

# A Conceptual Framework for Safe-and-Sustainable-by-Design to Support Sustainable Business Model Innovation and New Product Development




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## Authors

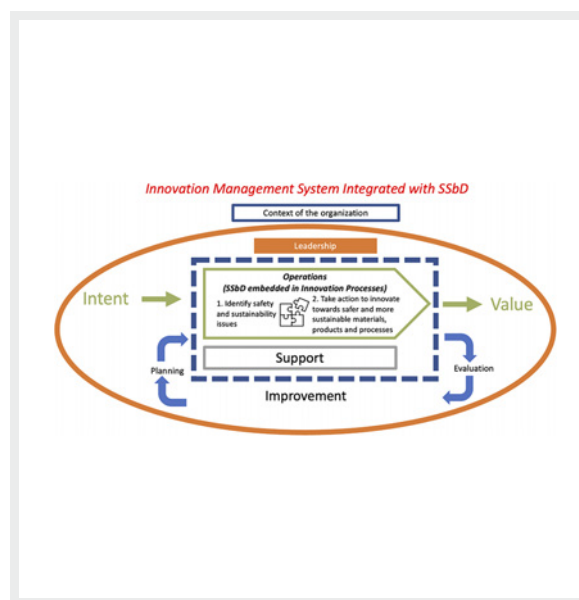
Stella Stoycheva<sup>1</sup>, Willie Peijnenburg<sup>2,3</sup>, Beatrice Salieri<sup>4</sup>, Vrishali Subramanian<sup>2</sup>, Agnes G. Oomen<sup>2,5</sup>, Lisa Pizzol<sup>6</sup>, Magda Blosi<sup>7</sup>, Anna Costa<sup>7</sup>, Shareen H. Doak<sup>8</sup>, Vicki Stone<sup>9</sup>, Arianna Livieri<sup>6</sup>, Vikram Kestens<sup>10</sup>, Irantzu Garmendia<sup>11</sup>, Hubert Rauscher<sup>11</sup>, Neil Hunt<sup>1</sup>, Danail Hristozov<sup>12</sup>, Lya G. Soeteman-Hernández<sup>2</sup>

## Affiliations

- 1 Yordas Group, Forchheim, Germany
- 2 Center for Safety of Substances and Products, National Institute for Public Health and the Environment (RIVM), Bilthoven, The Netherlands
- 3 Institute of Environmental Sciences (CML), Leiden University, Leiden, The Netherlands
- 4 TEMAS Solutions GmbH, Hausen, Switzerland
- 5 Institute for Biodiversity and Ecosystem Dynamics (IBED), University of Amsterdam, Amsterdam, The Netherlands
- 6 GreenDecision S.r.l., Venezia, Italy
- 7 Institute of Science and Technology for Ceramics (ISTEC), Italian National Research Council, Rome, Italy
- 8 In Vitro Toxicology Group, Institute of Life Science and Centre for NanoHealth, Swansea University Medical School, Swansea University, Singleton Park, Swansea SA2 8PP, Wales, UK
- 9 Nano-Safety Research Group, School of Engineering and Physical Sciences, Heriot-Watt University, Edinburgh, UK
- 10 European Commission, Joint Research Centre (JRC), Geel, Belgium
- 11 European Commission, Joint Research Centre (JRC), Ispra, Italy
- 12 East European Research and Innovation Enterprise, Sofia, Bulgaria

## SIGNIFICANCE

- Business model innovation (BMI) and new product development (NPD) processes need a sound framework for the successful integration of safety and sustainability considerations to foster sustainable innovations.
- Safe-and-Sustainable-by-Design (SSbD) is central to meeting policy ambitions and could be integrated with traditional IM tools to support sustainable BMI.
- A conceptual framework is proposed to achieve sustainable BMI and NPD by integrating traditional IM tools with SSbD using life cycle thinking (LCT) principles.
- SSbD and LCT should be embedded in the new certified training for professional designation for IM.



**Keywords**

Product innovation, New product development, SSbD, Chemicals strategy for sustainability, Future-proof innovation management system, Sustainable business model innovation

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**Correspondence**

Dr. Stella Stoycheva

Sustainability, Yordas Group, Äußere Nürnberger

Straße 62, 91301 Forchheim, Germany

[s.stoycheva@yordasgroup.com](mailto:s.stoycheva@yordasgroup.com)

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**ABSTRACT**

To reach a sustainable future and meet the UN's Sustainable Development Goals (UN SDGs), business model innovation (BMI) needs to explore theoretical and practical intersections of the traditional innovation management (IM) and new product development (NPD) processes with sustainability considerations. New environmental and health policy ambitions such as those presented in the European Green Deal and the EU Chemicals Strategy for Sustainability (CSS) challenge traditional IM theories on BMI and NPD processes. The Safe-and-Sustainable-by-Design (SSbD) concept is a central element of the CSS and demands a novel approach that integrates innovation with safety and sustainability (including circularity) of materials, products, and processes without compromising their functionality and/or commercial viability. Importantly, adopting such a concept can also prevent regrettable substitutions, future liability, and brand image issues for companies. To achieve this, companies must design products with minimal environmental impact, adopt circular economy principles, and ensure social responsibility throughout the value chain, while maintaining economic viability. By doing so, companies contribute to environmental, social, and economic sustainability. In this perspective, a conceptual framework is proposed on how to achieve sustainable BMI and NPD by integrating traditional IM tools with SSbD using life cycle thinking principles while considering external (changing legislation, new business standard requirements, competitive environments, technological developments, societal views) and internal drivers (company-specific targets, company culture, corporate strategy, management capabilities). SSbD and life cycle thinking should be embedded in newly developed training for IM professional designation. This is because innovation managers can play a key role in bringing this transition into practice.

**Introduction**

Business model innovation (BMI) has become a well-established phenomenon in management and organization theory and a central topic for debate in the innovation management (IM) field. But at the same time, theoretical and practical explorations of the intersections between BMI, the new product development process (NPD), and sustainability remain somehow overlooked [1–3]. This is important given that NPD is the backbone of innovation, one of the major concerns of our modern society, and a key driver to achieving sustainable development.

BMI represents a highly relevant concept, which is described in the literature in several ways: (1) a process by which management actively innovates the business model (BM) to disrupt market conditions [4]; (2) the discovery of a fundamentally different business model in an existing business [5]; (3) initiatives to create novel value by challenging existing industry-specific business models, roles, and relations in certain geographical market areas [6]; (4) the search for new logics of the firm and

new ways to create and capture value for its stakeholders [7], or (5) a reconfiguration of the BM's elements, the firm's activities, or the value proposition [5, 8, 9].

In summary, the BMI perspective is viewed as a holistic organizational innovation approach that helps keep the big picture in mind instead of focusing only on specific innovation topics described by traditional IM [10]. Not surprisingly, the BMI construct has been intensively explored empirically within IM research but predominantly from a strategy perspective [11, 12], starting various lines of research looking at the antecedents, moderators, mediators, and consequences of innovating BMs [13].

**Drivers for BM adaptation**

Research has focused on identifying drivers of BM adaptation, which include pressure from external stakeholders [14, 15], regulatory forces, changes in the competitive environment [16], opportunities arising from new information and communication technologies [17–19], and changes in the business

environment [9]. Internal factors triggering BMI include organizational [20] and management capabilities [21], organizational culture [22], and changes in a firm's strategy [23], among others.

### Performance implications, processes, and facilitators for business model adaptation

In addition to research on drivers, there are three other partly overlapping research streams: performance implications [24, 25], processes [26–29], and facilitators of BM adaptation [4, 30–37]. Overall, BMI can be driven by internal and external factors [3]. The motivation for BMI is to shape markets or industries by means of creating disruptive innovations [5, 38] and not just aligning and adapting for strategic [39] or organizational [40] reasons.

