Steering bio-innovations with a 'Safe and Sustainable by Design' approach

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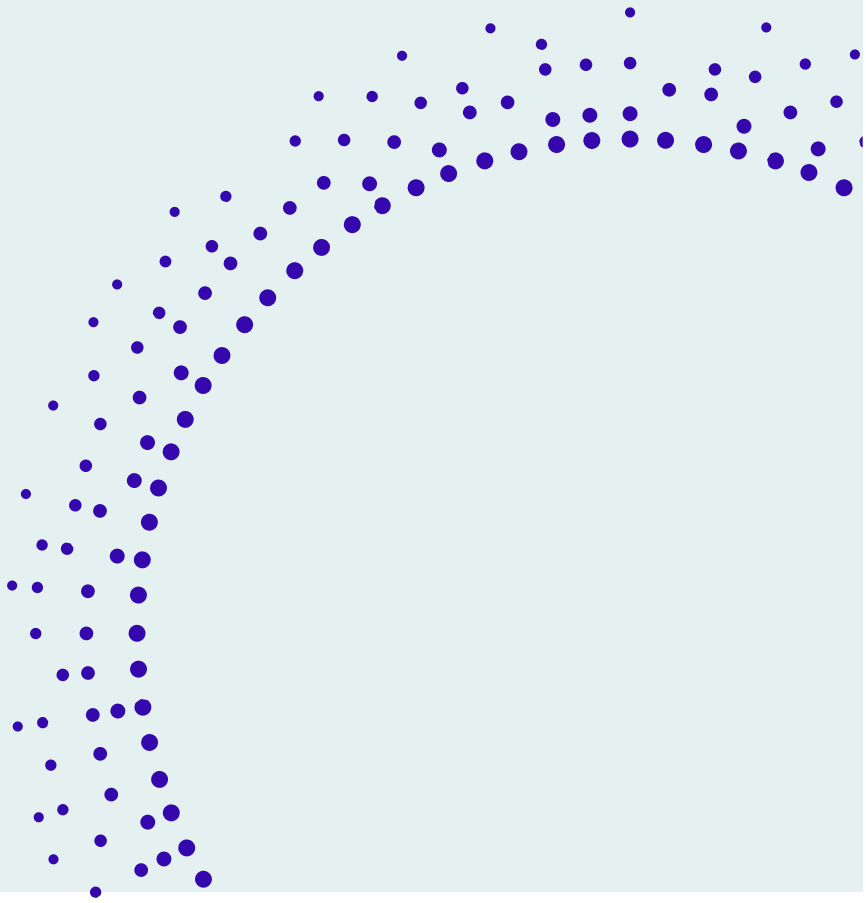

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Summary

Europe's shift from a linear to a circular, low-fossil economy demands a fundamental rethinking of how resources are produced, used, and managed. The EU's Safe and Sustainable by Design (SSbD) framework supports this transition by promoting proactive safety and sustainability considerations in innovation, especially within chemistry and biotechnology. This report outlines the policy context behind SSbD and illustrates its practical application through three NORCE case studies showcasing diverse biotechnologies. With Norway's strong industrial sectors, adopting SSbD is increasingly vital for competitiveness and alignment with evolving EU expectations. The report also highlights NORCE's growing expertise and offers insights for practitioners, policymakers, and researchers working to accelerate safe and sustainable bio-innovation.

Sammendrag

Europas overgang fra en lineær til en sirkulær, lavutslippsøkonomi krever nytenkning om hvordan ressurser produseres, brukes og forvaltes. EUs rammeverk «Safe and Sustainable by Design» (SSbD) støtter denne omstillingen ved å fremme sikkerhet og bærekraft som proaktive hensyn i innovasjon, særlig innen kjemi og bioteknologi. Rapporten gir en oversikt over den politiske konteksten for SSbD, og viser hvordan prinsippene kan omsettes til praktiske løsninger gjennom tre NORCE-caser som demonstrer ulike bioteknologiske tilnærminger. For norske industrisektorer blir innføring av SSbD stadig mer relevant for å styrke konkurranseevne og for å møte utvikling i krav fra EUs. Rapporten fremhever også NORCEs voksende kompetanse på SSbD og gir verdifull innsikt til praktikere, beslutningstakere og forskere som ønsker å akselerere trygg og bærekraftig bioinnovasjon.

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Preface

Many products that we use in our daily lives contain chemicals that can affect our health and living environment. This legacy of hazardous substances in products can inhibit the transition to a circular economy. The principle of Safe-and-Sustainable-by-Design (SSbD) is to take safety for human health and the environment and wider sustainability considerations onboard as design principles from early development stages onward. This can facilitate companies to produce healthier and cleaner products.

While there is now broad support for SSbD, various international bodies and networks are exploring how it can be operationalised. For example, in the context of the OECD working parties on nanotechnology and biotechnology, SSbD has been further elaborated into the Safe(r) (and Sustainable) Innovation Approach. Adoption of the concept by the European Commission as part of the European Green Deal has resulted in the JRC SSbD framework for chemicals and materials as a starting point for application and further development of the SSbD approach.

Public bodies have played an important role in the implementation of the SSbD concept in two ways. Firstly, by setting SSbD in the context of existing national and international policies. And secondly, in the context where public-private collaborations have been initiated to test and further operationalise the SSbD approach and framework, such as in case studies and in the development of tools and toolboxes. This report is a very valuable collection of experiences with the application of the SSbD framework in practice in a Norwegian setting. In the Netherlands, RIVM (the Dutch National Institute for Public Health and the Environment) has been involved in several of these initiatives, such as in the OECD, the SSbD workpackage in the European Partnership PARC, and several EU and national projects on SSbD of chemicals, advanced materials and biotechnology. These collaborations and dialogue of researchers, industry and policy makers in projects and public–private collaborations are important to further elaborate and operationalise the approach.

In industrial biotechnology, the worlds of chemical production and biotechnology come together. It is seen as an important driver in the transition to more sustainable biobased chemicals that can help to shape a circular economy. This report is the first study to integrate and discuss several case studies where SSbD framework has been applied in the context of industrial biotechnology. It is an accessible overview of the implementation of the SSbD framework in three research projects. This report provides examples that the integration of industrial biotech in the framework can work and highlights some challenges in doing so. Moreover, it provides starting points for further elaboration of the framework for application in industrial biotechnology. Reports like this are not only important to further shape the practical application of SSbD and build up knowledge, but also to connect worlds. This is essential for the transition to a circular economy and healthier living environment.

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Summary

Moving away from our predominantly linear economy toward a more circular, less fossil dependent one requires a fundamental transformation in how resources are produced, used, and disposed of. Industrial innovations in the chemical and biotechnology sectors are pivotal to this shift, enabling the development of safer, and more sustainable and circular solutions that drive a cleaner, more competitive Europe. To facilitate this change, the European Commission (EC) launched the Safe and Sustainable by Design (SSbD) framework in 2022, aligned with the ambitions of the European Green Deal and the Chemicals Strategy for Sustainability. The framework marks a shift from reactive risk management to proactive prevention, embedding safety and sustainability considerations from the earliest stages of the innovation. This aims to ensure that new products are not only functional but also safe for people and the environment, while contributing to broader sustainability goals.

