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ARTICLE

The "Safe and Sustainable by Design" Concept – A Regulatory Approach for a More Sustainable Circular Economy in the European Union?

Leonie Reins[1†] and Julia Wijns[2,3†]

[1]Erasmus University Rotterdam Erasmus School of Law, Rotterdam, Netherlands, [2]KU Leuven Faculty of Law, Leuven, Belgium and [3]3BIO, Ghent, Belgium

Corresponding author: Leonie Reins; Email: reins@law.eur.nl

Abstract

The creation of a more sustainable economy is one of the main targets of the European Green Deal and the new Circular Economy Action Plan. Technological innovation is needed, among other things, to render materials, products, and production processes more sustainable. Given the goals of the European Green Deal, the regulatory concept of "Safe and Sustainable by Design" is increasingly receiving attention. The concept is (arguably) a precautionary and preventative measure that is implemented at the early stages of the design of a technology. Therefore, it is often described as a tool for lowering the risks that follow from efforts to create a more circular economy. The concept was included in the European Chemicals Strategy of the European Commission. The aim of the strategy is to accelerate progress towards the discovery of more sustainable chemicals and towards a toxicity-free environment. In this paper, we will explore the benefits and disadvantages of integrating the "Safe and Sustainable by Design" concept into the regulation of technology. As a form of regulation by technology, this concept can enhance sustainability. We will first describe the origins of the concept and its current use. Then, we will analyse its implications for the circular economy.

Keywords: safety; sustainability; technology regulation

I. Introduction

Sustainability has been a popular topic for some time. Its prominence has grown with that of notions such as climate change and environmental degradation.[1] Interest in sustainability has also intensified in consequence of growing awareness of global pollution problems, which affect air, land, and soil, as well as freshwater, marine, and coastal waters.[2] In order to meet the challenges of climate change, the EU adopted the

† Both authors contributed equally to this work and thus share co-first authorship.

1 C A Ruggerio, "Sustainability and Sustainable Development: A Review of Principles and Definitions" (2021) 786 Science Total Environment 147481.

2 M MacLeod and Others, "The Global Threat from Plastic Pollution" (2021) 373(6550) Science 61–65; as well as S B Kurniawana and Others, "Current State of Marine Plastic Pollution and Its Technology for More Eminent Evidence: A Review" (2021) 278(123537) Journal of Cleaner Production; M U Ali and Others, "A Systematic Review on Global Pollution Status of Particulate Matter-Associated Potential Toxic Elements and Health Perspectives in Urban Environment" (2019) 41 Environmental Geochemistry and Health 1131–1162; United Nations Environment Programme (UNEP), "Towards a Pollution-Free Planet" (*Background report* 2017) available

European Green Deal (EGD).[3] The aim of that programme is to ensure that Europe becomes the first climate-neutral continent. The Green Deal plays a crucial role in the Commission's plan to implement the United Nations' 2030 Agenda and the Sustainable Development Goals (SDGs).[4] The EGD is intended to transform the EU economy by modernising it and by improving its resource efficiency and competitiveness.[5] The main objectives of the EGD are to reduce emissions of greenhouse gases to net zero by 2050, to sever the link between economic growth and the use of fossil fuels and other natural resources, and to ensure that no person or place is left behind in the pursuit of climate neutrality.[6] One of the ambitions of the EGD is to achieve zero pollution by 2050.[7] This ambition was set out in the EU Action Plan "Towards Zero Pollution for Air, Water and Soil",[8] which contains targets that should be met by 2030.[9] Furthermore, in light of the EGD, the EU adopted a new Circular Economy Action Plan[10] which aims to create a cleaner and more competitive Europe by transitioning to a greener and more circular economy. A circular economy entails the development of sustainable products and the reduction of waste[11]; therefore, those who strive to create it must address the problem of waste creation.

Innovation is crucial to efforts to create a circular economy in the EU and to develop more sustainable products with longer lifecycles. Innovation in the development of materials, products, and production processes is of paramount importance to those ends.[12] Innovative technologies that have the potential to aid this transition are emerging. They include compostable waste, renewable feedstocks, and renewable chemicals.[13] However, the technologies in question pose risks. Those risks vary across technologies, but they mostly concern human and animal safety, as well as the environment.

This contribution explores the potential of "Safe and Sustainable by Design" (SSbD), a novel regulatory approach to enhancing safety and sustainability and, therefore, to strengthening the EU circular economy. We propose that the SSbD concept could serve as a form of "regulation by design". The concept promotes the consideration of safety and sustainability in the early phases of the design of technology. Safety and sustainability could, in that case, be perceived as norms. We begin by describing the theoretical background to the regulation of emerging technologies and its challenges. Thereafter, the exposition turns to the origins of the SSbD concept. Then, we explore its content by tracing its development across EU policy and legislative documents, specifically the EU 2020 Chemicals Strategy.[14] Lastly, we discuss the benefits of SSbD and the challenges that it poses in order to explore its potential as a regulatory tool. On the whole, our purpose is to identify the ways in which the SSbD concept can (and cannot) contribute to the

at <http://wedocs.unep.org/bitstream/handle/20.500.11822/21800/UNEA_towardspollution_long%20version_Web.pdf?sequence=1&isAllowed=y> (accessed 21 February 2024).

[3] Commission, "A European Green Deal" (Communication) COM (2019) 640 final.

[4] Ibid., p 3.

[5] Ibid., pp 6–9.

[6] Ibid., p 4.

[7] Ibid., p 14.

[8] Commission, "Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil'" (Communication) COM (2021) 400 final.

[9] Ibid.

[10] Commission, "A New Circular Economy Action Plan For a cleaner and more competitive Europe" (Communication) COM (2020) 98 final.

[11] Ibid.

[12] C Schilling and S Weiss, "A Roadmap for Industry to Harness Biotechnology for a More Circular Economy" (2021) 60 Nature Biotechnology 9–11.

[13] Ibid.

[14] Commission, "Chemicals Strategy for Sustainability, Towards a Toxic-Free Environment" (Communication) COM (2020) 667 final.

regulation of emerging technologies and to the creation of a more sustainable and circular economy in the EU.

II. Theoretical framework – the regulation of innovation

In the regulation of technology, it is important to avoid a state of affairs in which every technology is regulated separately, a tendency that is also known as "the law of the horse".[15] Different technologies evidently have different characteristics, and one would be forgiven for assuming that all variations in characteristics call for novel regulations. If one considers the law of the horse, it becomes apparent that regulation should not target the specificities of one technology but a wide range of technologies. Otherwise, every emerging technology would call for a tailored regulatory response. It is important to examine the manner in which technologies are regulated when they emerge.[16] In this context, the term "regulation" should be interpreted in line with Black's definition: "*regulation is the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering and behaviour modification*".[17] It is clear from this definition, to which the exposition will return later, that the scope of the term is not limited to legislation – regulation has different modalities.[18]

The regulation of technologies entails certain challenges, including the Collingridge Dilemma, the pacing problem, the challenge of regulatory connection, the challenge of legitimacy, and regulatory capture.[19] The Collingridge Dilemma has to do with the expectation that regulators will act quickly when new technologies emerge.[20] However, little is known about technologies when they first appear. Consequently, regulators face uncertainty – the theoretical potential of the technology may be vast despite little being known about its impact or the harm that it may cause.[21] Relatedly, the pacing problem, which was first described by Dowes, refers to the temporal gap between regulations and the emergence of technologies, which makes it hard for the former to anticipate the latter.[22] The third regulatory challenge that concerns us here is that of regulatory connection, which was first described by Brownsword.[23] There is a disconnection between new technologies and laws. That disconnection casts the sustainability of regulation into doubt.[24] The fourth regulatory challenge that we examine has to do with legitimacy –

[15] L Lessig, "The Law of the Horse: What Cyberlaw Might Teach" (1999) 113(2) Harvard Law Review 501–549.

