Partnership for the Assessment of Risks from Chemicals

Milestone M8.1.1-2

Linking Innovation with Safety and Sustainability Assessment

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Abstract

Safe and Sustainable by Design (SSbD) has been advanced by the European Commission's Joint Research Center (JRC) as an approach toward the development of safer and more sustainable chemicals, materials and products. While the framework is intended to influence innovation, its practical integration into industrial innovation processes remains insufficiently explored. In industry, chemical and product development typically follows phased innovation processes that progressively reduce technical, environmental, and business uncertainties, narrowing the range of viable options as development proceeds. Understanding how safety, sustainability, and socioeconomic considerations are currently addressed within these processes is therefore critical for the effective uptake of SSbD.

This milestone presents the results of an in-depth qualitative exploration of current industrial practices through interviews and focus groups with companies operating at different positions in the value chain. The study examines the tools, methodologies, and decision-making approaches currently used to address safety and sustainability across innovation stages, identifies barriers and enabling factors for SSbD implementation, and derives implications for the design of the PARC SSbD toolbox. The findings provide empirical insights into how SSbD-related principles are already partially embedded in industrial innovation and highlight key considerations for aligning the framework with existing innovation practices.

Key Words

Safe and Sustainable by Design, Innovation, Stage-Gate, Risk Assessment, Sustainability, Socioeconomic Assessment

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1. Background

The Chemical Strategy for Sustainability (CSS) was launched in 2020 as part of the European Union's Zero Pollution ambition. Among its key actions is the promotion of chemicals that are safe and sustainable by design, which initiated the development of a dedicated Safe and Sustainable by Design (SSbD) framework. A first version of the SSbD framework was published in 2023 and opened for testing and feedback by stakeholders. Following several iterations informed by this testing phase, a final version of the framework was published at the end of 2025.

Safe and Sustainable by Design (SSbD) has been put forth as a voluntary pre-market approach to chemicals, focusing on delivering a specific function or service while avoiding volumes and chemical properties that may be harmful to human health or the environment (Caldeira, 2022). By integrating safety and sustainability considerations throughout the development of new and existing chemicals, products and processes, SSbD aims to steer the European chemical industry towards a green and sustainable industrial transition (Caldeira, 2022).

The SSbD framework specifies two components: an assessment phase in which the safety, environmental sustainability and socioeconomic aspects of the chemical are assessed, and a (re)design phase, in which design principles are applied to steer the chemicals, materials, or products towards a more desirable safety and sustainability profile (Caldeira, 2022). These components are intended to be applied within the context of chemical and product innovation processes as they occur in industry.

In practice, innovation in chemical and product development is commonly organized in companies through phased decision-making processes, such as the stage-gate model proposed by Robert Cooper (Cooper 2008; 1990) (see Appendix 1 for detailed description). In this model, a "stage" consists of a set of best-practice activities to be undertaken to acquire vital information and thereby reduce the risk of the project from stage to stage (Cooper 2008; 1990). The gates, designated by diamonds, are the Go/Kill/Hotspot decision points where the project team decides whether the project merits progression to the next stage (Cooper, 2008). According to CEFIC (2024), a formalized stage-gate process exists in approximately 20 companies in the European chemical sector, while less formalized strategic evaluation checkpoints addressing market, business and regulatory.

Following testing across different contexts and stakeholder groups, the SSbD framework has expanded to include additional elements. Notably, the introduction of a scoping assessment aims to define the objectives, principles and decision rules of the intended innovation. This is followed by the development of SSbD scenarios, which represent the outcome of the scoping analysis and identify the appropriate entry point into the SSbD assessment. In addition, the framework proposes a more explicit approach to evaluation and documentation of decisions.

Beyond SSbD, several approaches have previously aimed to integrate sustainability considerations into industrial decision-making. For example, the World Business Council for Sustainable Development (WBCSD) developed the portfolio sustainability assessment (PSA) methodology, which aims to support companies in steering their product portfolio towards improved sustainability performance. The aim of the PSA framework is to provide a robust methodology to move a product portfolio beyond regulatory compliance toward improved sustainability performance.While PSA has been in application for close to a decade, the chemical industry has reinstated SSbD within PSA (CEFIC, 2024,2022). CEFIC recommends implementing SSbD at the product-application-region-combination (CEFIC, 2024) fitting the implementation of SSbD within the stage-gate process which accompanies the development of new products from ideation to market launch.

Stage-gate innovation provides the practical context in which SSbD needs to be implemented within companies. While there are several suggestions on how to integrate safety and sustainability are in industrial innovation processes, such as those described in best-practice guidance from the International Organization for Standardization (ISO 2002; 2008; 2009; see Appendix 2 for examples) and initiatives such as the World Business Council for Sustainable Development's Portfolio Sustainability Assessment (WBCSD, 2017), it remains unclear to what extent these are systematically applied across companies and how they are operationalized in decision-making.

To achieve widespread implementation of the SSbD framework and to realise its intended objectives, it is therefore necessary to identify and critically evaluate how industrial innovation processes are organised in practice, and in particular how safety and sustainability assessments are currently conducted, integrated and used throughout the different stages of innovation.

2. Scope and Aim

The development of the Safe and Sustainable by Design (SSbD) framework has largely been driven by scientific and policy considerations. The stakeholders expected to apply SSbD in practice, however, are industry actors involved in chemical and product innovation. An in-depth understanding of how innovation is organised within companies, and how safety and sustainability considerations are currently integrated into decision-making, is therefore critical for the successful operationalisation of SSbD through relevant frameworks, tools and educational resources.

In line with this need, the Partnership for the Assessment of Risks from Chemicals (PARC) Work Package 8.1 aims to support the development and operationalisation of SSbD by contributing to the development of a toolbox for use by product development teams in industry. Within this context, Task 8.1.1 focuses on understanding the potential user perspective, needs and existing practices related to SSbD, in order to ensure that the toolbox and associated support structures are fit for purpose and aligned with industrial realities.

The scope of this study is exploratory and qualitative. It focuses on chemical and product innovation processes as they are organised within companies, with particular attention to how safety and environmental sustainability considerations—and where relevant socioeconomic aspects—are incorporated across different stages of innovation. The emphasis is placed on understanding how such considerations are used in practice to inform decisions, rather than on evaluating the scientific robustness, regulatory compliance or quantitative outcomes of specific assessment methods. The study is conducted from a toolbox development perspective, aiming to identify existing practices, information needs and gaps relevant for the design of practical SSbD support tools. Quantitative sustainability assessments, benchmarking of tools, verification of compliance with SSbD criteria and evaluation of products already placed on the market are outside the scope of this work.

The overall aim of the study is to generate insights into current industrial practices related to innovation, safety and sustainability in order to inform the further operationalisation of SSbD. This aim is addressed through the following overarching research questions: a) What is the current link between innovation, safety and sustainability in chemical and product innovation process? b) What does the state of the art within companies teach us about the further operationalization of SSbD?

These questions are explored through the following focus areas:

- **The chemical/material innovation process**
  - How does the innovation on development of new chemicals and materials work in the company? What steps are being taken? Who is involved? How is it decided?
- **Current safety and sustainability evaluations in the innovation process**
  - How are safety and sustainability now included in the innovation process? What about socioeconomic aspects? Which models and data are used? How does the company come to a decision and take the next step?
- **Response to European developments in safe and sustainable innovation**
  - How are recent developments in safety and sustainability thinking incorporated into the innovation process? What is needed in terms of knowledge, data and tools?
- **Enabling environment**
  - What are the policy and other drivers of innovation in the company? What is needed in terms of governance mechanisms, business models and educational needs?

To address these questions, in-depth interviews and focus groups were conducted with eight companies involved in chemical and product development, including both chemical companies producing novel chemicals (*producers* in REACH terminology) and developing chemical-based products (*formulators* in REACH terminology) operating at different positions in the value chain. The preference was for producers given the focus of SSbD. Given the substantial time commitment required from industry, the choice of companies was non-probabilistic, allowing for a diversity of innovation contexts relevant to SSbD.

Initial discussions were held with each company to explore interest and suitability for participation, provide information about the toolbox and interviews, and address any concerns. Teams of experts were assembled from both the company and the interview team to reflect the multiple areas of expertise involved in SSbD. Because exploring innovation within companies entailed handling potentially sensitive information, we proposed to prepare an interview report based on an MS Teams recording of the interview, which would be shared with the company and finalized together. Company names and identifying details were anonymized in the company reports.

We interviewed eight companies for approximately three hours each. Following an introduction of the company and PARC, the interaction followed a semi-structured questionnaire (provided in Appendix 3) with substantial discussion and clarification. Since the interviewers did not have a social science background, and indeed the exploration required in-depth knowledge of one or more aspects of SSbD, In order to follow best practices of social science, the interviewers were trained by social scientists on best practices on interview methods. Additional interviews on specialized topics (e.g. New Approach Methodologies (NAMs), cheminformatics) were scheduled when the company had substantial expertise in these areas.

This study provides an overview of the industrial context for SSbD, maps current safety and sustainability practices, and identifies information, knowledge, and process gaps to inform the development of an SSbD toolbox and associated support materials. The relevant framework is the 2023 version, as the updated framework was published after the completion of the interviews.

3. Summary of Case Studies

The case studies presented in the following sections are based on in-depth interviews with companies that vary in size, sector, and position in the value chain, and that differ in their familiarity with the Safe and Sustainable by Design (SSbD) framework. An overview of the interviewed companies and their main characteristics is provided in Table 1 illustrating the diversity of innovation contexts, sectors and levels of familiarity with SSbD covered by the case studies.

To support comparability and cross-case analysis, the insights from each interview are presented using a common structure. Each case study begins with a brief company profile, describing the company's role in the value chain and the sector in which it operates, as these factors influence regulatory pressures and innovation drivers. This is followed by a description of the innovation process, outlining how new chemicals or products are developed and how decisions are made. Subsequently, the case studies describe how safety and sustainability considerations are currently integrated into the innovation process. The cases then address how recent policy developments and the SSbD framework are perceived and reflected in company practices. Finally, each case study discusses the conditions required for an enabling environment, including organisational, regulatory and knowledge-related factors.

The individual case studies are anonymised and are not intended to be statistically representative. Rather, they provide illustrative examples of current practices and challenges relevant to the operationalisation of SSbD across different industrial contexts.

Table 1: Overview of interviewed companies and case studies included in the analysis

Cases	Company Size	Producer or formulator, value chain position	Sector	Innovation type and organization	Respondent Roles
4.1	SME	Formulator, middle	Wood protection in Construction	Product innovation led to creation of company, no stage-gate	Owner/inventor
4.2	Large	Producer, upstream	Industrial biotechnology	Process innovation, stage-gate process, Innovation Excellence team to direct the ideas	Sustainability unit member
4.3	Large	Producer, downstream	Specialty chemicals in consumer goods	Ingredient discovery, Iterative, dedicated Innovation Team	Business development, Regulatory affairs, Sustainability unit
4.4	Large	Producer, upstream	Advanced Materials for high-tech applications	Material innovation, stage-gate, evaluation of idea by stakeholders	Business development, Regulatory affairs, Sustainability unit
4.5	Large	Producer, midstream	Bioindustrial chemicals	Formal stage-gate process, handled by business development and sales team	Business development, regulatory affairs
4.6	Large	Producer, midstream	Specialty chemicals for various sectors	Formal stage-gate, Board of Directors' Innovation and Sustainability Committee	Business Development, Regulatory affairs, Sustainability unit
4.7	Large	Producer, upstream	Specialty chemicals for various sectors	Chemical innovation, stage-gate	Business Development,

					Regulatory affairs, Sustainability unit
4.8	Large	Formulator, downstream	Performance materials (silicones)	Incremental innovation, stage-gate	Business Development, Regulatory affairs, Sustainability unit

4. Case Studies

4.1. SME working in Wood Protection Domain

Interviewers from PARC and report authors: Vrishali Subramanian and Mirjam Schuiff

Company Profile

The company develops and markets a wood protection technology applied as a coating. It was established as a start-up by the respondent and a co-founder specifically to commercialise this product and is classified as a SME. The product is new to the market but is based on existing chemicals and therefore corresponds to a formulator in REACH terminology.

The main application areas are wood protection and construction, with customers primarily operating in professional settings. The company occupies a mid-value-chain position, sourcing chemicals upstream and supplying finished products for professional use downstream.

The technology combines linseed oil with a living, naturally occurring pigmented fungus. Together, these components prevent wood decay by reducing moisture uptake and providing protection against ultraviolet radiation. The product represents a radical innovation, as it introduces a novel functionality and sustainability-driven approach in the wood protection sector and is already commercially available.

The respondent is a consultant, academic and entrepreneur with more than 25 years of experience in wood protection. Due to the multiple hats he wears he has a unique vantage point on innovation in the wood protection field.

Innovation Process

R&D in SMEs is often developed in phases driven by availability of funding. Investors typically do not put money in solutions where they cannot recover their financing within two to five years. In large(r) corporation, projects expect have to return on investments within five (to ten) years.

The respondent developed and refined the linseed oil–based technology during his PhD in Germany and later throughout his professional career in the Netherlands. He noted that formal stage-gate innovation models may exist in larger companies, whereas innovation processes in SMEs are more eclectic and less structured.

For wood protection products, functionality is assessed using standardised tests, including colour stability, moisture resistance, dimensional stability under freeze–thaw conditions, and protection against microorganisms. Fire resistance is becoming an increasingly important requirement for wood products. For the linseed oil–based solution developed by the company, performance data are largely collected through in situ applications. These long-term pilot applications, conducted over several years, also serve as a form of third-party validation of the technology.

The respondent highlighted significant differences in innovation dynamics across countries. These differences relate to:

a) the availability of wood resources and wood-related expertise, as well as participation in associated knowledge networks (e.g. Germany, Poland, France);
b) innovation culture, particularly differences between Germany and the Netherlands; and
c) the institutional landscape. (few institutions with mostly limited knowledge, knowledge is valorised via spin-offs in NL vs many institutions with high level of knowledge which is valorised via 'spinins' in Germany).

In the Netherlands, innovation often originates from individuals high school education who approach experts to further develop solutions. While the Dutch innovation culture is perceived as open, it lacks strong engagement in wood-related networks and does not offer clear incentives for inventors to benefit from intellectual property or royalties. In contrast, Germany is described as more cautious in adopting new innovations, but its system is more systematic and structured, with clearer pathways for rewarding and commercialising innovations once they gain initial acceptance.

A key risk highlighted by the respondent is the long time to market for radical innovations. Even when development starts from state-of-the-art knowledge and technologies, changes in regulatory or market requirements during the development period may ultimately prevent a product from entering the market. This risk is particularly pronounced in the wood protection sector, where national market-entry certificates are often country-specific, while European certifications (CE) are more expensive and complex to obtain but allow EU-wide market access. Additionally, even products that reach the market may struggle with acceptance, as professional users often have long-standing commitments to established products and brands.

Current Safety and Sustainability Evaluations

The respondent does not express major concerns regarding chemical hazards associated with the product, noting that linseed oil is included in Annex I of Regulation (EU) No 528/2012 on the making available on the market and use of biocidal products, which means that it must comply with specific conditions to be eligible for a simplified authorisation procedure. Considerations related to chemical hazard are already incorporated at the business planning stage. Substances identified as hazardous in REACH dossiers or other databases are flagged, partly in response to heightened consumer awareness. National and European certifications are obtained where relevant, particularly for properties such as fire safety.

Sustainability is the starting point of the company’s innovation strategy. Life Cycle Assessments (LCAs) for Environmental Product Declaration in Norway and Belgium have been conducted, which are provided to customers upon request. Customers currently rarely request this information. One challenge identified is that LCAs for the product show relatively high impacts for land use in the production phase (as is the case for many bio based solutions) as well as maintenance-related impacts during the use phase.