This report outlines the context and recent policy changes shaped by European strategies and provides a structured overview of the SSbD framework. It also explores the practical application of SSbD in biotechnology through three real-life case studies drawn from NORCE's research portfolio, each illustrating radically different biotechnologies. Given Norway's strong industrial base in sectors such as energy, aquaculture, and bio-based production, understanding and implementing SSbD is becoming essential to maintaining competitiveness and aligning with evolving EU requirements. In this context, we have examined the implications of SSbD for bio-innovations, focusing on the use of (bio)chemicals, (bio)materials, and enabling (bio)technologies, all aimed at meeting society's growing demand for safer and more sustainable products.

Finally, the report reflects on NORCE's experience in building SSbD competence, offering key lessons learned and researchers' insight on what is needed to foster the wider adoption of SSbD in biotechnology research and innovation ecosystems. Biotechnology plays a critical role in achieving the green transition by enabling low-impact production systems, bio-based materials, and innovative solutions that reduce dependency on fossil resources. Strengthening SSbD integration in this sector enhances Norway's capacity for safe and sustainable innovation while ensuring alignment with European Union (EU) standards. This work is especially relevant for biotechnology practitioners aiming to incorporate safety and sustainability into their innovation processes. It also provides policymakers and researchers with insights on how to promote SSbD adoption. Collectively, these efforts advance national strategies for green transition and circular economy.

Contents

1 Europe's path towards a safe and sustainable circular economy

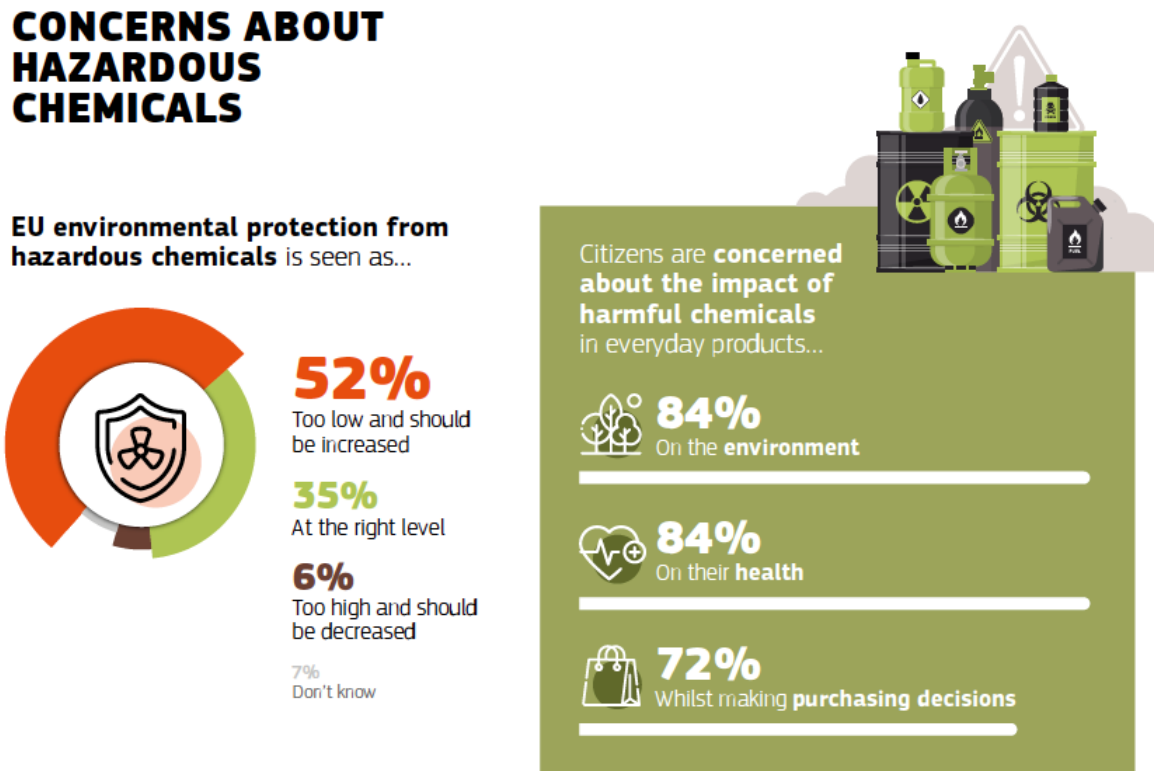
Reaching carbon neutrality in Europe by 2050 hinges on a circular economy that drives both economic growth and sustainability, harnessing renewable resources and smart, efficient production. Rising environmental pressures and society's demand for safer, greener products are accelerating the shift from linear production models to safer, more sustainable, circular processes. Industrial biotechnology is central to this transition, providing tools to build value chains that reduce emissions, replace hazardous substances, and enable truly circular resource flows.

1.1 The urgent need to transform the linear chemical industry

Chemicals are the building blocks of modern life. The chemical industry in Europe is the fourth-largest manufacturing sector, accounting for over 96% of manufactured goods and playing a crucial role in the EU's industrial resilience and competitiveness(1). While chemicals bring essential benefits, the sector's heavy reliance on finite fossil fuels and its linear "produce–use–waste" model creates significant risks for human health and the environment. Chemical pollution is now recognised by the UN Environment Programme as a major driver of the global "triple planetary crisis"(2), underscoring the urgent need for a more sustainable approach.

In Europe, about 70% of total chemicals produced have been classified as hazardous to human health, a level that has remained stable over the past decade(3). Our understanding of the risks associated with most chemicals on the market remains limited. Only those produced in volumes of at least one ton annually are subject to safety assessments, which cover about 23,000 chemicals out of an estimated 100,000 on the market by 2020(4). Moreover, there is even less knowledge about their sustainability impacts throughout product life cycles, revealing that current regulations do not fully guarantee the safety or sustainability of chemicals in use. This gap makes it difficult to reuse or recycle chemicals safely and underscores the need for a more preventive approach, one that goes beyond compliance to embed safety and sustainability from the moment chemicals are designed.

Public concern about chemical safety is also on the rise. A 2024 survey of 26,346 people across the EU's 27 member states revealed that 78% believe environmental issues directly affect their daily lives and health(5). Moreover, 84% worry about the presence of harmful chemicals in everyday products, both for their own health and the environment, and 72% consider chemical safety when purchasing products. More than half (52%) feel that EU protection against hazardous chemicals is too weak, and nearly 60% are willing to pay more for sustainable, recyclable, and repairable products. This growing awareness and willingness to change consumer behaviour create strong momentum for greener innovations.



Source: European Commission. Attitudes of Europeans towards the Environment. Special Eurometer. 2024.

Today, Europe's chemical industry is facing mounting pressures that threaten its competitiveness and resilience. Rising energy and feedstock costs, as well as geopolitical tensions, have sharply reduced production, causing the EU's global market share to decline by more than 50% since 2003. These trends highlight the urgent need for policies that speed up innovation rooted in safety, sustainability, and circularity. In this context, industrial biotechnology emerges as a powerful driver of change, offering biological pathways that can complement and enhance chemical processes. By enabling value chains that integrate both chemistry and biotechnology, it supports solutions that reduce reliance on fossil resources and strengthen the circular economy(6).

1.2 Industrial biotechnology as a catalyst for the circular bioeconomy

Europe's bioeconomy is built on strong scientific, technological, and industrial foundations, making it a major driver of competitiveness. In 2023, it was valued at up to EUR 2.7 trillion, employed 17.1 million people (around 8% of EU jobs), and invested EUR 23.2 billion in R&D(7). Within this landscape, biotechnology, an engineering discipline that harnesses the functions of living organisms, is transforming the way products and technologies are developed for societal and environmental benefit(8). By leveraging biological systems such as enzymes, microorganisms, and microalgae, biotechnology enables processes that use less energy, replace fossil-based inputs with renewable or waste-derived resources, and embed circularity into industrial value chains.