### Integrating sustainability to the process of NPD

Another central concept in IM looks at the process of NPD, which is based on the integration of multidisciplinary knowledge (scientific, technological, and market knowledge), resulting in a recognizably different product [41]. Looking at the knowledge base around sustainable NPD, prior research indicates that integrating sustainability considerations in the NPD process can be complex, risky, costly, and time-consuming [42, 43].

Studies consistently indicate that incorporating sustainability in the NPD at an operational level should adopt a lifecycle thinking (LCT) approach [44] and cover environmental, social, and economic impact assessments [44–46]. However, practical frameworks for this integration remain limited [43–52]. Generally, organization and management literature offers sound models for IM such as the Cooper Stage Gate model [53–56] and the Funnel model [41]. These models contribute significantly to the field of NPD but usually begin just after the point in the process where the idea has already been generated [57]. This “Fuzzy Front End” of NPD is often overlooked and is the focus point of this perspective [57]. In addition, there is a lack of in-depth exploratory studies explaining the sustainable NPD process in practical terms.

### Finding strategies to link sustainability with business model innovation (BMI) and NPD

The disconnect in the general organization and management literature between BMI, the NPD process, and the sustainability of the firm can be viewed as problematic for several reasons. Therefore, the motivation of this study is both theoretical and practical and tackles timely real-world problems for industry and policy making.

First, from a management and practitioner's perspective, the design of innovative and sustainable BMs is crucial for commercializing novel ideas, technologies, and products [58, 59]. Therefore, sound *theory* is needed to address the dynamic links between BMI, NPD, and product sustainability.

Second, in the wake of an era where sustainability is at the forefront of *policy making* that advocates proactive, sustainable-by-design approaches and solutions, IM literature

seems to fail to address the above-mentioned gaps. In the political arena, policy ambitions such as the European Green Deal (EGD) triggered the EU Chemicals Strategy for Sustainability (CSS) [60] (EC, 2020) to encourage and steer the chemical industry toward a long-term green transition. This transition includes the development of safer and more sustainable chemicals, materials, products, processes, and value chains [60], [61]<sup>1</sup>. As a result, *companies* and value chains are challenged to develop and apply safe and sustainable innovations in an LCT approach. LCT aims to address human and environmental impacts of chemicals, materials, and products throughout their life cycles in an integrated way to avoid unintended consequences [62]. This ensures that the safety, economic, environmental, and social impacts are favorable and prevents adverse issues arising after market entry [63]. A multistakeholder and multidimensional approach along the entire value chain and throughout the life cycle is needed. This approach should involve all stakeholders to improve the support toward sustainable innovation [64], thus enabling the creation of innovative and sustainable ideas and integration of external knowledge to drive innovation and balance between functionality, safety, and sustainability. The latter includes economic sustainability, circularity, and social and environmental impacts.

### Safe-and-Sustainable-by-Design (SSbD) and LCT principles as a strategy to achieving sustainable BMI and NPD

The SSbD concept is a central element of the CSS and demands the consideration of safety, sustainability, and circularity of materials, products, and processes without compromising their functionality and/or commercial viability [60]. SSbD aims at integrating safety and sustainability in the NPD process. Importantly, adopting such an approach can minimize the chance of regrettable substitutions (when one chemical is banned, only to be replaced with another chemical just as harmful, or potentially worse), future liability, and brand image issues for companies. Safety and other sustainability dimensions need to be accounted for in all life cycle phases of chemicals, materials, products, and processes in the IM system. Such a complex transformation goes far beyond just a single NPD process, and it is rather a case of sustainable BMI.

Sustainable BMI can be defined as a change in how a firm operates to create positive impacts or reduce negative consequences for the environment and society [65]. While there is a broad consensus about the importance of sustainability for firms, research on the transformation toward sustainable BM remains rare [66, 67]. Indeed, prior research on the topic offers various reviews [68–71]; nevertheless, the dynamics of implementing sustainable BMI remain relatively underexplored.

Furthermore, organization and management literature exploring the concept of SSbD for BMI is virtually absent.

<sup>1</sup> We consider “safety” as an integral part of “sustainability”. For the sake of aligning our vocabulary with the well-established SSbD trend, we use the term “safety and sustainability” in its meaning as “safety and other sustainability dimensions” (e.g., environmental, economic and social dimensions).

It is therefore clear that a framework that explains how SSbD can be applied to the NPD processes is needed to transform the organizations' BMI toward safe, sustainable, and circular products, processes, and value chains. To address this conceptual gap, we investigate the following research question: *What are the forces, rules, and conditions for successful integration of safety and sustainability considerations in the BMI and NPD process?*

The broad objectives of this research are therefore:

1. to identify the dynamics for integrating sustainability with traditional IM systems and understand the forces that affect its realization, and
2. to develop a novel conceptual framework with guidance on how to integrate the SSbD with traditional IM tools to achieve sustainable products.

### **Multicomponent nanomaterials (MCNMs) as a case study for the development of a conceptual framework for how SSbD can be applied to support sustainable BMI and NPD**

To achieve these objectives, this article uses a combination of an exploratory [72] case study research spanning an 18-month period in an SME manufacturing company producing novel advanced multicomponent nanomaterials (MCNMs) and an evidence-based literature review. The case study has been specifically chosen for several reasons.

First, the case of MCNMs is particularly interesting from a safety and sustainability assessment point of view. Despite being a key enabling cutting-edge technology, currently one of the greatest challenges of nanomaterial (NM) safety assessment is the rapid and diverse development of emerging manufactured NMs that consist of multiple conjugated components, such as in the case of MCNMs [72–76]. Due to their wide-ranging complexity (e.g., linkage of several NM types and forms, and/or NM-chemical combinations), an improved understanding of how these components interact with each other, with other NMs, and/or chemicals, possibly leading to mixture toxicity, is needed since unknown interactions may result in synergism, potentiation, or antagonism of hazards.

It is also important to establish how the identities of the MCNMs and the products incorporating them change throughout their full lifecycle, spanning release, weathering, and aging at different stages from manufacturing to use and end of life [77–79]. Challenges of the sustainability assessment of MCNMs are similar to the sustainability challenges for chemicals. The ambition is to minimize the consumption of raw materials and resources (water, solvents, land, and energy consumption), minimize waste, and minimize the overall environmental footprint during design, manufacturing, production, transport, use, and end of life [80]. It is also important to improve social benefits and optimize economic feasibility, viability, and value [81–83].

This case study in Technology Readiness Level (TRL) 3/4 was a good methodological fit [84] to answer our research question: first deep-diving into the challenges of applying SSbD to MCNM innovation and then extracting lessons learned to better link BMI, NPD, and IM with SSbD. In addition, it offered the research group unique access to follow a real innovation

sustainability-driven process. It was considered theoretically fit to be able to adequately explain what has not been addressed by existing theory [85].

