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To ensure planetary health and human well-being, innovations need to consider to be safe and sustainable-by-Design (SSbD) from the very beginning of the development of new chemicals, materials, products, and processes. In this context, our roadmap provides recommendations on how to bring SSbD to practical applicability and thereby contributes to the Sustainable Development Goals (SDGs). With the acceleration of the transition towards SSbD, a positive impact is expected in 'good health and wellbeing' (SDG3), 'water quality' (SDG6), 'decent work and economic growth' (SDG8), 'responsible consumption and production' (SDG12), 'climate action' (SDG13), 'life below water' (SDG14), and 'life on land' (SDG 15). Furthermore, through the specific agendas, our roadmap also contributes to 'quality education' (SDG4), 'Gender Equality' (SDG5), 'industry, innovation and infrastructure' (SDG9), and 'partnership for the goals' (SDG17).

Safe-and-Sustainable-by-Design Roadmap: Identifying Research, Competencies, and Knowledge Sharing Needs

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18 Abstract

The European Chemicals Strategy for Sustainability introduces the Safe-and-Sustainable-by-Design (SSbD) 19 20 concept. It goes beyond current regulatory compliance and aims to ensure the safety and sustainability 21 of novel chemicals, materials, products, and processes. It starts at early-innovation stages and follows the 22 chemicals and materials throughout their entire lifecycle. This perspective paper presents an SSbD 23 roadmap that explores current needs and gives recommendations for the practical operationalization of SSbD in industrial operations and processes. This roadmap was co-created including different SSbD 24 25 stakeholders and encompasses three interlinked agendas on (i) research needs, (ii) skills, competencies, 26 and education needs, and (iii) knowledge and information sharing needs. An overarching need is the 27 development of a common understanding of SSbD with clear definitions, terminology, and criteria. In 28 addition, SSbD operationalisation needs to be pragmatic and applied as early as possible in the innovation 29 process. From a research needs perspective, it is essential to integrate the different fields of innovation, safety, and sustainability. From a skills, competencies and education perspective, targeted training is 30 31 needed that balances the depth and breadth of SSbD required for a specific audience. These trainings 32 should not only convey hard/technical skills, but also soft/social skills to support more sustainability-33 oriented decisions on all levels. From a knowledge and information sharing perspective, a strategic plan 34 and a trusted environment are needed to support dialogue between all SSbD stakeholders while at the 35 same time protecting intellectual property (IP). The roadmap should help to coordinate planning for the implementation of SSbD at industrial, academic, policy, and regulatory level by defining actions and raise 36 37 strategic efforts.

39 **Keywords:** SSbD, Research needs, Skills and Competencies, Education and Training, Knowledge sharing

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40 Sustainability spotlight

41 To ensure planetary health and human well-being, innovations need to consider to be safe and 42 sustainable-by-Design (SSbD) from the very beginning of the development of new chemicals, materials, 43 products, and processes. In this context, our roadmap provides recommendations on how to bring SSbD to practical applicability and thereby contributes to the Sustainable Development Goals (SDGs). With the 44 45 acceleration of the transition towards SSbD, a positive impact is expected in 'good health and wellbeing' (SDG3), 'water quality' (SDG6), 'decent work and economic growth' (SDG8), 'responsible consumption and 46 47 production' (SDG12), 'climate action' (SDG13), 'life below water' (SDG14), and 'life on land' (SDG 15). 48 Furthermore, through the specific agendas, our roadmap also contributes to 'quality education' (SDG4), 49 'Gender Equality' (SDG5), 'industry, innovation and infrastructure' (SDG9), and 'partnership for the goals' 50 (SDG17).

