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Towards a future UK chemical sustainability strategy: what the UK can learn from the European Union Safe and Sustainable by Design framework

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The European Union (EU) Safe and Sustainable by Design (SSbD) framework has emerged as a promising tool for preventing regrettable substitution by incorporating safety, environmental and socioeconomic sustainability considerations into chemical innovation from the earliest design stages. Despite its conceptual strength, SSbD faces substantial implementation challenges which are related to change, methodological complexity and uncertainty and extensive data demands. More so, questions regarding operational feasibility raise concerns about the practical adoption, particularly in regulatory environments with limited institutional capacity. Following its withdrawal from the EU, the United Kingdom (UK) now operates an independent regulatory system under UK REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals), administered by the Health and Safety Executive. While retaining structural similarity to EU REACH, the UK regime functions under more limited data, fewer resources and capacity compared to the EU, and heightened fears of excessive regulatory burden. These conditions create the opportunity for system thinking for adoption of a preventive approach to how chemicals on the UK market are controlled and managed. This article argues that SSbD principles can be effectively operationalised within the UK by adopting proportionate, tiered-assessment structure supported by enhanced predictive modelling and by creating regulatory and policy incentives. By reframing complexity as a regulatory design challenge rather than a technical barrier, the UK can transition from reactive, substance-by-substance risk management towards an anticipatory, innovation-driven regulatory model. By adopting SSbD approaches, the UK could minimise regrettable substitution, strengthen regulatory certainty, enhance competitiveness, and promote the long-term sustainability of chemicals placed on the UK market.

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Sustainability spotlight

The EU Safe and Sustainable by Design (SSbD) framework offers a proactive approach to reducing risks from harmful chemicals by embedding safety and sustainability considerations at the earliest stages of innovation and design. Despite its potential, implementation remains challenging due to methodological complexity, substantial data requirements, and resource constraints. Drawing on lessons from the EU experience, this article explores how SSbD principles can be adapted to support chemical substitution and safe(r) alternatives within the UK chemicals regulatory and innovation landscape. Effective implementation of SSbD-informed approaches in the EU and UK could help prevent regrettable substitution and contribute to the achievement of several UN Sustainable Development Goals, including SDG3 (Good Health and Well-being) and SDG12 (Responsible Consumption and Production).

Introduction

Chemical regulation over the past half-century has achieved significant public health and environmental gains. Nevertheless, the persistence of regrettable substitution (RS), the replacement of one hazardous chemical with another that is equally harmful, or the shifting of impacts from one concern to another, reveals structural weaknesses in existing regulatory frameworks.[1–4] Rather than representing isolated policy failures, such substitutions expose systemic features of regulatory systems that are reactive, and oriented towards optimising short-term gains with poor regard for longer-term losses.[5]

The prevailing regulatory paradigm has traditionally centred on post-market risk evaluation and management.[3] Under frameworks such as the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (EU REACH),

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substances are assessed individually, often only restricted after years of evidence accumulation and subsequently replaced by alternatives that typically remain within the same functional or structural chemical families.[2–4,6] This cycle described by Geiser, (2015) as regulatory "whack-a-mole", produces iterative risk displacement rather than lasting reduction. As a result, human health and the environment experience continuous exposure to harmful substances.[7] Chemical pollution is now recognised as a major driver of biodiversity loss and a significant concern for public health.[8] The rapid increase of chemicals in commerce, outpacing the ability of regulatory systems to assess and manage their risks, emphasises the need for proactive and adaptive regulatory approaches.

Following the United Kingdom (UK) departure on 31 January 2020 from the EU, the UK now regulates chemicals independently under UK REACH.[9] Although UK REACH is closely modelled on EU REACH, it operates within its own distinct political, economic, and institutional context. Constraints such as more limited regulatory capacity relative to the European Chemicals Agency (ECHA) and the EU Member States,[10] reduced access to EU data, and heightened political sensitivity to regulatory costs may restrict ambition within the UK regulatory regime. Conversely, regulatory autonomy can offer opportunity for institutional innovation and the development of a framework capable of supporting genuine transition to safe(r) chemical alternatives on the UK market. Autonomy can also enable more rapid integration of emerging scientific knowledge such as advances in test methodology, predictive modelling, and sustainable chemistry than was previously possible within the EU system.

