View Article Online
View Journal

RSC Sustainability

Accepted Manuscript

This article can be cited before page numbers have been issued, to do this please use: C. Apel, A. Sudheshwar, K. Kümmerer, B. Nowack, K. Midander, E. Strömberg and L. G. Soeteman-Hernandez, *RSC Sustain.*, 2024, DOI: 10.1039/D4SU00310A.

ROYAL SOCIETY OF CHEMISTRY

View Article Online
DOI: 10.1039/D4SU00310A

Sustainability spotlight

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).

View Article Online
DOI: 10.1039/D4SU00310A

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

Christina Apel[a], Akshat Sudheshwar[b], Klaus Kümmerer[a,c], Bernd Nowack[b], Klara Midander[d], Emma Strömberg[d], and Lya G. Soeteman-Hernández[e,*]

[a] Leuphana University of Lüneburg, Institute of Sustainable Chemistry, Lüneburg, Germany
[b] Empa – Swiss Federal Laboratories for Materials Science and Technology, Technology and Society Laboratory, St. Gallen 9014, Switzerland
[c] International Sustainable Chemistry Collaborative Center ISC3, Bonn, Germany
[d] IVL Swedish Environmental Research Institute, Stockholm, Sweden
[e] National Institute for Public Health and the Environment (RIVM), Center for Safety of Substances and Products, Bilthoven, the Netherlands

* Corresponding author

View Article Online
DOI: 10.1039/D4SU00310A

Abstract

The European Chemicals Strategy for Sustainability introduces the Safe-and-Sustainable-by-Design (SSbD) concept. It goes beyond current regulatory compliance and aims to ensure the safety and sustainability of novel chemicals, materials, products, and processes. It starts at early-innovation stages and follows the chemicals and materials throughout their entire lifecycle. This perspective paper presents an SSbD 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 stakeholders and encompasses three interlinked agendas on (i) research needs, (ii) skills, competencies, and education needs, and (iii) knowledge and information sharing needs. An overarching need is the development of a common understanding of SSbD with clear definitions, terminology, and criteria. 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 integrate the different fields of innovation, safety, and sustainability. From a skills, competencies and education perspective, targeted training is needed that balances the depth and breadth of SSbD required for a specific audience. These trainings should not only convey hard/technical skills, but also soft/social skills to support more sustainability-oriented decisions on all levels. From a knowledge and information sharing perspective, a strategic plan and a trusted environment are needed to support dialogue between all SSbD stakeholders while at the 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 strategic efforts.

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

View Article Online
DOI: 10.1039/D4SU00310A

Sustainability spotlight

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).

View Article Online
DOI: 10.1039/D4SU00310A

Introduction

We are currently operating outside the planetary boundaries where six out of the nine planetary boundaries have been crossed.[1] With regards to the novel entities planetary boundary, urgent action is 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 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 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 current regulatory compliance, the SSbD concept promotes the (re)design of chemicals, materials, and products, while comprehensively accounting for their manufacturing, use, and end-of-life management 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 social and economic resilience.

The SSbD framework and methodological guidance published by the European Commission is a 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 be translated from a policy ambition to a practical, operational and implementable concept in industrial operations and processes, including training and education. The EU-funded IRISS project is developing an SSbD roadmap in co-creation which is a collaborative process of creating new value together with external experts and stakeholders, i.e. industry representatives, participants of webinars and scientific conferences, and regulators.[6] The roadmap encompasses three agendas addressing needs for (i) research, (ii) skills, competencies and education, and (iii) knowledge and information sharing that are strongly interlinked. While developing the roadmap agendas, the leading questions were: *What is needed to bring SSbD into practice? How can SSbD be implemented in practice?* This perspective presents the developed roadmap to support the SSbD implementation.

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*.