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52 Introduction

We are currently operating outside the planetary boundaries where six out of the nine planetary 53 54 boundaries have been crossed.¹ With regards to the novel entities planetary boundary, urgent action is 55 recommended in order to keep pace with safety related assessments and monitoring in a world where there is an increasing rate of production and releases of larger volumes and higher numbers of novel 56 57 entities with diverse risk potentials.² In reaction to this, the European Chemicals Strategy for Sustainability, a core element under the European Green Deal, calls for a transition to safer and more 58 59 sustainable chemicals and materials to support the goals of zero-pollution, a toxic-free environment.³ To achieve these goals, it introduces the Safe and Sustainable-by-Design (SSbD) concept. Going beyond 60 current regulatory compliance, the SSbD concept promotes the (re)design of chemicals, materials, and 61 62 products, while comprehensively accounting for their manufacturing, use, and end-of-life management 63 so that these innovations do not adversely affect human and environmental health at any point in their lifecycles. At the same time, SSbD promotes circularity, aims to meet societal needs, and to contribute to 64 social and economic resilience. 65

66 The SSbD framework and methodological guidance published by the European Commission is a 67 holistic Research and Innovation (R&I) approach,^{4,5} but to achieve the operationalization of SSbD, further necessities, requirements and barriers need to be addressed and overcome. SSbD needs to 68 69 be translated from a policy ambition to a practical, operational and implementable concept in industrial 70 operations and processes, including training and education. The EU-funded IRISS project is developing an 71 SSbD roadmap in co-creation which is a collaborative process of creating new value together with external 72 experts and stakeholders, i.e. industry representatives, participants of webinars and scientific 73 conferences, and regulators.⁶ The roadmap encompasses three agendas addressing needs for (i) 74 research, (ii) skills, competencies and education, and (iii) knowledge and information sharing that 75 are strongly interlinked. While developing the roadmap agendas, the leading questions were: What is 76 needed to bring SSbD into practice? How can SSbD be implemented in practice? This perspective 77 presents the developed roadmap to support the SSbD implementation.

79 SSbD Supportive Roadmap

The main recommendations to support SSbD implementation are shown in Figure 1. The recommendations are an extension to the SSbD building blocks that have been identified in a previous work.⁷ These are *corporate and societal strategic needs, risk and sustainability governance, competencies,* and *tools, methods and data management*.



Figure 1 IRISS' SSbD roadmap comprising of three agenda: (i) research needs, (ii) skills, competencies and education needs, and
 (iii) knowledge and information sharing needs and giving recommendations for the operationalization of SSbD.

88 Agenda for Research Needs

Developing a common understanding of SSbD with clear definitions, terminology, and criteria and 89 90 aligning goals and procedures both in concept and in practice is a key need, particularly as different 91 fields of safety and sustainability need to be integrated. Harmonized methodologies and tools 92 considering design thinking and lifecycle thinking are required for a pragmatic and flexible SSbD 93 approach. This approach has to be in alignment with the innovation process in industry, needs to 94 leave room for sector-specific considerations, and needs to also be applicable to secondary 95 materials that are of constantly increasing importance within a Circular Economy. To achieve this, a 96 dialogue on the topics and challenges including all stakeholders is needed, also to achieve 97 acceptance on all levels. For this pragmatic and flexible approach, toxicological sciences need to be 98 revolutionized to be more open to accepting new methodologies that are required for SSbD. Also,

the complexity for the required SSbD assessments needs to be translated to simple guidelines thatinnovators can easily apply in practice. In this regard, a comparison of different SSbD approaches

101 has been performed and, recently, a practical guidance has been published.^{8,9}

102 Research efforts should be directed towards early-stage safety and sustainability (environmental, 103 social, economic) assessment, taking also into account political and legal aspects, and integrating 104 them with the functionality of chemicals, materials, products, and processes, and services. For the 105 same, engineering tools (e.g., digital twins) that allow the implementation of SSbD at the (re)design 106 stage, having the life cycle in mind at the same time, are necessary. In addition, the different safety 107 and sustainability approaches need to be streamlined and complementary. This is needed given that 108 safety assessment is weight-of-evidence-based while sustainability assessment is a comparative 109 approach.

For *early-stage human and environmental safety assessments*, optimization and use of predictive tools such as *in-silico* tools (QSARs, read-across, AI/Machine learning) along with the application of New Approach Methodologies (NAMs, including 3D-models, organoids, organ-on-a-chip, and virtual human platforms) are necessary.