Current research efforts focus on responding to market demand for improved fire resistance, while sustainability and circularity considerations remain integral to product development. Social impacts are not assessed in a formalised manner, but the company places importance on employee satisfaction and professional development. Trade-offs between different sustainability dimensions are not explicitly managed. Instead, the company prioritises strengthening its core value proposition of low risk and reduced environmental impact from the outset.

Response to Recent Developments in European Policies

The respondent was previously not aware of the SSbD framework. After being briefed on it, he mentioned that these recent chemical developments were not very relevant to him since the product used no conventional chemical in the formulation.

Reporting on his discussions with the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), the respondent pointed to structural challenges in existing regulatory frameworks, which, despite their intentions, may hinder sustainable innovation. In the biocides sector, product development timelines of up to 20 years and high associated costs were identified as major barriers.

Enabling Environment

A stable and predictable regulatory framework was identified as critical for innovation in wood protection. Long development and approval timelines for novel biocidal products pose significant challenges, particularly for SMEs. For the respondent’s product, additional barriers include the risk-averse nature of the construction sector and its reluctance to adopt novel solutions.

Regarding desirable toolbox features, the respondent emphasised the need for an SSbD toolbox with a flexible and open workflow that can accommodate different types of users and innovation contexts. He stressed that toolbox development, as well as associated outreach and educational activities, should account for differences in innovation cultures across countries and sectors.

4.2. Design of Biobased Processes to Derive Chemicals

Interviewers from PARC and report authors: Vrishali Subramanian and Jaco Westra

Company Profile

The company is a large multinational producer of chemicals derived from biobased feedstocks using fermentation-based processes. Its products are supplied primarily to industrial clients, who use them as differentiated inputs in food, health and related applications. The company operates high upstream in the value chain and supplies multiple downstream markets.

Innovation within the company focuses primarily on the process level, as existing chemicals are produced using novel fermentation pathways and biobased precursors. As such, the company does not develop new chemical substances, but rather introduces new production processes for known chemicals. The respondent is an LCA practitioner within the sustainability unit of the company, responsible for process design and upscaling.

Innovation Process

Innovation at the company follows a highly iterative stage-gate model, coordinated by a dedicated team referred to as *Innovation Excellence*. Each innovation project is assigned a project manager, a business owner and a technical lead. At each stage gate, a group of internal experts (e.g. scientists, specialists, technicians, etc.) evaluates the project using a fixed template covering business case considerations, technical feasibility, regulatory and intellectual property aspects, and sustainability.

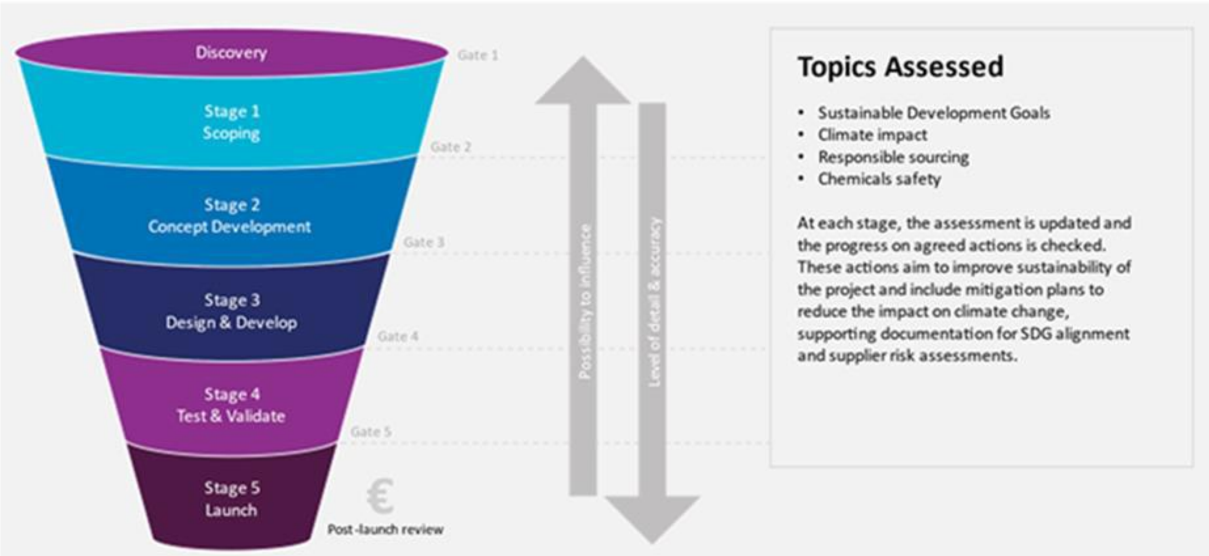

Figure 1: Innovation Framework within Biobased process company

Project initiation requires submission of a BOSCARD (Background, Objectives, Scope, Constraints, Assumptions, Resources and Deliverables) to a council of internal experts and decision-makers. Progression through gates is decided during gate-pass meetings, which may also define follow-up actions. Individual expert assessments do not automatically constitute a "no-go", but rather, concerns may be flagged as hotspots that require attention in subsequent stages (i.e. it is marked as problematic as it goes to the next gate).

The intended end applications of the chemicals and intermediates are typically defined early in the innovation process. Process development is therefore carried out with downstream requirements and market expectations in mind. The duration of innovation projects varies considerably, and market entry depends on factors such as capital expenditure requirements, technological readiness, market conditions and R&D timelines. Final decisions on progression and market entry are strategic in nature and are taken either by the president of the relevant business unit or by the Chief Sustainability and Science Officer (CSSO).

The respondent characterized the company's innovation process as as less structural than formal portfolio-steering approaches

Current Safety and Sustainability Evaluations

Safety and sustainability considerations are integrated throughout the innovation process, although the level of detail and timing vary across assessment dimensions.

Hazard and Risk

At Gate 2 of the stage-gate process, chemicals and raw materials are screened against the SIN list, with substances flagged if they are associated with hazardous properties. In such cases, substitution is explored. Any subsequent changes in raw materials trigger a renewed screening against the SIN List.

Risk is primarily framed in terms of regulatory compliance, with a strong focus on occupational safety and the reduction of total recordable injury rates through behaviour-oriented mitigation measures. Risk assessments are performed by subject matter experts and relevant stakeholders. Where risks are identified as high, mitigation plans are required. The scope of risk assessment encompasses a broad range of dimensions, including scientific/technical feasibility, supply chain robustness, regulatory status, environmental safety and sustainability risks, market acceptance, and business viability amongst many more.

Sustainability

Sustainability is a mission-driven element of the company's strategy, described through the overarching objective to "preserve what matters". This strategy is aligned with three Sustainable Development Goals: zero hunger (SDG 2), good health and well-being (SDG 3), and responsible consumption and production (SDG 12). Specific sustainability targets are defined under each goal and are pursued through innovation activities.

Sustainability is closely integrated with design of processes, with the aim of improving environmental footprint of existing chemicals through biobased precursors and fermentation processes.

Sustainability assessment begins at the early stages of innovation using process models (e.g. Aspen, gPROMS) combined with Excel-based impact calculations. Climate-related impacts receive particular attention at early stages, and techno-economic assessments are conducted in parallel. At intermediate technology readiness levels (TRLs), LCAs are performed, while process models are refined with stoichiometric and thermodynamic detail. If sustainability or economic performance is found to be insufficient, projects may return to the ideation phase or refocus on identified hotspots.

At higher TRLs, process models are sufficiently detailed to reflect actual plant conditions, enabling more comprehensive LCAs. Impact categories are aligned with the PEF methodology, with weighted results used to calculate and explain contribution of 80% of environmental impacts. LCAs are typically conducted on a cradle-to-gate basis, although cradle-to-grave assessments are performed upon request, highlighting the importance of value-chain collaboration

Beyond process-related sustainability, the company addresses supply chain risks through a responsible sourcing code. Suppliers are required to comply with codes covering human rights and agricultural practices, and high-risk materials are subject to certification schemes (e.g., RSPO certified palm oil and Bonsucro certified sugar). Where formal certification is unavailable, supplier self-assessments and periodic audits are applied. The company also participates in the Carbon Disclosure Project and has approved science-based targets aligned with a 1.5°C pathway.

Sustainability performance is evaluated relative to defined benchmarks, such as existing company products or commercial commodities, and in terms of contribution to achieve corporate sustainability targets.

Social and Economic Aspects

Formal social impact assessments are not currently integrated into the stage-gate process, although the company has expressed interest in further developing this dimension. A qualitative social value assessment is applied to existing products as a pragmatic alternative to full social life cycle assessment.

Economic aspects relate to the business case and the desired return on investment and are closely tied to the stage-gate evaluations. The company has its own models of revenue, cost and techno-economic evaluation. In times when sustainable investments are becoming talked about, the contradictory role of shareholders in pursuing the economic bottom line on one hand and sustainability on the other is highlighted.

Trade-offs

Trade-offs between different dimensions of performance are addressed through transparency and discussion rather than aggregation into a single score. Decision-makers emphasise the importance of maintaining disaggregated information to support informed judgement. Final decisions are reached through deliberation among decision-makers.

Response to Recent Developments in European Policies

The respondent is aware of the SSbD framework but expressed uncertainty regarding its future implications, including whether companies may eventually be required to demonstrate SSbD compliance. As the company focuses on improving fermentation-based processes for known chemicals rather than developing new substances, the applicability of the SSbD framework is not immediately clear. While the company has integrated sustainability considerations into its innovation processes for many years, it remains uncertain how SSbD would add value beyond existing practices.

Concerns were raised regarding the framework's ability to actively steer innovation. To make such a claim the framework must enable generation and elimination of ideas/alternatives. The hazard cut off, while its intention to decisively prevent unintended consequences is understood, poses questions of what a hazardous chemical is. It is also surprising that the hazard endpoints are more comprehensive than REACH. Furthermore, it is not easy to assess empirically if a chemical can be classified as hazardous.

Enabling Environment

Clear regulatory intent and stability were identified as key enablers for SSbD uptake in the sector. Raising awareness and targeted training on SSbD concepts and tools were highlighted as important educational needs. The respondent emphasised that SSbD should rely on measurable and operational concepts, rather than high-level principles that are difficult to quantify (e.g., shelf-life extension).

Learning is currently achieved through engagement with reports, workshops and webinars, as well as through hands-on participation in stage-gate processes. Practical tools, such as templates supported by concise guidance and short training sessions, are considered particularly helpful.

From the company's perspective, an SSbD toolbox should:

- Provide decision support through dashboards, rather than relying solely on aggregated single scores;
- Balance ease of use with analytical depth, allowing expert users to access detailed information where needed;
- Focus on mechanistic approaches at the moment, while acknowledging that Al may become important and change the way companies think about tools in some years;
- Be supported by improved databases for environmental and social assessments.

4.3. Safety and Sustainability Assessment unit in a Global Consumer Products Company

Interviewers from PARC and report authors: Vrishali Subramanian, Jaco Westra, Spyros Karakitosis, Penny Nymark and Lya Hernandez

Company Profile

The company is a large multinational consumer goods producer operating globally. It supplies ingredients and intermediate products to a wide range of downstream sectors, including food and health care, where final consumer goods may be branded or industrial. The company therefore operates primarily in the middle of the value chain, supplying downstream producers who finalise consumer products.

Innovation within the company spans multiple levels, including ingredient discovery, product formulation and process optimisation, with a strong focus on identifying and developing new chemical ingredients. The interview respondents are members of a central unit that provides guidance, digital systems and tools to support safety and sustainability assessments across the company. In addition, this unit develops and communicates methodological approaches in collaboration with external stakeholders, including academic researchers and practitioners.

Innovation Process

A defining feature of the company's innovation approach is the integration of business and sustainability strategy, which provides a shared direction for innovation activities. Innovation is primarily driven by customer needs, with proof of benefit assessed through a structured stage-gate process comprising four stages:

1. Ingredient Discovery,
2. Ingredient Evaluation,
3. Development and Testing, and
4. Production and Launch.

Across these stages, innovation decisions are guided by three core parameters: functionality, cost, and safety and sustainability. In the early stages, the innovation team receives a preliminary safety and sustainability prognosis based on available information. This is followed by the application of screening approaches to generate additional data. The complexity of data generation varies substantially, from relatively straightforward assessments for incremental innovations to highly complex data packages for novel chemistries.

As the business case develops and understanding of functionality improves, more detailed cost analyses and safety and sustainability assessments are conducted. Experts apply a weight-of-evidence approach, combining literature review with computational and experimental tools to identify hotspots requiring further evaluation or to justify progression to the next stage. The overall duration of the innovation process can vary considerably and may extend to five years for novel chemistries.

Stage-gate meetings play a critical role in discussing trade-offs and informing decisions. One example highlighted was a case in which LCA results indicated that a biobased material did not initially outperform a petrochemical alternative produced through a highly optimised supply chain. Nevertheless, the innovation was pursued because it aligned with the company's strategic direction and because impacts were expected to improve as the technology matured and scaled. Stage-gate discussions involve both technical and business personnel, with final investment decisions taken by an investment board (comprising of members in the business group).

Due to the unique vantage point of the company unit as a safety and sustainability research entity, they often collaborate closely with suppliers to generate life-cycle or ingredient-specific data. This is facilitated through data-sharing agreements that protect suppliers' proprietary and competitive information from the business units of the parent company.

All data are stored in internal knowledge systems and labelled with appropriate identifiers (e.g. data, source, confidentiality). Data formats range from spreadsheets to more advanced digital systems. The company aims to apply FAIR data principles at a level comparable to current academic practice.

Current Safety and Sustainability Evaluations

Hazard and Risk

The company has a longstanding commitment of more than 20 years on ending animal testing, driven by consumer wishes as well as scientific considerations. This commitment has led to the development and adoption of non-animal safety assessment approaches and the generation of human-relevant data. Building on the US EPA's Next Generation Risk Assessment vision, the company has developed NAMs-based frameworks covering endpoints such as skin sensitisation, inhalation toxicity, developmental and reproductive toxicity, and systemic effects. These approaches are often developed in collaboration with research partners in academia, government and the industry and are shared publicly through scientific publications and presentations. NAMs-based data are also included in regulatory dossiers, and the company engages in discussions with regulators to drive greater acceptance of non-animal safety approaches.

The company's NAMs approach is exposure-driven and tiered, relying on protective bioactivity exposure ratios rather than traditional risk characterisation ratios. Safety assessment begins with definition of use scenarios and expected exposure, followed by selection of candidate molecular structures. Initial screening combines literature review and *in silico* tools (e.g. QSARs and read-across) to evaluate potential consumer, occupational and environmental risks, with biodegradability often considered a key criterion.

This screening step guides hypothesis formulation about potential critical effects and relevant exposure concentrations. Subsequent evaluation includes occupational safety screening of manufacturing routes and environmental safety assessment based on projected market volumes. Then, risk assessment questions and safety hypothesis are tested by using bioactivity data through a broad suite of *in vitro* models (e.g., cell stress panels, *in vitro* pharmacological profiling, transcriptomics) and other non-animal safety assessment methods. Finally, these data are integrated through a weight-of-evidence approach, with bioactivity–exposure profiles derived from the most conservative points of departure.

The company listed some tools that can be used depending on assessment needs, including DEREK, OECD Toolbox, EPIWIN, CATABOL, PBK Models, CONSEXPO, Creme Exposure Model, PACEM Exposure Model, and Advanced REACh Tool.

Occupational safety assessments are refined using actual manufacturing processes and measures taken to reduce worker exposure (e.g. PPE), while environmental safety assessments are performed based on realistic release scenarios. Throughout the process, safety performance is balanced against functionality requirements. New ingredients must demonstrate safety while delivering functional performance comparable to or better than existing alternatives.

