2	through Innovation and Incentives in the EU
3	<u>Abstract</u>
4	The EU's Green Deal initiatives, including the Farm to Fork Strategy and the Chemical Strategy for
5	Sustainability (CSS), emphasize the need for developing plant protection products (PPPs) that meet both safety
6	and sustainability goals. In the EU, PPPs are regulated under Regulation (EC) No. 1107/2009 which sets
7	approval criteria to ensure human health and environmental safety. This legislation is complemented by
8	Sustainable Use of Pesticides (SUD) (Directive 2009/128) which aims to achieve sustainable pesticide use by
9	minimising risks to human health and the environment, while promoting use of Integrated Pest Management
10	(IPM) and non-chemical alternatives. Both legislations address the conditions of placing on the market and the
11	use of PPPs, neither directly address broader aspects of sustainability compliance, such as the lifecycle impacts
12	resource efficiency during design and manufacture and socioeconomic dimensions of sustainability. The EU
13	Commission's Joint Research Centre (JRC) Safe and Sustainable by Design (SSbD) framework offers a holistic
14	approach to chemical product innovation, minimising risks and maximising sustainability throughout a
15	chemical's lifecycle. This framework, combined with existing safety regulations, can advance sustainability of
16	plant protection products in-line with the European Green Deal and the CSS. Agrochemical manufacturers have
17	embedded SSbD-aligned practices in their innovation pipelines, but approaches used tend to be company-
18	specific and lack standardised metrics. Incorporating well defined sustainability criteria and incentives for
19	manufacturers would accelerate the development of PPPs that contribute to long-term agricultural sustainability
20	safeguard human health and the environment, and ensure food security in line with sustainable development
21	goals.
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23	Key words: Plant Protection Products (Agrochemicals), Pesticides regulation, Safe and Sustainable by Design
24	(SSbD), Sustainable Use, Sustainability criteria
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Greening Agriculture: Accelerating Safe and Sustainable by Design (SSbD) Plant Protection Products

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Introduction

Increasing global population is intensifying the pressure on food production to meet the demand of a growing population. The United Nations (UN) projects that the world population will reach 9.7 billion by 2050 and 10.4 billion by 2100 (United Nations, n.d.). This growth will lead to a significant rise in food demand and resources (Viola et al., 2016) requiring the food industry to increase production by 15% within the next decade (Bremmer et al., 2021; WHO & FAO, 2019).

Plant Protection Products (PPPs) bring benefit to crop production by reducing pest pressure and damage to crop, but may also negatively impact the environment, human health and biodiversity if not used according to label recommendation, the intended use rates and the approved mitigations measures (Campos et al., 2019; Abbes et al., 2015, Kaur et al., 2014; Mahmood et al., 2016; Mishra et al., 2023; Zhang et al., 2021). Consequently, the EU regulation for the approval of use of a PPP (Regulation (EC) 1107/2009) requires a thorough evaluation before PPPs are approved and authorised for sale and use, primarily ensuring that approved products meet regulatory criteria regarding acceptability of risks to human health and the environment. Regulation (EC) 1107/2009 ultimately focuses on the safety from the use of PPPs. While safety is a key pillar of sustainable use, the regulations are not intended to address other aspects of sustainability of the PPPs. These include environmental impacts throughout the lifecycle, sustainable sourcing of raw materials, implementing green chemistry principles, minimising carbon emissions, reducing resource demands and hazardous waste generation, as well as socio-economic factors.

In terms of chemicals and materials, Caldeira *et al.* defines sustainability as 'the ability of a chemical or material to deliver its function without exceeding environmental and ecological boundaries along its entire lifecycle, while providing welfare, socio-economic benefits and reducing externalities' (Caldeira et al., 2022), Prioritising sustainably designed PPPs can reduce environmental impact and support long-term agricultural productivity and food safety, aligning with the United Nations Sustainable Development Goals (SDGs), including no poverty (SDG1), zero hunger (SDG2), good health and wellbeing (SDG3), and responsible consumption and production (SDG12). The EU Commission 'Safe and Sustainable by Design' (SSbD) framework being developed by the Joint Research Centre (EC JRC), aims to provide guidance on developing safe and sustainable chemical products, encouraging innovation to reduce use of hazardous substances, and minimising impacts on human health, climate, and the environment (Caldeira et al., 2022). This article evaluates the alignment of EU pesticide