Recent advances in modern biotechnology, including genome editing and synthetic biology, are expanding these possibilities even further, driving breakthroughs in medicine, agriculture, aquaculture, and environmental applications. Innovations range from bio-based chemicals and biomaterials to advanced fermentation processes and low-carbon bio-manufacturing. Recognising this transformative potential, the EU formally classifies industrial biotechnology as a Key Enabling Technology and a cornerstone of the circular bioeconomy. This strategic focus supports climate goals, enhances resource efficiency, and fosters the creation of new bio-based value chains.

1.3 The evolving policy and regulatory landscape

European policies are rapidly evolving to support the development of safer and more sustainable innovations. The European Green Deal, launched in 2019, sets out the EU's roadmap to achieve a fully circular economy by 2050. A key part of this initiative is the Chemicals Strategy for Sustainability (CSS)(9), introduced in 2020. The CSS marks a major shift in EU chemical policy towards a "toxic-free" environment by restricting hazardous chemicals and promoting safer and more sustainable alternatives.

To support this transition, the EC's Joint Research Centre (JRC) developed a Safe and Sustainable by Design (SSbD) framework(10) to support the design, development and production of safer and more sustainable chemicals and materials throughout the innovation process. The SSbD concept represents a transition from remediation management to a more proactive prevention approach. The ongoing refinement of the SSbD framework is taking place alongside major regulatory updates to align industrial practices with the Green Deal's climate and environmental goals.

Last year, the EC announced two major initiatives to boost the competitiveness of the chemical and biotechnological industry: the Chemicals Industry Action Plan (CIAP)(11) and the new EU Bioeconomy Strategy. The CIAP aims to strengthen the competitiveness and resilience of the EU chemical sector through concrete actions, such as reducing energy costs, simplifying regulations, and directly supporting SSbD implementation through dedicated innovation hubs (Box 1). The new Bioeconomy Strategy focuses on making better use of Europe's land- and sea-based biological resources to build a cleaner, more competitive, and more resilient economy. The strategy prioritises scaling sustainable bio-based industries, empowering local bioeconomies, and ensuring that resource use remains within ecological limits.

Complementing these efforts, the forthcoming EU Biotech Act seeks to simplify regulatory processes and accelerate product approvals, creating a coherent and innovation-friendly legal framework for biotechnology and biomanufacturing. This framework is expected to cover key sectors including health, agriculture, aquaculture, energy, sustainability, economic security, and biosecurity.

This European direction strongly influences how individual nations define their own priorities. In Norway, biotechnology governance and risk management frameworks have taken shape around similar principles, emphasising responsible, sustainable and societally beneficial innovations.

Box 1: Key CIAP regulatory initiatives

- **Simplification of the CLP Regulation:** The Classification, Labelling, and Packaging of Substances and Mixtures(12) (CLP) Regulation is being streamlined through the 6th Omnibus package. This aims to simplify hazardous chemical labelling, allow clearer and more flexible designs, expand digital labelling, and reduce administrative costs and complexity.

- **Targeted revision of REACH**: Since 2007, the Registration, Evaluation, Authorisation, and Restriction of Chemicals(13) (REACH) has governed the registration and control of chemicals produced or imported in quantities above one ton per year. Some procedures, however, have proven complex, especially for small and medium-sized enterprises (SMEs). By the end of 2025, the Commission will propose a targeted revision to simplify and accelerate REACH processes while maintaining strong health, safety, and environmental protections.

- **Adopting a Digital Product Passport (DPP)**: Introduced under the Ecodesign for Sustainable Products Regulation (ESPR)(14), the Digital Product Passport will play a role in enhancing supply chain transparency and promoting circularity. Acting as a digital identity for products, it provides key information on materials, origin, repairability, recycling potential, and environmental impact. The proactive implementation of SSbD positions industries to be adequately prepared for these forthcoming regulations.

- **Innovation hubs**: Innovation hubs will speed up the adoption of the SSbD framework, and help companies, especially SMEs, design safer, sustainable chemicals by providing technical guidance, promoting the substitution of hazardous substances, and fostering collaboration across research and industry. Aligned with the SSbD framework revision in 2025, this initiative will be supported by EU funding, including €120 million from Horizon Europe (2025–2027) for SSbD-related projects that utilise AI and digital tools to drive innovation.

2 Norway's approach to biotechnology governance

Biotechnology innovations can significantly reduce carbon emissions, improve resource efficiency, and enable circular value chains. Yet these benefits come with risks, as technological advances often move faster than regulation, raising concerns about safety, environmental impacts, and public acceptance. Norway has a strong tradition of integrating ethical, environmental, and societal considerations into biotechnology governance, promoting responsible innovation that serves both society and the environment. This aligns well with the European SSbD ambition and provides a solid foundation for safe and sustainable bio-innovations. This section outlines the background and key approaches in Norway that have long aimed to balance innovation with robust risk management.

2.1 Relevant principles, frameworks and policies

The precautionary principle (PP) is a cornerstone of European environmental regulation(15), and is embedded in major legislative frameworks, including REACH(13), food law(16), and regulations governing genetically modified organisms(17) (GMOs). The PP, as outlined in Article 191 of the Treaty on the Functioning of the European Union(18), is a risk management approach aimed at ensuring robust environmental or health protection, especially when scientific data are limited, or a consensus is absent. REACH(13) covers the registration, evaluation, authorisation and restrictions of chemicals, and illustrates how the PP works in practice. For example, substances classified as substances of very high concern, such as endocrine disruptors, can face restrictions or require authorisation even when scientific uncertainty remains about their long-term effects. This demonstrates how precautionary measures can limit the possibility of harm while balancing innovation. Similarly, EU food law(16), applies the PP to ensure that food placed on the market is safe for consumers. Precautionary measures, such as stricter safety assessments, may be used when scientific uncertainty about risks exists.

Although the PP applies across diverse sectors, its implications are particularly relevant within biotechnology, where scientific uncertainty often intersects with sustainability goals and societal concerns. This is why our focus turns to the use of GMOs. In the EU, the PP applies to regulations of GMOs, ensuring that environmental and health protection take precedence whenever scientific uncertainty exists. It means that GMOs are only approved or released after rigorous safety testing and risk assessment, and if doubts remain, authorities may delay or restrict their use. This principle is embedded in the set of rules governing the authorisation of genetically modified products in the EU(17,19), requiring clear evidence of safety before authorisation and allowing post-market monitoring or bans if new risks emerge. Measures such as labelling and transparency also reflect this cautionary approach, allowing consumers to make informed choices. Applying the PP to GMO regulations involves balancing innovation, risk, and ethical responsibility in the face of incomplete scientific knowledge.

Although not an EU member state, Norway is closely associated with the EU through the European Economic Area agreement, which allows Norway to align with many relevant EU rules(20). Regarding GMO regulation, Norway applies stricter criteria than the EU. The Norwegian Gene Technology Act(21) requires that the production and use of GMOs are ethically and socially responsible and contribute to sustainable development. As a result, GMOs approved in the EU may still be rejected in Norway beyond safety reasons, such as sustainability and ethics considerations.

While the Act does not specifically mention the PP, its preparatory work does, and the principle is important for interpreting the sustainability requirement. In practice, precaution underpins regulation as approval of commercial use of GMOs is only possible when safety (i.e., the absence of adverse effects) is clear and when broader ethical, social, and sustainable development criteria are met. Uncertainty or doubt is a valid reason for refusal or more stringent regulation. In practice, the PP is applied through risk assessments, as well as monitoring and surveillance, on a case-by-case basis. Thus, precaution plays a key role in both EU and Norwegian systems: in the EU environmental law primarily as a risk management tool, and in Norway as part of a broader framework.