Sustainability

Sustainability assessments start with life cycle thinking and early warning heuristics based on in-house expertise at early stages (e.g., comparing biobased feedstock and petrochemical based one) and evolves into more detailed environmental sustainability assessments when more data becomes available at later stages. When sufficient quantitative process data are available, process flow diagrams are developed and used to support screening LCAs comparing innovative and existing alternatives.

Screening LCAs are used to determine the materials and processes that drive the impacts and to inform product reformulation in a way that decreases the impacts. Conducting full PEF studies for every product is not considered feasible. However, it is possible for experts to apply read-across from available studies and related corporate reporting data. For environmental sustainability assessment, commonly used tools are Simapro, Gabi, and Brightway.

The company unit applies a lot of thought over what proxy data and life cycle inventory (LCI) datasets are suitable to use in their LCAs, recognising the context-specific nature of certain impacts (e.g. water use). Close collaboration with suppliers supports sustainability analyses. The company unit has also been involved in methodological and data improvements in LCA, including spatial and regionally explicit models (e.g. contributing to improve the InVEST model with sediment and nutrient export to assess erosion, or incorporating the impact of tropical forest edges on carbon stocks into assessments).

Ecotoxicity and human toxicity impacts are generally excluded from LCAs, as these are addressed through risk assessment and because available LCA methodologies and data for these impact categories are considered insufficiently mature. The planetary boundaries concept was considered immature to be applied currently, especially in products assessments, due to challenges related to the differences between planetary boundaries and LCA impact categories, dynamic nature of economic impacts, and inconsistent definitions of safe operating space. Nevertheless, the company unit is engaged in collaborations to further explore this concept.

Social and Economic Aspects

The company does not perform formal product-level socioeconomic assessments. Instead, social impacts are managed through company-wide commitments and targets and are assessed at the functional or operational level. Social risk management is guided by internationally recognised standards and norms.

Human rights commitments are based on the International Bill of Human Rights (consisting of the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights), the International Labour Organization's Declaration on Fundamental Principles and Rights at Work, and the OECD Guidelines for Multinational Enterprises. For material sourcing, the company relies on certification schemes such as RSPO, Rainforest Alliance, FSC, PEFC and Fairtrade. For commodities and crops not covered by such schemes, a company-specific sustainable agriculture code is applied, that covers environmental and socio-economic aspects and is independently verified. The company will report its 2024 sustainability performance in line with the European Sustainability Reporting Standards.

Trade-offs

The respondents emphasised that trade-offs are not made on safety, when safety is defined in terms of exposure and hazard assessment. Safety must always be assured before market entry. Similarly, functionality must meet or exceed existing alternatives, as consumer acceptance is not expected for products with reduced performance, even if sustainability benefits are offered. Trade-offs therefore primarily occur between different sustainability dimensions or between sustainability improvements and economic considerations.

Response to Recent Developments in European Policies

The respondents were aware of the SSbD framework and characterised it as conceptual, noting that practical tool support would be required for effective implementation. Concerns were raised that the hazard cut-off may not be compatible with a wide range of applications, particularly those relying on exposure-driven NAM approaches.

Enabling Environment

Experts maintain and develop their expertise through a combination of professional training courses, participation in conferences, continuous engagement with the scientific literature, and 'on the job' training new skills or developing new knowledge (including collaboration with external research partners). Hence, key enabling factors identified include training and capacity building for tool use, effective communication and collaboration across the value chain, and the ability to manage large volumes of supplier data. The lack of regulatory acceptance of NAM-based approaches was identified as a barrier, limiting companies' ability to generate and interpret such data. Many companies were also perceived to lack the capacity to conduct LCAs or to generate robust value-chain data, leading to methodological inconsistencies and data quality concerns. Improved availability of physicochemical data was highlighted as an additional need.

From the company's perspective, an SSbD toolbox should:

- include a wide range of tools applicable to different innovation contexts;
- provide clear information on the domain of applicability of tools for different chemical classes;
- cater to different user profiles, offering advanced users the ability to interrogate results and customise analyses, while providing guided workflows, screening approaches, and simplified interfaces for less experienced users.

4.4. Advanced Materials based Applications

Interviewers from PARC and report authors: Vrishali Subramanian, Lya Hernandez, Evert Bouman, and Spyros Karakitsios

Company Profile

The company is a large global producer specialising in advanced materials used in applications across electronics, renewable energy, construction and the automotive sector. Its products are supplied as intermediate materials that are further processed by downstream manufacturers into final products. The company therefore operates primarily upstream of the value chain**.** Innovation within the company focuses on developing materials with specific performance characteristics required by customers, such as tailored shape, size and composition.

The respondents roles include members from business development, regulatory affairs, and sustainability unit.

Innovation Process

Innovation within several product divisions follows a stage-gate model, beginning with Stage 0 (Ideation), in which potential product ideas are generated and initially screened for business relevance. Innovation is strongly customer-driven, with new product concepts developed in response to specific downstream requirements. This approach aligns with the company’s strategic commitment to circularity and waste elimination.

Promising ideas move to Stage 1 (Concept Development), where a preliminary business case is established incorporating initial market research and financial estimates. At Gate 1, these ideas are evaluated by stakeholders, including vice presidents in divisional management responsible for innovation, sales and marketing development teams, and other business managers. Successful concepts proceed to Stage 2 (Business Case Development), where the business case is refined through detailed market analysis, technical development and financial forecasting. Gate 2 serves as a critical decision point to assess feasibility and viability before entering Stage 3 (Launch), in which preparations for market introduction are finalised. The final stage, Stage 4 (Value Capture), focuses on monitoring the value generated by the innovation.

The company implements continuous R&D to improve the efficacy and safety, as well as to investigate the applicability of new technologies and of their processes. Innovation drivers include both customer demand and EU regulatory pressure. As an upstream industry, the company adopts a relatively conservative approach to innovation, as system failures are not acceptable. Consequently, review and testing processes can be extensive. External factors such as ESG ratings also play an important role in phasing out critical substances and stimulating research and innovation.

A recurring challenge identified within the company is ensuring consistent adherence to the innovation process across teams, reflecting the need to balance creative flexibility and maintaining some level of process discipline. This balance is particularly important in an environment that is less process-driven than sectors such as oil and gas, where procedural compliance is more stringent.

Current Safety and Sustainability Evaluations

Hazard and Risk

The company works with a limited number of metals and chemicals, all of which have been assessed under REACH and are considered safe for their intended uses. As the sector increasingly moves towards the use of nanomaterials, the company is preparing to meet additional information requirements for nanoforms. This is supported through collaboration with external consulting firms and industry associations to ensure continued compliance with safety standards and regulatory expectations.

Regarding risks, the company distinguishes clearly between the safety of marketed products and occupational or workplace exposures. Proactive measures are taken to manage occupational risks, particularly those related to dust exposure, which is categorised broadly as inorganic dust. As the company operates at an early stage of the value chain, comprehensive assessment of downstream use scenarios is often not feasible, and risks associated with final applications may fall outside the company's direct control.

Sustainability

The company benefits from operating in a country with a high share of clean energy and increasingly relies on hydropower and bioenergy. Sustainability is closely integrated into the innovation process through commitments to circularity and waste elimination This approach is exemplified by efforts to reuse by-products and minimize waste and promote zero-waste principles within the business system.

Product development often involves experimenting with different elements to enhance material properties, with successful innovations scaled up and less beneficial options discontinued. Sustainability considerations are systematically reviewed during R&D, including the use of sustainable raw materials, processing methods and customer benefits such as reduced carbon footprint and extended product lifetimes.

Life cycle and energy efficiency assessments are conducted by in-house experts, particularly in response to customer requests for carbon footprint information. These assessments also support the identification of opportunities to further reduce electricity consumption and improve overall efficiency, underscoring the company's broader commitment to sustainability and efficiency. At each gate decision, a checklist addressing safety and sustainability is applied.

Health, Safety, Environment and Regulatory (HSE&R) assessments are an integral part of product development. Project managers schedule reviews with a corporate support function specialising in product stewardship, environmental performance and occupational health to ensure early identification of regulatory or safety constraints. This step is crucial, especially when R&D may propose using prohibited materials due to regulatory and safety concerns. By consulting with experts in regulatory compliance, occupational hygiene and environmental impact, potential roadblocks can be identified. Experts evaluate product use and applications and advise on necessary modifications.

The company also repurposes its waste products for uses in other industries, such as aluminum and concrete production. In return, waste from partner industries are recycled back into the company's production processes in closed-loop arrangements. Heat recovery systems further contribute to resource efficiency.

Social and Economic Aspects

The company has a team that deals with Corporate Sustainability Reporting Directive (CSRD) compliance, ESG reporting and life cycle assessment, including Environmental Product Declarations (EPDs). The expert in LCA conduct assessments when products are already on the market and when requested by customers using cradle-to-gate, gate-to-gate, or cradle-to-grave system boundaries.

Although metrics like minimum profitability or return on investment thresholds are not explicitly defined, the decision to progress a product to the next stage involves evaluating its potential to meet future revenue goals and its development costs. Economic viability and customer demand play crucial roles in determining whether a product moves forward in the development process. Overall, the approach to innovation and product development is characterized by a degree of pragmatism and flexibility, rather than strictly adhering to procedural mandates.

Response to Recent Developments in European Policies

The company adheres to Best Available Techniques (BAT) and complies with chemical restriction proposals, reflecting alignment with the objectives of the EU Green Deal, including sustainability, circular economy principles and safe chemical management. A significant challenge identified is the presence of substances on the critical raw materials list for which safe and sustainable alternatives are currently lacking. Substitution efforts are nevertheless pursued where possible, contributing to emission reductions and improved workplace safety. The development of polycyclic aromatic hydrocarbon (PAH)-free products was cited as an example of progress towards safer alternatives.

Enabling Environment

The SSbD framework was viewed as a useful conceptual tool, although additional guidance (potentially through practical case studies) was considered necessary to support implementation. Prior to the interview, the framework had not been actively considered within the company. Future implementation would likely require engagement with corporate management and support from external service providers, particularly in the early stages.

As an upstream producer developing basic materials for downstream use, the company noted that the "design" aspect of SSbD is more difficult to address than for companies operating further down the value chain. Design choices are largely limited to physical characteristics such as size and shape rather than chemical composition, which constrains the scope for SSbD-related redesign.

Training and capacity building on safety topics are addressed through regular internal and external audits. Sustainability-related training is approached at both corporate and divisional levels and is increasingly embedded at plant level through the company's business system, where continuous improvement and waste elimination are important topics.

While no dedicated, formal sustainability training programme is currently in place, the company considers this an area of ongoing development. In practice, sustainability learning is driven by customer interactions and requests. To support this, the company organises biweekly internal meetings for share and learn.

From the company's perspective, the following toolbox characteristics are considered relevant:

- A checklist-based workflow would be useful, given that the company does not work with or produce complex molecules. QSAR-based approaches are therefore of limited relevance in this context.
- Include tools that deal with environment, energy, water, LCA, etc. EuroMetaux has developed an environmental release model (MEED), which could be a useful tool in the metal industry to check existing values.
- Implement a workflow with a decision-tree-type structure, aimed at providing guidance on key considerations and expected outcomes rather than detailed modelling.
- Offer the possibility for users to skip criteria or questions that are not relevant to their specific context
- Add case studies or business cases for more niche companies that do not follow standard innovation pathways
- Have a generic and flexible toolbox design, as the chemicals and metals industries operate in different ways, and some challenges introduced under REACH affect these sectors differently

4.5. Chemical Development in Bioindustrial Sector

Interviewers from PARC and report authors: Vrishali Subramanian, Jaco Westra, Maja Haling, and Spyros Karakitsios

Company Profile

The company is a large global corporation operating across agricultural, food and industrial markets. It occupies a central position in global supply chains, with core activities including food production, commodity trading and the management of agricultural supply chains. Within its bioindustrial activities, the company produces chemicals and ingredients that are used across a wide range of applications, including furniture, textiles, construction materials, electronics, adhesives, coatings and lubricants.

In this context, a "product" typically refers to an individual chemical component, which can either be reactive or neutral, rather than a formulated end-product. These components may act as additives at low concentrations (approximately 0.1–1%) or as functional building blocks that constitute a substantial fraction of the final product (up to 20% or more). While there are instances where the company deals with formulated products, most of its innovation involve individual chemical components supplied early in the value chain. Respondent roles include business development, sustainability and regulatory affairs.

Innovation Process

The company seeks to maintain a balanced innovation portfolio, combining short-term, lower-risk projects with longer-term, higher-risk initiatives. Innovation decisions emphasise the selection of materials and processes that offer the most favourable safety and sustainability profiles, provided that performance requirements and pricing constraints are met. Meeting customer and industry needs while delivering equal or enhanced product performance is a central requirement.

Innovation typically begins with the identification of a qualified business opportunity that aligns with existing capabilities. These opportunities are driven by market trends, customer-specific demands, strategic priorities, or anticipated regulatory changes. Business development and sales teams play a key role in identifying sector needs and translating them into innovation projects.

Projects usually focus initially on a specific application field, such as electronic adhesives, which may encompass a broad range of potential products. While development begins with a targeted use, the company actively explores the potential for additional applications in other sectors. For instance, a product developed for electronic adhesives might later find application in the automotive sector. This approach allows the company’s existing toolkit to expedite market entries based on existing regulatory approvals. The decision to explore multiple applications is often driven by the product's success and the identification of new business opportunities.

Ideas are generated from multiple sources, including internal submission systems in some business areas (e.g., energy technology sector). Submitted ideas are evaluated by industry managers familiar with market demands and strategic priorities, with a focus on areas like automotive or industrial applications. Early testing of chemical characteristics begins at the outset and continues throughout development, combining laboratory testing and modelling. Promising ideas are prioritised and developed into business cases.

Innovation is managed through a stage-gated review process (Figure 2) that supports systematic evaluation from initial exploration through potential scale-up, allowing for the thorough examination of solutions and involving synthesis and plant teams, regulatory considerations, and a collaborative effort across various departments. The exploration phase, typically lasting up to six months, is critical for defining the solution and aligning strategy, business case and technological proposals. Progression beyond this phase reflects a commitment to development and possible scale-up, subject to predefined criteria. Decision-making on project continuation is managed at a higher level by balancing resource utilisation maximisation and strategic objectives

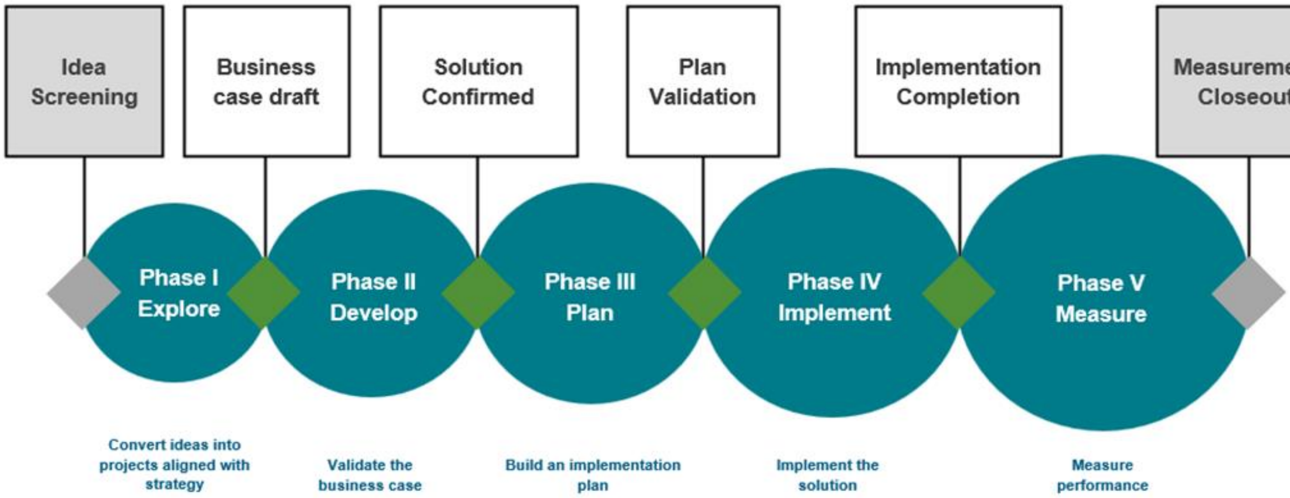

Figure 2: Depiction of the stage-gate process

Product design and manufacturing considerations are addressed in parallel. While manufacturing optimisation focuses on efficiency and sustainability, it typically does not fundamentally alter the initial product design. Throughout the innovation process, sustainability, safety and performance are reviewed holistically, from raw material sourcing through application and end-of-life considerations.