56 regulation with the SSbD framework, examples of how SSbD approaches are being incorporated by 57 agrochemical manufacturers and discusses the potential for sustainable by design criteria to be incentivised to 58 accelerate the development of sustainable advantaged products to the EU market. 59 60 Regulation of Plant Protection Products (PPPs) in the EU 61 In the EU, PPPs are regulated under EU Pesticides Regulation (EC) No. 1107/2009 (European Commission, 62 2009a) which ensures that PPPs on the market comply with human health and environmental protection goals, 63 while being effective against target pests or plant diseases (Lykogianni et al., 2021). The regulatory process is 64 thorough, requiring both active substances and formulated products to be fully evaluated prior to active 65 substance approval and product registrations at national level. Applicants must submit complete dossiers, 66 including studies on physicochemical properties, toxicology, metabolism, environmental fate, ecotoxicology, 67 residues and evidence of effectiveness against target pest or disease, according to Regulation (EC) No. 283/2013 68 for the active substances and Regulation (EC) No. 284/2013 for the PPPs, with exposure and risk assessments 69 for human and environmental safety being integral to the approval criteria. The EU regulatory process includes 70 regular re-evaluation and re-approval of active substances every 10 years (15 years for low-risk active 71 substances), which ensures continual updates to address evolving scientific understanding and risk assessment 72 requirements. 73 74 The Directive on the Sustainable Use of PPP (SUD) (EU Directive 2009/128) (European Commission. 2009b). 75 complements Regulation (EC) 1107/2009. The SUD promotes the use of low-risk products or non-chemical 76 alternatives, the implementation of integrated pest management principles (IPM), proper maintenance of 77 pesticide application machinery, and the training for pesticide handlers to minimise exposure. However, the 78 SUD primarily focuses on the use of the product, rather than the entire lifecycle of PPP. Figure 1 provides an 79 overview of the relationship between Regulation (EC) 1107/2009 and the SUD. 80 81 82 83 Safe and Sustainable design of plant protection products 84 The European Green Deal (European Commission. 2019) aims to support a more sustainable future and to

implement the United Nations' sustainability agenda 2030, including the Zero Pollution Ambition (European

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Commission. 2021). To achieve this, the Chemicals Strategy for Sustainability (CSS) outlines a set of actions. Specifically, within the CSS action 2.1 - Innovating for safe and sustainable EU chemicals, sub-action 2.1.1 aims to catalyse the shift towards chemicals, materials and products that are safe and sustainable by design (SSbD) throughout their life cycles, from resources extraction to end-of-life management (European Commission. 2020b). Similar to this, the Farm to Fork Strategy, launched by the European Commission in 2020 as a central pillar of the European Green Deal, broadens the perspective by aiming to make food systems fair, healthy, and environmentally sustainable (European Commission 2020c). While safety of the PPP is thoroughly evaluated under existing EU regulation, to align the development of PPP with the CSS, sustainable design throughout the products lifecycle should be pro-actively supported.

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To support the CSS implementation, EU Commission's Joint Research Centre (JRC) is developing a framework for the definition of Safe and Sustainable by Design (SSbD) criteria for chemicals and materials. The framework integrates the safety, environmental and socio-economic dimensions of sustainability (Calderia et al., 2022). The SSbD framework is a voluntary approach to guide innovation towards green and sustainable industrial transition, substitute or minimise the production and use of substances of concern and reduce impact on health, climate and the environment during sourcing, production, use and disposal (Calderia et al., 2022). The concept of SSbD is structured around two phases, 1. (Re)Design based on guiding principles from existing concepts, such as Green Chemistry to increase material efficiency, minimise hazardous materials and lifecycle considerations; and 2. Safety and Sustainability assessment, covering inherent properties, production safety, inapplication use, environmental sustainability and socio-economic assessment (Calderia et al., 2022). The guiding principles and assessment steps of SSbD focusing on hazard assessments and the 'Safe by Design' aspects, are already comprehensively addressed within Regulation (EC) 1107/2009 and the SUD. However, aside from safety, the broader scope of sustainability of a PPP are not intentionally incorporated in either legislation. Adopting SSbD principles in product development can reduce environmental impact from all stages of the product lifecycle, increase support for EU sustainability goals and meet consumer demands for ecofriendly products. The SSbD framework marks a significant shift from traditional risk management to a prevention-based strategy that emphasizes the design of safer and more sustainable chemicals from the outset (Furxhi et al., 2023).

