Environment International 207 (2026) 109974

Contents lists available at ScienceDirect

Environment International

journal homepage: www.elsevier.com/locate/envint

Review article

Advancing environmental risk assessment (ERA) of plant protection products through a systems-based approach to strengthen biodiversity protection☆

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ARTICLE INFO

Keywords:
Biodiversity
Conservation
Ecotoxicology
Environmental risk assessment
Plant protection products
Systems-based ERA

ABSTRACT

In the European Union, regulated products such as plant protection products (PPPs) must undergo prospective environmental risk assessment (ERA) and obtain regulatory approval before use. ERA evaluates the potential adverse effects regulated products may pose to the environment, aiming to ensure that their use does not result in unacceptable effects. Despite ongoing improvements accumulated empirical evidence shows that current chemical ERA practices fall short of ensuring sufficient environmental protection, highlighting the need for better alignment with real-world ecological and agricultural conditions. Advancing ERA requires not only integrating a more realistic understanding of environmental contexts, but also fostering interdisciplinary collaboration and engaging stakeholders through knowledge-sharing platforms and partnerships. Within this context, the Partnership for the Assessment of Risks from Chemicals (PARC) is exploring new avenues to transform PPP ERA through six key actions: (1) clarifying regulatory needs to ensure regulatory relevance and facilitate regulatory uptake of project outcomes; (2) benchmarking ERA against real-world data for calibration and explore ways to simplify ERA processes; (3) improving ERA comparability to enable cross-substance comparison and ranking; (4) increasing ecological realism to deliver more realistic, context-dependent ERA predictions along with effective risk mitigation and sustainable use measures; (5) updating and modernising ERA approaches to reduce uncertainty, unnecessary complexity, and animal testing; and (6) fostering the transition toward a systems-based approach by interconnecting stakeholders and integrating data, knowledge and expertise across regulatory frameworks. In doing so, PARC aims to advance PPP ERA toward a holistic, systems-based ERA framework that supports the progressive phase-out of animal testing. Together, these efforts emphasise the urgent need for an interdisciplinary ERA platform that integrates scientific knowledge across domains, enhances biodiversity protection against chemical stressors, and drives the transition toward systems-based ERA for PPPs.

☆ This article is part of a special issue entitled: 'B-SAFE: Science for ERA' published in Environment International.

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https://doi.org/10.1016/j.envint.2025.109974
Received 27 May 2025; Received in revised form 7 November 2025; Accepted 30 November 2025
Available online 3 December 2025

1. Introduction

Despite various international and national policy initiatives, global biodiversity continues to decline at unprecedented rates. This loss is driven by factors such as habitat deterioration and depletion, overuse of ecosystems, climate change, invasive species, and chemical pollution (IPBES, 2019; WWF, 2022; EEA, 2025). Agrifood systems contribute to these issues (e.g., Jaureguiberry et al., 2022; Rockström et al., 2025). Mitigating their environmental footprint is a significant challenge that requires immediate, integrated, and collaborative action (Halpern et al., 2022; Rockström et al., 2025).

Agrifood systems increasingly rely on chemical pesticides (i.e., plant protection products (PPPs)) to sustain crop yields (Marelli et al., 2025). In the European Union (EU), Regulation (EC) No 1107/2009 governs market placement of PPPs (European Parliament & Council, 2009). First, the European Commission must approve the active substance in a PPP. Then, EU Member States can authorise PPPs containing that substance for their national markets. Regulation (EC) No 1107/2009 requires proof that PPPs do not harm human and animal health, including vulnerable groups, or have unacceptable environmental effects, before they can be marketed. Consequently, a prospective environmental risk assessment (ERA) is conducted to evaluate the risks and potential adverse effects of the active substance in a PPP applied under realistic conditions of use.

Despite strict regulations on PPPs and their active substances, their direct application in the environment remains a significant concern for environmental protection and biodiversity conservation. Their widespread use leads to contamination of water, soil, and air, and contributes to biodiversity loss in Europe (e.g., Rigal et al., 2023; Pesce et al., 2025). For instance, PPP use significantly reduces bird and invertebrate populations, impacting ecosystem functions and services (Eng et al., 2017, 2019; Schulz et al., 2021; Faburé et al., 2025; Wan et al., 2025).