New Genomic Techniques (NGTs), such as CRISPR-Cas9, are powerful biotechnological tools capable of altering an organism's genetic material in a targeted fashion, in contrast to conventional GMO techniques. The alterations made by NGTs can be as small as a single nucleotide, making it difficult to detect, monitor, and trace. Associated risks include off-target effects and other unintended consequences arising from the use of NGTs. The debate on how to categorise and regulate NGT plants is currently underway in the trilogue negotiations in the EU, highlighting the urgency of establishing appropriate risk assessment and control measures to close the gap between technological advances and regulatory lag. A political agreement is anticipated soon, likely introducing a differentiated framework for NGT-1 and NGT-2 plants(22). NGT-1 plants are expected to be defined as those with genetic changes similar to genetic changes resulting from conventional breeding, excluding herbicide or insecticide resistance traits, which will fall under the NGT-2 category. NGT-2 will be regulated in accordance with the requirements of the GMO regulation. This approach aims to balance innovation with safety and transparency.

In May 2025, Norway's Parliament adopted amendments to the Gene Technology Act through the regulation "Lov om endringer i genteknologiloven"(23). These changes update the GMO legislation while maintaining the core purpose of the Act. Importantly, the amendments confirm that all GMOs, including gene-edited organisms, remain subject to case-by-case approval, supported by independent risk assessment, traceability and labelling. Furthermore, Norwegian regulatory bodies will monitor and align with any updates in the EU regarding the regulation of NGTs, specifically the criteria for categorisation as gene-edited versus non-gene-edited.

The Gene Technology Act focuses on the use of GMOs, including animals, plants and microorganisms, and now explicitly includes gene-edited organisms. In contrast, the Norwegian Biotechnology Act(24) governs the application of biotechnology in humans, ensuring ethical and societal considerations with the aim of protecting human dignity and health. Both Acts share the principle of responsible innovation, balancing technological progress with safety, ethics, and societal benefit. Together, they create a comprehensive

framework for biotechnology governance that covers industrial applications, environmental, agricultural, aquaculture, and human health domains.

Responsible Research and Innovation (RRI) is another risk management framework that ensures both societal and ethical reflection, in addition to technical safety(25). RRI is based on four principles, i.e., anticipation, inclusion, reflexivity, responsiveness, and six core dimensions: public engagement, gender equality, science education, open access, ethics, and governance(26). A key component of RRI is interdisciplinary collaboration between social and natural scientists at an early stage of development.

Safe-by-Design (SbD) is a proactive and preventive risk management approach that integrates safety considerations early in the research and innovation process, throughout the entire lifecycle of a product or process, from lab to landfill. Originally coined for nanotechnology(27), SbD has since been applied in biotechnology(28) with Dutch initiatives leading the way. This is reflected in pioneering stakeholder studies and practical tools designed for emerging biotechnologies such as CRISPR and synthetic biology(29). In the context of GMOs, SbD strategies guide careful selection of genetic modifications to minimise unintended effects, such as gene flow to wild populations, and incorporate measures to prevent environmental escape or persistence through physical and/or biological containment. The SbD framework follows an iterative design-test-assess-redesign loop, ensuring continuous improvement based on risk findings.

SbD can be viewed as a natural extension of the RRI approach(30) or as an example of RRI methodology(31), and in Norway, it is implicitly embedded within the RRI framework. While SbD focuses on human and environmental safety, the SSbD approach extends this focus to include environmental, social, and economic sustainability. The Norwegian Long-Term Plan for Research and Higher Education 2023–2032(32) emphasises the importance of integrating sustainability and safety considerations early in technology development, in line with principles like SbD.

2.2 Relevant authorities and scientific bodies

Norway is strongly committed to environmental stewardship. Norway's governance system involves a coordinated set of authorities and scientific bodies that provide oversight, guidance and research.

The Norwegian Environmental Agency (Miljødirektoratet) holds the main responsibility for climate and environmental management within the country(33). Regarding chemicals, the Norwegian Environmental Agency is responsible for overseeing the implementation of REACH, CLP, biocides, and persistent organic pollutant regulations within the country. In the area of GMOs, the Agency is the competent authority and coordinates application processes for GMO use and environmental release both nationally and within EU. It provides the Ministry of Climate and Environment (KLD) with an assessment and recommendation for a decision based on the Act's criteria. Final decisions on GMOs are made by KLD after consultation with other relevant ministries. The Agency receives expert advice from the Norwegian Scientific Committee for Food and Environment (VKM) and the Norwegian Biotechnology Advisory Board. VKM is responsible for the scientific evaluation of GMOs, providing risk assessments that address human and animal health, environmental impacts,

and Norwegian-specific conditions. In parallel, the Biotechnology Advisory Board assesses ethical considerations, sustainability, and societal benefits associated with the use of GMOs. In addition, the Norwegian Veterinary Institute monitors GMOs in food, feed, and seed, while the Norwegian Food Safety Authority (Mattilsynet) is responsible for sampling activities and managing health-related risks.

The Norwegian Ministry of Education has outlined overarching objectives and thematic priorities, identifying SSbD as a key health, safety and environment (HSE) policy for developing advanced chemicals and materials(32). These priorities strongly guide the Norwegian Research Council's funding strategies(34), which emphasise the integration of RRI into funding applications and research projects, making it a formal requirement into calls for proposals, encouraging researchers to address ethical, social, and sustainability aspects along technical innovation(35). The RRI approach has been particularly relevant in enabling technologies such as biotechnology, information and communication technologies and nanotechnology. While RRI is promoted in many countries, it often remains voluntary. In contrast, Norway has established dedicated learning centres, such as AFINO(36), which provide training and support on RRI.

Norway also places strong emphasis on research ethics through the National Committee for Research Ethics (FEK), and, of relevance here, the committee in Science and Technology(37) (NENT). Established under the Act on Ethics and Integrity in Research and appointed by the Ministry of Education and Research, NENT operates as an independent advisory body. Its mandate is to provide guidance on ethical issues in research within natural sciences, technology, and engineering, including biotechnology and other enabling technologies. NENT develops guidelines, issues statements, and advises researchers, institutions, and policymakers to ensure that innovation aligns with principles of sustainability, societal responsibility, and human dignity. While NENT does not have a regulatory role, its recommendations influence national research policy and funding practices, including the Research Council of Norway. By embedding ethical reflection into research and development processes, NENT complements regulatory frameworks and strengthens Norway's commitment to responsible and sustainable innovation.

The Norwegian Board of Technology(38) (Teknologirådet) complements these bodies by providing foresight and policy advice on the societal implications of emerging technologies, including biotechnology. Its role is to inform government and parliament through scenario analyses, stakeholder engagement, and public dialogue, ensuring that technological development aligns with democratic values and long-term sustainability. Together with the Biotechnology Advisory Board and NENT, the Board of Technology strengthens Norway's capacity for responsible innovation by integrating ethical, societal, and future-oriented perspectives into policy-making.

Building on this European and national foundation, the next section presents the SSbD concept and framework developed by the EC to guide industrial innovation.

3 A framework for guiding safe and sustainable by design innovation

SSbD is an approach that integrates, for the first time, safety and sustainability from the initial stages of chemical, material, or product development through the entire lifecycle. The SSbD concept builds on principles from related approaches, such as green chemistry, SbD, sustainable chemistry, and circular chemistry, while emphasising the precautionary principle to identify and mitigate risks early in the innovation process(10,39).