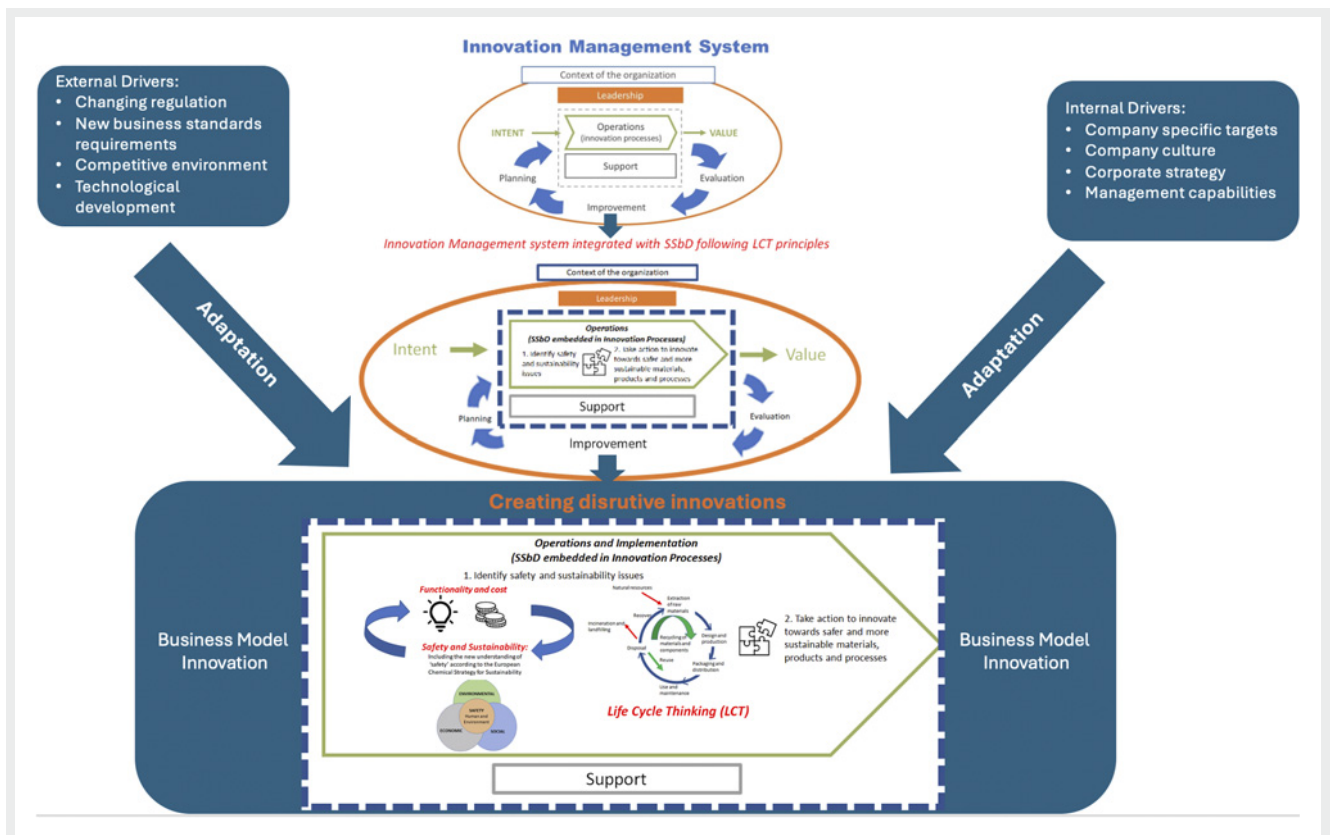
For our data collection, analysis, and interpretation, we used established best practices for data triangulation [72] and a grounded theory approach to offer an in-depth investigation of the sustainability-IM dynamics [86]. For the literature review, we followed the best practices for conducting systemic, evidence-based literature reviews from organization and management research (see the Methods section).

This work makes contributions to various fields. At the practical level, it fills an important knowledge gap by providing a sound framework to support sustainable innovations. At the methodological level, it advances technical, environmental, organization, and management sciences by bridging IM with safety and sustainability theories and practices through an exploratory case study of MCNMs. At the policy level, it contributes to knowledge generation in support of the transition to a more sustainable future by providing a science-based conceptual framework that incorporates LCT and SSbD. In what follows, we proceed by explaining the background and motivation for the study and review ongoing debates in the sustainability and BMI literature exploring different theoretical positions that can shed light on the inner workings of these dynamics. Then we outline the methodology and present the results of the study. On this basis, we develop a conceptual theoretical framework explaining the relationships and mechanisms underpinning the integration of SSbD and IM practices. We then conclude by discussing the implications and limitations of the study and offering avenues for future research.

## **Results**

### **A grounded model explaining the dynamics of sustainability-IM system integration**

Although the innovation process usually follows a standard routine (following an IM system (IMS)), it is characterized by constant changes, which are an attempt to accommodate different internal and external needs (i.e., changing regulatory demands, new business standards, changes in the competitive environment and technology development, etc). As the model (► Fig. 1) illustrates, there are various drivers that affect organizations' innovation process and thus require a BM adaptation. Those stem from diverse pressures from the organizational field, which shape the formulation of IM changes. However, those pressures are translated into new business practices by passing through the prism of the company's identity, culture, and capabilities (internal drivers). The main mechanism through which these changes are realized is BM adaptation. Once a disruptive element (such as incorporating SSbD, which requires a thorough adjustment of the internal workings of the organization) is included in the IMS, a new BMI emerges. Our findings reveal some interesting observations, which both confirm and extend our current knowledge in those streams of research. ► Fig. 1 presents the model developed based on our observations and confirmed by knowledge from existing literature.



► **Figure 1** A conceptual framework of sustainable business model innovation: the rules and guiding principles for successful integration of IM with SSbD following LCT principles.

The coherent, meaningful, and practical integration of an IMS with SSbD principles needs to be finely tuned in order to balance innovation with the criteria and tools from SSbD. As a foundation of our framework, we use the ISO 56002 standard for IMS [87]. The standard identifies seven key elements and eight principles that can be used to describe the IMS of an organization and its capabilities [88].

Following the ISO standard, we developed a canvas (► **Table 1**) that illustrates the rules and guiding principles for successful integration of IMS with SSbD following LCT principles. It includes the evidence-based literature review of “by-design” principles and guidance from JRC reports [81–83, 89] and from the NanoReg2 EU-funded Project [90, 91]. In addition, “by-design” goals and strategies for safety and design criteria and guidance (possible “by-design” actions) for sustainability are outlined for the development of the conceptual framework.

Traditionally, an IMS includes seven key elements: Context (realization of value), Leadership (future-focused leaders), Planning (strategic direction), Support (culture), Operations (exploiting insights), Evaluation (managing uncertainty), and Improvements (adaptability and systems approach) [87]. In our conceptual framework (► **Table 1**), the key elements of the SSbD IMS feature: (1) realization of value needs to include the changing policy landscape, for instance the EGD, CSS, the Critical Materials Act [92], Net Zero Industry Act and Circular

Economy Action Plan, the Ecodesign for Sustainable Products Regulation (ESPR), where SSbD is central; (2) future-focused leaders should have a vision and strategy aiming for safe and sustainable innovations; (3) the strategic direction of innovations should embed safety and sustainability criteria within the IMS; (4) changing culture by facilitating an infrastructure consisting of a transdisciplinary dialogue between material scientists, engineers, (eco)toxicologists, economists, and sustainability and regulatory experts is vital to identify all safety and sustainability aspects and embed them efficiently within the innovation process, as well as bringing the value chain actors together; (5) systemically building knowledge by applying safety and sustainability concepts during the innovation process; (6) managing/reducing uncertainty by setting up a monitoring schemes to assess the criteria and performance indicators for the implementation of SSbD and LCT principles; and (7) the integration of SSbD into the IMS will ensure adaptations to improve or change functionality will not adversely impact safety and sustainability. Based on the evaluation, specific strategies and control measures should be proposed to guarantee safer and more sustainable processes throughout the product life cycle. IM is based on a systems approach, with interrelated and interacting elements, and regular performance evaluation and improvements of the system are needed (► **Table 1**).