[16] R Leenes, "Regulating New Technologies in Times of Change" in L Reins (ed.), *Regulating New Technologies in Uncertain Times* (Heidelberg, T.M.C. Asser Press 2019) 3–17.

[17] J Black, "Critical Reflections on Regulation" (2002) Centre for Analysis of Risk and Regulation at the London School of Economics and Political Science, available at <http://eprints.lse.ac.uk/35985/1/Disspaper4-1.pdf> (accessed 21 February 2024).

[18] L Lessig, *Code: Version 2.0* (New York, Basic Books 2006).

[19] L B Moses "How to Think About Law, Regulation, and Technology: Problems with 'Technology' as a Regulatory Target" (2013) 5(1) Law, Innovation and Technology 1–20; B Morgan and K Yeung, "Theories of Regulation" in B Morgan and K Yeung (eds), *An Introduction to Law and Regulation* (Cambridge, Cambridge University Press 2007) 16–78.

[20] The Collingridge Dilemma refers to the uncertainty paradox faced by regulators when new technologies emerge, due to a knowledge gap on the implications of the technology. See in that regard: D Collingridge, *The Social Control of Technology* (New York, London, St. Martin's Press 1980).

[21] Ibid.

[22] L Downes, *The Laws of Disruption: Harnessing the New Forces that Govern Life and Business in the Digital Age* (New York, Basic Books 2009).

[23] R Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford, Oxford University Press 2008) 160–184.

[24] Ibid.

according to Brownsword, the deficient knowledge of regulators means that their responses to new technologies are likely to lack it.[25] Legitimacy depends not so much on outcomes but on the democratic credentials of decision makers.[26] Therefore, the position of the regulator is important for its legitimacy. The last regulatory challenge that we cover is regulatory capture, a concept that was first introduced by Stigler.[27] Regulatory capture occurs when the relationship between regulators and regulatees becomes so intimate that the interests of the latter come to be advanced at the expense of the common good.[28] In other words, capture furthers the interests of small groups in society.[29]

It was against this background that Wiener discussed the challenges and opportunities for the regulation of technology in the complex and rapidly changing technological landscape of the present era.[30] Wiener argued that traditional regulatory approaches, which focus on static standards and command-and-control mechanisms, may not be adequate in addressing the dynamic and uncertain risks and benefits of emerging technologies.[31] This view of Wiener's can be linked to the different approaches towards regulation that Black described. The traditional approach to regulation is rules based. Rules-based regulation, as its name implies, contains detailed prescriptions. One of the common disadvantages of rules-based regulation is its inflexibility, which gives rise to the regulatory challenges that were described in the preceding paragraph. In contrast to rules-based regulation, principles-based regulation relies on broadly defined principles. The properties of those principles include a broader scope of application and enhanced flexibility, relative to rules-based regulation.[32] Wiener, along with Brownsword[33] and other scholars, advocated the adoption of a more flexible and adaptive regulatory framework that utilises a range of regulatory tools and mechanisms, such as market-based incentives, participatory governance, and self-regulation by industry.[34] He also highlighted the potential of using technology to enhance the effectiveness of regulation, for instance through the use of digital platforms for information sharing, monitoring, and enforcement.[35] This type of solution is also known as "techno-regulation" or "regulation by technology".[36] According to Leenes, the term "regulation of technology" refers to traditional forms of regulation that focus on controlling the development, deployment, and use of technology through laws, rules, and standards. The aim of this approach is to set boundaries so as to ensure that technology operates in accord with accepted norms and values, including individual rights, and that it protects public safety.[37] In contrast, the term "regulation by technology" refers to a relatively new approach that relies on the use of

[25] Ibid., p 127.

[26] D Galligan, "Citizens' Rights and Participation in the Regulation of Biotechnology" in F Francioni (ed.), *Biotechnologies and International Human Rights* (Oxford, Hart Publishing 2007) p 342.

[27] G J Stigler, "The Theory of Economic Regulation" (1971) 2(1) Bell Journal of Economics and Management Science 3–21.

[28] Supra, note 20, pp 16–78.

[29] Supra, note 17.

[30] J B Wiener, "The Regulation of Technology, and the Technology of Regulation" (2004) 26(2–3) Technology in Society 483–500.

[31] Ibid.

[32] J Black, "Making a Success of Principles-Based Regulation" (2007) 1(3) Law and Financial Markets Review 191–206.

[33] Supra, note 24.

[34] Supra, note 31.

[35] Ibid.

[36] R Leenes and Others, "Regulatory Challenges of Robotics: Some Guidelines for Addressing Legal and Ethical Issues" (2017) 9(1) Law, Innovation and Technology 1–44; R Leenes, "Framing Techno-Regulation: An Exploration of State and Non-State Regulation by Technology" (2011) 5(2) Legisprudence pp 143–169.

[37] Ibid.

technology to regulate and monitor behaviour.[38] Regulation by technology can be defined as "*the intentional influencing of individual behaviour by building norms into technological devices*".[39] Leenes argued that, while the regulation of technology remains important, regulation by technology has the potential to be more effective and efficient in managing the risks and opportunities that are associated with technological innovation.[40] It has also been argued that technology is not a suitable target for regulation because it evolves constantly.[41] Karin Yeung discussed "regulation by design". This approach seeks to advance collective goals through the design of technology. According to Yeung, regulation by design involves the intentional shaping of the built environment or technological systems.[42] Yeung argued that regulation by design can be a powerful tool because it can influence behaviour without any explicit legal or regulatory interventions being necessary.[43] Design-based control mechanisms are extremely powerful because they operate *ex ante* rather than *ex post* and because they are self-executing, that is, because they do not demand human attention and interaction.[44]

III. Safe and sustainable by design: origins of the concept

As mentioned previously, SSbD was recently introduced into the Chemicals Strategy. SSbD might address certain regulatory challenges that arise when new technologies emerge. In this section, we examine the origins of SSbD and its current form. SSbD is an approach that can be explained most clearly by focusing on the two concepts from which it originated, namely "Safe by design" and "Sustainable by design".