Many academics, regulatory scientists, decision-makers, and stakeholders—including farmers, advisers, non-governmental organisations, and consumer or community groups—have consistently advocated for advancing the regulatory ERA framework for PPPs (e.g., Vijver et al., 2017; Schäfer et al., 2019; Topping et al., 2020; Liess et al., 2021; Weisner et al., 2021; Devos et al., 2022a, 2022b; Sousa et al., 2022; Sumpter et al., 2022; EASAC, 2023; Fisher et al., 2023; Nicholson et al., 2023; Axelman et al., 2024; Siddique et al., 2024; Bub et al., 2025). Their shared goal is to ensure that ERA better reflects real-world ecological and agricultural conditions, aligns with evolving policy targets such as those outlined in the European Green Deal, and meets growing societal demands for sustainable agrifood systems.

The current ERA framework does not fully account for sublethal, indirect, and trophic effects, nor landscape considerations (e.g., Sumpter et al., 2022; Fisher et al., 2023; Liess and Gröning, 2024; Solé et al., 2024; Tarazona et al., 2024; Faburé et al., 2025). It also fails to account for the combined effects of PPP mixtures that arise from sequential applications within specific cropping systems or from the use of different PPPs that lead to spatial co-exposure—both at the local (field) level and across broader spatial and temporal scales (e.g., Schäfer et al., 2014; Weisner et al., 2021; Sousa et al., 2022; Sumpter et al., 2022; EASAC, 2023; Nicholson et al., 2023; Williams et al., 2023; Tarazona et al., 2024). The fragmented regulatory landscape further complicates efficient resource and knowledge use (Sousa et al., 2022; Sylvester et al., 2023; Williams et al., 2023; Axelman et al., 2024).

To address these issues, a systems-based approach to ERA is advocated, integrating ecological realism and cross-disciplinary collaboration (e.g., EFSA, 2021; EFSA (Scientific Committee), 2021; Devos et al., 2022a, 2022b; Sousa et al., 2022; Williams et al., 2023; Axelman et al., 2024; Tarazona et al., 2024; Topping et al., 2020). This approach employs systems thinking to understand complex (including ecological and regulatory) systems by analysing how their interconnected parts function and interact, considering various perspectives, expertise, and boundaries. It considers the ecological system and the spatial and temporal scales of PPP exposure and effects. Additionally, it aims to enhance stakeholder connections and integrate data, knowledge and expertise within the PPP regulatory framework and across other regulatory regimes.

In 2022, the Partnership for the Assessment of Risks from Chemicals (PARC) was established as an EU-wide public-public partnership (PARC consortium, 2022). Its goal is to advance the European research and innovation in risk assessment to better protect human health and the environment from chemicals (Marx-Stoelting et al., 2023). PARC supports the EU Chemicals Strategy for Sustainability, the EU "Zero pollution" ambition, and EU and national chemical risk assessment and risk management bodies. It also aims to strengthen collaborations between stakeholders and sectors to address chemical safety challenges. PARC includes over 200 organisations from across Europe, including three European agencies, with a budget of 400 million euros (https://www.eu-parc.eu/).

Within PARC, Activity 6.4.4 "*Risk assessment to support and promote efficient overall protection of biodiversity*" focuses on advancing the ERA of chemicals to better protect biodiversity and the wider environment. Initially, the research targets PPPs, addressing both the EU-level regulatory ERA process for active substances and the national-level authorisation process for PPP uses. It is expected that PARC 6.4.4 results can be broadly applied to other chemicals. Currently, PARC 6.4.4 includes five research projects: (1) Clarifying regulatory needs; (2) Exposure; (3) Effects; (4) Benchmark; and (5) Landscape (see Fig. 1). Collectively, these projects aim to improve ERA by overcoming the limitations of the current substance-by-substance approach and adopting a more realistic consideration of the environmental context. Efforts focus on connecting data resources, integrating expertise, and developing holistic and systems-based approaches to make ERA fit for purpose. This publication outlines the initiatives of PARC 6.4.4 to advance PPP ERA in the EU and facilitate the transition to a more holistic, systems-based ERA framework, and emphasises the necessity of establishing an interdisciplinary ERA platform for knowledge-building to achieve these goals.