The EU's Safe and Sustainable by Design (SSbD) framework, currently a voluntary decision-making approach during the innovation process of chemicals and materials, was developed from the Chemical Strategy for Sustainability and embedded within the European Green Deal's objective of a climate-neutral economy by 2050.[11–14] SSbD aims to steer innovation towards safe(r) and sustainable chemicals by integrating safety considerations (hazard identification, exposure assessment, risk characterisation and risk management) with environmental and socioeconomic considerations at the earliest stages of chemical and material design. SSbD represents a paradigm shift from the traditional post-market risk management towards the proactive design of inherently safe(r) and more sustainable chemicals and materials. The revised EU framework is underpinned by four core principles: (i) a whole-system perspective that considers chemicals, materials, products, processes and their associated lifecycles; (ii) multidisciplinary engagement and collaboration among relevant actors throughout the innovation process; (iii) a holistic, iterative and tiered approach that progressively reduces uncertainty as new information becomes available; and (iv) transparency and traceability throughout the assessment and innovation process. Together, these principles seek to ensure that safety and sustainability considerations are embedded throughout the entire innovation pathway rather than being addressed retrospectively.[12] In principle, SSbD offers precisely the forward-looking approach needed to prevent RS since new chemicals and materials are designed with safety and sustainability consideration at the earliest possible stage. In practice, however, the framework is overly complex, administratively burdensome, and methodologically ambiguous.[8,15–17] According to Apel *et al.*, 2024, the complexity of the SSbD required assessments need to be translated into simple guidelines easily appliable by innovators. This complexity risks hindering widespread adoption of SSbD (particularly by small and medium-sized enterprises (SMEs)), thereby limiting the creation of an innovation environment for safe(r) chemicals.[8] Challenges such as insufficient assessment methods, extensive data requirements, need for system-based approaches, and resource constraints can further limit SSbD uptake.[8] For SSbD to transition from an abstract concept to a practical and proactive framework that supports broad-scale innovation, simplification is essential.[16] This is particularly relevant for the UK given that around 50% of UK businesses surveyed by the UK Government Department for Business & Trade identified regulation as a barrier to success.[18] While the UK does not currently have an equivalent SSbD framework, the EU's progress in developing and refining SSbD over recent years provides a valuable source of experience from which the UK can learn. This is particularly relevant given that the UK Environmental Improvement Plan provides an opportunity to embed considerations of sustainable chemical production and use within future reforms of UK REACH and broader UK chemicals policy.[19]

Chemical regulations aim to achieve a high level of protection of human health and the environment from risks associated with hazardous chemicals and to encourage their substitution with safe(r) alternatives. The current regulatory approach is largely reactive, addressing risks only after a chemical has been produced and used for many years. SSbD therefore, provides the needed paradigm shift by encouraging safety and sustainability considerations to be integrated earlier during (re)design and innovation stages. While the EU SSbD framework was developed as a broad innovation framework applicable to chemicals, materials, products and processes across different stages of innovation maturity, this article focuses specifically on how SSbD concepts can be adapted to support chemical substitution and safe(r) alternatives within the UK chemicals governance landscape, with the primary objective of preventing RS. This perspective article therefore addresses the following central question: how can the UK learn from the implementation challenges and complexity of the EU SSbD framework and operationalise SSbD principles effectively within UK chemicals landscape and regulatory decision-making? This article does not intend to provide a comprehensive implementation strategy for the full EU SSbD framework; rather, it seeks to highlight key action areas that the UK should consider if it wishes to embed SSbD-informed approaches within its chemical regulatory system and innovation landscape. We argue that the complexity of SSbD is not an inherent flaw but a design challenge and opportunity that can be addressed through five actions: proportionality and tiered assessment; targeted piloting; enhanced data capability including predictive modelling; creation of a national Hub and support centres; and the creation of regulatory and policy

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incentives to support wider SSbD adoption. By adopting a tailored approach, the UK can transform SSbD from an ambitious conceptual framework into a practical tool that can support chemical innovation and regulatory decision-making. The subsequent sections present five action areas with recommendations for the effective operationalisation of SSbD principles within the UK regulatory and innovation landscape. Although these actions draw on key concepts and elements of the EU SSbD framework, they have been adapted to reflect the UK's specific regulatory, economic, and political challenges in the post-Brexit landscape and are intended to support wider policy discussions on enabling and accelerating the adoption of safe and sustainable chemical innovation.

Five action areas for operationalising SSbD in the UK: lessons from the EU framework

Action area 1: develop a tailored, simplified and proportionate SSbD

Traditional chemical regulation typically follows a sequence of hazard identification, exposure assessment, risk characterisation and risk management. While scientifically robust, this approach is inherently retrospective, leading to regulatory interventions following substantial evidence of harm that has accumulated often years or decades after widespread use and exposure. Such delayed regulatory action can encourage reactive substitution practices that prioritise functional continuity over the elimination of underlying risks.[1] Organisations therefore tend to respond to regulatory pressures by maintaining product performance while making minimal structural modifications to molecules and formulations. Because chemicals are assessed individually within regulatory systems, structurally related substances may escape scrutiny until further evidence of harm emerges, as the examples of per- and polyfluoroalkyl substances (PFAS), flame retardants and bisphenols suggest.[3,5]

One of the central challenges of implementing SSbD lies in its complexity, specifically the high level of expertise and multi-stakeholder engagement it demands. These requirements can be prohibitive, particularly for SMEs, which often lack the necessary technical and financial resources. The complexity of SSbD stems from its expanded ambition to integrate safety with environmental and socioeconomic assessment within a single evaluative structure. However, complexity should not be confused with impracticality; many regulatory systems already use multi-criteria approaches, such as socioeconomic analysis under REACH authorisation. The main challenge is achieving operational clarity and proportionality of the SSbD. In the UK context, concerns about complexity are further amplified by limited resource constraints within the Health and Safety Executive (HSE) such as regulatory capacity to effectively manage risks from chemicals already on the UK market and by political pressures to streamline REACH for example in the post-Brexit landscape. Yet abandoning SSbD due to its complexity risks entrenching the long-term inefficiencies associated with innovation approaches that primarily focus on functional performance. The pressing question is therefore not whether SSbD is complex, but how such complexity can be sequenced, structured, and proportioned within UK chemical regulation to drive safe(r) and sustainable chemical innovation and prevent RS.