For *early-stage sustainability assessments*, in addition to conventional lifecycle assessment (LCA), the development of ex-ante/predictive environmental and social lifecycle assessment (LCA and S-LCA) approaches taking into account functionality parameters and tailored to assess the impacts even at low Technology Readiness Level (TRL) and early-innovation phases are needed. An integration of S-LCA as part of the LCA methods would be preferable. Moreover, *further development of tools* is required for reliability, comparability, and cross-platform compatibility and accessibility of all relevant data.

Furthermore, integrative tools are required that combine lifecycle methods: LCA which assesses environmental impacts, S-LCA which assesses social impacts, lifecycle costing (LCC) which assesses economic impacts, along with safety assessment methods which assess hazard and risk impacts. In the same context, it is necessary to further refine and quantify criteria for material performance.

To account for different behaviours, sensitivities, and impacts, a *diversity-data ecosystem*, including gender, sex, and vulnerable groups-aggregated data should be built and used for the abovementioned assessments. *Ontologies* need to be developed to optimize the use of these data throughout the innovation process. This may be achieved by applying Findable, Accessible, Interoperable and Reusable (FAIR) principles¹⁰ and Transparency, Responsibility, User focus, Sustainability, and Technology (TRUST) principles¹¹ to produce data.

131 SSbD will involve trade-offs between the safety, environmental, social, and economic sustainability

domains. Thus, specific guidance on managing these trade-offs for SSbD innovation is necessary,

also to have reliable certification and to avoid SSbD becoming a tool for green or sustainabilitywashing.

The scientific community, industry, policy makers and regulators are needed to address current SSbD research needs. A sound *Risk and Sustainability Governance system* supporting SDGs, circularity, and sustainable chemistry along with *chemical, material, and product management* is needed. SSbD alignment to current and upcoming safety and sustainability regulations is vital to prepare industry for future compliance needs. Furthermore, it is critical to *harmonize safety and*

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sustainability policies and their compliance while considering reporting, transparency, and contribution to regulatory preparedness. This is only possible after the *establishment of an infrastructure to support harmonization and standardization* that relies on validated and standardized test guidelines for all safety and sustainability dimensions. Finally, the governance system needs to establish incentives for the application of SSbD, i.e., certification schemes, labels, etc. that attract consumers and aid in marketing and funding SSbD products and research, thereby valorising the SSbD approach.

Additionally, research is required on business models. *Alternative business models* that incorporate
 SSbD need to be developed and implemented that support sustainable growth, allocate resources
 to operationalize SSbD in practice (e.g., money, time, expertise), and consider services and non material alternatives (i.e. thinking beyond chemicals).

152 Agenda for Skills, Competences, and Education Needs

Education and training should be target-group-specific and balance the depth and breadth of SSbD 153 154 that is needed for the specific audience. Therefore, harmonized SSbD trainings for different SSbD 155 stakeholders need to be developed and conducted i.e., (re)design and LCA training for future 156 engineers, constant updating of science, engineering and environmental knowledge for policymakers, and sustainability education for consumers. University curricula with a harmonized 157 158 syllabus in SSbD are necessary to equip students and our future workforce with the prerequisite 159 multi-disciplinary skillset (along with 'soft' or 'social skills' for communication, collaboration, co-160 creation, entrepreneurship), and support a common understanding of SSbD. In addition, SSbD 161 aspects such as sustainability, circularity (including their limitations too), and hazard/risk awareness 162 should be integrated into existing curricula. Furthermore, extra-occupational programmes and 163 industrial (in-house) training courses are essential to guide and upskill current workers on the 164 implementation on SSbD and to merge theory and expertise. All trainings should aim for a combined learning with industry and authorities and align education in academia with the actual SSbD practice 165 in industry and vice versa. SSbD education should be further tailored to specific industries and value 166 167 chains to accommodate their respective safety and sustainability idiosyncrasies.