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From the earliest design stages, SSbD encourages consideration of both safety and sustainability well before regulatory studies take place. To date SSbD has primarily been applied to industrial chemicals and not PPPs, reflecting the historical siloing of chemicals by use or sectors. The availability of extensive data for PPPs when compared to industrial chemicals for which the SSbD framework was originally developed, provides a foundation for adapting the framework's application to PPP. Agrochemical companies already employ advanced screening tools, computational models, and predictive toxicology to identify effective and safe molecules early on, ensuring that only the best candidates move forward in the innovation phase. These include implementing new alternative methods (NAMs) in early-stage development, such as *in-silico* genotoxicity and endocrine screening, and in-vitro fish toxicity assays (Henriquez et al., 2024). These methods enable rapid assessment of many analogues before resources are invested in full regulatory testing. Beyond safety screening, agrochemical companies have adopted green chemistry principles of product development and manufacturing. Corteva, for example has been a recipient of the U.S EPA Green Chemistry Challenge Award on more than five times for more sustainable innovation in manufacturing (Corteva, 2024). Agrochemical companies also report the use of life-cycle assessments (LCA) to design and evaluate more sustainable products throughout their value chain including comparative assessments of economic advantages of a product (Corteva Agriscience, 2024; Syngenta, 2024, Bayer Crop Science, 2024). These practices reflect SSbD principles, indicating that agrochemical companies meet safety regulations and actively pursue sustainable innovation in product design and manufacturing. However, methods and metrics are often company-specific, and tailoring the SSbD framework to agrochemicals offers the opportunity for development of standardised and consistent metrics and reporting. Socio-economic considerations are an optional, but important, part of SSbD and are especially applicable in the agrochemical sector. Products are typically developed by manufacturers in response to market and grower needs, and while socio-economic benefits are implied, they aren't necessarily explicit for regulatory approval. Clearly demonstrating agronomic benefits such as pest resistance management and compatibility with integrated pest management (IPM) as well as benefits to the grower such as yield increase, fewer applications and flexibility of use (e.g. variety of application methods, short post-harvest intervals) can justify the sustainable advantages of a product and its prioritisation for evaluation for approval. Table 1 summarises how SSbD principles align with current agrochemical development practices and EU regulatory framework.

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Sustainability of plant protection products, desirable properties and potential trade-offs

The use of multi-criteria decision analysis (MCDA) is also incorporated within SSbD framework as a core methodological approach to evaluate and compare chemicals and materials across key criteria of safety and sustainability. The use of MCDA supports the transparent and structured decision-making when assessing trade-offs between different safety and sustainability criteria, which is essential as SSbD assessments involve diverse and conflicting objectives (e.g. toxicity reduction vs. resource efficiency) (Abbate et al., 2024). This is particularly relevant for PPP which are one component of complex agricultural systems. While the need for sustainable PPPs is evident, the level of management and range of farming operations, each of them with varying levels of sustainability independent of chemical use, adds extra complexity to evaluating sustainability in agricultural systems. This involves trade-offs to ensure food security while minimising impact on ecosystems, such as soil health and water resources. It's also important to consider the economic impact on farmers such as whether the benefits of increased crop yield and quality outweigh the costs of purchasing and applying PPP, or the cost of using alternative crop protection solutions, and the sustainability of those alternatives. When determining relevant metrics and criteria for PPP sustainability assessments, trade-offs between use, function to support food security and wider agricultural system need consideration. Lykogianni et al., 2021 highlighted the complexities of evaluating the sustainable use of pesticides in agriculture and noted the multidisciplinary aspects which require input from all stakeholders to ensure sustainable food production. Table 2 provides high-level examples of perceived desirable properties of a sustainable agrochemical, their potential trade-offs, and the link to the sustainability components.