For Safe and Sustainable by Design (SSbD) to be effectively operationalised in the UK, a tailored, simplified, and proportionate application of the framework is required. Adopting a tiered and proportionate approach provides a pragmatic and structured strategy for managing the inherent complexity of SSbD. Following the initial publication of the SSbD framework in 2022, a revised framework was published by the EU in December 2025. This updated framework acknowledges the principle of a tiered SSbD depending on the innovation stage, available information and uncertainty level, recognising the need for simplification of the SSbD and progressively increasing the levels of assessment.[12] Progressive screening will ensure that the depth of analysis reflects the risk potential and sustainability implications of a substance. The tiered approach should begin with an evaluation of functional performance of the alternative(s) under consideration. During innovation, developers must first determine whether a candidate alternative can fulfil the performance requirements of the chemical it seeks to replace, and to what extent. This early evaluation is critical, as introducing sustainability criteria too early may lead to premature exclusion of promising alternatives.[16,20,21] Prioritising performance evaluation at the outset will ensure that technically feasible alternatives are identified and retained for further consideration.[20]

Following performance screening, candidate chemicals should undergo Tier 1 safety evaluation, entailing hazard information and use conditions (exposure). Substances with hazards of concern, *e.g.*, carcinogenicity, mutagenicity, or reproductive toxicity (CMR), (very) persistent, (very) bioaccumulative, and toxicity, or endocrine-disrupting properties should, in principle, be discouraged from scale-up without (re) design. In addition to hazard identification, consideration should be given to the conditions of use, including the settings where the use occurs, such as industrial or wide dispersive use. Chemicals used under industrial conditions with limited exposure and risk potential should proceed to Tier 2 simplified environmental screening. Where there is wide dispersive use, significant uncertainty or complex lifecycle considerations, a more comprehensive Tier 3 assessment should be performed, consistent with the iterative and proportionate approach promoted by the EU SSbD framework. Given that data availability is critical, the UK should invest in high-throughput computational methodologies to support both users and regulators.

Tier 2 involves a simplified environmental impact screening. Substances that pass Tier 1 screening criteria, and do not trigger exclusion based on predefined safety criteria would proceed to a screening-level assessment using rapid and pragmatic sustainability indicators. For substances with low exposure and risk potential (*e.g.*, used in controlled industrial applications), this screening assessment could include metrics such as indicative carbon intensity and resource criticality

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considerations. This approach avoids the resource intensity of full lifecycle assessment (LCA) while introducing system-level considerations. It enables innovators to identify potential environmental trade-offs and sustainability concerns at an early stage in the design process, before progressing to more detailed sustainability assessment where necessary.

Carbon intensity indicators are used to estimate the greenhouse gas emissions associated with a substance's production or supply chain. While full LCAs assess impacts across the entire lifecycle from raw material extraction to disposal, simplified carbon intensity indicators typically focus on production-stage emissions, enabling rapid climate-impact screening. Their use can help prevent situations where hazard-based substitution inadvertently increases climate burdens, highlighting potential trade-offs between toxicity reduction and greenhouse gas emissions.[22] Tools such as FineChem2 offer predictive insight into the carbon footprints of chemicals based on the simplified molecular input line entry system (SMILES) notation.[23] For example, alternatives that show lower toxicity may still rely on energy-intensive synthesis pathways or carbon-intensive feedstocks. Screening carbon intensity early in the innovation process can therefore help align chemical innovation with broader climate objectives, including the UK's 2050 net-zero commitments.[24] Importantly, the use of carbon intensity indicators need not impose disproportionate regulatory burdens. Regulators could establish sector-specific benchmark values or emission ranges for common chemical production routes, allowing companies to compare the carbon intensity of proposed alternatives against these benchmarks. Substances exceeding defined thresholds could be flagged for further analysis, potentially triggering a more detailed Tier 3 sustainability assessment including full LCA. Nonetheless, it is important to recognise that carbon intensity estimates are subject to methodological variability and system boundary choices, which can significantly influence outcomes and limit comparability across processes.[25,26]

In addition to climate impacts, sustainable chemical design must consider the availability and long-term sustainability of material resources used in chemical production. Many modern technologies depend on scarce or strategically important materials whose extraction may involve environmental degradation, geopolitical risk, or supply-chain vulnerabilities. To address this dimension of sustainability, resource criticality consideration can be incorporated as a Tier 2 screening indicator. Resource criticality refers to the degree to which a material is considered economically important while also being vulnerable to supply-chain disruption. Governments and international organisations increasingly assess raw materials according to their economic importance and supply risk, generating lists of critical raw materials that require strategic attention.[27] For example, institutions such as the European Commission alongside national bodies including the UK regularly evaluate raw materials based on these criteria, identifying those essential for industrial applications but subject to supply-chain vulnerabilities or geopolitical concentration. These include materials such as cobalt, lithium, rare earth elements, and other metals that play critical roles in advanced technologies and energy systems.[28–31] Resource criticality could therefore be incorporated into innovation screening by examining whether a proposed chemical alternative depends on materials listed on recognised critical-materials inventories. Where such dependencies exist, the alternative could be flagged for further evaluation, prompting consideration of whether less resource-intensive or more abundant substitutes could achieve equivalent functionality. Such use of resource criticality is particularly relevant for sustainable chemistry and materials innovation, where many emerging technologies including catalysts, advanced materials, and specialty chemicals depend on geographically concentrated supply chains. By incorporating resource criticality considerations into early design stages, innovators can avoid inadvertently creating new resource dependencies or sustainability bottlenecks. Moreover, resource criticality assessment is characterised by methodological diversity and a lack of harmonisation, with different approaches often yielding varying outcomes.[32] This reinforces the need to treat criticality metrics as screening tools rather than definitive measures. Furthermore, these assessments highlight the importance of circular economy strategies, including recycling, substitution, and material efficiency, to reduce reliance on scarce resources.[31] Integrating these considerations into chemical innovation frameworks can therefore support both environmental sustainability and long-term economic resilience.