This publication does not aim to present a fully standardised regulatory PPP ERA scheme. Instead, building on insights from the first three years of PARC 6.4.4, it outlines a concrete pathway toward systems-based ERA by: (1) engaging stakeholders to reframe the problem; (2) co-developing proof-of-concept solutions in critical areas; and (3) preparing practical, pilot-ready tools and approaches for near-term regulatory uptake. In doing so, it lays the essential foundations and defines prioritised next steps to operationalise an ERA that is ecologically realistic, scalable across landscapes and time, and interoperable with adjacent regulatory regimes.

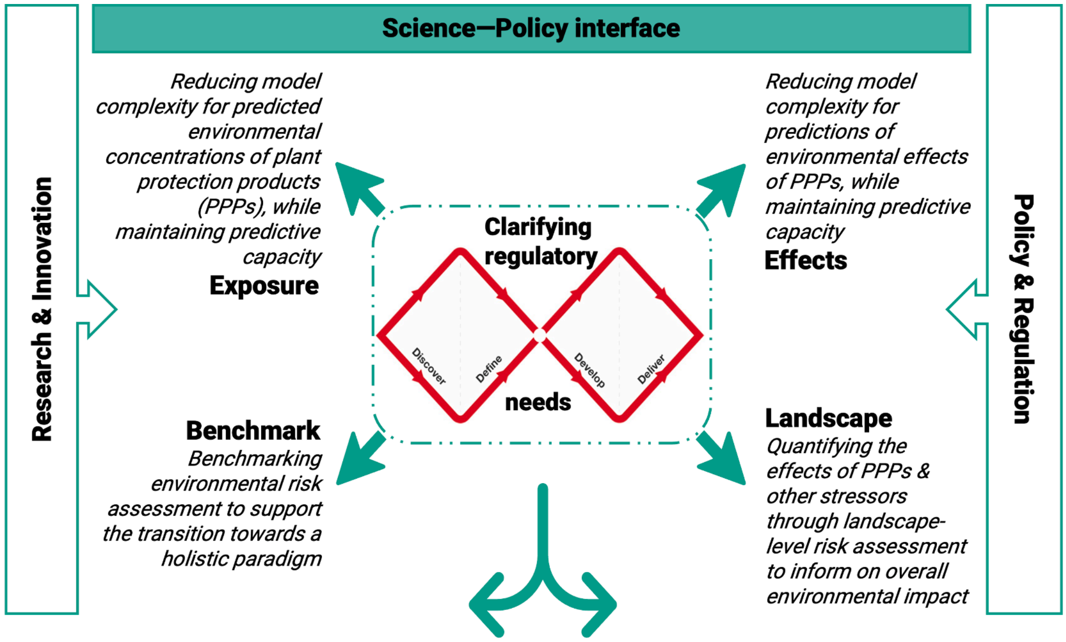

Fig. 1. Research projects under the Partnership for the Assessment of Risks from Chemicals (PARC). This figure illustrates the constellation of research initiatives within Activity 6.4.4 of PARC, which aims to advance the environmental risk assessment (ERA) of plant protection products toward a systems-based approach. The research operates at the science-policy interface, translating regulatory priorities into targeted scientific actions through the "Clarifying Regulatory Needs" (CRN) project. The CRN project serves as a strategic anchor, guiding the conceptual framing and methodological development of the four interconnected projects "Exposure", "Effects", "Benchmark" and "Landscape". These projects are designed to interact in a complementary and coordinated manner, ensuring scientific advancements remain aligned with evolving regulatory priorities and practical decision-making needs. The framework follows an iterative and collaborative knowledge-building process, consistent with the Double Diamond approach (Design Council, 2004), which supports structured exploration, inclusive problem framing, and co-development of solutions across disciplines, sectors, and regulatory domains. Deliverables from PARC 6.4.4 will include new methods, stakeholder engagement outputs, recommendations for regulatory uptake, and benchmarking frameworks to support comparability and prioritisation. These deliverables are designed to feed back into both research and innovation (R&I) and policy and regulatory development.

2. Innovative approaches to advance PPP ERA methodologies

The activities in PARC 6.4.4 aim to:

(1) Clarify regulatory needs to ensure regulatory relevance and facilitate regulatory uptake of project outcomes to bridge the science–policy gap;
(2) Benchmark ERA against real-world data for calibration and explore ways to simplify ERA processes, while increasing predictability;
(3) Improving ERA comparability to enable cross-substance comparison and ranking;
(4) Increase ecological realism to deliver more realistic, context-dependent ERA predictions along with recommendations for possible risk mitigation and sustainable use measures;
(5) Update and modernise ERA approaches to reduce uncertainty, unnecessary complexity, and animal testing;
(6) Foster the transition toward a systems-based approach by interconnecting stakeholders and integrating data, knowledge, and expertise within and across regulatory frameworks.