Safety focuses on preventing or minimising unacceptable risks to human health and the environment arising from a product, process, or technology. **Sustainability**, in turn, ensures that innovations meet present needs while operating within environmental limits across their life cycle and supporting long-term social and economic well-being. In the SSbD concept, both aspects are closely linked, with safety serving as a fundamental element across all sustainability dimensions (i.e., environmental, social, and economic). However, safety and sustainability do not always align, and trade-offs might be necessary(40).

SSbD is a young and evolving concept that still faces significant challenges in its implementation (see 3.2 section). To support the operationalisation of the SSbD concept, the EC's JRC has developed a technical framework(10). At this stage, the SSbD framework is not a regulation but rather is a voluntary approach promoted by the EC to encourage industry and research actors to move beyond mere regulatory compliance.

3.1 Framework structure

In brief, the SSbD framework includes two key components: scoping analysis and SSbD assessment. These are applied iteratively, aligned with the technology readiness level (TRL), as data and knowledge are gradually accumulated. The aim of the framework is to support decision-making throughout the innovation process, thereby helping to develop safer and more sustainable chemicals and materials over their entire life cycle.

3.1.1 Scoping analysis

Every assessment should begin by clarifying its purpose: What is the goal of the innovation? Which design principles guide its development? Who are the key actors involved throughout its lifecycle? The scoping analysis lays the foundation for understanding the system under study and determining which aspects will be evaluated for safety and sustainability. It integrates three essential components: defining the system, outlining redesign goals, and engaging with actors across the life cycle. By identifying and prioritising the most relevant issues, scoping provides clear boundaries and focus for the SSbD assessment within the broader research and innovation process(41).

3.1.2 SSbD assessment

The assessment consists of five steps, with the first three focusing on safety assessment and the final two addressing sustainability assessment. The order of the five assessment steps varies based on project needs and data availability.

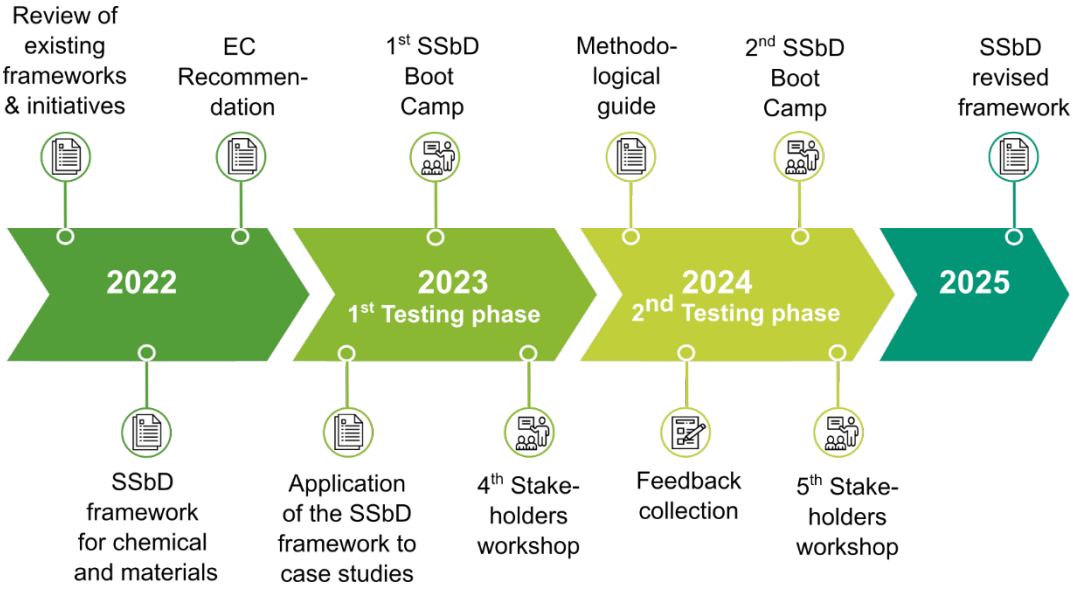
Safety assessment	**Step 1: Hazard Assessment of the Chemical/Material.** What are the inherent hazardous properties of the chemical/ material?	This step assesses the intrinsic hazardous properties of a chemical or material and applies the CLP classification criteria to categorise them as the most harmful substances, substances of concern, or other hazard categories. It also proposes a cut-off criterion to exclude the most harmful substances from further SSbD assessment, regardless of their sustainability.
	Step 2: Human health and safety aspects in the chemical/ material production and processing. Are workers protected during production?	This phase evaluates occupational health and safety during production, processing, and end-of-life of products containing the chemical or material. It builds on Step 1 by assessing potential worker exposure and related risks in industrial settings. Exposure scenarios describe activities, conditions, and risk management measures throughout the lifecycle, and a tiered risk assessment is applied based on data availability.
	Step 3: Human health and environmental aspects in the final application phase. What risks arise when the product is used?	This phase assesses the risks associated with the final product, including potential chemical releases during use or service life. It considers hazard and fate properties, exposure under different application scenarios, and risk mitigation measures, which together determine exposure probability and routes. This step builds on Steps 1 and 2 by focusing on use-phase safety and environmental impact.
Sustainability assessment	**Step 4: Environmental sustainability assessment.** How sustainable is the product's footprint?	Here, Life Cycle Assessment (LCA) is applied to evaluate environmental impacts across the chemical or material's life cycle. LCA is based on a functional unit, defined by ISO 14040:2006 as the quantified performance of a product system used as a reference. The SSbD framework recommends the Product Environmental Footprint (PEF) method, proposed by the EC, which measures performance across including climate change, resource depletion, water use, and toxicity, enabling a holistic lifecycle assessment from raw material extraction to end-of-life.
	Step 5: Socioeconomic sustainability assessment. How does the innovation affect people and society?	The final step addresses socioeconomic impacts. It maps relevant stakeholders and social aspects, while the economic part focuses on non-financial factors such as externalities across the chemical's life cycle. As methods are still maturing, this assessment step remains exploratory.

The framework provides a clear, structured method for assessing safety and sustainability

results within the scope of the analysis. Making effective decisions requires prioritising options that balance safety and sustainability while carefully managing trade-offs to prevent unintended outcomes. To facilitate this process, the framework recommends employing multicriteria decision analysis (MCDA) to systematically assess trade-offs and support informed decision-making(41).

3.2 Implementation progress and remaining barriers

The initial SSbD framework, defining key criteria and evaluation procedures(10), was introduced in 2022. By the end of that year, the EC recommended it as a voluntary approach to guide the development of safer and more sustainable chemicals and materials(42). Since then, several reports have been published, reviewing safety and sustainability aspects, methods, indicators, and tools(40), as well as presenting case studies that apply the SSbD framework(43). The EC's JRC has played an active role in supporting its implementation. Stakeholders from academia, research organisations, and industry have been invited to test the framework and provide feedback, which contributed to the release of an updated methodological guidance(41). The framework has completed a second round of testing and stakeholder consultations through case studies and workshops, followed by revisions based on the feedback received. A revised version of the framework was published at the end of 2025(44), although its practical application is still under development, and some challenges remain before full adoption.



The implementation timeline. Source: European Commission. “Safe and Sustainable by Design.” Accessed 17 Dec. 2025.