Tier 3 represents the most comprehensive assessment stage within the proposed UK approach and incorporates many of the detailed safety, sustainability and lifecycle assessment elements that characterise the EU SSbD framework. At this stage, a comprehensive evaluation of safety, environmental, and socioeconomic impacts across the lifecycle of a chemical or material is conducted to ensure that innovation decisions deliver genuine sustainability benefits and avoid burden shifting.[16] Tier 3 also enables consideration of broader sustainable-by-design, including socioeconomic impacts, circularity, recyclability, the use of renewable or bio-based resources and lifecycle environmental performance. Incorporating these factors alongside safety and functionality will help ensure that innovation delivers meaningful sustainability benefits across the value chain. Table 1 provides an overview of the proposed UK tiered SSbD approach. Importantly, one of the key lessons from the EU SSbD framework is that comprehensive safety and sustainability assessments can be highly data- and resource-intensive. Consequently, requiring such assessments for all chemicals and materials would be impractical and could act as a barrier to innovation, particularly for SMEs. The proposed tiered approach therefore seeks to retain the benefits of comprehensive SSbD assessment while ensuring that detailed evaluations are undertaken only when justified. Its application should therefore be targeted and proportionate, focusing on cases where earlier screening stages identify significant concerns, trade-offs, uncertainties, or where innovation decisions involve complex and potentially competing sustainability objectives.

This tiered approach reflects the iterative philosophy of the revised EU SSbD framework by progressively increasing the

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Table 1 Proposed tiered framework for operationalising SSbD principles in UK chemical innovation and regulatory decision-making

SSbD tier	Assessment focus	Purpose	Consideration	Decision criteria	Example tools/data sources
Functional performance evaluation	Early identification of performance needs	Identification of all potential candidate alternatives during early (re)design phase	Functional performance the alternatives need to meet	Go to Tier 1 if alternative(s) meet performance need	Organisation internal tools and approaches
Tier 1: safety screening: hazard, use conditions (exposure) and risk characterisation	Identification of intrinsic hazards, exposure and risk potential	Rapid identification of substances posing unacceptable risks to human health or the environment	Carcinogenicity, mutagenicity, reproductive toxicity (CMR); persistence, bioaccumulation and toxicity (PBT/vPvB); endocrine disruption; ecotoxicity and basic lifecycle, exposure and risk consideration	Has the alternative(s) passed the safety evaluation and use exclusively under industrial conditions with no potential for exposure to humans and the environment? Go to Tier 2 Or does the alternative(s) have any hazard of concern or not meeting safety criteria? Consider (re) design or detailed sustainability assessment (Tier 3) Or is there potential for exposure to the wider environment and/or consumer or is there high level of uncertainty? Consider detailed sustainability assessment (Tier 3)	EU/UK REACH registration data; hazard classification under the classification, labelling and packaging regulation (CLP); regulatory dossiers
Tier 2: simplified environmental screening	Early identification of broader sustainability trade-offs and uncertainties	Rapid screening to ensure substitution does not lead to increased climate burdens or resource scarcity risks	Carbon intensity indicators; resource criticality consideration (dependence on critical raw materials); energy intensity; feedstock origin (fossil *vs.* renewable)	Are there concerns regarding environmental exposure, dependency on critical raw material and/or potential for burden shifting? If so, consider detailed sustainability assessment (Tier 3)	Industrial emission factors; sectoral carbon footprint datasets, *e.g.*, FineChem2; critical raw material lists (*e.g.*, EU/UK critical mineral strategies
Tier 3: comprehensive sustainability assessment	Detailed evaluation of environmental and sustainability impacts across the entire lifecycle	In-depth evaluation where Tier 1 or Tier 2 indicators identify potential sustainability concerns	Full lifecycle assessment (LCA); supply-chain sustainability; circularity potential; waste generation; recyclability	Retained for chemicals with a complex lifecycle with potential for environmental or human health exposure or where there is a high level of uncertainty from Tiers 1 and 2	Sustainability assessment tools

depth of assessment in line with available information, uncertainty and decision needs. It will enable SSbD principles to be integrated into the UK chemical regulatory landscape and decision-making in a practical and efficient manner, reducing unnecessary burdens on industry while maintaining support for innovation. It can also help reduce the risk of RS by ensuring that alternatives are only advanced following holistic assessment of their impacts. By reserving detailed sustainability assessments for the most challenging cases, regulators can balance regulatory efficiency with robust sustainability outcomes.