2.1. *Clarify regulatory needs*

To effectively advance PPP ERA, it is crucial to understand the perspectives and concerns of various stakeholder groups. These stakeholder groups include policy makers, risk managers, regulators, risk assessors, academics, industry, non-governmental organisations, farmers, and agronomic advisors. While the stakeholder groups are established, the process of engaging specific actors within each category is ongoing. This iterative approach allows for the refinement of stakeholder involvement based on evolving project needs and feedback from initial consultations. Capturing their views on the current regulatory ERA framework and systems-based ERA, enables identifying the strengths and weaknesses of the existing system and exploring ways to improve it.

For the development of the 2022 PERA Roadmap (*Building a European **P**artnership for next-generation, systems-based **E**nvironmental **R**isk **A**ssessment*), commissioned by the European Food Safety Authority, Sousa et al. (2022) gathered preliminary insights into the current regulatory ERA frameworks and the potential for systems-based ERA for PPPs. This was achieved through semi-structured interviews and stakeholder workshops (see also Axelman et al., 2024). Their findings revealed that regulatory needs and priorities vary significantly depending on the stakeholder's perspective within the regulatory PPP ERA framework, highlighting the importance of continued dialogue with stakeholders to better comprehend both current and future regulatory needs. Such enhanced dialogue is essential for establishing a shared understanding of key terms and for co-developing a collective vision for systems-based ERA. Sousa et al. (2022) also emphasised the need for a unified and workable definition of what constitutes a systems-based approach to ERA, which would help guide further methodological development and regulatory alignment.

Under the "Clarifying regulatory needs" (CRN) project of PARC 6.4.4, current challenges and areas for improvement in PPP ERA are identified and mapped using an iterative and collaborative knowledge-building approach. This process is structured around the Double Diamond approach (Design Council, 2004), which supports exploration and refinement through phases of divergent and convergent thinking. This framing helps clarify how regulatory needs are translated into targeted research questions, data requirements, and methodological innovations.

A key focus of the "CRN" project is to address the complexity of PPP ERA by identifying where simplification is both feasible and beneficial. Through stakeholder engagement at European, national, and regional levels, including online surveys and follow-up workshops, the project collects views and concerns that help identify needs for improving regulatory efficiency and effectiveness. This two-way exchange ensures that data collection is guided by regulatory priorities, while also allowing regulatory ERA frameworks to evolve in response to emerging scientific insights and systems-level complexity. In parallel, the "CRN" project explores how to support the transition toward systems-based ERA by establishing a common understanding of key concepts, refining the vision for future ERA, and identifying pathways for regulatory uptake and acceptance of newly developed tools.

While proposing a specific regulatory ERA scheme may be premature at this stage, addressing procedural complexity—particularly where it arises from unnecessary assessment detail—is a critical area for development. This aligns with the preliminary findings of the PERA Roadmap (Sousa et al., 2022), which envisions a more streamlined and comparable, dossier-by-dossier authorisation process. Sousa et al. (2022) also highlight the opportunity to manage ecological aspects of ERA through a supporting process outside the core regulatory framework. This separation could help avoid duplication of effort and inconsistencies, while maintaining scientific integrity and improving overall efficiency.

2.2. Benchmark ERA against real-world data

Concerns have been raised about the increasing complexity of the regulatory PPP ERA framework. It has become difficult to navigate and lacks predictability in both risk assessment timelines and upcoming decisions, which may contribute to delays in decision-making (ZAPID, 2024). Much of this complexity stems from fragmented data sources and untested assumptions that can undermine both the accuracy and practical utility of assessments (Axelman et al., 2024). The pursuit of scientifically robust ERAs has resulted in an expanding body of guidance documents and EU data requirements, alongside regular updates to existing ones (e.g., ZAPID, 2024). However, as noted by ZAPID (2024), these changes do not necessarily translate into improved environmental protection or safety, instead they contribute to a fragmented and inconsistent ERA landscape across chemicals. Moreover, the growing complexity of the regulatory framework for PPP ERA might compromise its protective aim of eliminating high-risk PPPs and promoting safer alternatives, while potentially stifling growth and innovation. In response, PARC 6.4.4 explores ways to improve regulatory efficiency and effectiveness by simplifying models, focusing on key risk factors, and encouraging greater collaboration. This would support the development of science-based approaches for a simpler and faster PPP ERA process, while optimising data and resource utilisation.