1. Safe by design

"Safe by design" is an approach that is used to implement safety measures in the early stages of design and is also known as "safety by design" or "design for safety".[45] It is an instance of regulation "by technology" as classified above.[46] The focus on the early identification of risk means that the approach in question spans the entire lifecycle of a

[38] B van den Berg and R Leenes, "Abort, Retry, Fail: Scoping Techno-Regulation and Other Techno-Effects" in M Hildebrandt and J Gaakeer (eds), *Human Law and Computer Law: Comparative Perspectives* (Dordrecht, Heidelberg, Springer 2013) pp 67–87.

[39] Ibid.

[40] Supra, note 37, pp 143–169.

[41] L B Moses "How to Think About Law, Regulation, and Technology: Problems with 'Technology' as a Regulatory Target" (2013) 5(1) Law, Innovation and Technology 1–20.

[42] K Yeung, "Towards an Understanding of Regulation by Design" in R Brownsword and K Yeung (eds), *Regulating Technologies – Legal Futures, Regulatory Frames and Technological Fixes* (Oxford, Hart Publishing 2008) pp 79–107.

[43] Ibid.

[44] Supra, note 37, 143–169; K Yeung, "Are Design-Based Regulatory Instruments Legitimate?" (2014) King's Law Journal 27.

[45] P van Gelder and Others, "Safe-by-Design in Engineering: An Overview and Comparative Analysis of Engineering Disciplines" (2021) 18(12) International Journal of Environmental Research and Public Health 6329.

[46] Van Cleynenbreugel for example defines regulation by design as "A pro-active form of compliance through regulation, the law basically requires businesses to design or redesign their technologies so that certain **values** or **objectives** are respected by the technology itself." Van Cleynenbreugel, "EU By-Design Regulation in the Algorithmic Society" in Micklitz and Others (eds), *Constitutional Challenges in the Algorithmic Society* (Cambridge University Press 2021); Comparing this definition to the one of regulation by technology as adopted after van den Berg and Leenes, as adopted in this paper, the key differences seem to be that Van Cleynenbreugel focusses on the regulation of business and van den Berg and Leenes focus more broadly on the regulation of behavior, without limiting to a particular addressee. Further Van Cleynenbreugel focuses on values instead of norms, however the underlying notion of regulating through the implementation of values/norms into technology is similar.

product, from research and development to disposal.[47] "Safe by design" thus focuses on the stage at which products and processes are designed. It is precautionary and preventative because it entails the minimisation of hazards through prior assessments of potential risks – safeguards are implemented early.[48] The rationale of "Safe by design" is to develop materials, products, and processes in a manner that minimises risks to the environment and to human and animal safety.

"Safe by design" has a long history. The National Safety Council is thought to have been the first organisation to have suggested that it be implemented into U.S. policy, as reflected in a 1955 manual that the Council published.[49] In the U.S., the introduction of safety measures into the early stages of design is known as "Prevention through Design" (PtD),[50] which is thought to revolve around the "designing out" of risks.[51] Historically, the deficient design of machines and constructions in the U.S. was associated with numerous casualties, and worker safety in the country was considered to be poor. It was for this reason that the National Safety Council introduced PtD to the construction sector.[52] Nowadays, the influence of "Safe by design" is in evidence in design choices in quotidian objects. For example, kettles turn off automatically when the water in them has reached boiling point,[53] fuses are placed in plugs in order to avoid overheating and fires,[54] and the doors of elevators open automatically when there is an object between them.[55] These examples mainly pertain to safety measures in consumer products or construction. However, similar measures are nowadays employed in a wide range of industries, such as aviation, construction, and chemical engineering – in all of those cases, enhancing safety in the design of the product or process minimises potential hazards.[56] Sanchéz-Jiménez *et al.* studied the implementation of the "Safe by design" concept in nanotechnology. They argued that "Safe by design" is implemented in many sectors and that, even though these different sectors face different challenges, it is important to explore commonalities in order to stimulate the dissemination of the approach.[57] At present, the sector specificity of "Safe by design" applications makes defining its core principles a point of difficulty.

Although no general "Safe by design" principles have been proposed in the literature, several principles have been articulated in the context of various industrial sectors. The Australian government, for instance, has formulated three "Safe by design" principles,

47 OECD, "Moving Towards a Safe(r) Innovation Approach (SIA) for More Sustainable Nanomaterials and Nano-enabled Products, Series on the Safety of Manufactured Nanomaterials" (2020) available at <https://one.oecd.org/document/env/jm/mono(2020)36/REV1/en/pdf> (accessed 21 February 2024) 15.

48 Ibid.

49 I van de Poel and Z Robaey, "Safe-by-Design: From Safety to Responsibility" (2017) 11(3) Nanoethics 297–306; and National Safety Council, *Accident Prevention Manual for Industrial Operations* (Chicago, Illinois, USA, 3rd edition 1955).

50 National Safety Council, *Accident Prevention Manual for Industrial Operations* (Chicago USA, 3rd edition 1955).

51 P Schulte and Others, "National Prevention through Design (PtD) Initiative" (2008) 39(2) Journal of Safety Research 115–121.

52 Supra, note 51.

53 H M Ayu and D Rosdi, "Design and Analysis for the Improvement of Electric Kettle Performance" (2008) UMP Institutional Repository available at <https://core.ac.uk/download/159177774.pdf> (accessed 21 February 2024).

54 R Barrass, "Using Electricity" in R Barrass *Mastering Science* (Macmillan Master Series 1991) 311–323.

55 A Shrestha, "Safety Considerations for the Design of Modern Elevator Systems" (2019). Honors Theses available at <https://egrove.olemiss.edu/hon_thesis/1195> (accessed 24 January 2024) p 1195.

56 EU Commission, "Training and Workshop 19 March 2021 - Safe and Sustainable-by-Design criteria for chemicals, materials and products – First Stakeholders workshop" (2021) available at <https://environment.ec.europa.eu/events/safe-and-sustainable-design-criteria-chemicals-materials-and-products-first-stakeholders-workshop-2021-03-19_en> (accessed 21 February 2024).

57 A S Jiménez and Others, "Safe(r) by Design Implementation in the Nanotechnology Industry" (2020) 20 NanoImpact 100267.

namely "service provider responsibility", "user empowerment and autonomy", and "transparency and accountability".[58] The core principles, as we understand them, revolve around designing safer materials, products, processes, and services while remaining mindful of the need for precaution and prevention and stimulating innovation.