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Achieving sustainable agricultural practices requires balance between environmental, economic and social aspects while considering trade-offs for food security. Stakeholder engagement is important to reach a common understanding of diverse perspectives and values, and a participatory approach can enhance the relevance of sustainability analyses (Klapwijk et al., 2014). Setting clear and measurable sustainability criteria for the use and development of PPPs in the EU will encourage innovation and ensure the development of PPP aligns with the EU sustainability goals. The SSbD framework, though not specifically focused on PPPs, can provide a structured evaluation process to address these different trade-offs and integrate sustainability into PPP design, complementing existing EU pesticide regulation and the SUD.

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Sustainability and incentives

Hamlyn (2015) examines sustainability in the context of its potential to regulate pesticide use. The author highlights various sustainability elements such as environment, social and economics that should ideally be embedded within directives such as the SUD. The author concludes that the SUD takes a narrow approach, focusing primarily on risk management rather than fully embracing sustainability principles with their implementation. Integrating additional sustainability criteria into existing legislation could however add another layer of complexity to an already intricate regulatory system, potentially limiting innovation. Instead of imposing sustainability hurdles in addition to the regulatory requirements for safe use, one could indeed question whether the introduction of additional sustainability criteria, particularly on manufacture, lifecycle and socioeconomic factors are relevant for a legislation or if they could be addressed differently, such as incentivising the adoption of SSbD by manufacturers.

Innovation and incentives are two crucial components in the development of sustainable chemicals. Within Regulation (EC) 1107/2009 the incentivisation of lower-risk substances is stated "the evaluation of an active substance may reveal that it presents considerably less of a risk than other substances...to favour the inclusion of such substances in plant protection products, it is appropriate to identify such substances and facilitate the placing on the market of products containing them. Incentives should be given..." (European Commission., 2009b). An active substance can be designated low risk if it meets the regular approval criteria of Article 4 and in addition meets the low-risk exclusion criteria of point 5, Annex II of the Regulation, i.e., does not have human health classifications including, carcinogenic, endocrine disruption, mutagenic, reproductive toxicity, respiratory or eye sensitiser, is not explosive, has low toxicity to aquatic species and meets low persistence and bioconcentration criteria. Although, low risk substances and products follow the same evaluation and approval procedure as standard PPPs, the development of low-risk substances are incentivised through longer approval periods (up to 15 years instead of 10 years before re-evaluation), extended data protection (from 10 to 13 years in the EU and up to 15 years in the UK) as well as potential for fast-track authorisation, reducing the intended evaluation time period from one year to 120 days (European Commission., 2017).

The EU has 423 active substances currently approved for use as pesticides. Of these 77 are registered as low-risk substances. However, most of these low-risk substances are microorganisms such as *Bacillus* amyloliquefaciens or insect pheromones, including straight chain lepidopteran pheromones. Only 19 low risk substances are chemicals including urea, sodium bicarbonate and laminarin, making up just 4.5% of all

registered pesticides in the EU (EU Pesticide Database., 2025). This incentivisation for low-risk substances therefore typically applies to a narrow scope of substances. The criteria for low risk are only related to the direct risks from the use of the PPPs, and do not include the safety and sustainability of the product design and development throughout the lifecycle. This leaves scope for potentially expanding similar incentives, such as priority evaluation and reduced evaluation time to products which have followed a SSbD framework during their development.