The PARC 6.4.4 projects collaboratively aim to streamline ERA methodologies by addressing complexity at its root. By identifying key risk factors within representative agricultural and ecological contexts, they enable a focused approach on the most influential factors. This is achieved through benchmarking models of varying complexity against environmental monitoring datasets and applying sensitivity analyses to pinpoint essential model parameters, thereby minimising unnecessary detail and computational load. In this respect, it is crucial to evaluate the predictive power of models with differing levels of complexity and mechanistic detail. Such assessments help determine the appropriate degree of complexity required for regulatory ERA, guiding the selection of optimal methods, and fostering a systematic, data-driven refinement of prospective ERA approaches. A clear distinction must be made between the level of detail in models used directly for regulatory ERA and those applied to problem framing or understanding system behaviour. For instance, establishing benchmark thresholds for ERA may necessitate comprehensive systems models (Topping and Luttik, 2017) supported by field validation data. Conversely, the application of these thresholds can be effectively integrated into simpler, fit-for-purpose models that are readily deployable in regulatory contexts. The "Exposure" project under PARC 6.4.4 aims to simplify and enhance predictions for the exposure characterisation of PPPs under Regulation (EC) No 1107/2009. Currently, the exposure characterisation is highly sophisticated, relying on various models with numerous parameters influencing the predictions (Knäbel et al., 2012, 2014). In a proof-of-concept study, Boström et al. (2019) devised a simplified approach for calculating predicted environmental concentrations (PECs) in surface water and compared these PECs against measured environmental concentrations (MECs). This analysis highlighted the potential to streamline and calibrate exposure models used for regulatory purposes while ensuring sufficiently protective exposure predictions and achieving necessary levels of environmental protection. Overly complex regulatory PEC models can introduce parameters that are irrelevant to final risk characterisation. However, once these elements are explicitly included in regulatory ERA, such as through scenario parameterisation, they may gain legal relevance. This can prompt refinements aimed at adjusting the numerical risk assessment, potentially overburdening the regulatory process, and delaying decision-making.

The "Exposure" project further investigates this potential by using several exposure models to calculate PECs in surface freshwater at the edge of the field, covering drift, runoff, and drainage. These PECs are then compared with an extensive collection of MECs derived from available environmental monitoring data across EU Member States. This comparison—along with sensitivity analyses—aims to highlight the most influential model parameters and factors, with the ultimate goal of developing and implementing simpler PEC models that focus on those parameters most sensitive and relevant to ERA.

The "Exposure" project contributes to the calibration of models with measurements conducted under conditions pertinent to the model's application, as required by Regulation (EC) No 546/2011. The insights gained from this project could be used to evaluate and develop simpler PEC models for groundwater and the terrestrial environment in a similar manner.

The foundation of the 'Effects' project lies in recognising that calibrating ERA against real-world outcomes has revealed a fundamental mismatch between predicted and observed effects on invertebrate communities in agricultural streams. For example, a large-scale environmental monitoring study in Germany (Kleingewässer Monitoring, KGM) found that 81 % of the investigated sites failed to meet pesticide-related ecological targets (Liess et al., 2021). Building on this, the project expands its scope by incorporating data from additional environmental monitoring studies across the EU. This highlights the need to integrate outcomes from effect monitoring studies—such as those using PPP-specific biological indicators like the Species at Risk ($SPEAR_{pesticides}$)—into the ERA framework to improve the prediction of pesticide effects. These indicator systems that directly link shifts in community composition to pesticide exposure provide a clear measure of the real-world biological impact of PPPs. Incorporating these approaches into ERA allows for quantifying actual ecological effects under field conditions and validating laboratory-based prospective predictions. This integration creates a feedback loop where retrospective monitoring data refine prospective risk assessments, enabling ERA to evolve toward delivering robust, ecosystem-relevant threshold values for PPPs.