Action area 2: pilot SSbD to support regulatory strategy and guidance production

Attempting to implement SSbD universally from the outset would impose substantial administrative and technical burdens on UK regulators and industry. Given the methodological complexity inherent in integrating safety, environmental, and socioeconomic sustainability considerations into innovation decision-making, immediate universal implementation across all chemicals and sectors would be impractical.

Instead, targeted pilot programmes can support the SSbD principle of multidisciplinary engagement and collaborative learning across stakeholders. It also offers a pragmatic pathway for testing, refining, and institutionalising SSbD methodologies before extending them to the broader regulatory system. The European Commission has already adopted this approach, embedding pilot projects within the EU's Chemical Strategy for Sustainability to support the operationalisation of SSbD and recognising that iterative trial-and-error experimentation is required to translate conceptual frameworks into useable regulatory tools.[12] Pilot initiatives allow regulators, industry actors, and scientific experts to evaluate the feasibility of proposed assessment methods in real-world contexts. By applying SSbD methods to selected chemical groups or industrial sectors, UK policymakers can identify methodological challenges, data gaps, and operational barriers that may not be visible during theoretical framework development.[33–35]

In the UK, early SSbD pilot initiatives should focus on chemical groups associated with significant environmental and human health concerns, where the potential benefits of proactive intervention are greatest. PFAS are a particularly suitable candidate, frequently referred to as "forever chemicals" due to their extreme persistence in the environment.[36–38] PFAS are widely used in industrial processes and consumer products, resulting in extensive contamination of water, soil, and biota, alongside growing concerns about human health impacts. International attention to PFAS has accelerated, with growing calls for more comprehensive and anticipatory regulatory management strategies.[3,38,39] The PFAS group comprises thousands of chemically diverse substances that share persistent properties, making it a compelling example of the challenges posed by traditional substance-by-substance regulation. As such, PFAS provide an ideal test case for a more proactive, design-based SSbD approach that seek to prevent future problems at the innovation stage rather than manage them after widespread use has occurred.[5,40] A UK SSbD pilot could initially focus on relatively simpler substitution scenarios, before expanding to more complex industrial applications where performance requirements and sustainability trade-offs are less clear. This phased approach would align with the UK PFAS plan[38] while ensuring that ongoing exposure is managed effectively. Such pilots would also provide valuable practical experience for implementing SSbD approaches and help avoid future RS through a more holistic assessment of alternatives.

The selection of specific groups or sectors for piloting can offer important benefits, particularly where high-risk or high-priority substances such as PFAS are targeted, as these provide strong policy relevance, a substantial existing evidence base, and opportunities for high-impact regulatory learning. Sector-specific pilots (*e.g.*, in electronics, coatings or textiles) can further enable context-sensitive evaluation of sustainable chemical design. However, these targeted approaches also present limitations. For instance, insights derived from specific chemical classes or sectors may not be readily generalisable across the wider chemical landscape, particularly where hazard profiles, use patterns, or supply chains differ, for example nanomaterials. There is also a risk that prioritising well-studied or high-profile substances may bias methodological development, potentially overlooking less visible sustainability challenges or emerging technologies with limited data availability. Despite these constraints, the iterative nature of pilot initiatives will enable regulators to refine assessment criteria, streamline data requirements, and improve regulatory guidance for industry stakeholders. To be effective, piloting should not be limited to large corporations; it must include SMEs, academia, and third-sector organisations to ensure diverse perspectives and practical applicability across the innovation environment.[12] A pilot-based approach therefore offers a proportionate, adaptive strategy for early implementation.

Beyond methodological refinement, piloting has an essential role in building institutional capacity within organisations including regulatory agencies and industry. Implementing SSbD requires new tools, interdisciplinary expertise, and data infrastructure that may not yet be fully embedded within existing regulatory and innovation systems. Pilot projects can provide stakeholders with opportunities to develop internal capabilities in sustainability assessment, strengthen collaboration, and establish data-sharing mechanisms. This institutional learning is critical for ensuring that SSbD framework remains scientifically robust and operationally feasible. Importantly, these pilots do not necessarily require immediate legislative change. They could instead be implemented through regulatory guidance, voluntary innovation partnerships, or research-regulator collaborations. Over time, insights from pilot programmes could inform the development of standardised sustainability metrics, improve regulatory guidance, and support integration of SSbD principles into future updates of UK chemical policy. In this way, piloting will provide a pragmatic, low-risk, evidence-based pathway for progressively embedding SSbD into the UK's post-Brexit chemicals regulatory landscape, ensuring that regulatory requirements advance in parallel with scientific progress and stakeholder engagement.

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The difference in the UK regulatory landscape and institutional capacity compared to the EU means piloting within the UK should be targeted, agile, and based on a strategically differentiated approach. This approach could include high risk chemical groups or sectors as stated above or chemicals of national strategic importance such as advanced materials. Such a focused approach would allow deeper methodological development and faster regulatory learning, rather than spreading resources across a wide range of lower-priority applications.