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A successful example of prioritising the evaluation of sustainably advantaged products is from the US EPA Reduced Risk Pesticide Program, which is designed to expediate the regulatory approval of pesticides which pose a reduced risk based on a specific use, to human health and the environment when compared to alternative products already on the market. To obtain a reduced risk use status, the applicant must provide evidence supporting the substance's lower risk to human health, non-target species and water quality, lower application rates, compatibility with IPM, and the pesticides' role in pest resistance management, when compared with similar substances already on the market. If reduced risk status is approved, the pesticide may be registered in less than 18 months, which provides a significant competitive incentive when compared to a typical time of approximately 4 years for the approval of a conventional pesticide. The Reduced Risk Program has supported the replacement of more toxic pesticides with lower risk alternatives and has accelerated manufacturers to invest in safer, more sustainable products since 1994 (US EPA., 2024). Another consideration for incentivisation is the initial costs for incorporating SSbD principles into the development of a chemical, including implementing life-cycle assessments, modifying manufacturing systems as well as lack of in-house expertise to navigate complex and evolving sustainability frameworks may present a barrier for small to medium enterprises (SMEs). As a result, SMEs may be discouraged from investing in SSbD compliant innovations. The provision of targeted incentives such as technical support or streamlined regulatory evaluation for SSbD products can help lower these entry barriers and encourage broader participation in sustainable innovation.

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Conclusions and recommendations

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Safety is the cornerstone of European Union pesticide regulation, Regulation 1107/2009, and is prioritized within the agrochemical manufacturing sector. Alongside safety, the sector has increasingly adopted Safe and

Sustainable by Design (SSbD) principles, evident through early-stage hazard screening, the application of green chemistry during manufacturing, and the use of life cycle assessment (LCA) across product stages. Although these practices demonstrate alignment with SSbD principles, their implementation is often fragmented and varies between companies. Establishing a coordinated agrochemical SSbD framework could standardise reporting, harmonise metrics, and broaden the scope of sustainability beyond safety alone.

The SSbD framework should be positioned as a complementary mechanism, supporting innovation of products that comply with Regulation 1107/2009 safety requirements but are also designed and manufactured to maximise sustainability and agricultural benefits. Rather than introducing additional regulatory hurdles, SSbD should aim to recognise and incentivise practices that enhance sustainability. Promoting voluntary reporting and transparency within SSbD can establish positive drivers for industry innovation.

By incentivising the adoption of SSbD principles, the development of PPPs can be better aligned with the European Union's objectives for environmental stewardship and sustainable agriculture. Incentives are particularly relevant for small and medium sized enterprises (SMEs) to reduce the barriers to SSbD adoption such as limited internal resources for method development and initial investment costs.

Recommendations and actionable steps to further advance SSbD principles within EU PPP development could include:

- Fee reductions: Financial incentives, such as fee reductions, should be introduced for dossiers that include peer-reviewed SSbD evidence and meet established SSbD performance benchmarks.
- Encourage collaboration and standardisation: Encouraging early collaboration for reporting metrics and
 data sharing between companies, regulators, and stakeholders can reduce uncertainties during the
 development process from initial stages to help ensure effective integration of SSbD principles into
 new projects.
- 3. Market incentives via labelling: Establishing a voluntary EU label or recognition scheme for PPPs demonstrating verified SSbD advantages. SSbD labelled products may be prioritised by food chain partners or within public procurement processes, rewarding enhanced sustainability performance through market-driven incentives.
- 4. Priority evaluation for SSbD-Verified products: Introducing a mechanism for priority evaluation of PPPs that address SSbD verification criteria. This may include accelerated review timelines for dossiers demonstrating strong SSbD performance and alignment with EU sustainability targets.

262	The principles of the SSbD framework provide a robust basis for sustainable product design and can be tailored
263	to the specific characteristics of PPPs. By embedding sustainability considerations from the design phase
264	through to end use, while ensuring regulatory safety standards, the European Union can guide the agrochemical
265	industry to align with EU and UN sustainability goals.
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348	Figure caption and table headings
349	Figure 1: Overview of the EU regulatory process and relationship between Regulation 1107/2009 and
350	Sustainable use directive (Directive 2009/128/EC) (European Commission (2020a). (PPP = Plant Protection
351	Product; MRL = Maximum Residue Level. Highest concentration of the pesticide legally permitted on or in
352	food/feed; GAP = Good Agricultural Practices; IPM = Integrated Pest Management)
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354	Table 1: Summary of SSbD principles alignment with industry practices and EU regulatory requirement
355 356 357 358	Table 2: Examples of potential desirable properties for sustainable plant protection products and their trade-offs
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