By harnessing chemical and ecological field monitoring data from various EU Member States, the "Exposure" and "Effect" projects enhance the realism and relevance of exposure and effect predictions, with an initial focus on aquatic systems due to the availability of coordinated environmental monitoring data (e.g., through the Water Framework Directive, the NORMAN network, KGM, and national environmental monitoring programmes). The insights gained from these projects could in principle be applied to environmental field monitoring data from terrestrial environments in a similar manner. However, in practice, the availability of such data is currently limited, and only a small number of pilot studies may be feasible at this stage. A common feature across the "Exposure" and "Effects" projects is the use of field studies and environmental monitoring data to cross-validate model assumptions and ensure that ERA conclusions are sufficiently protective. For example, the "Effects" project compares monitored effects at the ecosystem level with modelled predictions, helping to identify key factors that link lower-tier studies to real-world ecological outcomes. This approach improves the capacity to extrapolate effect information from controlled laboratory conditions to complex field scenarios, ultimately supporting the development of more ecologically relevant and operationally feasible ERA tools.

2.3. Improving ERA comparability

Regulation (EC) No 1107/2009 introduces the concept of comparison primarily through the framework of comparative assessment and substitution, aiming to reduce risks by replacing PPPs containing hazardous active substances with safer alternatives. It also promotes the authorisation of low-risk PPPs, recognising their potential benefits for health and the environment. While Regulation (EC) No 1107/2009 encourages their use, the provision of incentives for marketing low-risk PPPs is more strongly supported in related policy initiatives such as the Farm to Fork Strategy. Regulation (EC) No 1107/2009 further implies that the risk profile of an active substance should be evaluated in relation to other substances in use, reinforcing the comparative nature of the assessment. This approach supports a more dynamic and context-sensitive risk assessment, where substitution decisions are informed by relative risk considerations. To this end, the "Benchmark" project under PARC 6.4.4 aims to develop and implement a harmonised approach to compare the environmental risks of different PPPs and ranking them according to their environmental risk profiles. This initiative seeks to streamline the ERA process, making it simpler and faster, while enhancing the predictability of upcoming decisions. This approach would allow the outcomes of any ERA performed for a specific PPP to be used as a benchmark for evaluating the risks of other PPPs. Such a comparative method may accelerate the ERA process of similar PPPs, tailor ERA efforts, and support the early identification of environmentally hazardous or risky PPPs.

Ensuring the comparability of ERAs for different PPPs by including previously evaluated and non-authorised or withdrawn products would also enhance its quality control by enabling science-based comparisons of environmental risk profiles across PPPs. In line with the EU Green Deal target to reduce the use and risk of chemical PPPs by 50 % by 2030, it is essential to understand how the environmental risk levels of newly authorised PPPs (including renewals) compare with those already on the market and with non-authorised or withdrawn PPPs. To support this, the "Benchmark" project will conduct a retrospective evaluation to assess the comparability between existing higher-tier studies and lower-tier studies for various PPPs.

In addition, it is important to acknowledge that comparative ranking of PPPs is currently based on ERA approaches that primarily rely on single-species toxicity endpoints and established metrics such as toxicity exposure ratios (TERs), hazard quotients (HQs), and PECs to predicted no-effect concentration (PNEC) ratios. However, indirect, cumulative, or ecosystem-level effects remain largely beyond the scope of these methods (see below). While EFSA has made progress in operationalising Specific Protection Goals to better link individual-level toxicity data to population- and community-level outcomes, significant gaps remain. Therefore, within a systems-based approach, it is essential to consider multiple dimensions of risk and, in particular, to benchmark ERA predictions against data from real-world conditions. This will help capture broader ecological impacts and ultimately improve the biodiversity relevance of risk assessments.

2.4. Increase ecological realism

Despite ongoing efforts, single-substance ERAs have faced criticism for not sufficiently aligning with real-world ecological and agricultural conditions (e.g., Topping et al., 2020; Axelman et al., 2024). Current regulatory ERA frameworks for chemicals primarily focus on assessing the risks of individual substances for specific uses and different organism groups in isolation. However, in practice, the environment is continuously exposed to a multitude of chemicals from various sources, and there is a growing scientific consensus that the resulting effects must be better integrated into ERAs. Moreover, indirect effects can occur across organism groups through trophic interactions and competition. Therefore, it has been suggested to enhance the ERA's ability to evaluate the real-life environmental impact of PPPs (Sousa et al., 2022; EASAC, 2023; Axelman et al., 2024). Achieving this requires integrating a more realistic understanding of the environmental context, including biodiversity, ecology, landscape aspects, and cropping and farm management practices (e.g., Sousa et al., 2022; Williams et al., 2023).