Although the SSbD concept is gaining momentum across Europe, key barriers remain. These include limited availability of data for early-stage assessments, the need for harmonised tools and metrics, the complexity of integrating multiple assessment dimensions, and the challenge of interdisciplinary collaboration(45–47). For biotechnology

specifically, biological uncertainty, context-dependent risks and gaps in sustainability assessment methods further complicate operationalisation(6).

Despite these challenges, progress is accelerating, with the EU currently integrating the SSbD concept into the Horizon Europe work programmes. A recent comprehensive review(48) of 45 EU-funded SSbD-related projects from the CORDIS database, covering both Horizon 2020 and Horizon Europe, shows that more than €286 million has been invested in this area as of February 2025. Most of this funding goes to research organisations (57%) and academia (25%), while industry (9%) and SMEs (8%) remain significantly underrepresented. Project activity is focused on textiles, electronics, automotive applications, and construction materials (63%), while important sectors for Norway, such as aquaculture and biotechnology, are largely overlooked. The focus on the type of materials and substances is similarly narrow, with strong emphasis on bio-based materials, nanomaterials, flame retardants, surfactants, per- and polyfluoroalkyl substances (PFAS), and plasticisers, reflecting current regulatory priorities but leaving other chemical classes insufficiently explored. Insights from ongoing research projects will be used to further improve and refine the framework in the coming years. Despite this progress, further work is needed to make SSbD fully practical, especially for research institutes and SMEs that often work with novel biological systems. The next section illustrates how SSbD principles can be applied in practice through biotechnology research carried out at NORCE.

4 Applying the SSbD approach in biotechnology research at NORCE

Although the SSbD framework was originally developed for the chemical sector, it has a broader applicability(29,49). Its effective implementation relies on close collaboration between industry, academia, research and technology organisations, as well as coordination across different industrial sectors. Yet, its use in industrial biotechnology remains underexplored. Expanding co-creation efforts and developing practical case studies will be crucial for testing, refining, and adapting SSbD assessment methods in this field(45). To contribute to this development, the SSbD framework has been applied to three case studies from NORCE's biotechnology portfolio, each showcasing a real-world application of emerging technologies leading to new products or processes, illustrating three distinct technological approaches.

OXIPRO is a 4-year project funded by the European Union's Horizon 2020 work programme, under its Research and Innovation Action (grant ID: 101000607)(50). The project focuses on harnessing enzymes to develop greener products and processes. The project targets TRL 3 to 5. Since enzymes used in over 1 ton in the European market are regulated as chemicals by REACH, their use cases may be relevant for SSbD assessments.

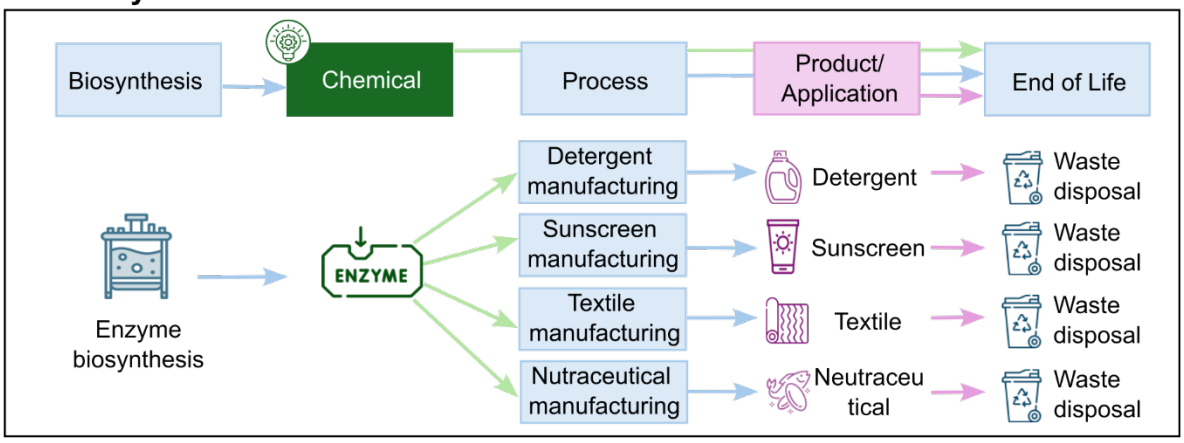
ENIGMA is a 4-year national project funded by The Research Council of Norway(51), where photonic crystals derived from genome-edited microalgae (diatoms) are used in biosensing and photocatalytic platforms. These applications include nanomaterials and thus are highly relevant for SSbD assessments. This, moreover, represents a case where more than one enabling technology (bio- and nanotechnologies) is combined.

Finally, **SafePhaeO3** is a 4-year national project funded by The Research Council of Norway(52). This project deals with developing algal cell factories using genome editing. This project does not involve chemicals or materials, but enabling biotechnologies. This case was used to investigate how the SSbD framework can be applied beyond its intended use for chemicals and materials, ensuring that bio-based innovations are developed with safety, sustainability, and societal impact in mind from the outset.

In the following, we outlined the scoping analysis outcomes for each of the three case studies, defining the context for the upcoming SSbD assessment.

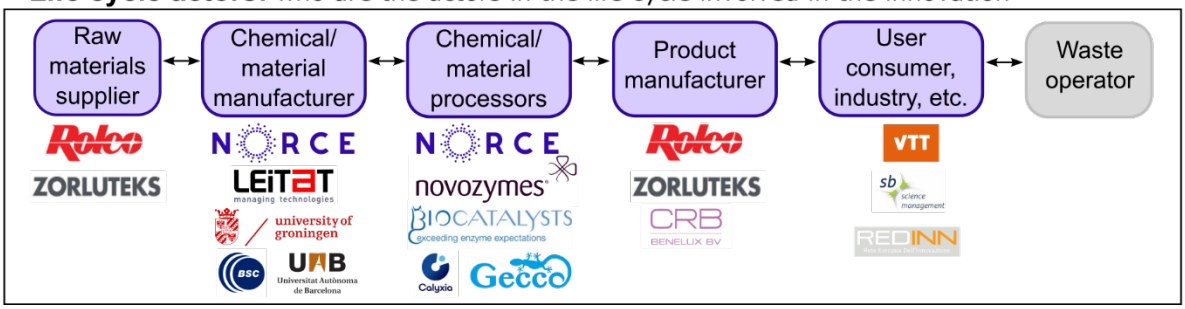
OXIPRO study cases: SSbD in biochemical innovation