SSbD strategies have been developed and illustrated in ► **Table 1**, which are in line with the considerations of the first



► **Table 1** Conceptual framework integrating IM with SSbD following LCT principles: overview of “by-design” goals and strategies for safety and design criteria and guidance (possible “by-design” actions) for sustainability from JRC reports [81–83, 89] and from NanoReg2 [90, 91].

Integration of IM with SSbD following LCT principles				
<b>IM element: CONTEXT</b> <ul style="list-style-type: none"> <li>Realization of value by applying SSbD, circular and regenerative strategies. See recent screening level approach to support companies in making safe and sustainable by design decisions at the early stages of innovation [94].</li> <li>Better dealing with the ‘Fuzzy Front End’ of innovation funnel [57] while keeping up with policy landscape is changing through the EGD, CSS, Critical Raw Materials Act, Zero Pollution Industry Act, and Circular Economy Action Plan where SSbD is central.</li> </ul>				
Discovery	Definition	Design	Development	Delivery
What is the opportunity that we might want to pursue?	What detailed needs must we satisfy?	How can we satisfy those needs: that is, can we come up with better features and solutions than those that already exist?	Which of these prospective features or solutions are actually worth investing in?	The final shakedown process: Can we reliably produce it, sell it, maintain it, and make money doing it? (questions adapted from Katz [57]).
Who is the customer that we want to target?	How should we measure how well we’re satisfying them: that is, to what specifications should we design?	How do we describe these features and solutions to our customers such that they will find them compelling and believable?	Which should we actually include in the final product?	
What are their major problems, from a high-level perspective, in achieving the task they have chosen to undertake?			If we do, how much will people be willing to pay for them?	
<b>IM element: LEADERSHIP</b> <ul style="list-style-type: none"> <li>Vision and strategy should aim for safe and sustainable innovations. A “do nothing strategy” is not sufficient. Companies must adopt circular, SSbD, and regenerative elements in their business models, start pilot initiatives, and build a transition strategy [94].</li> <li>SSbD supportive business models [102–106].</li> <li>Regenerative business models are based on the principles of sustainability, a circular economy, and biomimicry: <ul style="list-style-type: none"> <li>Sustainability: Regenerative businesses prioritize the health of the environment and the well-being of the people involved in their operations. They aim to create a sustainable future by minimizing their negative impact on the environment and actively restoring and regenerating natural systems.</li> <li>Circular economy: Regenerative businesses adopt circular economy principles by designing products and systems that are restorative and regenerative. This includes: <ul style="list-style-type: none"> <li>Circular inputs – using renewable, recycled, or highly recyclable inputs in production processes – enabling partial or total elimination of waste and pollution; while waste becomes an asset;</li> <li>Sharing economy concept - maximizing how idle assets are used across a community while providing customers with affordable and convenient access to products and services;</li> <li>Product as service – where the customer purchases a service for a limited time while the provider maintains ownership of the product and remains incentivized for the product’s ongoing maintenance, durability, upgrade, and treatment at the end of its use;</li> <li>Product use extension – designing products for repairability, upgradability, reusability, ease of disassembly, reconditioning, and recyclability of all components;</li> <li>Resource recovery – focusing on the end stages of the usage cycle, namely the recovery of embedded materials, energy, and resources from products at the end of use that is no longer functional in their current application [94].</li> </ul> </li> <li>Biomimicry: Regenerative businesses take inspiration from nature and adopt biomimicry principles in their operations. They aim to create systems that mimic natural processes and functions, such as closed-loop systems and regenerative agriculture [97].</li> </ul> </li> </ul>				
<b>IM element: PLANNING</b> Embed safety and sustainability criteria within the IM system.	Safety		Other Sustainability Dimensions	
	Goal/Strategy		Goal	Strategies
	Goal: Safe(r) material  Strategy: Design-out hazardous properties without affecting functionalities		Goal: <i>Material efficiency</i>  Description: Incorporating all the chemicals or materials used in a process in the final product or fully recovering them inside the process, thereby reducing the amounts of raw materials needed and generating less waste.	<ul style="list-style-type: none"> <li>Maximize yield during reaction to reduce chemical or material consumption.</li> <li>Recover more unreacted chemicals or materials.</li> <li>Select materials and processes that produce less waste.</li> <li>Identify the occurrence of the use of critical raw materials, in order to minimize or substitute them.</li> </ul>
<b>IM element: OPERATIONS</b> Apply safety and sustainability concepts during the innovation process.				

(Continued)

► Table 1 (Continued)

	<p>Goal: Safe(r) process</p> <p>Strategy: Minimizing release and potential exposure scenarios (occupational and environment).</p>	<p>Goal: <i>Minimize the use of hazardous chemicals or materials</i></p> <p>Description: Preserving the functionality of products while reducing or completely avoiding the use of hazardous chemicals or materials where possible. Using the best technology to avoid exposure at all stages of the life cycle of a chemical or material.</p>	<ul style="list-style-type: none"> <li>• Reduce and/or eliminate hazardous chemicals or materials in production processes.</li> <li>• Redesign production processes to minimize the use of hazardous chemicals/materials.</li> <li>• Eliminate hazardous chemicals or materials in final products.</li> </ul>
	<p>Goal: Safe(r) use and end-of-life</p> <p>Strategy: Minimizing release and potential exposure scenarios (user and environment).</p>	<p>Goal: <i>Design for energy efficiency</i></p> <p>Description: Minimizing the energy used to produce and use a chemical or material in the production process and/or in the supply chain.</p>	<p>Select or develop (production) processes that:</p> <ul style="list-style-type: none"> <li>• involve alternative and less energy-intensive production/separation techniques.</li> <li>• maximize energy re-use (e.g. integration of heat networks and cogeneration)</li> <li>• have fewer production steps.</li> <li>• use catalysts, including enzymes.</li> <li>• reduce inefficiencies and exploit available residual energy in the process or select lower temperature reaction pathways</li> </ul>
		<p>Goal: <i>Use renewable sources</i></p> <p>Description:</p>	<p>Promote the use of feedstocks that:</p> <ul style="list-style-type: none"> <li>• are renewable.</li> <li>• are circular.</li> </ul>
		<p>Conserving resources, by means of resource-closed loops or by using renewable material and energy sources.</p>	<ul style="list-style-type: none"> <li>• do not create land competition.</li> <li>• do not negatively affect biodiversity</li> </ul> <p>or processes that:</p> <ul style="list-style-type: none"> <li>• use renewable energy resources with low-carbon emissions and without adverse effects on biodiversity</li> </ul>
		<p>Goal: <i>Prevent and avoid hazardous emissions</i></p> <p>Description: Applying technologies to minimize or avoid hazardous emissions or the release of pollutants into the environment.</p>	<p>Select materials or processes that:</p> <ul style="list-style-type: none"> <li>• minimize the generation of hazardous waste and hazardous by-products.</li> <li>• minimize the generation of emissions (e.g. volatile organic compounds, total organic carbon, acidifying and eutrophication pollutants, and heavy metals).</li> </ul>
		<p>Goal: <i>Design for End of Life</i></p> <p>Description: Design chemicals and materials so that, once they have served their purpose, they break down into chemicals that do not pose any risk to the environment or to humans. Design chemicals and materials in a way that makes them fit for re-use, waste collection, sorting and recycling.</p>	<p>Avoid using chemicals or materials that impede end-of-life processes such as recycling.</p> <p>Select materials that are:</p> <ul style="list-style-type: none"> <li>• more durable (longer life and less maintenance).</li> <li>• easy to separate and sort.</li> <li>• valuable even after being used (commercial afterlife).</li> <li>• fully biodegradable for uses that unavoidably lead to release into the environment or wastewater.</li> </ul>
		<p>Goal: <i>Consider the whole life cycle</i></p> <p>Description: Applying the design criteria to the entire life cycle, from the raw materials supply chain to the final product's end of life.</p>	<p>Consider:</p> <ul style="list-style-type: none"> <li>• using reusable packaging for the chemical or material being assessed and for chemicals or materials in its supply chain.</li> <li>• energy-efficient logistics (e.g., reducing transported quantities, changing the means of transport)</li> <li>• reducing transport distances in the supply chain</li> </ul>