Current Safety and Sustainability Evaluations

Throughout the innovation process, all aspects from raw material sourcing to product application are reviewed, ensuring a comprehensive assessment of sustainability, safety, and performance. This holistic view underscores efforts to integrate sustainability and efficiency across the entire value chain, from initial design through to manufacturing and final use.

Hazard and Risk

The company’s innovation and product development approach considers the entire life cycle, from sourcing to end-of-life, with a strong focus on sustainability, safety, and regulatory compliance. The assessment of raw materials and final products involves basic human and environmental toxicology evaluations to support the preparation of safety data sheets and ensure compliance with global regulations.

The early engagement of regulatory teams at the beginning of the R&D cycle is crucial for identifying potential safety or compliance concerns related to raw materials. Where possible, the company's innovation teams are particularly mindful of the environmental and safety impacts of new chemicals, often preferring to utilise existing, polymer-exempt products to simplify development and regulatory pathways. Customer requirements and market expectations, particularly in sectors with stringent specifications, play a decisive role in shaping innovation choices. Original equipment manufacturers (OEMs) often define prohibited substances and technical constraints.

The company actively reassesses products if new hazard classifications emerge through regulatory developments or additional testing. Substances classified as carcinogenic, mutagenic or reprotoxic (CMR) are of particular concern, and efforts are made to avoid their use in favour of safer alternatives that protect manufacturing sites and employee well-being.

The company's Supplier and External Manufacturing (SAM) team is dedicated to engaging with suppliers of chemicals and materials and operates across four global regions. Suppliers are required to provide information on registration, toxicology, and risk assessment details through questionnaires. However, challenges may exist due to a team's primary expertise in certain areas, which may not always align with the specific needs for chemical-related information. However, there is a need for more focused questionnaires to efficiently gather chemical-specific information, especially for products with applications differing from their traditional use.

The risk assessment process includes a comprehensive review of legal and regulatory requirements, as well as company-specific standards. This includes evaluation of quality systems, sustainability certifications and safety data sheets, with particular attention to ensuring that safety data sheet (SDS) information is current and complete. Furthermore, the decisions regarding the acceptability of certain hazards, like irritants or substances with specific functionalities (e.g., epoxy or acrylic), depend on the intended end use and the customer's ability to manage associated risks safely.

Sustainability

While performance and cost are the primary drivers of product development, sustainability is increasingly embedded across the innovation process. considerations span raw material sourcing, manufacturing, distribution, application and end-of-life. Key focus areas include decarbonisation, renewability, environmental performance, biodegradability and enabling circular economy solutions.

The company uses Together for Sustainability as a baseline for PCF assessment and increasingly applies LCA and comparative studies to better understand product sustainability. Numerous PCF, LCA and Environmental Product Declaration (EPD) studies have been conducted in-house and with external consultants, particularly for construction applications where EPDs are common. However, challenges around comprehensive LCAs remain due to the diversity of products and their applications. They emphasize the importance of customer collaboration to extend LCAs to final products. This strategic focus on LCA studies not only aids in optimizing the use of bio-based raw materials but also addresses customers need to understand broader environmental metrics to aid data backed decision-making.

Additionally, considerations for the end-of-life impact, including biodegradability and recyclability, are integral to sustainability evaluations for many applications. LCA is recognised as a critical tool but insufficient on its own for comprehensive sustainability and safety evaluations, highlighting that life-cycle thinking must be combined with safety considerations. The extensive data requirements of LCA present challenges, particularly when evaluating new technologies where assumptions about products being replaced are necessary.

Due to these challenges, the company is investing in digital tools to support sustainability assessment and to expand its LCA capabilities over time. This multi-year effort aims to balance a strong focus on carbon footprint with broader environmental impact considerations. The growing prevalence of EPD requirements across sectors suggests that similar regulatory expectations for transparency and sustainability are becoming prevalent. The increasing convergence between SSbD principles and regulatory expectations such as the Ecodesign for Sustainable Products Regulation (ESPR) underscores the broader industry need for a standardised approach to sustainability, highlighting the need for dialogue with regulators to ensure cohesive policy development and implementation.

Overall, sustainability is central to the company's purpose. Efforts include science-based targets for emission reduction, protection of land and water resources, and improving the livelihoods of farmers and communities across the value chain. Current targets include a 10% reduction in operational emissions (Scope 1 and 2) by 2025 and a 30% reduction in Scope 3 emissions associated with products sold by 2030.

Social and Economic Aspects

While the company has no formal socio-economic assessment process, the company adopts a holistic approach to socio-economic sustainability. Priority areas include land use, biodiversity, water stewardship and farmer livelihoods. For high-risk commodities such as palm oil, South American soy and cocoa, the company has developed specific action plans and applies a range of risk assessment tools (e.g. Maplecroft, Global Forest Watch, World Resources Institute) in collaboration with NGOs to identify and mitigate sustainability risks.

The company supports farmers through training, financial and technological assistance aimed at improving productivity, resilience and livelihoods. In regions with elevated social risks (e.g., Southeast Asia, East and West Africa), efforts focus on empowering smallholders, improving access to clean water and addressing labour rights. Certification schemes are used where appropriate but for ensuring aspects of sustainability such as human rights and environmental protection are considered insufficient on their own. Instead, the company emphasises long-term partnerships, transparency and incremental improvement in these supply chains. Moreover, transparency and traceability in supply chains are key and supported through customerfacing portals and industry initiatives like the TRACT platform, a collaboration aiming to standardize transparency across commodity supply chains.

The company's water sustainability goal involves operational water use assessments and community-level programs in water-stressed areas, such as introducing subsurface irrigation for corn farmers in Mexico to improve water efficiency and resilience to droughts. These comprehensive strategies demonstrate commitment to socio-economic sustainability, addressing global challenges through targeted actions, partnerships, and transparency initiatives across global supply chains.

Response to Recent Developments in European Policies

Regulatory and sustainability assessments are conducted to ensure global compliance and alignment with sustainability goals which influences the selection of ingredients and processing methods. Decision-making on product development considers both the potential for exceptional performance and the suitability of raw materials for responsible manufacturing.

The company highlighted increasing regulatory and market pressures in certain industries (i.e., lubricants), such as the eco-design for sustainable products and green claims substantiation. These considerations raise questions regarding the relationship between emerging regulatory frameworks and the SSbD concept, highlighting the dynamic interplay between regulatory compliance, sustainability, and innovation in the chemical industry. Moreover, the company notes that while many data are increasingly available, challenges remain related to data gaps, the need for industry-wide collaboration, and the importance of pragmatic approaches to implementation.

Enabling Environment

The company identified challenges in implementing SSbD, including the absence of standardised guidelines and the complexity of comparing innovations across different gate review systems. Moreover, while non-animal methods are preferred for testing where possible, certain product specifications (i.e., dossiers) still require animal data. The company’s reliance on agricultural feedstocks as well as the incorporation of one product into many applications further add complexity to the SSbD process.

Training and knowledge development related SSbD-relevant topics are supported through regular internal meetings, town halls, internal webinars, and online training materials covering environment, health and safety, and new product development. Internal webinars are organised at multiple levels, including corporate, functional and business category levels, and are accessible to all employees.

From project initiation, sustainability considerations, such as prioritising bio-based feedstocks and aiming for non-hazardous benchmarks, are embedded in innovation decisions. Collaborations across the value chain is actively pursued to enable cradle-to-gate analyses and to demonstrate sustainability benefits through case studies. The development of an SSbD tool was seen as a potential enabler of stronger value-chain collaboration and more consistent sustainability practices. However, harmonisation between SSbD principles and emerging regulations such as ESPR remains an important need.

From the company’s perspective, an SSbD toolbox should:

- Provide examples of both good and poor practice to support learning;

- Provide core assessment steps that are applicable across industries, enabling comparison of outcomes;
- Incorporate upcoming regulatory requirements and clarify their links to SSbD.

4.6.Development of Specialty Chemicals

Interviewers from PARC and report authors: Joanke van Dijk, Vrishali Subramanian, Jaco Westra, and Spyros Karakitsios

Company Profile

The company is a large, global specialty chemicals producer with a diverse portfolio of products used across a wide range of applications. It operates primarily in the middle of the value chain, supplying chemical substances and intermediates that are further processed by downstream industries. The company predominantly focuses on the development of, as well as improvements to existing chemistries to meet evolving market and sustainability requirements. Respondent roles include business development, sustainability and regulatory affairs.

Innovation Process

The company's innovation activities are guided by an overarching innovation strategy developed every three years by the Board of Directors' Innovation and Sustainability Committee. This corporate strategy is translated by each business unit into its own innovation strategy, defining focus areas, funding allocation, annual innovation targets, and roadmaps.

The company has developed six technology R&D platforms across business units of Catalysis, Process Technology, Polymer Science, Surfactants, Phosphorus Chemistries and Biotechnology. These platforms focus on four strategic themes: the hydrogen economy, circular solutions, digital innovation, and the bioeconomy. A central database stores the research work (e.g., potential chemicals candidates) and a high-throughput lab can synthesize a number of compounds with slightly different structures.

Innovation opportunities are identified through agile innovation workshops, including workshops with customer as well as short- (one month) and longer-term (two to six months) workshops with cross-functional teams supported by innovation coaches. These activities aim to identify solutions with improved environmental and social governance (ESG) profiles and market fit. In the earliest stages of innovation, functionality is the main parameter.

Once innovation opportunities are identified, a four-stage stage-gate process starts consisting of stages called Scout, Scope, Execute and Commercialisation. Through iterative development, project teams translate global trends and unmet customer needs into value propositions that support profitability and growth and discover attractive business opportunities. Technical and environmental uncertainties are progressively reduced and additional funding is allocated. Tasks and responsibilities during the innovation process are defined using a RACI matrix (Table 2), which supports coordination across functions.

Table 2: RACI matrix illustrating roles and responsibilities across the different stages of the innovation process (R = Responsible: performs the activity; A = Accountable: delegates and reviews the work; C = Consulted: provides input and feedback; I = Informed: is informed once a decision or action has been taken)

Innovation Stage	Action	Project Leader	Business Unit Assessment Responsible	Business Unit Sustainability Manager	Company Sustainability Affairs Responsible
Scouting stage	Answer sustainability related questions for all projects	R, A	I		
Scope stage	Schedule, conduct, and document R&D assessment at end of Scope phase based on 39 criteria	**R**	**A, C**	I	**C, I**
Execute stage	Schedule, conduct and document full assessment before commercialisation	I	**R**	**A**	**C, I**
Post commercialisation	Create and share quarterly overview on full assessments to be done.		**R**	**R**	**A**
	Create and share quarterly overview on R&D assessments to be done.	**R**	**C**	**R**	**A**

A healthy innovation culture is fostered through training on the stage-gate process, encouragement of experimentation, and tolerance for failure in early stages. Collaboration on innovation concerning global sustainability challenges involves close engagement with customers, as well as industrial and academic partners.

Current Safety and Sustainability Evaluations

Hazard

Safety considerations are integrated early in the innovation process, once a preliminary understanding of the chemical structure required to deliver desired functionality is established. Potential hazard endpoints relevant to substances of very high concern (SVHC) classification are explicitly considered.

Initial assessments rely on consultation of a cheminformatics data management system that provides data on the target chemical structure and structurally similar substances. This open system supports companies by and contains information on more than 450,000 chemical structures, including REACH data for over 14,500 substances, and supports property prediction based on known properties of similar chemicals. The system is supported by the European Chemicals Agency (ECHA) by giving access to non-confidential registration data. Additionally, AMBIT is integrated into the company's CompTox Suite, which is an *in silico* for toxicological and ecological hazard prediction and which combines QSARs and, where possible, NAMs.

Risk and Sustainability

The company applies a bespoke safety and sustainability assessment methodology comprising 39 criteria relevant to R&D projects, covering a cradle-to-grave perspective, with additional criteria applied to commercialised products (Table 3). These criteria are documented in a dedicated guidance booklet that includes assessment questions (some optional), supporting tools, and scorecards for each stage. The resulting scorecards form the basis of the stage-gate presentations and discussions and are documented in an online system.

The assessment addresses a wide range of safety, environmental, social and economic considerations, many of which are evaluated qualitatively. While the Portfolio Sustainability Assessment framework commonly uses region-specific units of analysis (so-called Product Application Region Combination (PARC)), the company has chosen not to differentiate by region in its safety and sustainability assessments. In addition to these criteria, products are benchmarked against market averages. To actively steer sustainability transformation, products assessed as non-sustainable within this assessment, will not be pursued further in the innovation process.

Safety risk assessment aims to cover the entire life cycle as far as possible. By combining predicted exposure and toxicity information, risk estimates are generated and further evaluated. LCAs are not conducted for the whole portfolio and are not considered suitable for early innovation stages due to their data intensity and time requirements. LCAs are therefore not used as a tool to assess potential products during the innovation phase, avoiding unwanted development.

Social and Economic Aspects

Economic impacts are considered by the company in the R&D phase, as a product that is not economically attractive will not be developed further. Trade-offs are evaluated to balance the company's sustainability ambitions with market need, including customer willingness to pay a higher price, for example for certified or more sustainable products.

Social aspects are primarily assessed upstream through evaluation of biodiversity impacts and sustainable sourcing practices. Supplier-related programmes and certification schemes are in place. The Procurement organisation and Responsible Sourcing programme play a central role in ensuring implementation of the Supplier Code of Ethics, including requirements related to child labour. Additional initiatives include Together for Sustainability (TfS) and EcoVadis. Where gaps are identified, the company engages with suppliers to address these and improve sustainability performance. Assessments may be repeated iteratively until final result is good and according to the company's ambition. Generally speaking, if there are more risks than benefits, this is not accepted

Response to Recent Developments in European Policies

The company's internal assessment framework has been partly inspired by the SSbD framework. The respondent believes that SSbD can be used as a tool to guide innovation. However, the respondent also expressed concerns regarding the availability of the quantitative data that SSbD might require and whether such detailed assessments are necessary to achieve the overarching objective of steering portfolios towards a sustainable portfolio.

From the company's perspective, the Portfolio Sustainability Assessment approach is already closely aligned with SSbD principles and has demonstrated value for portfolio steering. Given the size of the company's product portfolio, conducting highly detailed SSbD assessments for all products would exceed the capacity of existing sustainability teams. The bespoke internal process is therefore considered to provide comparable depth of information in a more practicable manner.

Concerns were also raised regarding the ambition to develop a single SSbD framework applicable to all chemicals and industries. Based on the company's experience, this would require criteria to be formulated in a sufficiently flexible manner. More rigid and detailed framework could limit applicability across sectors and types of chemicals. There would be cases where the framework couldn't be used. In addition, the framework's strong focus on hazard cut-offs was questioned, as some products or raw materials need to have active properties due to their intended functionality, and thus have hazard associated to them.

