for example.
- Actively help to develop SSbD into a system that all chemical companies use.
- Foster strong cooperation with Dutch universities, research institutions and governmental bodies to establish an SSbD community.
- Promote substantive discussions on SSbD, not only in forums focusing on substances, but also in contexts related to environmental sustainability, innovation, and the transition to sustainable materials.
- Clearly articulate the opportunities and significance of SSbD to company leadership of VNCI members.
- For the circular (materials) transition: work on agenda and projects to produce chemicals from sustainable carbon sources. For sustainable carbon from CO/CO₂ the FutureCarbonNL consortium was set up.
- Establish and enhance partnerships with other stakeholders across product value chains, including bioresource producers, waste management companies, and brand owners.
- Development and scale-up of innovative conversion technologies via national innovation support programs (National Growth Fund) focussing on chemical recycling and biobased chemicals.
- Advocate for the development of additional policies and objectives related to the circular economy, facilitating the implementation of circular strategies and enhancing alignment with climate and energy policies.
- Inception of a Circular Critical Raw Materials innovation initiative.
- The VNCI, in collaboration with Chemistry NL, funded the Start-up Round Table, which supports sustainable chemistry start-ups.

11. Building a new generation of SSbD agents

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This essay describes the competencies that chemical engineers need to 'do chemistry differently': they need to be able to question their own assumptions, collaborate with other disciplines and integrate safety and environmental performance in the design of chemicals and chemical products.

Chemistry has brought us many innovations and useful products that have become indispensable to our daily lives. However, how we have deployed chemistry and chemical products in our lives and global economy has caused the crossing of the planetary boundary for new chemical compounds years ago, resulting in many environmental problems and challenges. For instance, pollution by plastics, PFAS and chemical pesticides have disrupted ecosystems. We have become aware that to solve and prevent such problems from happening again in the future, we must change the way we do chemistry. Such change presents an opportunity to reshape the way we innovate to arrive at responsible, safe, and sustainable designs of chemical products and processes—but it also comes with challenges. Doing chemistry differently requires chemical engineers with different competencies and skills. Ideally, chemical engineers should apply a holistic perspective when designing new chemical compounds and products, which comes down to three main skills.

They need to be able to:

1. question their own assumptions and knowledge barriers on what is safe, what is sustainable, what (adverse) effects we could foresee, and how we can anticipate these;
2. work together with people from other disciplines, as all are needed to design for safety and sustainability;
3. integrate broader considerations like safety and environmental performance in addition to 'functionality' of the chemical.

In this essay, I present a way to build a new generation of chemical engineers who can take on the challenge of making chemical innovation more safe and sustainable through integrating Safe and Sustainable by Design (SSbD) principles in education. This includes acquiring ethical and philosophical skills for responsible decision-making, engaging in transdisciplinary work, and adopting a design approach that allows for inclusion of multiple criteria.

The concept

SSbD is an approach comprising engineering and procedural principles to arrive at safe and sustainable innovations in the chemical industry. The concept provides guidelines for developing materials and implementing process conditions with fewer hazards or lower risks. Innovations in development come by necessity with a lack of knowledge and thus uncertainties. To fill in such knowledge gaps responsibly,

the SSbD approach iteratively integrates knowledge on the adverse effects of a material, product, or process into the design process. This way, a range of measures can be designed and implemented with the aim of anticipating potential issues (proactive or preventive measures) and acting accordingly to newly obtained knowledge (reactive measures) once an innovation matures. A holistic perspective must be applied as many issues occur due to (external) effects once introduced in society and nature.