(Continued)

► Table 1 (Continued)

		Goal: <i>Design to minimizing negative and foster positive social impacts.</i>	<ul style="list-style-type: none"> <li>Minimize occupational and consumer health risks: support health &amp; safety of local community's living conditions, safety management a work, management of worker's individual health, product safety, impact on consumer health.</li> <li>Human rights: Support basic rights &amp; needs including fair wages, appropriate working hours, no forced labor, human trafficking and slavery, no discrimination, social/employer security and benefits, access to basic needs, respect for human rights and dignity.</li> <li>Social benefit: Contribute to economic and technology development via fostering education, job creation, joint research.</li> <li>Support skills, knowledge and employability, promotion of skills and knowledge for local community and consumers.</li> <li>Governance (value chain): promoting value chain with social responsibility</li> </ul>
		Goal: <i>Design to optimize economic impacts</i>	<ul style="list-style-type: none"> <li>Use life cycle costing (LCC) to assess and optimize total cost over the life cycles the product including externality costs (e.g. the costs associated with environmental emissions, worker safety, and health protection, and land eco-remediation</li> <li>Functionality (optimize product performance)</li> <li>Optimize product cost (purchase and production cost)</li> <li>Optimize profitability (added value, net present value, financial profit and payback period)</li> </ul>
IM element: EVALUATION			
<ul style="list-style-type: none"> <li>Measure progress. Companies should measure their progress towards their circular, SSbD and regenerative goals and track the impact of their efforts.</li> <li>Set up a monitoring scheme to assess the process of innovating with SSbD and LCT principles.</li> </ul>			
IM Element: IMPROVEMENT			
<ul style="list-style-type: none"> <li>Identify areas for improvement and adjustments.</li> </ul>			
System Approach			
<ul style="list-style-type: none"> <li>Embed SSbD in the system approach through iterative cycles of evaluation and improvement.</li> </ul>			

national Chemical Leasing initiative driven by the German Federal Environment Agency in 2009, and include (1) reduction of adverse impacts on the environment, health, energy, and resource consumption caused by chemicals and their application and production processes; (2) no substitution of chemicals by substances with higher risk; (3) improved handling and storage of chemicals to prevent and minimize risks; (4) generation of economic and social benefits; and (5) monitoring of the improvements [93].

Also, the three main safe-by-design pillars [91] (► Table 1) have been adopted to be integrated into an IMS. The safety and sustainability assessment follows a stepwise approach according to the following steps: (i) hazard assessment of chemicals and materials (including human health, environmental, and physical hazards); (ii) human health and safety aspects in the chemical/material production and processing phase (occupational safety and health aspects including acute and chronic human health hazards, physical properties, hazards from release behavior, and process-related hazards); and (iii) human health

and environmental aspects in the final application phase [81]. Step iv is environmental sustainability and aims to maintain and preserve the environment and natural resources, without hampering economic development, by minimizing the environmental footprint, promoting circularity, and minimizing the waste and emission generated at each life cycle stage of the new material. Social sustainability (step v) is addressed by considering health and safety aspects related to the manufacturing, use, and end-of-life stage of the product. Also, social criteria such as support for basic human rights, transparency, responsible communication, and consumer product experience are included. Economic sustainability ensures economic stability and that the material, chemicals, products, and processes are economical and efficient.

### MCNM case study major findings

The project managers in the SME addressed the SSbD challenges by developing a multidisciplinary innovation ecosystem



and bringing together the different expertise in material science, human and environmental toxicology, sustainability (environmental, social, economic, recycling), and regulatory. This was possible because the innovation managers of the SME were part of an European Project. In general, SME innovation managers do not have the expertise in-house, yet they can apply alternative strategies such as taking part in external partnerships, creating networks with academia, or reaching out to consultants to have access to the necessary expertise. There were several SSbD strategies employed. For the safety aspect, strategies included substitution of hazardous substances with MCNMs, optimization of powder handling to reduce worker exposure, replacing solvents in the process for safer process safety, using liquid versus air suspension, and reducing the release/migration. For the sustainability aspect, strategies included: replacing critical raw materials with MCNMs, reducing water consumption, reusing material lost during production, reducing energy use in the production process, recycling and reusing the solvents lost in the process by distillation, reducing CO<sub>2</sub> emissions, improving recyclability of materials, and decreasing time and temperature in the process. The results of two industrial case studies using the framework from the project have been recently published [94], namely nano-enabled PFAS (polyfluoroalkyl substances)-free antisticking coating for bakery molds, and nanodrops of essential oil anchored to the surface of nano clays and encapsulated in a polymeric film. The results indicate that these innovative materials have a high probability of having better safety, functionality, and sustainability performance compared to conventional benchmark materials [94]. In this context, “Functionality” is defined as the ability of a product to be useful and to achieve the goal for which it was designed. Criteria such as durability, performance, versatility, and reliability have been used to measure functionality.

### Strategies for dealing with data scarcity early in innovation

In the case study of MCNM, a qualitative, screening approach was used to identify potential safety and sustainability issues at an early research and development (R&D) phase [94]. This type of screening approach revealed information gaps and raised awareness of potential safety and sustainability concerns, which in turn triggered the need for action. For the safety dimension, the eventual presence of hazardous materials, such as carcinogenic, genotoxic, endocrine disrupting, and the physical hazard properties of the MCNM were investigated along the entire life cycle; mainly with *in silico* methods (read-across) and expertise from the multidisciplinary team. Other aspects such as the release and emission of hazardous substances due to the production of the MCNM and the related enabled product, e.g., the possible release of carcinogenic, persistent, bioaccumulating substances from the product, and the transformations of any released MCNM were also assessed along the life cycle were also considered. For the environmental sustainability dimension, aspects considered included the use of critical and/or renewable materials, the energy sources, the use of water, as well as consideration related to the generation of

waste and greenhouse gas (GHG) emissions, chemical emissions in environmental compartments, possibility to recycle the waste generated during the production process, and reusing any byproducts/co-products. For the social sustainability dimension, aspects considered included respect for the living conditions of affected local communities, the policies and restrictive procedures for the traceability of raw materials, minimization of social issues related to the acquisition of raw materials and resources, the promotion of regional products, the social responsibility of suppliers, the technological development and educational opportunities, and the screening of possible end-of-life treatment options. For the economic sustainability dimension, aspects considered included the provision of the costs of the raw materials and their transport, the materials production, products manufacturing and waste disposal, the installation costs for implementing SSbD actions, the direct economic benefits of using the innovative product, and the direct costs of the end-of-life treatment. This screening approach is in line with the scoping analysis in the EC JRC SSbD methodological guidance [83] where the information needed to define the SSbD system is assessed through the engagement with the SSbD system partners for the application of the framework, and where the nature and purpose/objective of the (re) design of the SSbD system is identified. It needs to be kept in mind that this is an iterative process.