SSbD system



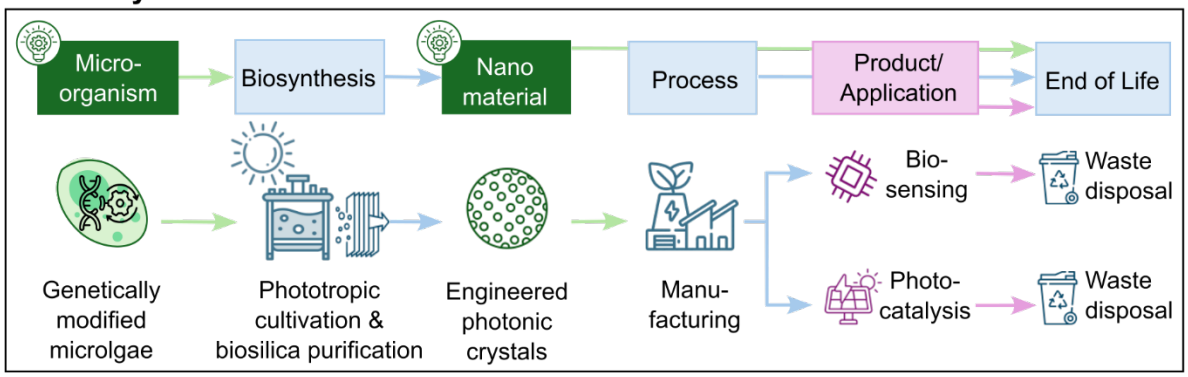
Innovation case	Detergent	Sunscreen	Textile	Neutraceutics
Goal What is the goal of the innovation?	Enhance disinfection at low temperatures for consumers	Replace harmful UV filter ingredients with natural alternatives	Wastewater reuse, reduced energy & harmful chemicals input in cotton production	Transforming fish by-products into odourless protein supplements for humans
(re) design action What type of innovation and design (molecular, process or product) are applied?	Breakthrough innovation applying a molecular design based on bioengineering oxidoreductase enzymes to be used in the manufacturing process			
SSbD design principles What design principles underpin the innovation?	Reducing energy consumption (SSbD3) Reducing hypochlorite and quats use (SSbD5)	Replacing harmful ingredients (SSbD5) Improving the product's biodegradability (SSbD7)	Reusing and minimising water use and waste (SSbD1 & 4) Less hazardous chemicals during bleaching (SSbD2)	Minimising and upcycling fish waste (SSbD1 & 4) Increasing marine-sourced proteins for human consumption
Maturity of innovation When is the SSbD implemented?	Low (TRL 3)	Low (TRL 3)	Low (TRL 3)	Low (TRL 3)
Preliminary SSbD scenario for assessment	Which life cycle stage(s) are most affected by the use of enzymes in the manufacturing process? (e.g. raw materials, processing, or final use)			

Life cycle actors: who are the actors in the life cycle involved in the innovation



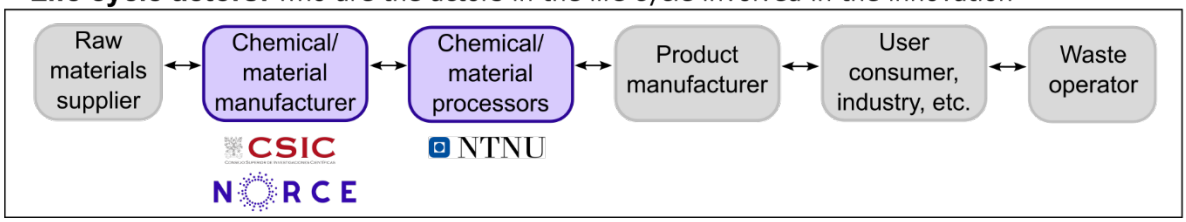
ENIGMA study case: SSbD in bio-based nanomaterial innovation

SSbD system



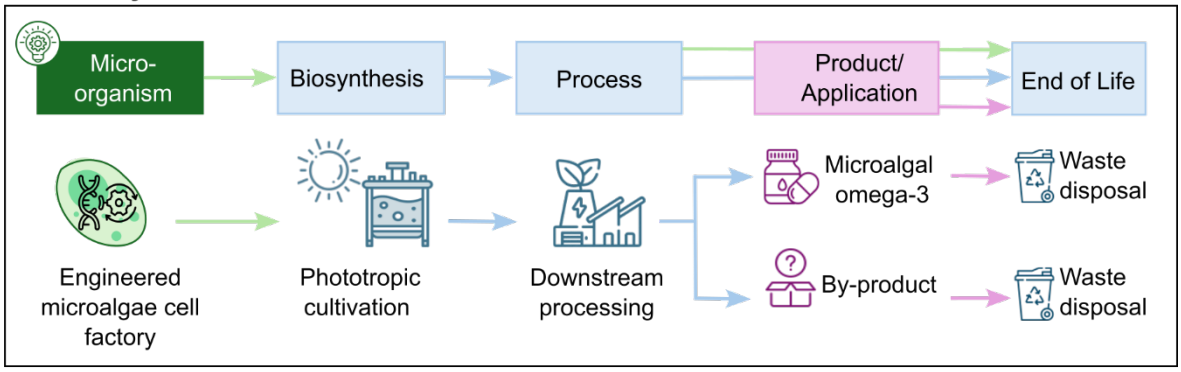
Innovation case	Engineered photonic crystals
Goal What is the goal of the innovation?	Introduce a novel nanomaterial with novel functions to reduce the costs, energy consumption, and utilisation of critical raw materials in the manufacturing of photonic crystals.
(re) design action What type of innovation (incremental or breakthrough) and design (molecular, process or product) are applied?	Breakthrough innovation applying a molecular design to tailor the photonic properties of diatom silica-based cell walls by gene editing techniques, enabling a full optical range for a variety of applications.
SSbD design principles What design principles underpin the innovation?	Minimise the use of Critical Raw Materials (SSbD1) Minimise the use of toxic solvents and heavy metals during manufacturing, and increase the biodegradability of the nanomaterial (SSbD2) Minimise energy-intensive process with biobased alternative (SSbD3) Using microalgae as a renewable feedstock grown with solar energy (SSbD4).
Maturity of innovation When is the SSbD implemented?	Low (TRL 3)
Preliminary SSbD scenario for assessment	What are the potential hazardous properties of the new genetically engineered microalgae? Which life cycle stage(s) are most impacted by using a GMO strain in the manufacturing process? What measures are needed to prevent GMO risks?

Life cycle actors: who are the actors in the life cycle involved in the innovation



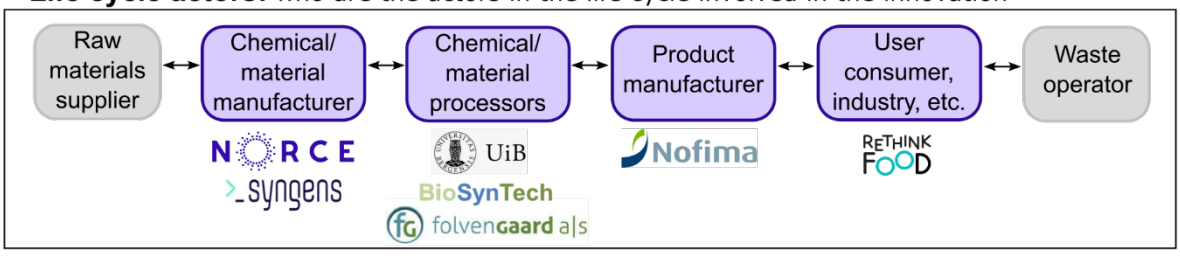
SafePhaeO3 study case: SSbD in enabling (bio)technologies

SSbD system



Innovation case	Microalgal cell factory
Goal What is the goal of the innovation?	Develop a novel biofactory platform to produce omega-3 fatty acids, providing a sustainable alternative to fish-based production.
(re) design action What type of innovation (incremental or breakthrough) and design (molecular, process or product) are applied?	Breakthrough innovation applying a molecular design to create safe and efficient microalgal biofactories for omega-3 production by gene editing techniques, enabling a secure platform for future biotechnological applications.
SSbD design principles What design principles underpin the innovation?	Avoid antibiotics by using an antibiotic-free selection system and transgene expression for GM microalgae (SSbD2). Utilise microalgae as a renewable feedstock cultivated with solar energy (SSbD4). Prevent accidental GMO release by genetically engineering biocontained microalgae (SSbD5).
Maturity of innovation When is the SSbD implemented?	Low (TRL 2-4)
Preliminary SSbD scenario for assessment	What are the potential hazardous properties of the new genetically engineered microalgae? How do safety features integrated into a cell factory influence the safety and sustainability of the product life cycle?