Recently, the "Safe by design" concept has been criticised in the literature for being too narrow in its scope – it only focuses on safety.[59] According to recent studies on "Safe by design" in nanomaterials, sustainability should also be considered.[60] An approach that combines safety and sustainability could prompt designers to reduce risks early and to direct their attention to the entire lifecycle of a product.[61] The implementation of "Safe by design" is complex because the designers must assess not only ordinary hazards but also matters such as energy use and waste creation, as well as the expenses that the measures which they propose would entail.[62] This point emerges readily from a recent study in which the "Safe by design" concept was blended into other approaches, one of which was sustainability. It transpired that an exclusive focus on risk and exposure assessments is likely to prove counterproductive – sustainability and economic assessments should also be conducted in order to account for the complexity of design.[63] Likewise, in the Netherlands, "Safe by design" has been studied in relation to the circular economy and in the context of biocomposites.[64] The report from one Dutch study exemplifies the connection between "Safe by design" and the circular economy, in that it reflects careful consideration of sustainability and product lifecycles throughout the design process.[65]

2. Sustainable by design

"Sustainable by design" is another approach that focuses on early-stage action. It entails taking sustainable principles into account during the design of products or processes.[66] To understand the implications of "Sustainable by design", one must first adopt a working definition of sustainability. To the present ends, according to the UN Glossary, sustainability is defined as "*In ecology: Economic development that takes full account of the environmental consequences of economic activity and is based on the use of resources that can be replaced or renewed and therefore are not depleted*".[67] Relatedly, development is sustainable

[58] Australian Government, "E-safety Commissioner, 'Safety by Design – Principles and Background'" (2021) available at <https://www.esafety.gov.au/industry/safety-by-design/principles-and-background> (accessed 20 March 2023)). In nanotechnology, Morose proposed five principles, namely "size, surface and structure", "alternative materials", "functionalisation", "encapsulation", and "quantity reduction". WorkSafe New Zealand introduced five principles for the design of structures, plants, or substances, namely "a risk management approach", "lifecycle", "good documentation and communication", "frequent monitoring and review", and "a capable team", see further G Morose, "The 5 Principles of 'Design for Safer Nanotechnology'" (2010) 18(3) Journal of Cleaner Production 285–289.

[59] B Salieri and Others, "Integrative Approach in a Safe by Design Context Combining Risk, Life Cycle and Socio-Economic Assessment for Safer and Sustainable Nanomaterials" (2021) 23 NanoImpact 100335.

[60] Ibid.

[61] Ibid; OECD, "Sustainability and Safe and Sustainable by Design: Working Descriptions for the Safer Innovation Approach" (OECD Series on the Safety of Manufactured Nanomaterials No. 105., 2022) available at <https://one.oecd.org/document/ENV/CBC/MONO(2022)30/en/pdf> (accessed 21 February 2024).

[62] Supra, note 58.

[63] Ibid.

[64] A Kallergi and L Asvelt, "Biocomposite: Safe-by-Design for the circular economy" (TU Delft, assigned by the Dutch Ministry of Infrastructure and Water management, 2021) available at <https://www.rijksoverheid.nl/documenten/rapporten/2021/10/28/biocomposite-safe-by-design-for-the-circular-economy> (accessed 21 February 2024).

[65] Ibid.

[66] S Walker, *Sustainable by Design – Explorations in Theory and Practice* (1st edn, London, Routlegde 2006).

[67] UN Glossary, "Sustainability" available at <https://unterm.un.org/unterm2/en/view/2157aa72-e958-45b8-968b-97906e176f0d> (accessed 21 February 2024).

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when it does not jeopardise the ability of future generations to meet their needs.[68] Sustainability is often divided into three notions that represent its main dimensions: economic viability, ecological protection, and social equity.[69] Our contribution mainly focuses on the ecological dimension of the concept. A direct link can be observed between sustainability, sustainable development, and the ambitions of the EU that were described previously, which are enshrined in the EGD and the Circular Economy Action Plan. The targets that are set out in the EGD and the EU Circular Economy Action Plan were both established with a view to contributing to the SDGs.[70]

Sustainability is key to maintaining a liveable planet for current and future generations.[71] In the literature, "Sustainable by design" has not been discussed extensively from a sustainability perspective. Nevertheless, the integration of sustainability into the development of products and processes can be observed in several sectors, such as construction, architecture,[72] and the production of fabrics.[73] In the book *Sustainable by Design*, Walker addressed the background of sustainable development and sustainability and its relationship to "Sustainable by design". According to Walker, conventional businesses and development norms and values are often incompatible with sustainable development.[74] Therefore, it would be desirable to integrate the principles of sustainability into the modern economy, which would require a shift in perspective.[75] Walker suggested that it could be useful to adopt an approach whereby products are designed and produced with sustainable-development principles in mind.[76] At present, "Sustainability by design" is gaining traction in the EU. As part of the new Circular Economy Action Plan, the Commission is promoting the sustainable design of products, which it calls "ecodesign". The Commission plans to propose a legislative initiative that focuses on sustainable-product policy, with a focus on climate neutrality, resource efficiency, the circular economy, and waste reduction.[77]

Approaches that are similar to "Sustainable by design", such as "Circular by design", have also been addressed in the literature.[78] The European Environment Agency (EEA) has focused on "Circular by design" due to the challenge of product circularity.[79] "Circular by

[68] UN World Commission on Environment and Development, "Report of the World Commission on Environment and Development: Our Common Future" (1987) UNGA A/42/427 (Brundtland report); ibid; For an in depth discussion on the differences between sustainable development and sustainability refer to J S Dryzek, *The Politics of the Earth: Environmental Discourses* (2nd edn, Oxford University Press 2013) 145ff.

[69] B Purvis, Y Mao and D Robinson, "Three Pillars of Sustainability: In Search of Conceptual Origins" (2019) 14 Sustainability Science 681–695.

[70] E Eckert and K Oleksandra, "Sustainability in the European Union: Analyzing the Discourse of the European Green Deal" (2021) 14(2) Journal of Risk and Financial Management 80; P Schroeder, K Anggraeni and U Weber, "The Relevance of Circular Economy Practices to the Sustainable Development Goals" (2018) 23(2) Journal of Industrial Ecology 77–95; J M Rodriguez-Anton and Others, "Analysis of the Relations between Circular Economy and Sustainable Development Goals" (2019) 26(8) International Journal of Sustainable Development & World Ecology 708–720.

[71] B J Brown and Others, "Global sustainability: Toward Definition" (1987) 11 Journal of Environmental Management 713–719.

[72] See for instance: Y H Ahn and Others, "Drivers and Barriers of Sustainable Design and Construction: The Perception of Green Building Experience" (2013) 4(1) International Journal of Sustainable Building Technology and Urban Development 35–45; and G M Sabnis, *Green Building with Concrete Sustainable Design and Construction* (2nd edn, Boca Raton, CRC Press 2015).

[73] X Chen and Others, "Circular Economy and Sustainability of the Clothing and Textile Industry" (2021) 3(12) Materials Circular Economy.

[74] Ibid.

[75] Ibid.

[76] Ibid.

[77] Supra, note 11, 3–4.

[78] European Environment Agency, "Circular by design – Products in the circular economy" (EEA Report no. 6, 2017) available at <https://www.eea.europa.eu/publications/circular-by-design> (accessed 21-02-2024).

[79] Ibid.

design" is about examining the relationship between products and the circular economy.[80] Therefore, a systematic approach and transition theory are applied.[81] There is considerable overlap between "Circular by design" and "Sustainable by design" because both consist of principles that are directed at making products more sustainable. The importance of "Sustainable by design" is also implicit in the Regulation on sustainable product policy and ecodesign that the Commission has proposed.[82] In its Communication on Making Sustainable Products the Norm, the Commission noted that its objective was to promote the design of "*more sustainable, circular and energy performing products*"[83] and that Eco-design for Sustainable Products Regulation (ESPR) would be at the core of that endeavour.[84] The trend towards more sustainable and circular product design in the EU can easily be inferred from these references.