The strategies applied for dealing with data scarcity in the MCNM case study were to first rely on the extensive knowledge of the multidisciplinary team, followed by *in silico* approaches such as Quantitative Structure–Activity Relationships (QSARs), read-across and integrated approaches to testing and assessment (IATAs). Later in the innovation process, New Approach Methodologies (NAMs), including high throughput screening and *in vitro* assays are considered. For MCNMs, extra considerations are needed to account for (a) the complexity of physical and chemical composition; (b) the emerging properties driving the MCNM functionality; (c) the potential for MCNM components to transform with different kinetics, leading to complex exposure scenarios; (d) prioritization of grouping decisions related to material properties (what they are), fate/toxicokinetics (where they go) and the hazard mechanisms (what they do). From a sustainability perspective, ex-ante/prospective Life Cycle Assessments (LCAs) are used early in the innovation process, followed by full LCAs later in the innovation process.

### Reflections

Having innovation managers identify the relevant safety and sustainability issues early in the innovation process increases the speed and likelihood of bringing solutions to the market (“fail early, fail cheap” logic) and shape the successive trade-off decisions. The uptake of the framework can be accelerated by educating innovation managers and stimulating multidisciplinary collaborations. The biggest advantage of this framework is that for the innovation manager the number of potential candidates is reduced with increasing TRL, leaving only a small number of promising candidates going into the scale-up phase. The SMEs from the project have extended the application of

SSbD to other case studies by applying the lessons learned from this work. The biggest challenge is to have an assessment framework that is supported by data and tools to allow the identification of the nonviable options as quickly as possible within any innovation process.

## Discussion

This perspective proposes a conceptual framework on how to integrate IM tools with SSbD using LCT principles considering external (changing regulation, new business standard requirements, competitive environment, technological developments, societal views) and internal drivers (company-specific targets, company culture, corporate strategy, management capabilities) to achieve sustainable BMI and NPD. It attempted to answer some central yet uninvestigated topics in IM literature by offering unique multidisciplinary insights. Our work is directly relevant for both theory and practice as the design of innovative and sustainable BMs is crucial for commercializing novel ideas, technologies, and products. At the same time, our results are timely and relevant for the global policy agenda, which seeks to operationalize SSbD/Design for sustainability efforts in order to contribute to achieving sustainable development.

SSbD following LCT principles aims to support companies and innovation managers to anticipate safety and sustainability impacts and to address these without compromising the functionality of the material, chemical, product, and process. It supports decision-making in each step of the innovation process and allows innovators, manufacturers, organizations, industry, companies, and policymakers to identify opportunities for improvements and consequently pinpoint those life cycle segments with the most significant impact on safety and sustainability.

Our key technical result was the development of a canvas that illustrates the rules and guiding principles for the successful integration of SSbD following LCT principles in IMS. Our work reveals several insights on how this is done in practice and develops practical recommendations.

From a *context perspective*, SSbD has implications for management systems including assessing value chain safety and sustainability impacts in IM, in addition to external and internal issues and trends.

From a *leadership perspective*, senior management should adopt SSbD-supportive BMs and demonstrate leadership and commitment by establishing an innovation vision, strategy, and policy, including the necessary roles and responsibilities [64, 95–99]. In addition, SSbD and LCT should be part of the training of the new profession designation for IM to ensure managers are equipped with the right skills needed in innovation roles [100].

## Lessons learned

**A multidisciplinary team is needed to facilitate and accelerate safe and sustainable innovations**

From a management perspective, a transdisciplinary dialogue between material scientists, engineers, human and environmental

toxicologists, and professionals and experts in sustainability, recycling, and regulation, is needed to identify all safety and sustainability aspects, along each life cycle stage, while, at the same time, retaining product performance and economic efficiency. There are communication issues that need to be overcome to achieve an LCT approach and connect stakeholders in the lifecycle.

**SSbD is only possible when clear and simple communication of data on safety and other sustainability dimensions, both internally and externally, between different disciplines and stakeholders**

Any operational SSbD following LCT principles will require data relating to the different safety and sustainability dimensions early in the innovation process. The framework for SSbD criteria [81] outlines how to define the data needs for the safety and environmental dimensions of SSbD. Here, grouping and read-across framework [101] have been developed to support the efficiency and reliability of data assessment. Also, the eNanoMapper (<https://www.enanomapper.net/>) is a good example of the generation of findable, accessible, interoperable, and reusable (FAIR) data and common reporting templates.

**Different LCA tools require lots of data and expertise**

For sustainability to be taken into consideration from an early stage of the innovation process, the use of sustainability assessment tools (i.e., Environmental LCA (E-LCA), Social LCA (S-LCA), Lifecycle Costing (LCC)) should be applied to support the decision-making process. Indeed, these tools can be applied along the innovation process to compare alternative SSbD measures, to identify potential hotspots/red flags/issues (e.g., resource use during the production process), and hence identify measures to minimize the environmental footprint of a material [102]. E-LCA has been already applied in several sectors (chemical, food, energy, building, etc.) and several studies have been published on nanotechnologies [103, 104]. An E-LCA-based approach offers the advantage of providing a broader view of the environmental performance (i.e., on climate change, resource use, ecosystems, and biodiversity), allows to address potential impacts at each life cycle stage, and enables the investigation of different scenarios before a novel material or new technology is launched into the market. A recent screening-level approach that supports companies in making safe and sustainable design decisions at the early stages of innovation has been published [94].

**Including social and economic aspects in SSbD and IM is crucial**

JRC reports [80–83, 88] provide guidance on the economic and social impact of products. Social LCA has been developed with a list of relevant criteria and data needs. System boundaries need to be harmonized for economic and social LCA with the environmental LCA in their joint application [105]. Recently an easy-to-use, cost and time-efficient socioeconomic analysis was developed to guide users through their SSbD decision-making regarding newly developed advanced materials and nano-enabled products. The results of this initial screening can

be further used for more detailed analysis in the later stages of product development by performing a full social life cycle assessment (S-LCA) [106].

### Innovation managers need multidisciplinary training to apply SSbD

The profession designation for IM along with the development of a codified body of knowledge in IM (for instance, the ISO 56002 Guide Standard) is an opportunity to ensure managers are equipped with the right skills needed in innovation roles [100]. The IM profession designation should integrate SSbD and LCT in their curriculum to be able to support safe and sustainable product innovation. This multidisciplinary team needs to be able to work effectively together to co-create SSbD strategies.

### Summary of theoretical, managerial, and policy implications

Scholars investigating (sustainable) BMI have largely focused their attention on developing lengthy descriptions of sustainable BMI mainly from a strategic point of view, while little attention has been paid to “opening the black boxes” and engaging in a more exploratory focus. At a theoretical level, an important contribution of this study is the development of a grounded conceptual model that explains the mechanisms through which the innovative sustainability–IMS integration process is realized. We have identified various drivers that affect organizations’ innovation process and thus require a BM adaptation. These are driven by diverse external pressures from the organizational field (i.e., changing regulatory demands, new business standards, changes in the competitive environment and technology development, etc.) and internal (company-centric) such as company identity, culture, and capabilities. While these changes impose BM adaptation, once a disruptive element (such as incorporating SSbD) is included in the IMS, a new BMI emerges.

At the *practical level*, it fills an important knowledge gap by providing a sound framework to support sustainable innovations (see Discussion section for more detailed managerial implications).

At the *methodological level*, it advances technical, environmental, organization, and management sciences by bridging IM with safety and sustainability theories and practices exploring the unique case of MCNMs.

At the *policy level*, it contributes to the generation knowledge in support of the transition to a more sustainable future by providing a science-based conceptual framework that incorporates LC and SSbD thinking.