While the goal of SSbD is to eradicate (potential) risks and hazards and to prevent issues from arising in the first place, history has shown us that we can remain unaware of the adverse effects of chemical products until damage has been done. As our world is already filled with such chemical compounds, e.g. CFCs, asbestos and glyphosate, SSbD principles should also be considered for degradation, recycling, and external environmental effects. Therefore, a chemical product's value chain should be considered to the largest extent possible. By consulting a range of stakeholders in an innovation's early development stage, one can gain insights into potential issues related to safety and sustainability, and use this knowledge to make design choices accordingly, to eventually arrive at a collective, safe, and sustainable design. As these aspects depend on many factors, the involved stakeholders' expertise should reflect this, for instance, ecologists, (bio)ethicists, philosophers, policymakers, toxicologists, and representatives of industry and nature conservation organisations. This way, potential issues or risks may become known early on in the process, and different design choices can be made to circumvent the potential issue, or preventive measures can be developed and implemented.

This new generation chemical engineers needs to be able to make decisions responsibly and assessing the importance of missing information.

However, some adverse consequences can be difficult to predict and imitate in laboratory settings or through simulations, as they occur through external effects in nature. For example, an additive that makes car tyres' rubber longer lasting turned out to react with ozone, forming a new compound highly toxic to a specific species of salmon³⁰. This illustrates that the innovation process is never finished, and we should allow for iterations; we need to be able to learn from our mistakes or matters initially overlooked. Policymakers and regulators are also crucial to such adaptations and refinements.

The challenge

Designing for safety and sustainability comes with challenges and uncertainties; when innovations are still in their early design phase, how can we determine a threshold to decide on what is safe or sustainable 'enough'? To deal with such questions, our chemistry education should be set up differently. The transition to SSbD can only be made with more broadly trained chemists with a different mindset, one that urges to consider safety and sustainability in the early design stages of chemical substances and processes, encourages working with other disciplines and acknowledges the limits of one's own expertise.

But how to arrive at engineers that have these specific capabilities? What exactly should become embedded in education to develop this mindset? Engineers need to be able to apply a holistic perspective to new chemical innovations. Besides knowledge of technical matters, feasibility, and economic motives, they must also gain insight into product-, process- and environmental safety, sustainability, and other potential issues. For this, students must acquire interdisciplinary skills and learn to think from a value chain perspective. Stakeholder engagement and co-creation are therefore essential. 'Future-proof' chemical engineers must be able to recognise their own boundaries regarding knowledge and expertise and learn to identify what knowledge and information is missing and in what disciplines or domains that can be found. Thereby, they should have the skills to decide responsibly on where to draw the line for identifying and assessing potential issues arising—we cannot consider everything that can happen to chemicals during their entire life cycle.

Value chains and system boundaries

Arriving at safe and sustainable chemical products and processes demonstrates the importance of considering the entire value chain, but where does it end? There comes a moment when decisions need to be made for a developing technology to proceed to the next level in development. In addition, while sustainability assessments and life cycle assessments (LCA) provide valuable information on the environmental impact of a product or process, their predictive value depends on the system boundaries. These determine the inputs, outputs and impacts considered in such an assessment. This raises the question of where to draw the line regarding such a system boundary and how reliable such assessments are when many aspects are still uncertain. For instance, we can develop an alternative to the chemical pesticide glyphosate, but what range of potential effects do we need to consider?

Does our ecosystem end with application in soils, or should we also consider the external effects of compounds and organisms in groundwater or wastewater treatment systems?

While newly developed chemicals are only allowed on the market with proper testing, only so much can be imitated in laboratory settings and simulations. In addition, such tests are generally designed to check for direct effects of exposure and the expected issues—it is hard to grasp long-term, indirect effects. Therefore, implementing an SSbD mindset in chemical engineering requires a multi-actor perspective. Besides toxicologists and experts in LCAs one should consult ecologists, (bio)ethicists, prospective users, policymakers, safety scientists, and society representatives to arrive at a mutually shared understanding and assessment of safety and sustainability. Together, knowledge gaps can be indicated through multiple perspectives, and, for instance, additional risk research can be set up. This should be an iterative process in which newly obtained knowledge is fed back into the design process as the chemical innovation matures. Design choices can be (re)considered accordingly. This will also ensure that designs become resilient and suffer less from lock-ins, for instance by preventing the dependence of industries on a particular hazardous chemical compound or product. We now know that PFAS come with severe health risks, but due to their favourable characteristics, they are also widely used in materials and technologies needed for the energy transition. Such dilemmas are what the chemical industry, and thus the new generation of chemical engineers, have to try to prevent from happening in the future. This calls for a responsibility pertaining to the chemical industry and illustrates the importance of sharing newly obtained knowledge and data. PFAS being the most descriptive, there are many examples of companies that decided to follow through with their chemical product, despite having new information on detrimental effects. Sharing this information, thus enabling early reaction, could prevent dilemmas and lock-ins.