Action area 3: dDevelop data capabilities to support SSbD implementation and working

Following the UK's withdrawal from the EU, complete access to regulatory data infrastructures associated with EU REACH has become more limited for UK regulators and industry. For example, after the UK left the EU, the registration data for approximately 20 000 substances held by ECHA was not transferred to the HSE.[41] Historically, these databases contained extensive toxicological, ecotoxicological, and environmental fate information generated by European registrants. Limited access to these data resources can therefore create challenges for the assessment of chemicals within the UK regulatory system, highlighting the need for strategic investment in predictive scientific tools and enhanced national data infrastructures. More broadly, such investment should form part of a wider policy initiative to support the operationalisation of SSbD and effective risk management in the UK. Predictive computational models and data-driven techniques, including *in vitro* screening and *in silico* approaches, can facilitate the early identification of potential safety and sustainability concerns before extensive experimental testing occurs, allowing innovators to rapidly screen substances for problematic properties during early stages of chemical design. In doing so, predictive modelling can reduce reliance on long-term experimental studies and animal testing, accelerate assessment processes and support more proactive risk management, thereby strengthening the practical implementation of SSbD within the UK chemicals landscape.

Developing UK capacity in predictive methodologies supplemented by pre-existing available (eco)toxicological test data is essential to ensure that regulatory agencies and industry can make informed decisions relating to chemical innovation. Investment in predictive modelling can help offset data limitations resulting from post-Brexit regulatory divergence, while strengthening the scientific foundation of UK chemical regulation. The UK animals in science strategy aims to phase-out animal testing wherever possible for chemicals and environmental testing, and safety and toxicity of potential novel human and veterinary medicines.[42] Similarly, a review by the UK Hazardous Substances Advisory Committee (HSAC) recommends establishing centres of excellence and a UK national reference laboratory to develop and validate new approach methodologies (NAMs), thereby supporting their wider uptake in regulatory risk assessment.[43] Creating such centres would provide opportunities to develop national expertise, expand predictive modelling capabilities, and reinforce the transition toward a more anticipatory, design-oriented regulatory framework required for safe chemical management. Predictive methodologies are particularly valuable within SSbD because they allow safety and sustainability considerations to be integrated directly into the design stage. Rather than assessing safety only after substances have entered commerce, predictive tools can enable screening of potential molecular structures prior to synthesis. Many organisations such as agrochemical and pharmaceutical companies use predictive models and computational tools to screen chemicals during the early design phase.[21,44] These capabilities can guide innovators away from hazardous structural features, assist in prioritising safe(r) alternatives, and ultimately help ensure that chemicals entering the market are both functionally effective and environmentally sustainable.

The wider adoption of alternative methods to animal testing in regulatory decisions is limited among others by validation and uncertainty concern and their ability to replicate biological systems satisfactorily;[42] in addition, complex endpoints such as repeated-dose toxicity, carcinogenicity, and chronic toxicity are not yet fully captured by existing non-animal methods, making it difficult to replace *in vivo* studies entirely while maintaining a high level of protection for human health and the environment.[45] However, uncertainties are not limited to data generation including use of predictive methods; it can also be an issue in material characterisation especially for complex or unknown materials, hazard identification including use of assessment factors, and during exposure assessment. Where uncertainties exist, adequate documentation is necessary.[12] For example, one way for uptake in the UK regulatory landscape is for regulators to consider implementing alternative test methods by first applying them to either low-risk chemicals or high-concern substances such as PFAS. The results from these alternative approaches should then be compared with data from existing or targeted animal studies to evaluate their reliability and performance. Additionally, regulators may consider applying higher uncertainty factors to account for the limitations and remaining uncertainties associated with alternative methods during the early stages of adoption.

Beyond modelling capacity, data availability and accessibility are fundamental to effective SSbD implementation. SSbD requires timely access to reliable, high-quality data on hazards, exposure potential and socioeconomic impacts. In the absence of comprehensive registrant data from EU REACH, the UK must take steps to build and curate its own data portals. A key challenge in this regard is that many relevant datasets are fragmented across institutions, proprietary systems, academic publications, and commercial laboratories. This fragmentation can limit the ability of innovators and regulators to make well-informed decisions, slow down substitution processes, and create unnecessary duplication of testing. Strengthening national data repositories, improving metadata standards, and supporting coordinated data governance structures are therefore essential for a functioning and practicable SSbD. To address these challenges and support SSbD adoption, UK data infrastructures should be developed and governed in line with the FAIR principles that data should be Findable, Accessible,

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Interoperable, and Reusable.[11,16] Applying FAIR principles will ensure that scientific and regulatory datasets can be readily located, understood, integrated across platforms, and reused for multiple decision-making purposes. For example, interoperable toxicological and sustainability datasets would support the integration of multiple indicators into SSbD assessments, while ensuring that industry can efficiently access regulatory-relevant information during innovation. FAIR-aligned data infrastructures would also facilitate the use of machine learning, quantitative structure–activity relationship (QSAR) models, and other predictive tools that depend on well-structured, standardised datasets.

Equally important is the creation of mechanisms that improve data sharing among stakeholders. SSbD relies on collaboration among industry, regulators, academia, and civil society; yet data-sharing processes are often hindered by confidentiality concerns, inconsistent data formats, and unclear expectations around proprietary information.[5,40] Establishing structured data-sharing frameworks such as trusted data intermediaries, secure data enclaves, standardised reporting templates, or pre-competitive data-sharing platforms can help overcome these barriers.[46] Such structures would enable companies to contribute non-confidential hazard, exposure, and sustainability data to shared databases, thereby improving the evidence base available for both innovation and regulation. Collaborative data-sharing agreements could also support iterative SSbD pilot projects, enabling researchers and decision-makers to compare methodologies, validate assessment tools, and identify gaps requiring additional research and investment.