View Article Online
DOI: 10.1039/D4SU00310A

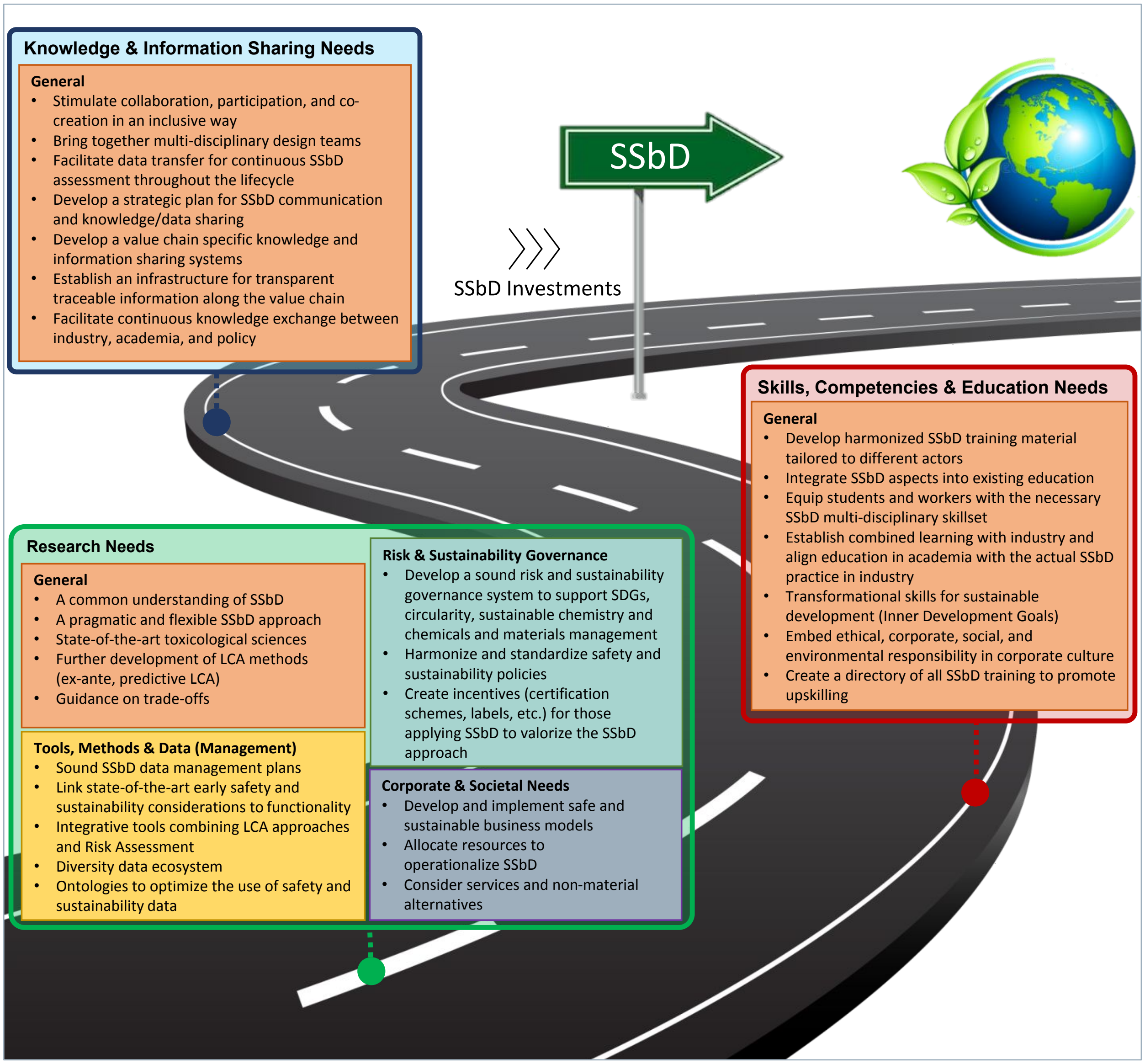

Figure 1 IRISS' SSbD roadmap comprising of three agenda: (i) research needs, (ii) skills, competencies and education needs, and (iii) knowledge and information sharing needs and giving recommendations for the operationalization of SSbD.

Agenda for Research Needs

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

View Article Online
DOI: 10.1039/D4SU00310A

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 that innovators can easily apply in practice. In this regard, a comparison of different SSbD approaches has been performed and, recently, a practical guidance has been published.[8,9]

Research efforts should be directed towards *early-stage safety and sustainability (environmental, social, economic)* assessment, taking also into account political and legal aspects, and *integrating them with the functionality* of chemicals, materials, products, and processes, and services. For the same, engineering tools (e.g., digital twins) that allow the implementation of SSbD at the (re)design stage, having the life cycle in mind at the same time, are necessary. In addition, the different safety and sustainability approaches need to be s*treamlined and complementary.* This is needed given that safety assessment is weight-of-evidence-based while sustainability assessment is a comparative 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 above-mentioned 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) principles[10] and Transparency, Responsibility, User focus, Sustainability, and Technology (TRUST) principles[11] to produce data.

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 sustainability washing.

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 c*hemical, 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*

View Article Online
DOI: 10.1039/D4SU00310A

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).