In practice, this would mean that the new generation of chemical engineers should be able to identify what knowledge they are missing and where to get it from. They should be able to contact, involve, and work with actors with different expertise, see the added value of such additional insights, and discuss and co-create. Students should acquire these skills in their education. They should learn chemistry, including methods to assess notions of safety and sustainability, such as risk assessments and LCAs, but should also be involved in interdisciplinary projects. This way, they can

gain insights into the boundaries of their knowledge, and develop the needed skills to tackle important questions like what safe and sustainable enough is, and where a product's value chain ends.

Ethics and project-based learning

I have argued why SSbD is needed to train a new generation of chemical engineers and what aspects of SSbD should be considered. This new generation needs to be able to make decisions responsibly—determining what safe or sustainable enough is, and assessing the importance of missing information. Such questions place great responsibility on them, so they should also be equipped with responsible decision-making tools. Ethics of technology are of utmost importance in teaching students how to deal with dilemmas, what weight to assign to findings on potential issues and the respective trade-offs for responsible decision-making.

Many engineering programs include engineering ethics, which includes principles and guidelines that engineers should follow to make responsible decisions. However, these principles and theoretical guidelines can remain rather abstract for chemical engineering students. Students need to learn by doing—only then abstract notions like 'responsibility' can become tangible. In project assignments or project-based learning, students can learn from actual cases in which a clear dilemma is set.

Applied ethics and SSbD principles can be integrated into education by letting students work on (historical) cases on which much information is available. That way, dilemmas are presented clearly, and the potential consequences of any decision or action for this case can be overseen. These dilemmas need to come from practice, as they must be able to empathise and realise that such dilemmas can also arise later in their career. For instance, students must recognise that safer or more sustainable alternatives often lead to value conflicts; they could be more expensive and require different process conditions such as a higher temperature or lower pH. In such choices, there is not one correct answer, but a responsible decision depends on the argumentation provided and, thus, the weight assigned to a specific value. For instance, sustainability may be favoured over a chemical's reaction rate. At Delft University of Technology, we aim to integrate ethics and SSbD principles in courses in several Bachelor's (BSc) and Master's (MSc) programs. For instance, in a BSc chemical engineering course on sustainable process technologies, we let students

work on cases in which they are given two options for adjusted process conditions: an established method that is efficient and predictable and one that aims to increase safety and sustainability but comes with uncertainties in terms of effects. By determining and analysing various factors that play a part in responsible decision-making (e.g. efficiency, costs, effectiveness, sustainability, safety and security), students have to recommend which adjustment can be considered the most responsible choice from their perspective. Therefore, students must indicate knowledge gaps and provide recommendations on how these could be overcome, for instance, through SSbD principles. Again, there is no right or wrong answer, but it helps students develop a broader perspective to a case rather than just a technical one. Most importantly, they face the boundaries of their own knowledge and expertise, which illustrates the importance of working together with others.

The stakes are high; together, we can make safe and sustainable chemistry work.

Following this, creating the SSbD mindset through project-based learning is ideally suited for MSc projects or thesis research. In such projects, students consider early-stage technologies or applications. This means the system boundaries and outcomes are uncertain and potential value conflicts are as yet unknown. It is up to the students to engage with other actors to gain insights into missing knowledge and learn how to co-create. Such interdisciplinary work reflects the complexity of innovating responsibly and clarifies the need for holistic perspectives to work towards safe and sustainable designs in chemistry.