Enabling Environment

Within the company, there are already clear policies formulated to incorporate safety and sustainability requirements in innovation. For the successful implementation of the SSbD concept, clarity on the benchmarks and assessment criteria would be required to align or adapt existing processes.

Educational needs vary depending on employee roles and expertise. As a globally operating company, a key challenge is to make everyone aware of the SSbD concepts and communicate why EU-level guidelines are relevant beyond the European context.

From the company's perspective, an SSbD toolbox should:

- provide benchmarks to identify critical aspects of chemicals and raw materials and guide identification and interpretation of information;
- enable transparency across the entire life cycle, from raw material sourcing to product use and recycling, to support decision-making;
- integrate existing tools and enable interoperability between them;
- ensure that safety-related elements of the toolbox are clearly linked to CLP requirements.

Table 3: Criteria for safety and sustainability assessment (grey highlights for additional criteria applied to commercialised products)

	RAW MATERIALS	**PRODUCTION**	**USE**	**END OF LIFE**
Climate Action	GHG footprint, raw material production (direct and indirect)	GHG emissions, production (direct and indirect, for product grouping)	GHG emissions, use phase (direct and indirect, for product grouping)	
			Emissions in the use phase (dust, NOX, SO2 in the application and/or end-of-life of the product grouping)	
Water	Water footprint of raw material production (including the effect of water conservation measures)	Water consumption in the production (product grouping)	Water consumption in the use phase (including the effect of water conservation measures)	
Sustainable Bioeconomy	Use of renewable raw materials (or chemicals based on renewables raw materials)		Supporting transition to a Bioeconomy (identifies product grouping / innovation project that are supporting a bioeconomy, only applicable for products that target to support the transition to a bioeconomy)	Biodegradability /Compostability (industrial use concept may be applied)
	Use of non-food competing renewable raw materials (if renewable raw materials are used, intends to clarify if they compete with food or animal feedstock)			
	Sustainability certification of renewable raw materials			
	Genetically Modified Organisms (GMO, support the increase in transparency and understanding on their origin)			
Circularity		Use of recycled material in the production (product grouping)	Reduction of product resources at customers (reduction of 3rd party materials at the production process of our customers enabled by the product grouping)	Support for re-use or recycling of articles (potential of the product grouping to hamper the re-use or recycling of articles at the end-of-life and assesses the recyclability of end products containing the product grouping)

		Recycling of side products from production (amount of side products, and unreacted raw material which are generally considered to be waste after product manufacture and that are transferred into the recycling / reuse process instead of being incinerated or landfilled)	Supporting customers transitioning towards a circular economy (the product grouping supports customers in using more circular resources, only applicable for products which the primary function is to enable customers to use recycled materials)	End of life evaluation (assesses the actual end-of-life situation of the product grouping. Products for which the end of life is directly connected to the end-of-life of its application (e.g., as part of coating of cars, as additive in plastic packaging, etc.) should be evaluated in criteria 36 (industrial use concept may be applied)
			Use of circular packaging	Support for re-use or recycling of articles (assesses the potential of the product grouping to hamper the re-use or recycling of articles at the end-of-life and assesses the recyclability of end products containing the product grouping)
				End of life evaluation (assesses the actual end-of-life situation of the product grouping. Products for which the end of life is directly connected to the end-of-life of its application (e.g., as part of coating of cars, as additive in plastic packaging, etc.) should be evaluated in the criteria above (industrial use concept may be applied).)
Safety	Chemical hazard of raw materials	Hazardous waste classification in the production	Levels of solvents and VOCs in the use phase (uncontrolled emissions)	
		SVHC substance profile (identifies concentrations of SVHC over 0,1% weight-for-weight)		
		Chemical hazard profile of the final product and exposure during application		

Social value Creation	Impact on biodiversity due to raw material exploration, including own mining (impacts on protected areas, areas of high biodiversity outside of protected areas or topics covered by the Nagoya Protocol.)		Third-party certification of product	Partnerships and collaboration along the value chain (collaborations both from downstream and upstream which creates explicit sustainability value to the product, only applicable if there are 3 partners or more involved.)
	Sustainable sourcing / EcoVadis (increase in transparency and gain assurance of our supply chain upstream)		Overall sustainability benefit to customers	EU Taxonomy (eligibility and alignment of the product grouping to the EU Taxonomy)
	Traceability in the supply chain			
	Raw material scarcity (identify the dependency of the product groupings on materials considered scarce or that may become so in the future)			
Performance		Material efficiency in the production (relation between the material input and the output of the production process)	Additional performance features and benefits to the customer	
			Material efficiency in the use phase	
Waste & Pollution		Waste generation in production (excluding wastewater)	Waste generation in the use phase	
			Wastewater formation in the use phase	

4.7. Global Chemical Producer

Interviewers from PARC and report authors: Joanke van Dijk, Vrishali Subramanian, Jaco Westra, and Spyros Karakitsios

Company Profile

The primary chemical company produces diverse chemicals with a wide variety of downstream applications/sectors (e.g. plastics, speciality chemicals, construction, electronics). Respondent roles include business development, sustainability and regulatory affairs.

Innovation Process

Innovation is driven by a global customer base across different industries and sectors, which define the performance requirements for new developments. Innovation activities are also shaped by existing and emerging regulations in the regions where products are marketed.

The innovation process begins with the business opportunity generation and ideation stage, aiming to identify market needs and relevant technology trends based on customer input, scientific literature and research activities. At this stage, it is assessed whether an existing chemical or compound already produced by the company can meet customer performance requirements. In parallel, producibility is evaluated within the relevant business unit. If no suitable existing solution is identified, development of a business case is initiated, which moves from the lab phase, the pilot phase and lastly to market launch. Throughout this process, the chemical solution space is progressively narrowed down based on weight-of-evidence evaluations or insufficient data.

The business case development phase must provide sufficient justification to decide whether a new chemical should be synthesised and tested in the lab, as the lab phase is usually when the projects get more expensive. Specifications for minimum performance and functionality are defined based on customer requirements, corporate standards and legal obligations. These specifications guide go/no-go decisions throughout the innovation process.

During the laboratory phase, performance, safety and sustainability criteria are further defined, investigated and prioritised. This results in the selection of candidate substances for further lab development and scale-up. Candidates are progressively screened out as testing proceeds, and a final assessment is performed to classify the chemical/product against the specifications set at the beginning of the innovation. This assessment forms the basis for the decision on whether a product will be launched.

Trade-offs, particularly between safety, sustainability and performance, are use-specific and depend on the level of understanding of downstream applications. The company has developed its own guidance for conducting safety and sustainability assessments during R&D at a corporate level. The company has different cut-off criteria for different use cases as in certain applications it is not possible to achieve performance without functionality. Hazard cut-off criteria, exist for consumer use. Whereas for professional and industrial use, risk is deemed a more relevant parameter.

Certain functions within the company are always involved during the innovation process. Longer-term and more radical innovation usually start at the corporate level, while incremental innovation is more commonly driven within business units. Multidisciplinary project teams include expertise from product stewardship, analytical R&D, and toxicology. The actual composition of the project team can vary depending on the innovation requirements.

Decision-making within the stage-gate process is collective and follows a "four-eyes principle". Expert teams conduct the assessments and develop recommendations, while corporate sustainability functions act as challengers and are responsible for confirming the outcomes. If confirmation is not achieved, further exchange and assessment are required. This governance structure helps ensure alignment with corporate sustainability targets, including portfolio-level objectives related to the share of products classified in the highest sustainability categories.

Current Safety and Sustainability Evaluations

Hazard and Risk

The company distinguishes between two hazard assessment approaches: 1) for new substances and 2) for substances already available on the market.

1) *New substances*

Hazard assessment for new substances is tailored to the intended application and initially focuses on identifying the most relevant hazard endpoints. During business case development, expert judgement, weight-of-evidence approaches and read-across from data-rich substances are applied using internal data and literature sources. At this stage, the chemical structure is known but not physically available yet.

In silico tools are used to predict hazards, particularly mutagenicity and, for consumer applications, skin sensitisation, general toxicity and persistence, as these endpoints are the most valid ones. Not all relevant endpoints can be addressed at this stage due to the lack of reliable models. Endpoints that are not able to be covered as well as endpoints for which a concern is raised via the screening will be tested in the lab phase.

During the lab phase, the acute toxicity endpoints (e.g., acute oral toxicity, skin and eye irritation, mutagenicity, and skin sensitization) are assessed, primarily using *in vitro* methods, to exclude substances with carcinogenic, mutagenic or reprotoxic (CMR) properties and, increasingly, endocrine-disrupting properties. Environmental toxicity such as biodegradability and mobility are evaluated to exclude potential PMT or vPvM concerns, in line with the company's minimum requirements for basic toxicity data. For applications involving consumer exposure or environmental release at the end-of-life, bioaccumulation and broader PBT/vPvB considerations are also included.

As innovation progresses, testing strategies increasingly align with requirements for substance registration. Whether innovation continues and what trade-offs need to be made always depends on the specific application of the chemical and the testing strategy.

2) *Already marketed substances*

For substances already available on the market but not yet produced by the company, existing data are reviewed to identify potential no-go concerns. This assessment is based on evaluation of available studies and data gap analyses. Depending on the intended application and registration strategy (e.g., tonnage band), additional endpoint data may be required. When the company thinks about producing the substance, potential by-products are also assessed before a final testing strategy is defined and implemented.

The company illustrated the application-specific nature of hazard and performance criteria with several examples. For consumer-facing applications, such as fragrances used in clothing, skin sensitisation is considered a strict no-go criterion, and ecotoxicity is prioritised due to the potential for diffuse emissions. In contrast, for professional or industrial applications involving trained workers and controlled exposure, other performance or sustainability criteria may take precedence.

The respondents emphasised that assessment priorities are driven by the intended use context, exposure scenarios and associated risks. While regulatory frameworks provide guidance once the intended application and market are known, there is no standardised guidance for hazard assessment during early innovation stages. As a result, early screening relies on assembling available information from different sources and tools, combined with expert judgement, while accepting a degree of uncertainty. As innovation progresses and additional data become available through testing, assessments are refined and adapted to the specific molecule and application. This iterative, case-specific approach was described as both a challenge and a necessity, requiring close collaboration across disciplines throughout the innovation pathway.

Regarding risk assessments, exposure levels are estimated using mathematical models, and risk estimates are derived by comparing hazard and exposure information. The company distinguishes between three main use scenarios, each associated with different exposure potentials:

1. consumer use,
2. professional use, and
3. industrial use.

For each scenario, exposure scenarios define the „conditions of use" of a substance assessed as being safe (e.g., exposures well below a threshold), including recommended operational conditions and risk management measures. These are communicated along the value chain.

Sustainability including Socioeconomic Assessment

Sustainability is considered during different stages of innovation, with environmental, economic and social aspects assessed in an integrated manner using internal frameworks and tools. Environmental sustainability can act as a driver for innovation and influence the initial design, for example by initiating projects aimed at improving existing products.

The company seeks to apply life-cycle thinking wherever possible, although limited data availability often constrains full life cycle assessment. Where supplier data are not yet available, databases are used to fill gaps as far as possible. In early innovation stages, it is challenging to gather data. Therefore, simplified assessment methods, such as carbon footprint screening, are applied. The company emphasises that assessments based on poor-quality data should be avoided, as they may lead to misleading conclusions, which is harmful for business.

Corporate-level sustainability assessments for all innovation projects are conducted in line with internal guidance documents that allow for expert judgement and are aligned with ISO standards, covering 16 environmental impact categories. The relevance of specific impact categories varies by application and sector. For example, biodegradability may be prioritised where recycling or upcycling is not feasible and environmental release cannot be fully prevented. Additional customer-defined sustainability criteria, such as substitution of fossil-based feedstocks with renewable alternatives, are also considered.

The overall objective of sustainability assessment is to demonstrate that new products outperform existing market alternatives. Social impacts are addressed through internal guidance applicable during R&D and for final products, with assessment aligned to ISO 14075.

A range of tools is used to support hazard, exposure and sustainability assessments at different stages of the innovation process. These include QSAR models to obtain an initial indication of potential toxicity, exposure estimation tools applied in the context of REACH registration (e.g. ECETOC TRA), and kinetic models used on a case-by-case basis. In addition, the company relies on internally developed tools for sustainability assessment, including social aspects, as well as dedicated tools and databases for carbon footprint calculations and environmental data, such as Scott and SPHERA.

Response to Recent Developments in European Policies

The company is actively engaged in SSbD-related discussions beyond its own operations, including participation in Horizon Europe projects, industry associations, and conferences. The company has also contributed SSbD test cases, reflecting an active role in shaping and testing emerging approaches.

With respect to SSbD, the company highlighted several considerations. Hazard-based cut-off criteria should differentiate between uses and consider the full life cycle of products to ensure that benefits arising during the use phase are adequately captured. The company stated that many chemicals do have their positive contribution in the actual use phase and then not necessarily in their production phase. SSbD assessment should be based on existing, widely accepted methodologies, tools and standards. Flexibility was considered essential, with data requirements reflecting both data availability and the maturity of the innovation. Finally, clearer definitions of SSbD objectives, requirements and approaches to trade-offs were identified as necessary to support practical implementation.

Enabling Environment

The company identified data availability as a key challenge for implementing SSbD, particularly with respect to life cycle assessment and the availability of tools capable of assessing the full range of endpoints required under the SSbD framework.

Educational needs related to SSbD vary across the different disciplines involved in innovation. Based on the structure of the SSbD framework, distinct skill sets are required for toxicology, regulatory affairs, sustainability assessment and innovation management. Specialists in toxicology, regulation and sustainability need to understand the underlying concepts of SSbD, the types of assessments involved, and how these translate into their daily work. Innovation managers play a coordinating role and require sufficient insight across these disciplines to effectively manage SSbD-related assessments within project teams.

The respondents emphasised that it is unrealistic for a single individual to conduct a comprehensive SSbD assessment in depth. Instead, multidisciplinary collaboration is essential. Given the rapid pace of technological and methodological development, regular training activities, shared platforms for discussion, and opportunities to exchange experiences with new tools were identified as particularly valuable. While many promising tools are being developed in academic and policy contexts, their applicability in an industrial setting is not always straightforward, highlighting the need for training and dialogue focused on practical implementation.

From the company’s perspective, it is important that an SSbD toolbox is accessible to researchers who do not have in-depth expertise across all safety and sustainability disciplines. The toolbox should therefore enable users to apply SSbD-relevant assessments without requiring extensive additional consultation or expert input.

Innovation is a business-critical activity and high confidentiality is needed in early stages with regard to new structures and properties. It is desirable to be able to use commercially available tools in in company servers.

4.8. Global Formulator Company

Interviewers from PARC and report authors: Vrishali Subramanian, Jaco Westra, Tomas Rydberg, and Spyros Karakitsios

Company Profile

The company is a multinational consumer goods corporation that produces advanced materials primarily for industrial applications. The interview was conducted with representatives of a subunit focusing on silicones and silicone-based products, which share several characteristics with the metals industry. The company operates relatively downstream in the value chain being a formulator, and innovation in this business area is predominantly incremental. Respondent roles include business development, sustainability and regulatory affairs.Innovation Process

Innovation follows a consumer-centric approach aimed at delivering products with high performance and value while embedding safety and sustainability considerations from the earliest stages. Target customers and their needs are the primary drivers of innovation, complemented by considerations related to product quality, brand communication, regulatory compliance, cost and commercial viability. New product development involves input from a broad range of internal specialists, including safety experts and consumer behaviour analysts, to define success criteria and ensure alignment with sustainability goals.