On the whole, "Sustainable by design" is an approach that entails designing sustainable and circular products in order to meet environmental goals. However, according to Walker, remaining focused on the long term is often difficult due to the ambiguity of concepts such as the SDGs.[85] Such initiatives can command the attention of the public durably only if they possess a certain emotional appeal and if they affect daily lives. Walker further explained that if one wants to change one's perspective on materialism, one must see the new and more sustainable approach to design as an end in itself. Such a shift can only be achieved by accounting for environmental and social considerations and not solely by relying on the abstract notion of a sustainable society or by participating in conversations about the environment.[86] Changing perspectives on design and consideration of the environment and society can thus aid the creation of a more sustainable world. This said, safety should not be ignored.[87] Alaranta and Turunen have argued that a circular economy involves stronger reliance on recycled materials, which can contain hazardous substances that are not present in the original materials or products. Regulations should promote the safe handling and disposal of hazardous waste and chemicals, as well as improving transparency and the sharing of information about the composition of recycled materials.[88] Alaranta and Turunen also emphasised the importance of designing products with circularity in mind and of considering the potential risks that are associated with the use of recycled materials.[89] In their view, focusing on safety will ensure that the benefits of the circular economy are not outweighed by its negative impacts on human health and the environment. What is needed is a comprehensive regulatory framework that considers the entire lifecycle of products, from design to disposal.[90]

As discussed previously, the concept of "Safe by design" is considered to be too narrow because it does not account for sustainability. Combining safety and sustainability might produce a more comprehensive approach to design. Some recent studies have focused on

[80] Ibid. Circular by design is focused on products, and essentially how to turn products from linear lifespans, to (less polluting) non-linear lifespans or preferably circular lifespans. This in turn is a (major) part in the idea of a circular economy. See also for further reading: A Mestre and T Cooper, "Circular Product Design: A Multiple Loops Life Cycle Design Approach for the Circular Economy" (2017) 20 The Design Journal s1620–s1635; M R van den Berg and C A Bakker, "A Product Design Framework for a Circular Economy" (2015) PLATE & TU Delft 365–379.

[81] Ibid.

[82] Commission, "Proposal for a regulation of the European Parliament and of the Council establishing 'a framework for setting ecodesign requirements for sustainable products'" COM (2022) 142 final.

[83] Commission, "On making sustainable products the norm" (Communication) COM (2022) 140 final, p 4.

[84] Ibid.

[85] Supra, note 67, p 55.

[86] Ibid.

[87] J Alaranta and T Turunen, "How to Reach a Safe Circular Economy? Perspectives on Reconciling the Waste, Product and Chemicals Regulation" (2021) 33(1) Journal of Environmental Law 113–136.

[88] Ibid.

[89] Ibid.

[90] Ibid.

safe and sustainable innovation, whereby "Safe by design" is combined with lifecycle assessments.[91] Salieri *et al.* thus combined a lifecycle assessment, an assessment of human and environmental risk, and an assessment of the economic viability of the concept in the context of nanomaterials.[92] They found that the combination in question can result in products, processes, and materials that are more sustainable, more competitive, and safer.[93]

IV. Safe and sustainable by design: insights from the chemicals sector

The EU chemicals sector is currently subject to a rules-based regulatory framework, which comprises approximately 40 legislative documents, including the REACH[94] Regulation.[95] The European Commission has noted, in its 2020 Chemicals Strategy among other documents, that the hazardous properties of certain chemicals that are used industrially can harm human health and the environment.[96] The Commission therefore concluded that new chemicals and materials should be safe and sustainable and that new processes are needed to ensure that the chemicals sector can become climate neutral.[97] It covers chemical substances, materials, and products.[98] The Chemicals Strategy addresses the risks and the sustainability concerns that chemicals involve, including the safety of chemical mixtures, chemical toxicity, and harm to the environment.[99] The Chemicals Strategy is part of the EGD and contributes to the aim of zero pollution by 2050.[100]

In light of the foregoing, the Commission introduced the SSbD concept. SSbD integrates safety and sustainability considerations into the entire lifecycle of a chemical substance, material, or product, from design to disposal, in order to reduce environmental impacts and to improve human health and safety.[101] The Strategy is meant to boost innovation while protecting human health and the environment,[102] and it reflects high expectations about the potential of SSbD in the chemicals sector. It is important to understand how the Commission defines SSbD. As far as the Chemicals Strategy is concerned, SSbD is defined as a "*a pre-market approach to chemicals that focuses on providing a function (or service)*" so as to eliminate the use of harmful chemicals and reduce the carbon footprint of the industry.[103] Therefore, it is intended to enhance the safety and sustainability of materials, products, and production processes prior to market entry. In the Chemicals Strategy, the Commission noted that regulation should incentivise the substitution of potentially hazardous chemicals with ones that are safe by design.[104] Evidently, the Commission plans

[91] Supra, note 60, p 100335.

[92] Ibid.

[93] Ibid.

[94] Regulation of the European Parliament and of the Council (EC) 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (2006) OJ L136/3/.

[95] Commission, "Chemicals Strategy for Sustainability Towards a Toxic-Free Environment" (Communication) COM/2020/667 final, p 1.

[96] Ibid., p 2.

[97] Ibid., p 1.

[98] Ibid., p 5.

[99] Ibid., pp 6 & 12.

[100] Commission, "Green Deal: Commission Adopts New Chemicals Strategy Towards a Toxic-Free Environment" (*Press Release* 2020). available at <https://ec.europa.eu/Commission/presscorner/detail/en/ip_20_1839> (accessed 21 February 2024).

[101] Supra, note 96; and C Caldeira and Others, "Safe and Sustainable by Design Chemicals and Materials – Framework for the Definition of Criteria and Evaluation Procedure for Chemicals and Materials" (JRC Technical Report 2022) available at <https://doi.org/10.2760/487955> (accessed 21 February 2024).

[102] Supra, note 101.

[103] Supra, note 96, p 4.