### Limitations and future research

We acknowledge the limitations of our study. First, stemming from the exploratory focus of the research, our findings reveal interesting results about the realization of sustainable BMI following an “idealized” innovation process following ISO standard frameworks, while in reality, many innovations do not follow such a strict routine. In addition, informed by a single

case, this research is able to capture one side of the sustainability-innovation dynamics. A future line of research that can complement these findings could be a replication study or multi-case study approach to further confirm and enhance the suggested framework (to ensure the uptake and utilization of the proposed framework, it will be tested in the newly started Horizon Europe SUNRISE project ([www.sunrise-horizon.eu](http://www.sunrise-horizon.eu))). Specifically, we acknowledge that a more comprehensive investigation of other various disruptive elements (such as the SSbD concept) can change the BMI process. Second, our canvas represents an integration of evidence from various literature including frameworks that are currently being tested and further revised. Future research should focus on incorporating such revisions and operationally testing the framework. Although such a research project may be difficult and timely to conduct due to problems of access, we foresee it as a promising research agenda, which can provide a more holistic view of how the business community experiences and implements innovative sustainability practices in their operations. Such a research agenda can make a significant contribution to organization and management theories by closing the gap between the world of practice and theory. A summary of future lines of research is provided in ► **Table 2**.

### Conclusions

Driven by the need for BMI and NPD to explore intersections with sustainable IM, this perspective introduces SSbD as a tool for environmentally sustainable innovations. A conceptual framework is proposed on how to integrate IMS with SSbD using LCT principles, without compromising product functionality or their technical and/or commercial viability. Challenges and possibilities of integrating SSbD and LCT to IMS are discussed given that SSbD is a central component of the CSS. Transitioning to “by-design” thinking means adopting a new way of working by integrating safety and sustainability as early as possible in the innovation process. This new way of working can be put into practice by integrating SSbD into IMSs.

For practitioners, integration of SSbD following LCT principles to IM requires:

From an *operational view*, prioritizing “by-design” thinking and integrating SSbD in IM practices. Supporting strategies include:

- Obtaining relevant data on safety and other sustainability dimensions at reasonable levels of resources.
- Development and use of integrated safety and sustainability databases.
- Better use of in silico approaches such as read-across.
- Development of tools integrating and weighing safety and sustainability.
- Further development of social and economic tools.

From a *planning and operations perspective*, embedding and applying safety and sustainability criteria within the IMS as early as possible in the innovation process.

From a *management perspective*:

- An SSbD and LCT Management System is needed that not only steers innovation but also aims toward safe and

► **Table 2** Future lines of research.

Field	Future research lines/questions
Management and organization science	<ul style="list-style-type: none"> <li>▪ Replication or multi-case study approach to enhance and validate the developed framework</li> <li>▪ What other disruptive elements affect the dynamics and implementation of sustainable BMI?</li> </ul>
Environmental and materials sciences	<ul style="list-style-type: none"> <li>▪ Testing the framework in real industrial case studies</li> </ul>

sustainable innovations that support the company's management portfolio by preventing regrettable substitutions, future liability, and brand image issues for companies. Safety and sustainability need to be accounted for in all life cycle phases of chemicals, materials, products, and processes in the IMS. The proposed conceptual framework shows how to integrate IM (particular planning and operations) to ensure that the design and development of chemicals, materials, products, and processes are safer and more sustainable for humans and the environment, and deliver the expected performance and value to stakeholders throughout the value chain.

- A reorganization of internal company infrastructure and process to facilitate a transdisciplinary dialogue between material scientists, engineers, human and environmental toxicologists, and professionals and experts in sustainability, recycling, and regulation, is needed to identify all safety and sustainability aspects, along each life cycle stage, while, at the same time, retaining product performance and economic efficiency.

From a *planning perspective*, a quality control system related to the IM is needed along with the development of an SSbD monitoring system.

From an *education and training perspective*, the training of innovation managers to SSbD thinking is essential as the recent professional designation for IM is an opportunity to have greater influence in organizational strategy and bringing SSbD closer to practical applicability to meet policy ambitions and toward the development of a future-proof innovation system.

## Methodology

### Conceptual background

This section explores the main discourse around sustainable BMI and introduces in detail the current SSbD knowledge base. This section also advocates the need for a sustainable NPD and BMI based on the presented SSbD case study that serves as a background to explain our resulting framework.

### (Sustainable) BMI

A recent movement in the literature is the emergence of sustainable BMI, which is described as a change in the way a firm operates to create positive impacts or to reduce negative consequences for the environment and society [65]. Sustainable BMI is characterized by (1) the incorporation of sustainable principles or goals into the existing value proposition, (2) the

extension of the value creation concept from economic value to shared value [107], (3) the consideration of nonfinancial interests in the decision-making process and (4) managers who act as sustainability leaders to promote a new mindset within the whole organization [108]. A key activity of sustainable BMI is transforming a standard value proposition toward a more sustainable value proposition that allows value creation by considering the needs of customers, shareholders, suppliers, partners, community, society, and the environment [109].

Recently, a new framework was proposed to include value proposition, value creation delivery and value capture [100]. For the value proposition, a new sustainable value is needed that supports a renewed purpose arising from an authentic motivation and passion within the firm's organizational culture. Within the customer's sphere, there is a need to create value and the essential resources, activities, and partnerships to deliver, including a guarantee for transparency and ethics [65]. It is important to note that there are four types of sustainable BMI: (1) sustainable start-ups creating a new organization with a sustainable BM; (2) sustainable BM transformation where the current BM is changed, resulting in a sustainable BM; (3) sustainable BM diversification where a sustainable BM is established without major changes in the existing BMs of the organization; and (4) sustainable BM acquisition where an additional, sustainable BM is identified, acquired, and integrated into the organization [14, 71]. Nine generic sustainable BM strategies (or "archetypes") have been developed by Bocken et al [69]. and Ritala et al. [110]: (1) maximize material and energy efficiency; (2) close resource loops; (3) substitute with renewables and natural processes; (4) deliver functionality rather than ownership; (5) adopt a stewardship role; (6) encourage sufficiency; (7) repurpose for society or the environment; (8) inclusive value creation; and (9) develop sustainable scale-up solutions.

Even though there is progress in the direction of sustainable BMI, a validated measurement scale for sustainable BMI is not yet available [111]. A 10-item scale has been conceptualized under sustainable value proportion innovation, sustainable value creation and innovation delivery, and sustainable value capture innovation [111]. Considering the great interest toward sustainable BMI, it is clear that the field is in its infancy, and more research is needed to better understand this phenomenon.

In summary, while previous literature has defined well that sustainable BMI emerges as a complex multistakeholder transformation process that often involves incorporating heterogeneous metrics based on various stakeholders' needs [112], the dynamics and the internal workings of this process have been

overlooked. Furthermore, Lozano [113] and Geissdoerfer et al [71]. identified a gap in the research around sustainable BMI design and implementation. Our work aims to answer this call and advance previous literature on this topic (i.e., 65) by offering a novel framework that explores the dynamics for integrating sustainability with traditional IMS and explains the forces that affect its realization.

## Policy landscape

In the policy arena, recent initiatives such as Design for Sustainability (D4S) [114] and the EC's publications on SSbD chemicals and materials [80–83, 88] provide knowledge in the field of SSbD. In particular SSbD forms a clear case for interlinking sustainable BMI, NPD, and IM.

After the publication of the CSS, the EC's Joint Research Centre (JRC) reviewed safety and sustainability dimensions, aspects, methods, indicators, and tools [89] and developed the SSbD framework [81]. The SSbD framework aims to (i) steer the innovation process toward the green and sustainable industrial transition; (ii) substitute or minimize the production and use of substances of concern, in line with, and beyond existing and upcoming regulatory obligations; and (iii) minimize the impact on health, climate, and the environment during sourcing, production, use, and end-of-life of chemicals, materials, and products. Successful implementation of SSbD will ensure the design and development of chemicals and materials that are safer and more sustainable for humans and the environment and deliver the expected performance and value to stakeholders throughout the value chain, thus determining the future of innovation. A JRC Technical Report on the first applications of the SSbD framework to case studies was published [82] along with methodological guidance [83]. After a testing period, SSbD criteria will be developed for the application and assessment of SSbD. Organizations such as the European Environment Agency, the Organisation for Economic Co-operation and Development Working Party on Manufactured Nanomaterials Safe(r) and Sustainable Innovation Approach (SSIA) Steering Group, the European Chemical Industry Council (Cefic), and the International Chemical Secretariat (ChemSec) are all contributing to bringing SSbD to practice [114–120].