As a downstream user, the company recognises the importance of engaging suppliers across the value chain to support sustainable innovation. Collaboration with external partners, particularly for chemical development, requires internal managerial approval and a shared commitment that proposed solutions are technically viable and compliant with company standards. Trade-offs are often discussed, i.e., a negative impact on one area may be accepted if it results in substantial improvements in environmentally critical dimensions.

The stage-gate process spans from the initial stages of idea generation to the final launch of a product. Early stages translate consumer needs into technical requirements and assess whether existing chemicals or technologies can meet these needs. In general, new chemicals are not introduced infrequently, as solutions already existing within the company portfolio are preferred wherever possible. If gaps remain, exploratory analyses are undertaken to identify alternative solutions.

At each gate, cross-functional teams comprising safety, consumer insights, technology and business experts assess progress against predefined criteria. Safety experts define criteria related to toxicity and regulatory compliance, consumer insights teams assess acceptance and use patterns, and technologists establish technical feasibility benchmarks. Such stage-gate reviews evaluate projects against predefined success criteria and determine whether a project proceeds, is ceased, or requires additional research in the next phase. Decision-making integrates performance, safety, carbon footprint climare and other life-cycle impact considerations, as well as certifications for responsible sourcing. These dimensions are not aggregated into a single score but are considered separately to preserve transparency.

Safety and sustainability assessments are embedded throughout the innovation process to avoid late-stage failures. Collaboration with suppliers and conservative, tiered assessment approaches are used to prioritise data generation. Such assessments are tailored to specific use cases to align them with the intended final application. Additionally. Rigorous assessments ensure compliance with regulatory standards. Where substances have known hazards (e.g., enzymes), formulation strategies and risk management measures are applied to minimise risks and adhere to safety protocols while maintaining functionality.

The company places strong emphasis on continuous and iterative improvement. Past project experiences and accumulated insights are systematically used to refine risk assessment methodologies and strengthen product safety and sustainability over time. For example, historical shifts in ingredient choices, i.e., the replacement of phosphates in response to eutrophication concerns, highlight how decision-making has evolved to more systematically account for broader environmental and safety impacts. Feedback generated at each stage-gate checkpoint informs further refinement of projects that progress, with efforts focusing on optimising safety, sustainability and performance. Conversely, projects that fail to meet predefined criteria or raise significant concerns may be halted or redirected to address identified issues before advancing.

Current Safety and Sustainability Evaluations

Hazard and Risk

Throughout the stage gate process, safety considerations are vital. Hazard and risk assessments are conducted early and iteratively throughout the stage-gate process and are tailored to intended use scenarios. Exposure routes, application contexts and potential environmental releases are explicitly considered. Additionally, tiered risk assessment models are applied, starting with conservative assumptions and progressively refined as additional data become available.

The company is a downstream user and collaborates closely with suppliers on chemical development and applies NAMs to support early hazard assessment and reduce vertebrate animal testing. NAMs are developed both internally and through industry and academic collaborations and are used as part of a broader weight-of-evidence approach. Examples include transcriptomics combined with read-across on molecular docking to explore toxicity, pharmacokinetic modelling to estimate internal doses and NOAELs, quantitative weight-of-evidence approaches to evaluate fish embryo toxicity as an alternative to OECD 203, and matched molecular pair analysis (MMP) to explore structure–toxicity relationships.

Standardised exposure databases and internal tools are used for human safety assessment, complemented by data from trade associations (e.g., AISE, Cosmetics Europe) and internal datasets. For environmental safety, sector-specific environmental release scenarios (SPERCs) and consumer use conditions support harmonised exposure assessments. Tools such as ECETOC TRA are applied within tiered frameworks, where conservative models are initially implemented to allow for safety assessments without attempting a high level of accuracy.

Sustainability

With the shifting market and societal expectations, sustainability is positioned alongside cost, performance and safety within the company’s business strategy. Clear environmental goals have been defined across operations and supply chains, including carbon goals, climate action, waste reduction, water conservation, and nature protection, with specific targets for reducing Scope 3 upstream emissions.

Sustainability assessment typically begins with screening-level LCAs and progresses to more detailed ISO-compliant LCAs towards market introduction, if needed for claims. Human and ecotoxicity impacts in LCAs are not utilized but instead the focus is on regulatory environmental and human risk assessments. The company highlights its longstanding use of LCA to assess environmental performance of its products and manage trade-offs across 16 indicators, including environmental impact, safety, circularity, and societal pressures.

In LCA, it's rare for one alternative to outperform another in every aspect. Trade-offs are explicitly managed. For example, changing to cardboard packaging may reduce emissions but increase land use, which is managed through forestry certification. Similarly, bio-based alternatives may lower carbon footprints while increasing land use. Expert judgement is therefore considered essential to complement computational tools and avoid reliance on rigid thresholds to address complexities.

Acquiring data from suppliers, particularly for Scope 3 emissions, remains a key challenge. While major suppliers are proficient at tracking scope 1 and 2 emissions, their capability to accurately quantify scope 3 emissions, particularly in dispersed supply chains, is an obstacle. Whereas smaller companies often lack the resources and skills to provide primary data, which makes data collection a time-consuming process. Efforts are underway to systematically map Scope 3 emissions and identify opportunities to reduce carbon footprints. However, pre-competitive collaboration with industry peers and authorities to develop shared data platforms and methodologies can be constrained by competition law. Regulatory engagement and harmonisation of data validation approaches remain critical to ensure accuracy and consistency, given the variability arising from differing upstream methodologies. While public databases such as Ecoinvent are useful, they do not always align with company-specific methodologies.

The company's approach to data harmonisation and validation is documented by organisations such as the World Business Council for Sustainable Development. However, sustainability assessment processes remain highly dependent on their specific purpose, for example whether they are used for hotspot identification or for comparison of alternatives. Work is ongoing across industry organisations to develop more standardised procedures. The company emphasises the importance of human expert involvement in decision-making and weighting processes and therefore prefers tools that are designed for specific assessment purposes.

The company adopts a flexible SSbD approach that combines product innovation, value-chain engagement, and consumer education (e.g., promoting lower-temperature washing). Business units are given autonomy to focus on areas where they can have the greatest impact, while corporate oversight ensures alignment with overarching sustainability targets. To support such efforts, systematic data collection is enhanced via corporate systems to facilitate consistent and accurate data tracking.

Consumer-related sustainability concerns play an important role in shaping the company's business strategy. Common concerns include claims such as "free from toxic ingredients", "made from natural or vegan ingredients", "CO_2-neutral", and "no plastic waste". While some of these concerns align closely with the company's sustainability vision, others reflect differing perspectives on hazard versus risk or address areas where immediate technical solutions are not yet available. In cases where expectations cannot be fully met, the company seeks to inform and educate consumers through transparent and credible communication. Consumer behaviour change is recognised as critical but challenging and is addressed through science-based partnerships with credible organisations, and monitoring via surveys and connected-home data. However, sustainability alone is not enough to drive consumer choice. A product must also offer the same or superior performance.

For different product categories, the company applies a stable internal framework, referred to as the company footprint, which serves as a sustainability compass. This framework assesses manufacturing, formulation, use, and end-of-life stages across a defined set of indicators. In most cases, the use phase is identified as the dominant contributor to overall environmental impact, and impact profiles tend to remain relatively stable across product categories unless there is a fundamental redesign of the product.

The footprint focuses on five main areas: primary and fossil energy consumption during production and use, greenhouse gas emissions, freshwater use and total waste generation. Strategies to achieve climate and sustainability goals include formulating weight-efficient materials, decarbonising existing materials, exploring alternative feedstocks (e.g., bio-based or recycled materials), and implementing novel processes such as carbon capture. These efforts require close collaboration with suppliers and harmonisation of data and methodologies across companies. Classification and labelling of final products, in conjunction with sustainability assessments, are critical to categorize sustainability improvements, which are seen as relative. Instead of an absolute “sustainable” label, this approach aims to improve performance compared to existing solutions.

PEF are not conducted systematically for all products. Instead, LCAs (ranging from screening-level to detailed studies) are performed for major product families, as PEF category rules are not yet available for all categories. The company considers PEF requirements to be more granular and prescriptive than ISO-based LCA approaches, particularly with respect to data sources. Moreover, while there are parallels between the JRC SSbD framework and PEF, both may be overcomplicating the process of data requirements and increase overall tediousness. While highly standardised PEF approaches are expected to influence future LCA and carbon footprint practices, they are not currently considered practical for every product at the individual SKU level due to their complexity and resource intensity.

Absolute sustainability approaches, such as those based on planetary boundaries, have not yet been implemented, although exploratory work is planned. Overall, the company acknowledges the importance of investing in and exploring absolute LCA for potential future applications, although they are not considered immediately applicable. The company also exercises caution in interpreting toxicity-related impact categories in LCA, noting that methods addressing ecotoxicity and human toxicity remain insufficiently mature. Nevertheless, elevated USEtox scores trigger more detailed analyses to identify contributing factors and inform decision-making. Toxicity-related LCA outputs are therefore regarded as complementary to regulatory hazard and risk assessments, providing broader environmental context rather than duplicating safety evaluations.

Social and Economic Aspects

The company does not conduct formal social LCAs but addresses social responsibility through a range of programmes and standards covering responsible sourcing, community support, equality, inclusion, and ethical conduct. Societal expectations and consumer concerns are explicitly considered in their business strategy, recognising their importance for market acceptance.

Response to Recent Developments in European Policies

The company expressed concerns regarding the compatibility of the JRC SSbD framework with industrial innovation processes, particularly the burden it may place on researchers, its data intensity, limited prioritisation options, and potential overlap with existing regulations such as REACH. Greater clarity is needed on implementation details, weighting approaches and interpretation of supplier information by downstream users.

The company also raised concerns that hazard-based classifications under CLP, i.e., the classification of enzymes as respiratory sensitisers, could pose barriers to SSbD implementation despite long histories of safe use when risks are properly managed. In sectors such as detergents, enzymes are essential for performance and sustainability benefits, underscoring the need for a lifecycle-based rather than hazard-only perspective.

The company suggested that alternative approaches, such as bonus–malus systems, could better reflect trade-offs by penalising hazards while allowing benefits to offset risks. This nuanced system could also provide warnings and opportunities to instigate further data generation. However, there remains scepticism regarding the practicality of multi-criteria decision analysis, given potential inconsistencies across assessments.

Sector-specific initiatives, such as the A.I.S.E. Green Ribbon programme, were highlighted as examples of pragmatic approaches that reward performance-based sustainability improvements, such as effective cleaning at lower temperatures, and may offer more actionable models than highly prescriptive frameworks. this method focuses on practical and actionable measures for implementation. It places particular emphasis on performance within sustainability assessments, in contrast to some existing frameworks that prioritise chemical-to-chemical comparisons and may insufficiently account for performance and weight efficiency.

Enabling Environment

The company has a long-standing commitment to safety and sustainability, supported by scientific contributions, integrated corporate goals, centralised data systems for exposure and toxicology assessments, carbon footprinting, and LCA, and rigorous internal data validation processes. Simplified, purpose-specific tools and methodologies are made available to R&D

staff to support early decision-making. Furthermore, the company actively participates in external initiatives to harmonise methodologies and develop sector-relevant sustainability tools.

Safety and sustainability expertise within the company is supported through a combination of recruitment and continuous professional development. Personnel are typically hired with strong academic backgrounds in relevant disciplines, complemented by internal trainings and seminars to support ongoing professional growth. Employees are also encouraged to participate in external workshops, conferences and scientific congresses.

Efforts are made to democratise sustainability knowledge and tools across the organisation, enabling employees of all levels to contribute meaningfully to SSbD-related processes. User-friendly, validated tools tailored to specific assessment purposes are considered essential, particularly for non-experts.

From the company’s perspective, an SSbD toolbox should:

- provide access to knowledge and context, not only rules and standards, to include expert judgement;
- include user-friendly tools, particularly to support smaller companies with limited resources;
- address methodological challenges in modelling biogenic materials and the comparison of different types of materials with the same chemical structure through clear, purpose-specific rules;
- be developed in collaboration of authorities with industry consortia (e.g., A.I.S.E., Cosmetics Europe) to ensure sector relevance;
- adopt a balanced approach that considers the full lifecycle impact of substances and that does not halt innovation based solely on initial hazard classifications;
- explicitly incorporate performance metrics alongside safety and sustainability indicators.

5. Findings

5.1. Overall Findings and Insights

Companies need to operate in an evolving policy, legislative, business and market environment and are required to continuously align their innovation activities accordingly. Strategic change in this context can be understood as a realignment of a firm's product-market environment in response to changes in market, demand, or policy priorities (Cooper, 2008). While environmental and human health risks of chemicals and products have traditionally been addressed through regulation, increasing consumer demand for sustainability has led to the development of additional internal approaches, such as the PSA, to steer innovation towards more sustainable outcomes (WBCSD, 2017).

Alignment of Innovation and Sustainability

Across the interviews, innovation and sustainability were consistently described as being guided by overarching company-level strategies. These strategies are usually developed periodically and apply across business units, allowing new chemical, product or process developments to contribute to shared strategic goals. The "areas of protection" (i.e., safety and sustainability criteria of chemicals, products and processes applied during innovation) are therefore largely driven by the alignment between innovation and sustainability goals of the company. Where such alignment exists, innovation choices can be made that simultaneously address business objectives and sustainability goals. Two of the interviewed companies (4.3 and 4.8) explicitly highlighted the integration of sustainability and business strategy as a key enabler for clearer direction in safe and sustainable innovation.

The stage gate process is managed by a cross functional team across the company. Technical development typically occurs within business unit, but considerations of environmental, economic and social factors is cross functional and companywide (global). These typically include a global regulatory affairs unit concerned with implementation of REACH and relevant vertical regulation, global sustainability unit concerned with implementation of the Portfolio Safety Assessment, local or global units concerned with business aspects and global unit implementing the company's social commitments. Sector organisations can also occasionally play a role by choosing an integrated response to external developments that has the ability to scale sustainable transitions.

Innovation Management

Innovation processes in larger companies are typically organised through structured stage-gate systems, managed by cross-functional teams. While technical development is often embedded within specific business units, assessments of environmental, economic, and social aspects are commonly coordinated at a company-wide or global level. These functions may include regulatory affairs units responsible for REACH and sector-specific legislation, sustainability units overseeing portfolio-level sustainability assessments, business units addressing commercial viability, and units responsible for implementing corporate social commitments.

Although innovation is highly non-linear, stage-gate models provide a framework for progressively reducing uncertainty related to technical feasibility, economic performance and environmental impacts of an (incremental or radical) idea. Most large companies described innovation processes consisting of four to five gates, between ideation and market entry. In contrast, the interviewed SME did not follow a formal stage-gate model but instead follows logical developmental steps in the innovation process. The SME innovation process is less structured and more steered by opportunities, network contacts and time and resource.

Each stage gate is associated with defined criteria (or areas of protection for safety and sustainability assessment), required deliverables (e.g. expert assessments to facilitate discussions in stage-gate meetings) and deliberations during meetings. While the innovation process typically comprises several stages, safety and sustainability assessments were found to follow a three levels consisting of an exploratory phase, a development phase, and a market phase (Figure 3).