Life cycle actors: who are the actors in the life cycle involved in the innovation



5 SSbD competence at NORCE

NORCE has taken a leading role in operationalising the SSbD framework through targeted capacity-building initiatives and participating in the EC's public consultations for the revision of the framework. These efforts aim to equip researchers with the interdisciplinary skills and systems-thinking mindset needed to embed SSbD principles across the innovation chain, from basic research to industrial application and policy development. Investing in SSbD capacity building enables the early integration of safety and sustainability into research and product development, fostering cross-sectoral collaboration between academia, industry, and regulators. This leads to informed decision-making based on life cycle assessments, exposure scenarios, and socioeconomic considerations, ultimately promoting public trust and transparency in emerging technologies and products.

The SSbD approach represents a cultural and methodological shift. It requires a deep understanding of complex systems, life cycle thinking, risk assessment, and stakeholder engagement. To implement SSbD effectively, NORCE has cultivated a workforce that is not only technically proficient but also capable of navigating ethical, regulatory, and societal dimensions of bio-innovations.

In the following, we share some of the learning points faced while implementing the SSbD framework in projects. These may be absorbed in future developments of the SSbD framework.

5.1 The SSbD learning experience in cases

From case studies, it was evident that the scoping analysis is an essential starting point for the SSbD assessment. By fostering communication and collaboration among the research partners, the scoping analysis helped researchers step back and consider the "bigger picture" by applying life cycle thinking. This process supported a shared understanding of the innovation goals and enabled the team to jointly identify the design principles needed to achieve them. Researchers identified SSbD design principles such as material efficiency (SSbD1), energy efficiency (SSbD3), and hazard prevention (SSbD5), which guided the bio-innovations from their early stages.

Because research and innovation projects differ in their needs, goals, and involved actors, the scoping analysis was essential for identifying and prioritising the most relevant issues. This process helped define clear boundaries and focus areas for the SSbD assessment. The iterative nature of the SSbD framework, in which scoping and assessment are revisited as new data emerge, enabled researchers to pursue a simplified SSbD assessment that can be refined over time as the innovation develops.

Effective SSbD implementation requires strong interdisciplinary and cross-sectoral collaborations, a point reinforced by findings from a recent biomanufacturing case study(53). The assessments frequently required expertise from toxicologists, LCA specialists, social

scientists, and biotechnologists, underscoring the value of engaging diverse teams and stakeholders early in the innovation process(48). This early collaboration enabled researchers to share experiences and develop a shared understanding of SSbD principles across the value chain. The case studies also revealed a clear need for SSbD-specific training, with researchers calling for structured educational programs and sector-tailored guidance to build capacity. We therefore recommend integrating SSbD training into research projects and academic curricula, as well as promoting cross-sector learning, to strengthen future implementation.

5.2 Main obstacles faced in applying the SSbD framework

The case studies revealed that the SSbD framework, while well-intentioned, is often seen as methodologically complex and highly data-intensive. Without a uniform SSbD methodology, researchers were forced into a case-by-case approach, which can feel overwhelming, especially for early-stage innovators with limited resources. This raises a key question: how can SSbD be made both holistic and accessible?

A major barrier is the limited availability of data at low TRLs. Early-stage innovations typically lack comprehensive information on hazards, exposure, and lifecycle impacts, constraining the robustness of SSbD assessments. High-throughput new approach methodologies (NAMs) and AI have the potential to help address these gaps(46), but their effective use depends on adequate infrastructure and user capacity. Even where data are available, transparency and data sharing remain limited. Initiatives such as the PARC SSbD toolbox(54), currently under development, aim to address these challenges by providing a curated set of models, workflows, algorithms, and databases for generating and sharing SSbD-related results in line with FAIR and TRUST principles. Early, hands-on training in the use of this toolbox is therefore recommended. In addition, tools such as the Digital Product Passport and the innovation hubs proposed under CIAP (see Box 1) may further enhance transparency and traceability across value chains.

Assessing SSbD in highly multi-interdisciplinary innovation cases presents an additional challenge. Evaluations often struggle to capture the full complexity of interconnected processes, with upstream stages, such as feedstock sourcing and chemical production, frequently overlooked. This results in incomplete assessments and limits comparability across projects. Addressing this issue requires more standardised and pragmatic implementation approaches. Potential solutions include starting with a single, clearly defined application scenario and progressively expanding the assessment as data becomes available(45). Linking SSbD assessments to established lifecycle assessment databases can also support the systematic inclusion of upstream impacts, improving both robustness and usability.

The case studies revealed persistent uncertainty around trade-offs between safety, sustainability, and socioeconomic considerations, consistent with findings from previous assessments(45). The application of hazard-based cut-off criteria in safety assessments can be particularly challenging for certain technologies and may inadvertently exclude substances, such as enzymes, that represent best-available options when properly

managed. The absence of a clear definition of "safe" further increases subjectivity and leaves innovators uncertain about compliance. These findings underscore the need for clearer guidance on how hazard criteria should be applied across different technology types within the SSbD framework.

Socioeconomic assessment methods are the least developed dimension of SSbD. Tools such as life cycle costing (LCC) and social LCA (S-LCA) lack methodological maturity, data availability, and integration with environmental assessments. In a recently closed consultation, the EC was interested in how well the SSbD framework supports assessments of socioeconomic sustainability, underscoring that further development of these methods will be essential for achieving a more balanced and comprehensive SSbD evaluation(46).

Overall, SSbD assessments demand substantial time, expertise, and coordination, posing challenges for smaller teams or early-stage projects. To anticipate these needs, project proposals should integrate life cycle thinking from the outset and involve relevant actors across the value chain as partners or advisors.

Finally, the voluntary nature of the SSbD framework may limit its widespread uptake. To encourage broader adoption in Norway, supportive policies and incentives will be essential. For instance, integrating SSbD requirements into The Research Council of Norway's funding programmes could help stimulate demand and promote more consistent implementation. Additional measures, such as tax incentives, public procurement criteria, and recognition schemes, could further reinforce adoption across industry and research sectors.

6 Concluding remarks

The transition to a circular bioeconomy demands a fundamental rethinking of how we design, develop, and assess new technologies. The SSbD framework offers a pathway to embed safety and sustainability considerations in the early stages of innovation. Through this report, we have explored the policy context, conceptual foundations, and practical application of SSbD in biotechnology, drawing on real-world case studies from NORCE's research portfolio.

Our experience demonstrates that SSbD represents a cultural shift in how innovation is approached. It requires interdisciplinary collaboration, systems thinking, and a willingness to engage with uncertainty and complexity. While the framework provides valuable guidance, its implementation is still evolving. Challenges such as methodological complexity, data limitations, and underdeveloped socioeconomic assessment tools must be addressed to ensure broader adoption.

We hope this report contributes to the ongoing dialogue on how to operationalise SSbD and supports the development of more robust, inclusive, and future-proof innovation ecosystems. By sharing our learning experience, we aim to inspire others to adopt and adapt SSbD in their own research and innovation efforts.

Capacity-building efforts at NORCE have demonstrated that, with appropriate support, researchers can integrate SSbD principles across diverse innovation settings. Our ambition is for the knowledge, tools, and practices developed here to serve as a resource for research institutions, industry partners, and policymakers. To achieve broader implementation across the Norwegian research and innovation system, it will also be essential to establish targeted incentives that encourage organisations to embed SSbD systematically into their own work.

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