The EC Recommendation [121] on establishing a European assessment framework for SSbD chemicals and materials describes key expected actions by industry including (i) using the SSbD framework when developing chemicals and materials; (ii) making FAIR data for SSbD assessment available; (iii) supporting the improvement of assessment methods, models, and tools; and (iv) supporting the development of professional training and educational curricula on skills related to safety and sustainability of chemicals and materials.

Based on the performed analysis, key issues were identified that relate to bringing SSbD to practical applicability and integrating safety and sustainability into the innovation process and one solution identified to achieve this goal is to embed SSbD into IMS, including BMI and NPD. While both theory and practice lack an in-depth clear explanation of how such

integration should be realized, we propose here a conceptual framework on how to integrate IMSs with SSbD using LCT principles considering external (changing regulation, new business standard requirements, competitive environment, technological developments, societal views), and internal drivers (company-specific targets, company culture, corporate strategy, management capabilities).

Our work bridges knowledge from several fields (environmental, material, management, and organization sciences), thus providing a unique contribution to the various fields. It supports both policy and practice by providing a sound framework to support sustainable innovations and the transition to a more sustainable future. From a methodological perspective, it advances technical, environmental, organization, and management literature by bridging IM with safety and sustainability theories and practices through an exploratory case study of MCNMs.

## Detailed methodology

This study incorporates a combination of varied methodological approaches employed by a multidisciplinary research team to convene into a single framework able to incorporate knowledge from environmental scientists, regulatory experts, social and sustainability scientists that can “speak” to various stakeholders. However, as our main target audience includes IM scholars and practitioners, the research agenda was predominantly led by the best practices to conduct exploratory studies in management and organization fields. In specific, (1) we used a case study approach to explain theoretically the process of integrating sustainability with IMS and understand the forces that affect its realization; (2) at a technical level following the EC Recommendation [121], a literature review was done to support an evidence-based approach to create the building blocks of a novel conceptual framework, supported with guidance, that assists users to integrate SSbD with traditional IM tools to achieve environmentally sustainable innovations.

## Case study

### Research setting

This research was informed by the unique opportunity to explore the work of an SME aiming at creating a novel MCNM designed to be used for food applications. The company's intention is that it should outperform conventional materials with the same application from a safety and sustainability point of view while maintaining functionality. This was a collaborative work in the framework of an ongoing research and innovation project, H2020 SUNSHINE, and involved a participant observation period of nearly 18 months granting the opportunity to employ data collection methods commonly used for ethnographic research [122]. Methodologically, these conditions grant that the research relies on the logic of theoretical sampling falling under the condition of presenting an opportunity for unusual research access [72]. Moreover, the situated analysis [123] adopted here provided a rich avenue to capture the micro-level dynamics of the sustainable BM implementation meta-routine [124], which gave insights not only from within but also across a number of routines constituting the meta-routine realization.



## Data collection

This study employed data collection methods commonly used for ethnographic research [122], such as participant observation, formal in-depth semistructured interviews, and informal conversations. The data collection was complemented using additional secondary sources, such as the company's publicly available data in the form of official documents available on the company website, press releases, and news articles.

## Data analysis

The data analysis was conducted in an iterative fashion consistent with an inductive, grounded theorizing approach [85, 125], that involved developing insights by analyzing the primary and secondary data, emerging observations, and existing literature in an iterative process [126]. The analysis followed the exemplar first- and second-order analysis approach [86], which involved (i) extracting recurrent concepts and themes through in vivo codes (i.e., assigning labels to a section of data, using a language taken from that section of the data) and descriptive coding (i.e., summarizing the basic topic of a passage of qualitative data) and grouping them into emergent categories (first-order analysis), followed by (ii) moving the analysis to a more theoretical level aimed at extracting the explanatory dimensions from the emerging patterns of data via seeking for relationships between and among first-order findings to facilitate assembling them into higher-order themes (second-order analysis).

## Literature review to support evidence-based approach

We followed the best practices for conducting systemic, evidence-based literature reviews [127] to obtain the building blocks for the development of the novel integrative framework. The main aspects of this approach, as summarized in [127] were: (i) development of clear and precise aims and objectives; (ii) preplanned methods; (iii) comprehensive search of all potentially relevant articles; (iv) use of explicit, reproducible criteria in the selection of articles for review; (v) an appraisal of the quality of the research and the strength of the findings; (vi) synthesis of individual studies using an explicit analytic framework; (vii) balanced, impartial and comprehensible presentation of the results. Following the method, a review protocol was designed to address the above-stated question, containing specific rules for inclusion/exclusion criteria, a quality assessment tool (based on expert judgment), and a common data extraction format.

Firstly, an overview of different IMSs and SSbD approaches was made, including those developed in previous EU-funded projects and in the recent framework developed in the context of implementing the EC CSS [81–83, 89–91, 102, 103, 116–118, 128–130]. An overview of regulatory and policy documents supporting some aspects of SSbD was made and presented in Supplemental Table 1. To support the application of SSbD with currently used International Organization for Standardization (ISO) standards, an overview of ISO documentary standards supportive of certain SSbD aspects (Supplemental Table 2) was made and the standards were classified according to the SSbD relevant elements contained therein as structure, process,

and content. In ISO terms, structure refers to the organizational elements that need to be in place to implement some aspects of SSbD (e.g., specific department or individual roles), including context and leadership. A “process” refers to the way to implement it (e.g., design or audits), including planning and support. Finally, “content” refers to criteria and other content-related aspects (e.g., LCT) used to measure progress and improvement. It can be seen from Supplemental Table 2 that ISO standards offer most guidance on process aspects, followed by content and, finally, structure.

Secondly, an inventory of “by-design” criteria and guidance from JRC reports [81–83, 89] and from the NanoReg2 EU Project [90, 91] (Supplemental Table 3) was made. This was generated from an overview of information needed for assessing safety and sustainability. For this, a literature review was performed with the search terms “safe-by-design”; “SSbD”; “safety tools”; “sustainability tools”; “safety and sustainability information needs and safe-by-design”; “SSbD information needs” [80, 81, 83, 89–91, 102, 103, 116–118, 128–134]. The first round of results was screened to identify relevant tools that can be applied for implementing SSbD from a safety and sustainability perspective and from a “by design” perspective in complex materials such as MCNMs. This resulted in a list of qualitative and quantitative safety and sustainability tools available to address the SSbD profile of chemicals and materials at different stages of the innovation phase (see Supplemental Table 4). A literature search was also performed for SSbD-supportive BMs such as “regenerative business models” and “circular economy business models”.

Thirdly, the ISO 56002:2019 [87] from the literature search was reviewed and used. It provides guidance for the establishment, implementation, maintenance, and continual improvement of an IMS for use in all established organizations and it contains key elements and principles for IM. The ISO Framework was integrated with safety, sustainability, functionality, and economic dimensions across the various life stages of a material, chemical, product, and process (Supplemental Tables 1–5) to develop the backbone of our conceptual framework. Our methods, analyses, and findings were in line with recent systematic reviews focusing on the SSbD construct [136].

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## Contributors' Statement

All authors contributed equally

## Conflict of Interest

The authors declare that they have no conflict of interest.

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