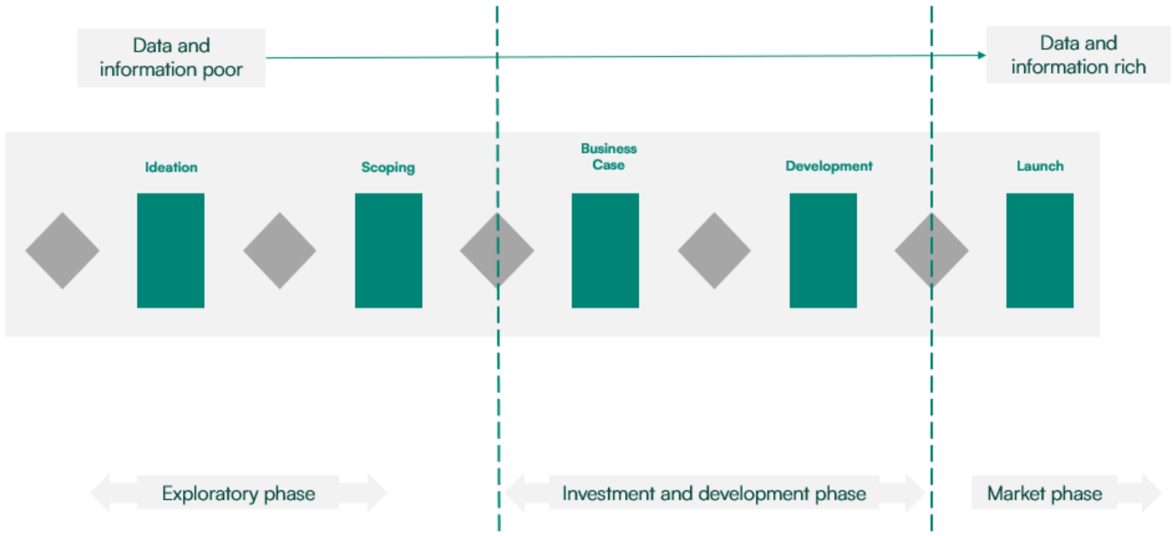

Figure 3: Overview of the three levels of safety and sustainability assessments (exploratory, development, and market phase) and how it aligns with the stage-gate-model by Cooper.

Safety and Sustainability Considerations in Innovation

The exploratory phase is characterized by limited time and financial resources and quick exploration of multiple alternatives. generally defined at this stage, based on customer needs. The primary objectives are proof of principle ("does it work?") and proof of benefit ("does it meet customer needs with feasible economics?").

This phase calls for quick analysis of numerous options in order to "Fail early, Fail cheap". Typical safety assessment involves screening approaches, including *in silico* tools based on chemical similarity principle, control banding, checklists, literature review, as well as expert judgement. Sustainability assessment plays a more limited role in the exploratory phase, and heuristic approaches based are typically used. An important exception is process innovation, where detailed process models and measurements enable prospective or ex ante LCA. In line with PSA principles, sustainability considerations are usually addressed at the portfolio level unless product-specific assessments are requested by customers.

In the investment and development phase, dedicated resources are allocated for further development of a promising concept. Safety assessment typically entails the exposure-led approaches, including NAMs, and anticipates impending regulatory requirements. Sustainability assessments are still not mandatory but gains importance in process innovation and in cases where customers request Product Environmental Footprints (PEFs). At this stage, sustainability assessments may range from identification of hotspots along the life cycle to screening LCAs, sometimes conducted in collaboration with value chain partner to perform a cradle to grave analysis. Climate-related impacts are consistently prioritised, reflecting long-standing corporate and sectoral commitments.

In the market phase, functionality is proven and market pathways are defined. Safety assessments now focus heavily on regulatory requirements. Sustainability assessment is typically conducted at the portfolio level, with product-level PEF studies performed in selected cases. While concepts such as planetary boundaries were considered interesting by some companies, they were generally regarded as too immature for operational application at present.

Influence of Innovation Type and Value-Chain Position

The starting point of innovation (i.e., novel chemical development, product formulation, or process optimization) strongly influences the choice of safety and sustainability assessment approaches. The company's position withing the value chain further shapes assessment needs and feasibility.

For example, when the innovation is process-based, hazard assessment often involves known substances and established procedures, whereas sustainability assessment of process design plays a substantial role. In other sectors, high capital investment requirements and rigid value-chain dependencies limit the possibility for change. Furthermore, in some cases, specific safety and sustainability tools are not applicable (e.g. QSARS do not exist for metals and inorganics).

Based on the interviews, five distinct kinds of SSbD approaches could be identified:

a) Chemical or material design,
b) Product formulation,
c) Process,
d) Value chain optimisation, and
e) Circularity or service-based approaches

Overall, SSbD is likely to be company and industry specific. Safety and sustainability practices ranged from the use of specific computational tools to reliance on certification schemes and sector-specific standards.

Decision-Making and Trade-Offs

Decision-making at stage-gate meetings is inherently multi-criteria and collaborative. Final decisions are not driven by single metrics but by strategic considerations, including corporate and sustainability strategy, economic performance, customer needs and reputational risk. A recurring theme was the importance of balancing functionality requirements with safety and sustainability within the constraints of economic feasibility.

5.2. Key Observations

Below is a summary of the key learnings from the company interviews:

- The specific (foreseen) use context of a chemical is an important driver for setting priorities in an assessment and testing strategy. For example, chemicals used in consumer products are treated differently than chemicals used as an intermediate in industry. Hence, contextualisation and scoping are essential steps to move forward. A scoping assessment is added in the revised SSbD framework.
- Multinational companies rely heavily on expert judgement and specialized expertise, specifically in early stages of innovation.
- A wide range of assessment tools is used, including QSARs, screening tools, exposure models, and LCA-based tools, which can either be publicly available tools or company-internal tools/databases. Running tools and interpreting the results is done by in-company specialists.
- Computational tools are combined with other approaches such as literature screening, read-across, *in vitro* assays, comparative LCA studies, chemical process modelling, etc.
- Companies often make use of in-depth knowledge of the specific market and value chains they are operating in. Some companies make use of market specific shared datasets for assessing exposure or sustainability aspects.
- Data confidentiality is an important pre-requisite for companies to start working with a public toolbox.
- Socioeconomic assessment is generally less developed and, where present, is often embedded in certification schemes or procurement guideline
- Given the diversity of expertise and deep dives on trade-offs in stage gate meetings, one respondent mentioned the stage-gate process itself as the key source of learning on SSbD.

5.3.Implications for Further Development of the PARC SSbD Toolbox

Below we listed a number of observations and ideas that might be taken up in the further development of the PARC SSbD toolbox.

- Several innovation entry points are identified (chemical, product, process) which need to be accounted for the toolbox.
- We have identified the elements of what can be called a 'tiered approach'. This line of thinking (from a first basic assessment toward a more detailed) has been incorporated in the toolbox.
- Multidisciplinarity and expert judgement are important elements of innovation-related decision-making. The toolbox accommodates this need to some extent by supporting collaborative work among different users within project teams.
- Problem scoping, including use and application scenario and life cycle and a value chain perspective, is essential.
- The toolbox should support assessment of information needs, availability and quality across innovation stages.
- The inclusion of sector-specific standards and datasets (e.g. use, exposure, concentration ranges in products, LCA-type data, etc.) in the context of the toolbox needs to be considered further.
- The toolbox focus is now mainly on computational tools. This should, in time, be expand to a larger set of approaches that provide SSbD relevant information.
- Decision making is a complex process, comprising many expert inputs from several disciplines. Although the decision itself is a company internal process, the toolbox should try to make the information situation as transparent as possible.
- Data confidentiality must be explicitly addressed in the toolbox design.

6. Conclusions

This study set out to explore how safety, sustainability, and socioeconomic considerations are currently integrated into chemical and product innovation processes in industry, and what this implies for the further operationalisation of SSbD. Through in-depth interviews and focus groups with eight companies operating across different sectors, sizes, and positions in the value chain, the study provides a grounded view of how innovation is organised in practice and how existing assessment approaches relate to the ambitions of SSbD.

Across all case studies, innovation was found to be organised as a phased and iterative process, most commonly structured through stage-gate-like approaches. These processes serve to progressively reduce uncertainty with respect to technical feasibility, market viability, regulatory compliance, and safety and sustainability performance. As innovation progresses, the number of potential options narrows, with less promising alternatives filtered out based on a combination of expert judgement, available data, and strategic considerations. While the degree of formalisation differs between SMEs and large multinational companies, all cases demonstrated a structured logic of early screening, progressive refinement, and decision-making at defined checkpoints.

Safety considerations are generally well embedded in innovation processes, driven primarily by regulatory requirements and corporate product stewardship practices. Hazard identification and risk assessment are typically application-specific and exposure-driven, with companies distinguishing clearly between consumer, professional, and industrial uses. Early-stage assessments rely heavily on expert judgement, read-across, *in silico* tools, and conservative assumptions, while later stages increasingly align with regulatory testing and registration requirements. NAMs are already used by several companies, particularly to support early screening and to reduce animal testing, although regulatory acceptance and data availability remain limiting factors.

Sustainability assessments are more heterogeneous in their scope, depth, and timing. Many companies apply sustainability considerations from the early stages of innovation, but the form this takes varies widely, i.e., from heuristic screening and hotspot identification to detailed LCAs at later stages. Climate-related impacts, particularly carbon footprint, are the most consistently addressed dimension of sustainability, reflecting both corporate climate targets and external market and policy pressures. Broader environmental impacts, circularity, and resource use are increasingly considered, although often at portfolio or product-family level rather than for individual innovations. Full LCAs or PEFs are typically reserved for cases where claims, customer requests, or regulatory requirements necessitate them, due to their data intensity and resource demands.

Socioeconomic aspects are the least formalised component across the case studies. While economic viability is a core decision criterion throughout innovation processes, social impacts are generally addressed indirectly through responsible sourcing programmes, supplier codes of conduct, certification schemes, and compliance with international norms and standards. Explicit product-level socioeconomic assessments are rare.

A key finding of this study is that SSbD cannot be understood or implemented as a single, uniform approach across all innovation contexts. The starting point of innovation as well as the company's position in the value chain, sectoral context, and regulatory exposure, strongly shape which assessment approaches are feasible and meaningful. Five broad SSbD entry points could be distinguished: chemical/material innovation, product innovation, process innovation, value-chain optimisation, and circularity or service-based innovation. Each of these entry points is associated with different data needs, tools, and decision logics.

Decision-making within innovation processes is consistently described as multi-criteria and deliberative. Rather than relying on single scores or rigid thresholds, companies combine information on functionality, safety, sustainability, cost, strategic fit, and reputational considerations through discussion and expert judgement. Trade-offs are unavoidable and are typically resolved through strategic decisions informed by corporate priorities, customer expectations, and regulatory constraints. Transparency about uncertainties and limitations of available data is seen as essential to credible decision-making.

The findings have direct implications for the development of the PARC SSbD toolbox. First, flexibility is essential: the toolbox must accommodate different innovation entry points, levels of maturity, and sector-specific realities. A tiered approach, allowing users to move from simple screening to more detailed assessments as data and resources become available, aligns well with existing industrial practices. Second, the toolbox should support, rather than replace, expert judgement and multidisciplinary collaboration. This includes enabling collaborative workflows, documenting assumptions and uncertainties, and avoiding over-aggregation of results into single indicators where this obscures decision-relevant information. Additionally, tools and guidance must help users define use scenarios, value-chain contexts, and relevant life-cycle stages early on, as these fundamentally shape assessment priorities and outcomes. Finally, issues of data confidentiality, interoperability with existing tools, and alignment with established standards and regulatory frameworks are prerequisites for uptake in industry.

In conclusion, the case studies show that many elements of SSbD are already present in industrial innovation practices, albeit under different labels and driven by diverse motivations. Rather than introducing an entirely new assessment logic, the challenge for SSbD lies in building on existing practices, making implicit decision criteria more explicit, and providing practical support that fits within real-world innovation processes. By grounding SSbD in the realities of industrial decision-making, the PARC toolbox has the potential to meaningfully support safer and more sustainable innovation across a wide range of sectors and company types.

This study has some limitations that should be considered when interpreting the findings. First, the selection of companies was non-probabilistic and based on willingness and capacity to participate, reflecting the substantial time commitment required for in-depth interviews. As a result, the case studies are not statistically representative of the European chemical industry as a whole, but rather provide illustrative insights into a range of innovation contexts. Second, the findings rely primarily on self-reported information from company representatives, which may reflect organisational perspectives and practices as they are intended or perceived rather than how they are applied in all instances. Third, the level of detail varied across case studies depending on the expertise of interviewees, the sensitivity of information discussed, and the specific innovation contexts considered. Finally, only one case study represents SMEs, limiting the extent to which the findings can be generalised to smaller companies, which often operate under different resource and organisational constraints.

Despite these limitations, the study provides a robust qualitative foundation for understanding current industrial practices and for informing the further development of SSbD-oriented tools and guidance.

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8. APPENDIX

8.1. Appendix 1: Stage Gate Primer

(Adapted from: Cooper 2008)

Stage 1 Ideation—The trigger for the process is the first stage, involving discovery or idea generation. Quality ideas are essential to a successful technology program and thus technology ideas from multiple sources must be sought for consideration at Gate 1. While idea generation is often done by scientists or technical people, it can also be the result of other activities, such as:

- A strategic planning exercise, where strategic arenas are identified, and possible Technology Development research directions are mapped
- Technology forecasting and technology roadmapping
- Brainstorming or group creativity sessions focusing on what might be.
- Scenario generation about future market and technological possibilities.
- Customer visitation programs and voice-of-customer initiatives.
- Active idea solicitation campaigns within the organization

Gate 1 This first gate is the idea screen, the initial decision to commit a limited amount of time and money to the research project. This gate should be a gentle screen, which poses the question: Does the idea merit expending any effort at all? Criteria for Go are largely qualitative, are scored at the gate review by the gatekeepers, and should include such items as:

- Strategic fit and impact.
- Strategic leverage.
- Likelihood of technical success.
- Likelihood of commercial success.
- Reward or the “size of the prize” if successful.

The Gate 1 gatekeeper or decision-making group is typically composed of senior R&D people, such as the corporate head of technology (VP R&D or CTO), other senior R&D people, along with representatives from corporate marketing and business development to ensure commercial input.

Stage 2 *Scoping*—The purpose of this Scoping stage is to build the foundation for the research project, define the scope of the project, and map the forward plan. The effort is limited, typically to not much more than two weeks. Stage 1 activities are conceptual and preparation work (see Figure 2), and include a technical literature search, patent and IP search, competitive alternatives assessment, resource gaps identification, and a preliminary technical assessment.

Gate 2 This second screen the decision to begin limited experimental or technical work in Stage 2. Like Gate 1, this gate is also a relatively gentle screen, and poses the question: Does the idea merit undertaking limited experimental work? Gate 2 is again largely qualitative, and does not require financial analysis (because the resulting product, process or impact of Technology Development are still largely unknown). The gatekeepers are the same as at Gate 1.

Stage 3 *Business case*-The purpose of Stage 2 is to demonstrate the technical or laboratory feasibility of the idea under ideal conditions. This stage entails initial or preliminary experimental work, but should not take more than 1–2 person-months, and last no longer than 3–4 months. Activities here typically include undertaking a thorough conceptual technological analysis, executing feasibility experiments, developing a partnership network, identifying resource needs and solutions to resource gaps, and assessing the potential impact of the technology on the company.

Gate 3 is the decision to deploy resources beyond 1–2 person-months, and opens the door to a more extensive and expensive investigation, Stage 3. This gate decision is thus a more rigorous evaluation than at Gate 2, and is based on new information from Stage 2. Gate criteria resemble those listed for Gate 1 previously, but with more and tougher sub-questions, and answered with benefit of better data. The Gate 3 gatekeepers usually include the corporate head of technology (VP R&D or CTO), other senior technology or R&D people, corporate marketing or business development, and the heads of the involved businesses (e.g., general managers). Because Gate 3 is a heavy commitment gate, senior managers of the business units that will take ownership of the resulting technology should be the Gate 3 gatekeepers. Their insights into the commercial viability of the project are essential at Gate 3; further, more early engagement ensures a smoother transition to the business unit once the commercial phase of the project gets underway.