[104] Ibid., p 5.

to develop criteria for the safety and sustainability of chemicals, to establish a network in order to promote co-operation and information sharing, to provide financial support in order to maximise the uptake of safe and sustainable materials and products, to address skills gaps in industry, to establish key performance indicators, and to promote the use of safer chemicals through legislation on industrial emissions. The Commission is also intent on guaranteeing the safety of consumers and the environment while promoting economic growth and innovation. Furthermore, in 2021, the EU followed up on the 2020 Chemicals Strategy with an Implementing Decision on the adoption of the Horizon Europe Work Programme for the 2021–2022 period.[105] In this Work Programme, explicit reference is made to the need for international collaboration on safety ad sustainability by design.[106]

In 2022, the Joint Research Centre (JRC) established a framework for the definition of criteria and evaluation procedures that can determine whether specific chemicals and materials comply with SSbD.[107] The framework is intended to provide guidance for industry and other stakeholders in assessing the safety and sustainability of chemicals and materials throughout their lifecycles. The framework contains eight SSbD principles, namely (1) material efficiency, (2) minimising the use of hazardous chemicals or materials, (3) design for energy efficiency, (4) the use of renewable sources, (5) preventing and avoiding hazardous emissions, (6) reducing exposure to hazardous substances, (7) designing for end of life, and (8) considering entire lifecycles.[108] These principles are a compilation of concepts from, among others, green chemistry,[109] green engineering,[110] and circular chemistry.[111] The JRC report also contains a framework which is designed to promote innovation and improvements to the design of safe and sustainable chemicals and materials, as well as to ensure the safety of consumers and the environment. The framework does not include specific criteria for evaluating chemicals and materials. Instead, it outlines a procedure for defining criteria and evaluation procedures that has five steps: a hazard assessment, an assessment of human health and safety matters in the production and processing phase, an assessment of human-health and environmental aspects in the final application phase, a lifecycle assessment, and an assessment of social and economic sustainability.[112]

In the light of the JRC report, the Commission recently published a Recommendation that purports to establish a framework for SSbD criteria and assessments.[113] The aim of the SSbD framework is to promote innovation and applied science.[114] Accordingly, it applies to research-and-innovation activities, and it is directed at businesses and other stakeholders. The SSbD framework defines criteria for chemicals and materials. Those criteria ought to contribute to achieving the ambitions of the Chemicals Strategy. It is important to note

[105] Commission, Implementing Decision amending Commission Implementing Decision C(2021)1940 on the adoption of the work programme for 2021–2022 within the framework of the Specific Programme implementing Horizon Europe – the Framework Programme for Research and Innovation and on its financing as regards the 2022 budget (2022) C/2022/2975 final; see: 7. Digital, Industry and Space available at <https://eur-lex.europa.eu/resource.html?uri=cellar:c1f95e49-d11b-11ec-a95f-01aa75ed71a1.0001.02/DOC_8&format=PDF> (accessed 21 February 2024) pp 115ff.

[106] Ibid.

[107] Supra, note 102.

[108] Ibid., pp 26–28.

[109] P Anastas and J C Warner, *Green Chemistry: Theory and Practice* (Oxford, Oxford University Press 1998).

[110] P Anastas and J Zimmerman, "Design through the Twelve Principles of Green Engineering" (2003) 37(5) Environmental Science & Technology 94A–101A.

[111] T Keijer, V Bakker and C Slootweg, "Circular Chemistry to Enable a Circular Economy" (2019) 11 Nature Chemistry 190–195.

[112] Supra, note 102.

[113] Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for "safe and sustainable by design" chemicals and materials (2022) L 325/179.

[114] Ibid., recital 14.

that SSbD goes beyond regulatory compliance. The Commission articulated principles that underpin the SSbD framework. The fact that such principles have been established arguably suggests that SSbD is moving away from the rules-based regulatory approach towards a more principles-based one, which, however will complement rather than replace the existing regulations on chemicals. The principles that the Commission has articulated include a principles-first hierarchy, cut-off criteria for the design of chemicals and materials, the iterative minimisation of environmental pressures through the use of dynamic boundaries, optimal data use for comparative purposes, the transparent communication of relevant and non-confidential data across the supply chain, and coherence.[115]

The Commission indicated that the procedure for the formulation of SSbD criteria has two stages. The first stage focuses on (re)design principles and covers three stages of the design progress: molecular design, process design, and product design.[116] The second stage of the framework entails a safety and sustainability assessment which proceeds in four steps. The first step is a hazard assessment that zooms in on the intrinsic properties of the chemical or material. The objective is to identify hazards prior to processing, production, and use. The second step emphasises the safety of production and processing in relation to human health. The assessments will be performed in line with the Directives on occupational health and safety. The third step revolves around human health and environmental matters in the final application phase. In this step, the risks and hazards to human health and the environment that the use of the material or chemical poses are assessed. The fourth and last step is to perform an environmental sustainability assessment that accounts for the lifecycle of the chemical or material.[117]

According to the Commission, the two stages of the framework for formulating SSbD criteria are intended to guide the development of tools and methods for assessing the safety and sustainability of chemicals and materials as well as to promote innovation and improvements to the design of these products.[118] The framework also emphasises the need for collaboration between stakeholders, including industry, regulators, and academia. That collaboration should ensure that the assessment of chemicals and materials is comprehensive and transparent.[119] The framework is intended to guide industry and other stakeholders in promoting the safe and sustainable design of chemicals and materials.[120]

The policy documents on SSbD that were just described indicate that SSbD can be considered a form of principles-based regulation. Black *et al.* explained that this term implies expanding the use of broadly worded measures that set standards for businesses at the expense of detailed prescriptions.[121] In the context of the Chemicals Strategy, SSbD serves as a set of safety and sustainability norms that are enshrined in general criteria, which have a wide scope of application in the chemicals sector.[122]

SSbD will be tested for two years, starting from May 2023. The first phase of the test involves the submission of reports on the implementation of SSbD to the Commission. The reports will be submitted on a voluntary basis, feedback will be collected, and a guidance report will be issued.[123] The second phase of the process will begin in May 2024. Its

115 Annex to the Commission Recommendation (EU) 2022/2510 of 8 December 2022 establishing a European assessment framework for "safe and sustainable by design" chemicals and materials (2022) L 325/179.

116 Ibid., p 2.

117 Ibid., pp 188–189.

118 Ibid., p 180.

119 Ibid., p 183.

120 Ibid.

121 Supra, note 33, p 195.

122 Supra, note 96; Supra, note 116.

123 EU Commission, "Safe and Sustainable by Design – The Commission Recommendation in a nutshell" available at <https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/

structure will be the same as that of the first phase. After the tests are complete, the SSbD framework will be revised on the basis of the information that is accumulated.[124]

Some recent changes to the EU regulatory landscape might be relevant to SSbD. One of them is the proposal for an Ecodesign Regulation.[125] The proposal sets up a structure for establishing ecodesign criteria that are applicable to specific product categories. The primary goal will be to enhance environmental sustainability.[126] The delegated Commission Regulation on new hazard classes in the classification, labelling, and packaging of substances and mixtures (CLP) is another relevant policy initiative.[127] Regulation (EC) No 1272/2008[128] on CLP has been revised to reflect accumulated experience and gains in scientific knowledge. The revision involves the introduction of new hazard classes and criteria.[129] Lastly, two of the key objectives of the proposal for a Regulation on critical raw materials[130] are to ensure that those materials can circulate freely within the internal market and to improve their capacity to contribute to sustainability and the pursuit of a circular economy.[131]

Overall, within the scope of the Chemicals Strategy, the SSbD concept can, depending on its actual implementation, be considered a form of principles-based regulation that coexists with the current rules-based regulatory framework for chemicals. In that regard, SSbD has the potential to result in safer and more sustainable chemicals, materials, and substances by setting policy norms on safe and sustainable design in the chemicals sector.