Final thoughts on SSbD

A study program that integrates an SSbD mindset is itself an iterative process in which we constantly learn, adjust, implement changes, and repeat the cycle all over again—a program that covers exactly all SSbD elements. This is a gradual process. Some students need time to let the idea sink in of becoming a chemical engineer with a broader skillset compared to their predecessors, which may even cause some resistance. And that is fine. Every lecture, project, or thesis on designing for safety and sustainability is one step in the right direction.

Over the past years, SSbD has gained momentum as part of the EU Green Deal to make Europe's chemical industry safer, more sustainable, and even circular. Many industry partners are collaborating with the Joint Research Center to establish clear SSbD guidelines for which EU funding has become available. However, to adopt SSbD in this industry, they need people who can do this. Therefore, funding should also become available for educational institutions to develop a framework that embeds the required SSbD elements in education programs, such as applied ethics, co-creation, stakeholder engagement, and project-based learning. Member States could use this framework to initiate and monitor such developments in education and to strengthen their current educational system.

Now that SSbD is gradually becoming more implemented in industry practices, this gives rise to many new insights and knowledge on potential risks, issues and hazards. Ideally, the iterative character of an SSbD design process should become integrated with policy and regulation on SSbD and. If new knowledge arises, we should take full advantage of this to transition towards safe and sustainable chemistry.

We are never done learning. The adoption of SSbD principles continues after completion of a BSc or MSc program. We encourage institutions and organisations to host events for professionals and postgraduates³¹.

The stakes are high; together, we can make safe and sustainable chemistry work.

Closing Chapter: Safe and Sustainable by Design: to be continued

Kim Doornebosch, Kees Le Blanch,
Daan Schuurbijs

A wide embrace

If there is anything that the essays in this volume make clear, it is that the concept of Safe and Sustainable by Design (SSbD) is widely embraced. A wide variety of institutions have contributed to this collection of essays—from governments and agencies to knowledge institutions and the business community, both at European and national level. The idea of SSbD is evidently recognised as part of the answer to the questions and challenges the world faces today in the field of safety and sustainability—or at least as the direction in which we should look for answers.

Without exception, all contributions emphasise the importance of collaboration across disciplines, value chains and policy areas. These calls for collaboration emphasise that SSbD is essentially a collective endeavour. Without broader support SSbD would be a powerless and fruitless concept. But this is clearly not the case, as demonstrated by the various supportive contributions in this collection of essays.

A broad selection of suggestions

The essays provide various suggestions and ideas for different audiences. They raise awareness of the responsibilities of companies and provide tools and methods to realise these responsibilities in practice. Researchers and practitioners are presented with several methods to implement SSbD. They receive concrete incentives to engage in ‘molecular design’, to focus on specific social priority areas, to exchange with colleagues and to share their learning experiences. Several essays contain suggestions for developing new substances and products from a different, new mindset, and in particular for training future chemists in this.

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Especially for policymakers, the essays contain an abundance of ideas and recommendations. Policymakers are called upon to prioritise areas where SSbD is most needed, to create an EU-level knowledge centre from which guidance and good practices can be shared (and which can perhaps act as a ‘trusted environment’), and to concretely stimulate the raw materials transition. Almost all essays contain paragraphs outlining the consequences of certain desired developments of SSbD for required government policies across traditional policy silos. In this respect too, this bundle is mandatory reading for policymakers.