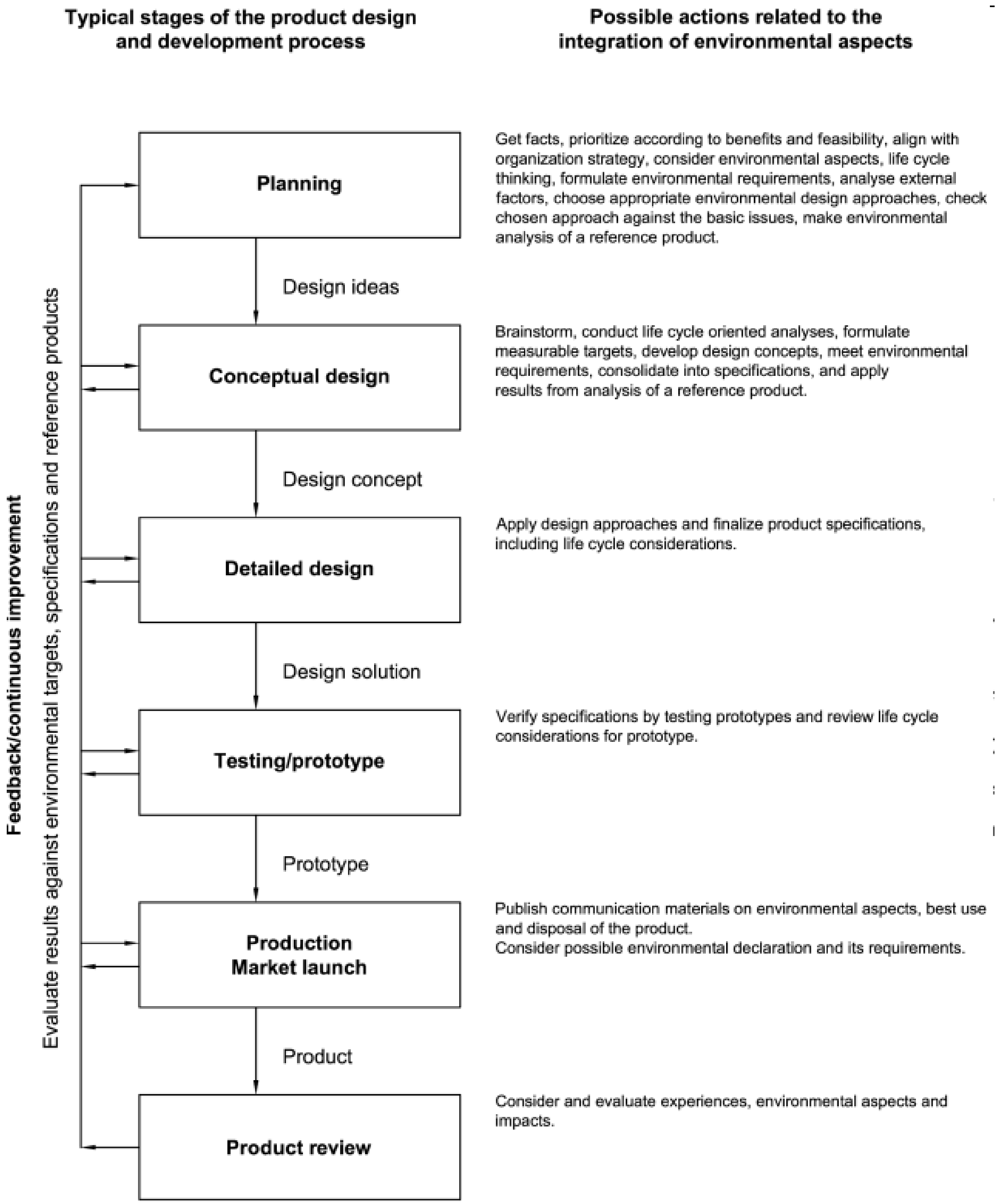
Stage 4 *Development*- The purpose of Stage 3 is to implement the full experimental plan, to prove technological feasibility, and to define the scope of the technology and its value to the company. This stage could entail significant expenditures, potentially person-years of work. Besides the extensive technical work, other activities focus on defining commercial product or process possibilities, undertaking market, manufacturing and impact assessments on these possibilities, and preparing an implementation business case. Sound project management methods are employed during this lengthy stage, including periodic milestone checks and project reviews. If the Technology Development project veers significantly off course, or encounters serious barriers to completion during Stage 3, the project is red-flagged and cycled back to Gate 3 for another Go/Kill decision.

Gate 4 is the final gate in the Technology Development process and is the “door opener” to one or more new-product or process development projects (see Figure 3). Here the results of technical work are reviewed to determine the applicability, scope and value of the technology to the company, and the next steps are decided. Note that this Gate 4 is often combined with an early gate in the usual product development process. Gate-keepers are typically the senior corporate R&D people, corporate marketing or business development, plus the leadership team from the relevant business that will assume ownership of the resulting commercial development projects.

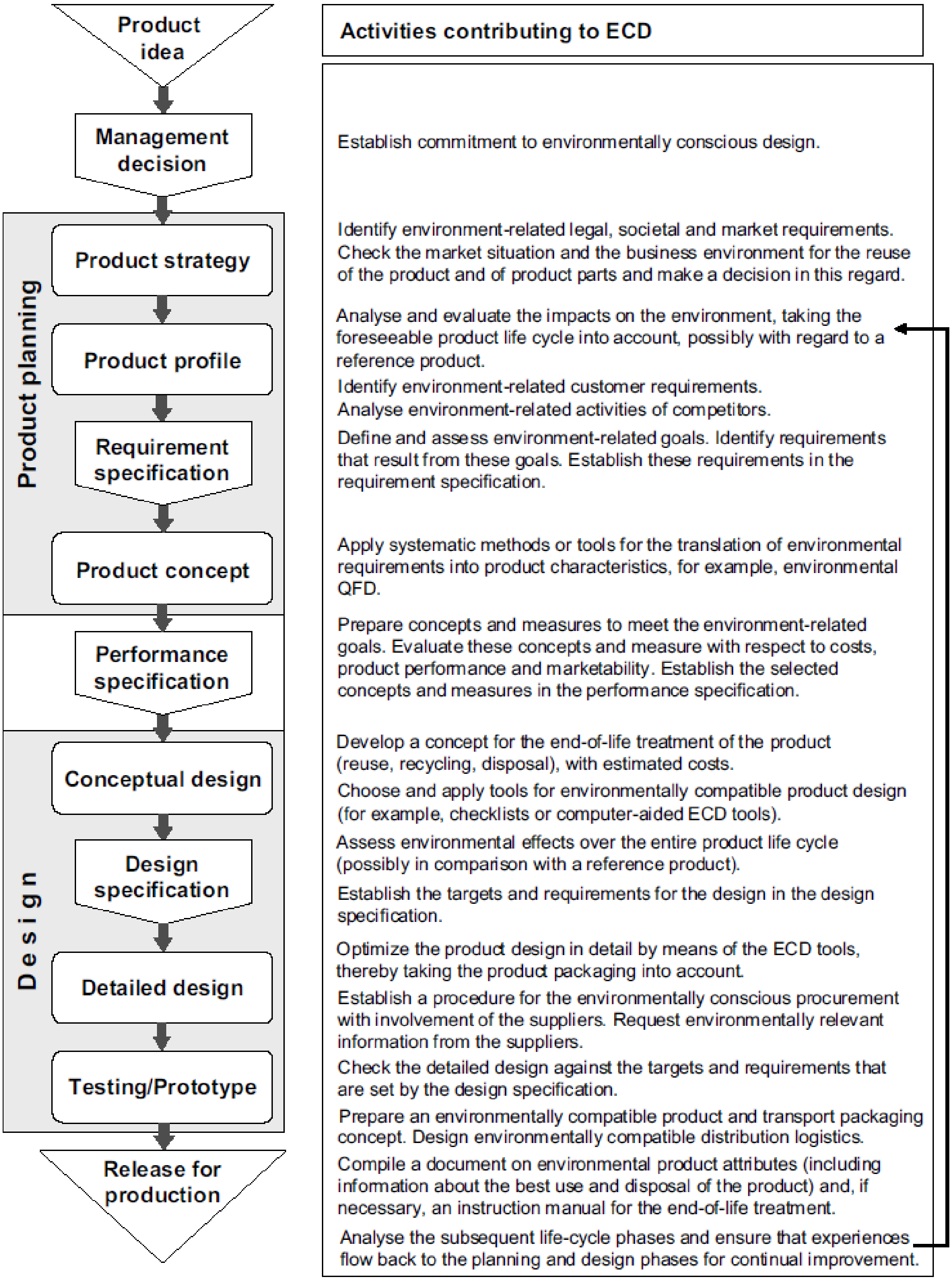
	Score = Zero	*Score = Ten Out of Ten*
1. Business Strategy Fit		
Congruence	Only peripheral fit with our businesss' strategy.	Strong fit with several key elements of strategy.
Impact	Minimal impact; no noticable harm if project is dropped.	The business's future depends on this project. project.
2. Strategic Leverage		
Proprietay position	Easily copied; no protection.	Position protected through patents, trade secrets, raw material access, etc.
Platform for growth	Dead end; one-of-a-kind; one-off.	Opens up many new product possibilities.
Durability (technical and marketing)	No distinctive advantage; quickly leapfrogged by others.	Long life cycle with opportunity for incremental spin-offs.
Synergy with corporate units	Limited to a single business unit.	Could be applied widely across the corporation.
3. Probability of Technical Success		
Technical gap	Large gap between solution and current practice; must invent new science.	Incremental improvement; easy to do; existing science.
Project Complexity	Difficult to envision the solution; many hurdles along the way.	Can already see a solution; straightforward to do.
Technology skill base	Technology new to company; almost no skill internally.	Technology widely practiced withing the company.
Availability of people and facilities	Must hire and build.	people and facilities immediately available.
4. Probablility of Commercial Success (in the case of a TD project with potential for new products)		
Market need	Extensive market development required; no apparent market exists at present.	Product immediately responsive to a customer need; a large market exists.
Market maturity	Declining markets.	Rapid-growth markets.
Competitive intensity	High; many tough competitors in this field.	Low; few competitors; week competition.
Commercial applications development skills	New to company; we have no/few commercial applications skills here; must develop.	Commercial applications skills and people already in place in the company.
Commercial assumptions	Low probablility of occuring; very speculative assumptions.	Highly predictable assumptions; high probablility of occuring.
Regulatory and political impact	Negative.	Positive imoact on a high-profile issue.
5. Reward		
Contribution to profitability	Rough estimate: less than $10M cumulative over 5 years.	Rough estimate: more than $250M.
Payback period	Rough estimate: greater than 10 years.	Rough estimate: less than 3 years.
Time to commerical start-up	Greater than 7 years.	Less than 1 year.

8.2. Appendix 2: Integration of Environmental Aspects in Design and Development

ISO 14062:2002 https://www.iso.org/obp/ui/#iso:std:iso:tr:14062:ed-1:v1:en . In the meantime it has been withdrawn.



ISO 62430:2019 describes principles, specifies requirements and provides guidance for organizations intending to integrate environmental aspects into the design and development in order to minimize the adverse environmental impacts of their products. It can be obtained at https://www.iso.org/standard/79064.html .



QFD = Quality Function Deployment

IEC 747/05

Figure 2 – Integration of environmental aspects into the design and development process in the electrical and electronic industries: possible model 1

8.3. Appendix 3: Semi-structured questionnaire

Questionnaire for companies

Main Topic	**Questions**
Introduction (0-10')	- Introducing ourselves - Introducing PARC - Goal and protocol of interaction & analysis - Permission to record and take notes
Chemical/Material innovation process (10-30')	Can you give a general overview of the new chemical development (NCD)/ product development (PD) activities ongoing in your company?
	What is the starting point of any R&D project in your company?
	How is NCD/PD organized in your company? Who is involved?
	Would you say there are clear decision points ("stage gates") between the different stages? Which criteria play a role in the decision points between the stages?
	What aspects of functionality or performance are important to your products?
Current Safety/Sustainability/ Socioeconomic Assessment (30-60')	Does safety currently play a role in any phase of NCD/PD? Where? IF not, why?
	Does sustainability currently play a role in any phase of NCD/PD? Where? If not, why doesn't sustainability assessment play a role according to you?
	Does socioeconomic assessment currently play a role in any phase of NCD/PD? Where? If not, why doesn't socioeconomic assessment play a role according to you?

	What tools and methods do you currently use for safety and sustainability assessment? Socioeconomic???
	How do you obtain data to apply these tools and methods? How do you deal with data quality and uncertainty?
	Are design strategies usually linked to the results of your safety and sustainability assessments? Do you apply design principles (e.g. green chemistry) without assessments?
	Can you provide some examples of design principles or strategies that you frequently apply in your design process?
	How do you deal with tradeoffs among different impacts ?
Response to European developments in safe and sustainable innovation (60-75')	Are you aware of the EC's SSbD Framework?
	What is your opinion on the EC's SSbD framework?
	Could you apply it in your NCD/PD process? Do you see any challenges?
	What are some desirable features-technical and non-technical- for the toolbox?
Enabling Environment (75-85')	Which incentives could play a role in making SSbD practical in your company or sector?
	What are the educational or training needs to implement SSbD? What additional knowledge do you need beyond what you currently have?
Offers and needs + conclusion (85-90')	Would you like to be involved in PARCs SSbD activities?
	What did we forget?

Questionnaire for consultants, academia, and other relevant stakeholders

Main Topic	Question
Introduction (0-10')	- Introducing ourselves - Introducing PARC - Goal and protocol of interaction & analysis - Permission to record and take notes
Chemical/Material innovation process (10-30')	Can you give a general overview of Research & Development you have participated in as a researcher and consultant?
	How is innovation organized in companies? Which personnel are typically involved, and what are their contributions?
	Would you say that many companies use something like a stage gate model? there are clear decision points ("stage gates") between the different stages? If yes, how do they assess whether a project is ready for the next step in the innovation process?
	How is functionality or performance assessed during innovation in your sector? What tools and methods are currently used for assessment of functionality?
Current Safety/Sustainability/ Socioeconomic Assessment (30-60')	Does safety currently play a role in any phase of innovation? Where? If not, why doesn't safety assessment play a role according to you? If yes, What tools and methods are currently use for safety assessment? How do companies obtain data to apply these tools and methods? How do they deal with data quality and uncertainty? In your view, is the current attention to chemical safety in early innovation adequate?
	Does sustainability currently play a role in any phase of innovation? Where? If not, why doesn't sustainability assessment play a role according to you?

	If yes, What tools and methods are currently used for sustainability assessment? What are the boundaries of their LCA? Do they look at chemical life cycle or product life cycle? How do companies obtain data to apply these tools and methods? How do they deal with data quality and uncertainty? In your view, is the current attention to sustainability in early innovation adequate?
	Does social or economic assessment currently play a role in any phase of innovation? Where? If not, why doesn't social or economic assessment play a role according to you? If yes, what tools and methods are currently used for social and economic assessment? How do companies obtain data to apply these tools and methods? How do they deal with data quality and uncertainty? In your view, is the current attention to socioeconomic assessment in early innovation adequate?
	How do companies in your sector typically deal with tradeoffs among safety, sustainability and functionality ?
	Can you provide some examples of design principles or strategies for safety and sustainability that are frequently applied in your sector?
Response to European developments in safe and sustainable innovation (60-75')	Are you aware of the EC's SSbD Framework?
	What is your opinion on the EC's SSbD framework?
	Do you think it possible to apply it in current innovation processes?
Enabling Environment (75-85')	Which incentives could play a role in making the EC SSbD practical in your sector?
	What are the educational or training needs to implement SSbD? What additional knowledge does your sector need?
	How your sector engage on the SSbD topic?
	What did we forget?