Agenda for Skills, Competences, and Education Needs

Education and training should be target-group-specific and balance the depth and breadth of SSbD that is needed for the specific audience. Therefore, *harmonized SSbD trainings for different SSbD stakeholders* need to be developed and conducted i.e., (re)design and LCA training for future engineers, constant updating of science, engineering and environmental knowledge for policymakers, and sustainability education for consumers. *University curricula* with a harmonized syllabus in SSbD are necessary to equip students and our future workforce with the prerequisite multi-disciplinary skillset (along with ‘soft’ or ‘social skills’ for communication, collaboration, co-creation, entrepreneurship), and support a common understanding of SSbD. In addition, SSbD aspects such as sustainability, circularity (including their limitations too), and hazard/risk awareness should be *integrated into existing curricula*. Furthermore, extra-occupational programmes and industrial (in-house) training courses are essential to guide and upskill current workers on the 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 in industry* and vice versa. SSbD education should be further *tailored to specific industries and value chains* to accommodate their respective safety and sustainability idiosyncrasies.

It is important that trainings also encourage an attitude and qualities that support more sustainable lifestyles and business behaviours. This is particularly important not just for the general public that would buy and consume future SSbD products, but also for leadership as the new mindset also 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 producer responsibility,[12] the mindset of the company itself and its employees will not change. These types of skills and qualities are defined in the Inner Development Goals (IDGs) framework to 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.

View Article Online
DOI: 10.1039/D4SU00310A

Agenda for Knowledge and Information Sharing Needs

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

Conclusions

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

View Article Online
DOI: 10.1039/D4SU00310A

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.

Conflicts of interest

There are no conflicts to declare.

Funding

IRISS receives funding from the European Union's Horizon Europe research and innovation program under grant agreement no 101058245. UK participants in Project IRISS are supported by UKRI grant 10038816. CH participants in Project IRISS receive funding from the Swiss State Secretariat for Education, Research and Innovation (SERI).

Acknowledgments

The authors would like to thank all contributors from the co-creation sessions, especially the IRISS WP3 team and the value chain contributors: Claudia Som (Empa, Switzerland), Elina Huttunen-Saarivirta and Anna Tenhunen-Lunkka (VTT, Finland), Johanna Scheper and Andreas Falk (BNN, Austria), Eugenia Valsami-Jones, Cris Rocca, and Maurice Brennan (University of Birmingham, UK), Amaya Igartua and Gemma Mendoza (TEKNIKER, Spain), Lutz Walter (Textile ETP, European Technology Platform for the Future of Textiles and Clothing, Belgium), Beatriz Ildefonso, David Storer (CLEPA, European Association of Automotive Suppliers, Belgium), Philippe Jacques, Marcel Meeus (EMIRI, Energy Materials Industrial Research Initiative, Belgium), Johan Breukelaar (EFCC, European Federation for Construction Chemicals, Belgium), Dmitri Petrovykh (INL, International Iberian Nanotechnology Laboratory, Portugal), Catherine Colin, Maudez Le Dantec (IPC, Industrial Technical Centre for Plastics and Composites, France), Chaima Elyahmadi, Annika Batel (IFRA, International Fragrance Association). The authors would also like to specially thank Anne Chloe Devic who is the coordinator of value chains in IRISS.

References

1 K. Richardson, W. Steffen, W. Lucht, J. Bendtsen, S. E. Cornell, J. F. Donges, M. Drüke, I. Fetzer, G. Bala, W. von Bloh, G. Feulner, S. Fiedler, D. Gerten, T. Gleeson, M. Hofmann, W. Huiskamp, M. Kummu, C. Mohan, D. Nogués-Bravo, … and J. Rockström, Earth beyond six of nine planetary boundaries, *Science Advances*, 2023, **9**, 1–16. DOI: 10.1126/sciadv.adh2458.

2 L. Persson, B. M. C. Almroth, C. D. Collins, S. Cornell, C. A. de Wit, M. L. Diamond, P. Fantke, M. Hassellöv, M. MacLeod, M. W. Ryberg, P. Søgaard Jørgensen, P. Villarrubia-Gómez, Z. Wang and M. Zwicky Hauschild, Outside the Safe Operating Space of the Planetary Boundary for Novel Entities, *Environmental Science & Technology*, 2022, **56**, 1510-1521. DOI: 10.1021/acs.est.1c04158.