V. Safe and sustainable by design: regulatory benefits and challenges

The table below overviews the benefits of adopting the SSbD approach and the challenges that its adoption entails from the perspectives of technology and law (Table 1). These benefits and challenges form the subject matter of this section. The list in the table is not intended to be exhaustive as far as technology and the law are concerned. Furthermore, it does not account for social and economic considerations, which are outside of the scope of the paper.

1. *Technological perspective*

a. Potential technological benefits

From a technological perspective, SSbD could be beneficial because it addresses safety risks at an early stage of the design process. If safety and sustainability are addressed *ex*

key-enabling-technologies/chemicals-and-advanced-materials/safe-and-sustainable-design_en> (accessed 21 February 2024).

[124] Ibid.

[125] Supra, note 83.

[126] Commission, "Ecodesign for Sustainable Products Regulation" available at <https://Commission.europa.eu/energy-climate-change-environment/standards-tools-and-labels/products-labelling-rules-and-requirements/sustainable-products/ecodesign-sustainable-products-regulation_en#:~:text=The%20proposal%20establishes%20a%20framework,and%20other%20environmental%20sustainability%20aspects> (accessed 21 February 2024).

[127] Commission Delegated Regulation EC 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (2022) L 93/7.

[128] Regulation of the European Parliament and of the Council (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (2006) L353/1.

[129] Supra, note 128 recital 5.

[130] Commission, "Proposal for a regulation of the European Parliament and of the Council to create a framework for ensuring a secure and sustainable supply of critical raw materials, and to amend regulations (EU) 168/2013, (EU) 2018/858, 2018/1724, and (EU) 2019/1020" COM (2023) p 160.

[131] Ibid., p 2.

Table 1. Non-exhaustive list of potential benefits and challenges of the adoption of the SSbD approach from a technological and a legal perspective.

	Potential Benefits	Potential Challenges
T	*Ex ante* safety and sustainability	Lack of knowledge about technological risk
E	Active risk awareness	Complexity of implementation
C	Fostering innovation	Conflicts between safety and sustainability
H	Flexible principles-based regulation	Legal uncertainty
L	Simpler rules and standards	Compliance and enforcement
E	Transparency of legal objectives	Legitimacy and accountability
G	Wider scope of application	Regulatory capture
A	Management of regulatory challenges	Liability*
L	Compliance with existing rules	Potential clashes with WTO rules*

*Liability and potential clashes with WTO rules are outside of the scope of this paper because that domain is so complex that it would require a separate investigation.

ante, the likelihood of materials, products, and processes complying with EU safety and sustainability regulations increases. Addressing safety and sustainability *ex ante* is therefore beneficial – products would be more likely to be approved for the EU market when their safety and sustainability have been considered comprehensively at the design stage and by reference to their entire lifecycles.

Furthermore, SSbD principles could increase awareness of risks and stimulate the safe and sustainable design of products and processes. No general definition of risk awareness has crystallised in the academic literature. However, it is a settled proposition that risk assessment entails the entire process of identifying, analysing, and evaluating risk.[132] Therefore, the analysis of environmental impacts by reference to the whole lifecycle of a product or process could make the process of designing and development more efficient.

Lastly, the SSbD principles can foster technological innovation. A framework that comprises guiding principles rather than specific rules can induce gains in substantive compliance. Designers would be forced to think beyond rules. We argue, therefore, that SSbD, as a form of principles-based regulation, could encourage innovation when norms on safety and sustainability are introduced. The Directorate-General for Research and Innovation has also noted that SSbD framework encourages innovation in the effort to replace dangerous substances.[133] As a general matter, innovation can be stimulated by implementing SSbD principles – awareness of safety and sustainability criteria could prompt scientists to devise alternative principle-compliant solutions.[134] Such a development would allow businesses to experiment and discover new and superior means of achieving the outcomes that they desire.

[132] Commission, 20 actions for safer and compliant products for Europe: a multi-annual action plan for the surveillance of products in the EU (Communication) COM 2013 76 final, Action 5 2015-IMP-MSG-15.

[133] Directorate-General for Research and Innovation, "Recommendation for safe and sustainable chemicals" (European Commission 2022) available at <https://research-and-innovation.ec.europa.eu/news/all-research-and-innovation-news/recommendation-safe-and-sustainable-chemicals-published-2022-12-08_en> (accessed 31 March 2023).

[134] OECD, "Regulatory reform and innovation" (1997) available at <https://www.oecd.org/sti/inno/2102514.pdf> (accessed 21 February 2024); and K Blind, "The Influence of Regulations on Innovation: A Quantitative Assessment for OECD Countries" (2012) 41(2) Research Policy 391–400.

b. Potential technological challenges

From a technological perspective, difficulties arise when risks are unknown. Uncertainty about risks to safety and sustainability is particularly pronounced when new technologies emerge or when new substances are being developed. The identification of some risks requires in-depth knowledge. Uncertainty about the implications of an emerging technology is particularly germane at the early stages of product or material design. Lack of information can make it difficult to integrate safety and sustainability features into a product, process, or material.

The complexity of the implementation of the SSbD approach can be another source of difficulty. Implementation efforts require multiple factors and stakeholders to be considered. This complexity is underscored by the requirement for a thorough analysis that spans the entire product lifecycle.[135] Success hinges on the integration of diverse forms of expertise on safety and sustainability, as well as on the skilful implementation of these requirements by engineers. Consequently, existing product-design and manufacturing processes are seldom amenable to the incorporation of SSbD.

Lastly, it can be argued that the safety and sustainability aspects of the SSbD approach are mutually contradictory. This argument raises the possibility of trade-offs between safety, sustainability, and other factors, such as cost, performance, and aesthetics. Van Gelder *et al.* also acknowledged the veracity of this proposition. They indicated that the prevention of risk might require sacrifices on other dimensions, such as sustainability, equity, and financial cost.[136] The simultaneous consideration of safety and sustainability can thus make equilibrium difficult to achieve during the design process. In facing this issue, a systems approach could be adopted to provide for a more holistic view on safe and sustainable design that would benefit the circular economy and the sustainability of resources.[137]

2. Legal perspective

a. Potential legal benefits

Turning to legal matters, SSbD can be considered a form of principles-based regulation, in line with Black's definition.[138] Recall that Black defined regulation as "*the sustained and focused attempt to [(1)] alter the behaviour of others [(2)] according to defined standards or purposes [(3)] with the intention of producing a broadly identified outcome or outcomes*". She has also described the advantages of principles-based regulation.[139] To the present ends, those advantages may be summarised as follows: first, as far as the alteration of the behaviour of others is concerned, principles-based regulation provides more flexibility for businesses. They only need to demonstrate that they observe the principles and objectives that have been set by the regulator before engaging in regulated operations. Second, Black's definition also refers to "*defined standards and purposes*". In that respect, principles-based regulation has the benefit of simplicity, and it is often more transparent than rules-based regulation because its underlying tenets and objectives are clearer. Consequently,

[135] Supra, note 58; Supra, note 65.