A productive clash of ideas—let's discuss

With so many contributions from so many different angles, it is inevitable that some ideas presented in this collection are at odds with others. Sometimes there is even outright tension between these ideas. For example:

- According to ChemSec's contribution the use of Substances of Concern is always at odds with SSbD. Yet the VNCI believes that the use of hazardous substances in the production process is not incompatible with SSbD, if that ultimately provides the best solutions.
- In addition to the JRC 'Framework for the definition of criteria and evaluation procedure for chemicals and materials' to which various articles refer, some other essays (e.g. by Cefic and Balkenende) present specific design and assessment methods. It is not clear how these frameworks and methods relate to each other. Do they complement each other, do they get in each other's way or are they pure alternatives?
- Some contributions focus on a comparative assessment of existing chemicals, others on the development and optimisation of new chemicals. In both approaches, the chemical industry is given a core role in finding solutions to current safety and sustainability crises. In contrast, some other articles focus on the desired functionalities, which can also be provided by non-chemical means and by players other than the chemical industry. It is conceivable that these approaches complement each other, but it could also be that they involve completely different perspectives and policy orientations.

These and other diverse points of view mainly illustrate that SSbD is a young and still developing concept. Its development takes place from very different disciplines and schools of thought. In that respect, the presence of these different points of view in one volume offers an excellent opportunity to identify, address and discuss these areas of tension with each other—and perhaps also: to try out the different approaches in practice and learn from them together.

That immediately leads to an observation that should not go unmentioned at the end of this collection: for the further development of the SSbD concept, it is crucial that ideas about and experiences with the various aspects of SSbD are confronted and discussed, including among policymakers. This means that in addition to the publication of this collection, it is also very important to organise opportunities to exchange ideas with each other (conferences, workshops) and to think about

creating a next collection of essays. Ideas are already circulating for a policy-oriented conference in early 2025 following-up on this collection of essays.

Issues for the next collection of essays

This collection was created by selecting a number of key players in the field of SSbD and asking them for their contributions. Given the breadth of topics discussed, it is inevitable that some topics have remained underexplored. This is both inevitable and, perhaps, fortuitous: in this respect too, this collection of essays immediately provides suggestions for the next one.

Specific suggestions for themes to be discussed are:

- the further refinement of European policy frameworks to be established;
- a further elaboration of an approach aimed at developing functional (including non-chemical) alternatives;
- the opportunities and barriers for SSbD in economic terms (including possibilities to overcome them);
- the role of capital and investors. And above all:
- further concretising and giving substance to SSbD (who exactly can do what and how?);
- presenting successful and unsuccessful examples of SSbD in practice.

To be continued

This collection of essays was not intended to be the last word on SSbD, and it certainly isn't. The intention was to exchange ideas, inspire and provide food for discussion. We invite all those involved in the SSbD playing field to participate in the conversation (for example at the conference early 2025), to contribute ideas and experiences themselves and, of course, to walk the talk. To be continued!

Endnotes

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- 2 [Safe and sustainable-by-design - cefic.org](#)
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- 12 [IRISS \(iriss-ssbd.eu\)](#)
- 13 [Strategy to promote substitution to safer chemicals through innovation](#)
- 14 [Safe Chemicals Innovation Agenda](#)
- 15 [Framework for the definition of criteria and evaluation procedure for chemicals and materials](#)
- 16 [Three things people should talk about in the breaks at the EU's big SSbD event \(chemsec.org\)](#)
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- 24 OECD (2023), [Safe\(r\) and Sustainable Innovation Approach \(SSIA\)](#)
- 25 [Tools relevant to SSbD for nanomaterials and nano-enabled applications \(See https://www.nanosafetycluster.eu/nsc-overview/nsc-structure/ongoing-projects\)](#)
- 26 Soeteman-Hernández, Lya et al. [Perspective on how regulators can keep pace with innovation: Outcomes of a European Regulatory Preparedness Workshop on nanomaterials and nano-enabled products](#), *NanoImpact*, Volume 14, 2019, 100166, ISSN 2452-0748
- 27 [Early Awareness and Action System for Advanced Materials \(Early4AdMa\): Pre-regulatory and anticipatory risk governance tool to Advanced Materials \(oecd.org\)](#)
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Essays on Safe and Sustainable by Design