In addition, the generation and availability of transparent methodologies and open-access tools can help prevent SSbD from becoming overly resource-intensive. Reliance on accessible, standardised methods would reduce the need for extensive capacity increases across industry and regulatory bodies while supporting consistent application of SSbD criteria.[17] By embedding FAIR principles, promoting data-sharing, and investing in predictive and computational approaches, the UK can build a coherent, future-ready data system. Such a system would enable smooth implementation of SSbD, reduce scientific and regulatory uncertainty, and ensure that both innovators and regulators are equipped to support the transition toward safe(r) and more sustainable chemicals. More so, to address the challenges of global trade of chemicals and products containing chemicals, the UK should consider partnering with other organisations such as the EU and governments in other jurisdictions to develop data capacity and knowledge exchange.

Action area 4: establish national SSbD Hub and support centres

Regulatory support will be essential if SSbD is to evolve from a conceptual framework into a widely adopted industrial practice. Although SSbD has the potential to prevent RS by guiding the development of safe(r) chemicals and materials, many companies particularly SMEs may lack the technical expertise, data resources, or methodological guidance required to apply safety and sustainability assessment tools during early innovation stages. Without structured institutional support, SSbD risks remaining aspirational rather than becoming a practical driver of safe(r) chemical design. UK regulators must therefore play an enabling role by providing platforms, guidance, and technical assistance that help translate SSbD principles into operational decision-making within industry.

A practical mechanism for delivering this support in the UK would be the establishment of a national SSbD Hub and support centres, bringing together regulators, industrial innovators, academic researchers, and civil society organisations to share knowledge and co-develop practical solutions to the challenges associated with sustainable chemical design. A national Hub would support cross-sector collaboration, consistent with the multidisciplinary engagement principle of SSbD. By facilitating structured dialogue and deliberation among these groups, the support centres could help bridge the gap between regulatory expectations and real-world innovation processes. This is particularly important because SSbD implementation often involves navigating complex trade-offs between safety, environmental performance, technical functionality, and socioeconomic impact. For the UK, this means establishing a central Hub to coordinate the activities of local support centres established in the various regions of the country closer to the businesses being supported. These centres can be hosted by academic institutions given the research nature of the SSbD. Dedicated support centres could therefore provide a forum to jointly evaluate trade-offs, build common definitions, and identify balanced solutions that promote both sustainability and innovation objectives.

Beyond facilitating dialogue, a national SSbD Hub and support centres could provide technical guidance and capacity building for both industry and regulators. The Hub could develop standardised guidance documents on applying predictive tools, sustainability indicators, and lifecycle thinking in chemical innovation. It could also deliver tailored training programmes and workshops to familiarise industry stakeholders with emerging methodologies, such as computational toxicology, lifecycle screening, and digital hazard assessment tools. Such activities would help ensure that companies especially SMEs possess the necessary knowledge and skills to integrate SSbD considerations into product development pipelines. Another important function of a Hub would be the development and dissemination of shared data resources and decision-support tools. Effective SSbD implementation depends heavily on access to high-quality scientific data, modelling tools, and sustainability benchmarks. In the post-Brexit regulatory landscape where UK access to certain European regulatory databases has reduced, national coordination of data infrastructure becomes increasingly important. The Hub could therefore play a central role in curating datasets, maintaining predictive modelling platforms, and providing open-access tools that can help companies identify safe(r) alternatives and compare chemicals against sustainability benchmarks.

The Hub and support centres could also act as a catalyst for collaborative pilot projects involving regulators, industry, and

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academic researchers. Such projects would allow stakeholders to test SSbD methodologies within specific chemical sectors or product categories, generating practical insights into the feasibility of proposed assessment approaches. Lessons learned from these pilots could then inform regulatory guidance, refine assessment criteria, and support gradual scaling of SSbD across the broader UK chemical sector. Ultimately, national SSbD support structures, particularly a dedicated SSbD Hub, could play a central role in translating policy ambitions into practical outcomes. By enabling knowledge exchange, supporting methodological development, and fostering collaborative problem solving, such a Hub would help create the institutional conditions necessary for SSbD to become an integral component of the UK's evolving chemical regulatory landscape. Through this enabling role, regulators would not only promote SSbD adoption but also help to establish a more innovation-friendly, proactive, and sustainability-focused regulatory system.

Action area 5: create regulatory and policy incentives to support wider SSbD adoption

Creating regulatory and policy incentives for SSbD adoption is critical for accelerating the development and uptake of safe(r) chemical alternatives. Although SSbD provides a valuable framework for integrating safety, environmental and socioeconomic sustainability into chemical design, its practical uptake may remain limited unless there are clear regulatory and market drivers.[3,47] Incorporating SSbD-informed evidence into regulatory decision-making could strengthen transparency and traceability in chemical innovation and substitution decisions. Regulatory recognition, targeted incentives and proportionate incorporation of SSbD requirements into existing chemicals regulatory frameworks can help provide certainty, reduce ambiguity and encourage investment in safe(r) and more sustainable innovation.