[136] Supra, note 46, p 6329.

[137] E Iacovidou, J Hahladakis and P Purnell, "A Systems Thinking Approach to Understanding the Challenges of Achieving the Circular Economy" (2021) 28 Environmental Science and Pollution Research 24785–24806. Accordingly, 'a system-approach is holistic in the sense that it allows for application across multiple systems. This means, and contrary to a single-system approach, that no problems potentially arise in other or adjacent systems than the one being addressed.' For further reading see also M Leach and Others, "Equity and Sustainability in the Anthropocene: A Social–Ecological Systems Perspective on Their Intertwined Futures" (2018) 1 Global Sustainability e13.

[138] Supra, note 18.

[139] Supra, note 33, p 195.

businesses find it easier to discover what is expected of them, and regulators find it easier to communicate their expectations. SSbD can be a source of general design criteria, which are more accessible than complex sector-specific regulations. Third, turning to Black's reference to outcomes, principles-based regulation is more responsive to changing circumstances and market conditions. It allows regulators to adapt their approach as new risks emerge and to respond more rapidly to market developments. On the whole, then, principles-based regulation is more flexible, innovative, cost effective, transparent, and responsive than rules-based regulation. For these reasons, it can benefit both businesses and regulators.[140]

Furthermore, SSbD has a wider scope of application because it is based on principles. This wider scope of application could address the law-of-the-horse problem, that is, the problem of current regulation being so specific that it becomes inapplicable to emerging technologies. SSbD could also partly resolve the pacing problem, the challenge of regulatory connection, and the Collingridge Dilemma. The pacing problem and the challenge of regulatory connection, which concern the time gap between the emerging technology and regulation as well as the sustainability of laws, could be addressed through SSbD when the technology that is being regulated is from a sector in which SSbD is already in use.[141] Considering the Collingridge Dilemma, which has to do with the uncertainty paradox that regulators face when they regulate, SSbD poses challenges in the context of emerging technologies with unknown implications and risks. The lack of knowledge that was described in the section on challenges from a technological perspective can be linked to the Collingridge Dilemma. The Collingridge Dilemma thus persists. However, when more knowledge becomes available, the SSbD approach suggests that the designer should return to the research-and-development phase as soon as new information indicates that the technology should be redesigned.[142] Therefore, even though information and knowledge might be lacking at the beginning of the design process, precaution, prevention, consideration of safety and sustainability, and redesign might enable the problem that Collingridge described to be remedied.

Lastly, the SSbD approach can enhance compliance with existing regulations. By integrating safety and sustainability considerations into the design process, companies can ensure that their products and technologies are compliant with environmental regulations or health and safety standards.[143] Furthermore, the SSbD approach can lead to improved protection of human health and the environment, which has important legal implications. At present, governments around the world must enact highly specific laws and regulations in order to pursue those ends.[144] By adopting the SSbD approach, companies can ensure that their products and technologies are designed so as to minimise adverse impacts on the environment and public health. In this way, they may avoid costly fines and other legal sanctions. However, it must be conceded that SSbD can become a box-ticking exercise in compliance, a problem to which we return in the following subsection.

[140] J Black, "Principles Based Regulation: Risks, Challenges and Opportunities" (Speech at the University of Sydney, Australia 2007).

[141] R b. Carter and G E Marchant, "Principles-Based Regulation and Emerging Technology" in G E Marchant and Others (eds), *The Growing Gap Between Emerging Technologies and the Law* (Dordrecht, Springer 2011) pp 157–166.

[142] Supra, note 116, p 2.

[143] Commission, Safe and Sustainable by Design: A Vision for the Chemicals Strategy for Sustainability Towards 2030 (Communication) COM(2020) 66 final.

[144] United Nations Environment Programme, "Towards a Pollution-Free Planet: background report" (2018) available at <https://www.unep.org/resources/report/towards-pollution-free-planet-background-report> (accessed 21 February 2024).

b. Potential legal challenges

The legal difficulties that stem from the adoption of SSbD coincide partially with those that attend on principles-based regulation in general. According to Black, the first challenge of principles-based regulation in general has to do with legal uncertainty and with the difficulty of complying with principles.[145] Principles-based regulation can lack clarity and specificity, which makes compliance more difficult to enforce and evince. Furthermore, inconsistencies can arise because principles-based regulation relies on judgment and interpretation. Different regulators may interpret identical principles differently, which can lead to divergent outcomes. Since principles-based regulation comprises general principles that are less prescriptive than specific rules, it can be more difficult to measure compliance objectively. This difficulty can hinder attempts to evaluate the effectiveness of the SSbD approach and to identify areas for improvement.

Relatedly, principles-based regulation relies on judgment and interpretation, which can undermine legitimacy and accountability. As far as the former is concerned, SSbD, as a regulation-by-design approach, is premised on the notion that the designer's choices are a form of regulation of the technology. The designer must also consider safety and sustainability, which are collective goods. According to Yeung, regulation by design may be illegitimate for several reasons, including ineffectiveness, poor alignment with constitutional values, and unrepresentativeness.[146] Furthermore, that SSbD affords designers a margin of discretion in choosing how to comply with the principles raises the risk of regulatory capture. Designers and researchers are not legitimised publicly. At the same time, their decisions about safety and sustainability can have tremendous impacts, especially on the development of emerging technologies in industries that are regulated parsimoniously or not at all. In these contexts, it is difficult to hold designers accountable for their decisions.

IV. Conclusion

The novelty of SSbD stems from the combination of "Safety by design" and "Sustainability by design". It has received much attention in the EU chemicals sector. Since SSbD is a concept of recent coinage, it is important to assess its potential and its influence on the design of materials, products, and processes. SSbD principles can be used as regulatory tools that enhance sustainability and promote a more circular economy. SSbD can serve as a form of regulation by technology. We argued that SSbD should be treated as principles-based regulation, in that its safety and sustainability criteria regulate design. We also argued that SSbD might be treated as design-based regulation because it is premised on the notion that the design of technology contributes to the achievement of regulatory goals. We identified a non-exhaustive list of potential legal and technological advantages and disadvantages. On the whole, SSbD has the potential to promote safety, sustainability, and environmental protection in product design and manufacturing because it is a flexible form of regulation that can foster innovation. SSbD can also address some of the regulatory challenges that arise when new technologies emerge, such as the pacing problem and the challenge of regulatory connection. However, its disadvantages, especially those that pertain to legitimacy and accountability, need to be considered carefully.

The Commission has thus far limited the application of the concept to the chemicals sector. We recommend that more research be conducted on the potential of SSbD in other domains, such as synthetic biology, before it is adopted as a general approach to

[145] Supra, note 141.
[146] Supra, note 45.

regulation. The challenges that we identified need to be explored in greater depth in order to determine whether they can be overcome. Until that research materialises, we recommend that SSbD, instead of being cast as "regulation by technology", should be perceived as a complement to existing regulation and thus as another form of "regulation of technology".

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