3 European Commission, Directorate-General for Environment, Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment, *Publications Office of the European Union*, 2020,

View Article Online
DOI: 10.1039/D4SU00310A

https://op.europa.eu/en/publication-detail/-/publication/f815479a-0f01-11eb-bc07-01aa75ed71a1/language-en/format-PDF/source-341094563

4 C. Caldeira, L. Farcal, I. Garmendia Aguirre, L. Mancini, D. Tosches, A. Amelio, K. Rasmussen, H. Rauscher, J. Riego Sintes and S. Sala, Safe and sustainable by design chemicals and materials: framework for the definition of criteria and evaluation procedure for chemicals and materials, *Publications Office of the European Union*, 2022. DOI: 10.2760/404991.

5 E. Abbate, I. Garmendia Aguirre, G. Bracalente, L. Mancini, D. Tosches, K. Rasmussen, M. J. Bennett, H. Rauscher and S. Sala, Safe and Sustainable by Design chemicals and materials - Methodological Guidance, *Publications Office of the European Union*, 2024, Luxembourg, DOI: 10.2760/28450.

6 IRISS Project [Internet], IRISS – The International SSbD Network. https://iriss-ssbd.eu/ [Accessed July 2024].

7 L. G. Soeteman-Hernández, C. Apel, B. Nowack, A. Sudheshwar, C. Som, E. Huttunen-Saarivirta, A. Tenhunen-Lunkka, J. Scheper, A. Falk, E. Valsami-Jones, C. Rocca, M. Brennan, A. Igartua, G. Mendoza, K. Midander, E. Strömberg and K. Kümmerer, The Safe-and-Sustainable-by-Design concept: Innovating towards a more sustainable future, *Environmental Sustainability*, 2024, ***[Under Review].***

8 C. Apel, K. Kümmerer, A. Sudheshwar, B. Nowack, C. Som, C. Colin, L. Walter, J. Breukelaar, M. Meeus, B. Ildefonso, D. Petrovykh, C. Elyahmadi, E. Huttunen-Saarivirta, A. Dierckx, A. C. Devic, E. Valsami-Jones, M. Brennan, C. Rocca, J. Scheper, … and L. G. Soeteman-Hernández, Safe-and-sustainable-by-design: State of the art approaches and lessons learned from value chain perspectives. *Current Opinion in Green and Sustainable Chemistry*, 2022, **45**, 100876. DOI: 10.1016/j.cogsc.2023.100876.

9 Cefic, Safe and Sustainable-by-Design: A Guidance to unleash the transformative power of innovation, Cefic Report, 2024, https://cefic.org/app/uploads/2024/03/Safe-and-Sustainable-by-Design-a-guidance-to-unleash-the-transformative-power-of-innovation.pdf [Accessed July 2024].

10 M. D. Wilkinson, M. Dumontier, I. J. Aalbersberg, G. Appleton, M. Axton, A. Baak, N. Blomberg, J.-W. Boiten, L. B. da Silva Santos, P. E. Bourne, J. Bouwman, A. J. Brookes, T. Clark, M. Crosas, I. Dillo, O. Dumon, S. Edmunds, C. T. Evelo, R. Finkers, … and B. Mons, The FAIR Guiding Principles for scientific data management and stewardship, *Scientific Data*, 2016, **3**, 160018. DOI: 10.1038/sdata.2016.18.

11 D. Lin, J. Crabtree, I. Dillo, R. R. Downs, R. Edmunds, D. Giaretta, M. De Giusti, H. L'Hours, W. Hugo, R. Jenkyns, V. Khodiyar, M. E. Martone, M. Mokrane, V. Navale, J. Petters, B. Sierman, D. V. Sokolova, M. Stockhause and J. Westbrook. The TRUST Principles for digital repositories, *Scientific Data*, 2020, **7**, 144. DOI: 10.1038/s41597-020-0486-7.

12 European Union, Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE), *Official Journal of the European Union*, 2012, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012L0019-20180704.

13 Inner Development Goals [Internet], Inner Development Goals - Transformational Skills for Sustainable Development, https://innerdevelopmentgoals.org/ [Accessed March 2024].

14 European Commission, Directorate-General for Employment, Social Affairs and Inclusion, European Skills Agenda for sustainable competiveness, social fairness and resilience, *Official Journal of the European Union,* 2020. https://op.europa.eu/en/publication-detail/-/publication/2f32539f-bc34-11ea-811c-01aa75ed71a1/language-en/format-PDF/source-341096671.

View Article Online
DOI: 10.1039/D4SU00310A

Data Availability Statement

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