Within the UK, one route to encourage wider SSbD adoption is through better alignment with UK REACH and other chemicals-related regulatory frameworks including those governing plant protection products. UK REACH already encourages the replacement of hazardous substances where safe(r) alternatives are available, particularly through authorisation and restriction processes. Whilst SSbD is currently implemented as a voluntary decision-support framework, wider adoption is likely to require stronger policy and regulatory incentives that encourage its integration into innovation and chemical management processes. Clear and predictable regulatory signals can provide the confidence needed to stimulate growth and development of sustainable chemistries. For example, the proposed tiered SSbD approach could be incorporated into existing UK REACH mechanisms, with the depth of SSbD-related information requirements increasing in proportion to production volume, exposure potential and risk profile. Such an approach would build on existing regulatory requirements while providing a structured pathway for integrating safety and sustainability considerations earlier in the innovation process. Initially, SSbD elements could be introduced through guidance and voluntary schemes, with gradual incorporation into regulatory requirements as methodologies, data availability and industry experience mature.

Such policy and regulatory signals are particularly important for supporting long-term industrial investment. Chemical innovation often requires substantial investment and lengthy development times, meaning that companies must anticipate future policy and regulatory expectations when setting research priorities and making capital investment decisions. Providing

Table 2 Comparison of the proposed UK action areas with selected elements of the EU SSbD framework

Proposed UK action area	Relevant EU SSbD elements	UK-specific adaptation and additional considerations
Action area 1	Reflects the EU SSbD framework of iterative and proportionate approach, where depth of assessment increases according to innovation maturity, available information and levels of uncertainty	Introduce functional performance as an initial screening step and tailors assessment depth according to intended use, lifecycle complexity, and associated uncertainties
Action area 2	Consistent with the EU SSbD emphasis on case studies, pilot studies and practical testing to support implementation and methodological refinement	Prioritise early SSbD pilots for chemicals and sectors of strategic UK relevance, such as advanced materials, nanomaterials and high-priority chemical groups of concern including PFAS
Action area 3	Reflects the EU SSbD emphasis on evidence-based decision-making supported by data generation, predictive tools and progressive reduction of uncertainty	Promote the use of predictive models, higher uncertainty factors during early-stage development, and comparison with experimental data to build confidence in non-animal methods. Develop UK data infrastructures consistent with FAIR principles
Action area 4	Consistent with the EU recognition of support structures and stakeholder collaboration as important enablers of SSbD implementation	Establish a central UK SSbD Hub to coordinate national activities and support regional centres, while addressing specific UK regulatory and industrial needs
Action area 5	Reflects the EU objective of incorporating safety and sustainability considerations in innovation and decision-making processes	Create regulatory and policy incentives that encourage SSbD adoption, including integration of SSbD-informed evidence within UK REACH authorisation, restriction and data requirement processes, alongside funding, guidance and innovation support mechanisms

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clear incentives and recognising SSbD-informed evidence within regulatory decision-making could increase confidence that investments in safe(r) and more sustainable chemistries are likely to remain viable in the long term. In this way, policy and regulation can serve not only as mechanisms for managing risks but also as instruments for stimulating innovation and accelerating the transition towards safe(r) and more sustainable chemical solutions.

Table 2 summarises how the five proposed UK action areas draw on relevant elements of the EU SSbD framework while incorporating adaptations and additional considerations to reflect the UK's regulatory and institutional landscape.

Conclusions

Increasing awareness of the environmental and human health impacts associated with hazardous chemicals has exposed the limitations of traditional regulatory approaches, which are often reactive and address risks only after substances have entered the market. SSbD offers a more proactive alternative by integrating safety and sustainability considerations into the earliest stages of chemical innovation, thereby reducing the risk of RS and supporting the development of safe(r) and more sustainable chemicals. While the ultimate objective of SSbD is the routine development of chemicals that are both safe(r) and sustainable, current limitations in data availability, methodological maturity, and specialist expertise necessitate a simplified and progressive approach to its implementation. As knowledge, data resources, digital tools, and assessment methodologies continue to evolve, comprehensive SSbD assessments are likely to become increasingly feasible and more routinely integrated into chemical innovation and decision-making processes.

Although developed within the context of EU policy, the SSbD framework provides valuable concepts and principles that can be adapted to the UK's post-Brexit regulatory environment. The recommendations presented in this article should be viewed as a targeted application of selected SSbD concepts and principles to chemical substitution and safe(r) alternatives, rather than a full implementation of the EU SSbD framework. Through five action areas centred on proportionate assessment, predictive tools, targeted pilot programmes, institutional support, and policy and regulatory incentives for wider SSbD adoption, this article proposes a practical pathway for operationalising SSbD principles within the UK chemical regulatory landscape. Ultimately, SSbD presents an opportunity to strengthen the UK's chemicals strategy by shifting the focus from managing risks after they emerge to preventing them through better design during innovation. If supported by appropriate regulatory, technical, and institutional measures, SSbD could become an important component of a modern, innovation-friendly, and sustainability-oriented UK chemicals policy.

Conflicts of interest

The authors declare no conflicts of interest.

Data availability

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

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