168 It is important that trainings also encourage an attitude and qualities that support more sustainable 169 lifestyles and business behaviours. This is particularly important not just for the general public that 170 would buy and consume future SSbD products, but also for leadership as the new mindset also 171 needs to be embedded in the corporate culture. Without anchoring aspects such as ethical, social, and environmental responsibility in corporate culture in alignment with the concept of extended 172 producer responsibility,¹² the mindset of the company itself and its employees will not change. 173 174 These types of skills and qualities are defined in the Inner Development Goals (IDGs) framework to 175 create a sustainable global society and includes for example critical thinking and co-creation skills.¹³

SSbD trainings should be easily accessible for everyone internationally and be specific mixture of several approaches and formats, for example online courses (e.g., massive open online courses (MOOCs)) and onsite trainings (e.g., summer schools or bootcamps). Accessibility is needed to support lifelong learning in alignment with the European Skills Agenda.¹⁴ Finally, all the SSbD training (including but not limited to MOOCs, Summer Schools, events, etc.) should be traceably compiled into a directory.

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183 Agenda for Knowledge and Information Sharing Needs

184 Successful SSbD implementation relies on communication, participation and co-creation in an 185 inclusive way. Design teams supporting multidisciplinary decision making need to have full access 186 to SSbD information and data (also meta data) of a new product from the entire value chain(s); this 187 also includes related ones e.g. as for resources needed. Therefore, collaborations among the 188 stakeholders along the entire value chain and across different value chain(s) are necessary to facilitate transparent and traceable data transfer for continuous SSbD assessments. This could be a 189 190 direct feedback loop from end-of-life to (re)design along the value chain, also including feedback on 191 data gaps. To realistically achieve such collaboration, a robust strategic plan for SSbD 192 communication and knowledge/data sharing needs to be defined. Such a strategic plan should 193 provide a general framework, but also include sector-specific considerations and take into account 194 the realities within the sector's supply chains. It should also include how best to reach and engage 195 with small and medium-sized enterprises (SMEs) within value chains and encourage data sharing for 196 downstream users. Also, a *platform enabling continuous exchanges* between industry, authorities, 197 academia, NGOs, and policy needs to be established and nurtured specifically for SSbD. Such a 198 platform should be a safe data-sharing space to protect intellectual property (IP; e.g. blockchain) 199 and act as a trusted environment that can be used not only for direct knowledge/data exchange, 200 but also to share experiences, best practices, lessons learned, and discuss success factors and 201 pitfalls. Furthermore, both SSbD Help Desks and Expertise Center at national and European level to 202 support the SSbD implementation are required.

204 Conclusions

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The development of a common understanding of SSbD with clear definitions, terminology, and criteria is an overarching need. In addition, SSbD operationalisation needs to be pragmatic and applied as early as possible in the innovation process.

From a research needs perspective, it is essential to develop and promote SSbD data management following FAIR and TRUST principles, to develop a sound risk and sustainability governance system to support harmonization and standardization of safety and sustainability methods and results, and to develop business models that are supportive of SSbD (corporate & societal needs).

For the skills, competencies and education needs, harmonized training material is needed, adapted to different audiences (industry, academia, policy makers, regulators). This targeted training needs to balance the depth and breadth of SSbD required for a specific audience by not only conveying hard/technical skills, but also soft/social skills to support more sustainable decisions on all levels.

For the knowledge and information sharing needs, a coordinated and easily accessible network and platform is urgently needed to bring all the different initiatives in innovation, safety, sustainability, and circularity together for the practical application of SSbD. For this, a strategic plan and a trusted environment are needed to support dialogue and co-creation between all SSbD actors while at the same time protecting IP.

To ensure planetary health and human well-being, and avoid any additional damage, innovations
 need to consider SSbD at very early stages of development of new chemicals, materials, products,
 and processes. It is acknowledged that a learning by doing approach is needed to translate the JRC

- 224 SSbD framework to business operations. Thus, this roadmap provides recommendations on how to
- bring SSbD to practical applicability with the synergistic efforts of industry, academia, NGOs, policy
 makers, regulators and all stakeholders along the life cycle.

228 Conflicts of interest

229 There are no conflicts to declare.

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No primary research results, software or code have been included and no new data were generated or analysed as part of this review.