Regulation (EC) No 1107/2009 specifically emphasises the need to assess multiple uses of the same PPP in an area, indirect and delayed effects, as well as trophic effects at the landscape scale by considering landscape structures. To address this, the "Effects" project explores ways to: (1) advance ERA methodologies to better assess sublethal, indirect, trophic and long-term effects; (2) evaluate the impact of PPP exposure on communities of non-target organisms in agricultural landscapes (e.g., competitive displacement of vulnerable species, long-term shifts in community structure and biodiversity); and (3) improve the extrapolation capacity from lower-tier studies to real-life conditions. To address sublethal effects, the project is using and extending models like the Stress Addition Model (SAM), which predicts the combined effects of multiple stressors, including chemicals with different modes of action and environmental factors (Liess et al., 2016). The SAM model, originally developed for mortality, is being adapted to assess other endpoints such as reproduction and is being applied to both aquatic and terrestrial organisms (Liess and Gröning, 2024; Shahid et al., 2024a,b; Wehrli et al., 2024). This multiple-stress model can be applied to realistically upscale laboratory toxicity data to ecosystem-level conditions. In contrast, the $SPEAR_{pesticides}$ approach (Liess and von der Ohe, 2005) is used to single-out pesticide effects from other environmental stressors at both community and ecosystem levels. This enables the assessment of direct and indirect impacts of PPPs on biodiversity, as demonstrated in recent studies (Liebmann et al., 2024; Siddique et al., 2024). These insights and tools lay the groundwork for a more realistic, systems-based ERA and may, in principle, be adapted to terrestrial environments as more environmental field monitoring data become available.

The "Landscape" project aims to better integrate landscape aspects and their variability into PPP ERA, considering environmental and ecological conditions as well as associated cropping and farm management practices. The project addresses cumulative exposure from repeated and multiple uses of the same PPP and the combined effect of multiple PPPs applied within a given area across seasons. To enhance realism, the project also considers the impact of other stressors, particularly cropping and farm management practices and climate change.

The "Landscape" project is designed to advance the application of landscape-level risk assessment by employing tools that quantify the effects of PPPs and other stressors across spatial and temporal scales. This approach enables a more comprehensive evaluation with a focus on ecosystem-level outcomes. The conceptual framework for landscape-based ERA is still under development and builds upon recent advances in landscape modelling (Tarazona et al., 2024).

This work involves designing a generic and flexible landscape ERA conceptual model, focused on the spatial and temporal dimensions of a systems-based approach, that integrates different components (e.g., environmental fate models, effects models, environmental scenarios, environmental monitoring tools). Its applicability will be tested through case studies in both terrestrial and aquatic systems representing diverse agricultural landscapes and climatic conditions. These case studies will support model evaluation and refinement of the proposed framework (Tarazona et al., 2024).

A primary challenge for the "Landscape" project is to develop tools that enable more context-specific ERAs while addressing the need to reduce the complexity of regulatory assessments. The proposed approach involves identifying risk drivers for relevant agricultural landscapes and conducting sensitivity analyses of models to determine the appropriate level of detail. Instead of integrating complex landscape models directly into the ERA, this approach uses them to develop simpler assessment tools. Additionally, the project aims to deliver tools that facilitate the identification and assessment of context-dependent risk mitigation and sustainable use measures.

Through the "Effects" and "Landscape" projects, PARC 6.4.4 is laying the groundwork for a meaningful shift in ERA—from traditional single-species endpoints toward biodiversity-level outcomes. These projects are developing tools and methodologies that capture sublethal, indirect, and long-term effects on ecological communities, while also integrating spatially explicit models to assess exposure and recovery at the landscape scale. By linking laboratory toxicity data with field observations and embedding ecological structures into modelling frameworks, PARC 6.4.4 intends to enhance ecological realism.

In general, integrating environmental monitoring data (i.e., retrospective ERA) into the ERA of chemicals requires further scientific development. This integration hinges on a better understanding of the relationships between chemical use, environmental exposure, and ecological impact (Sylvester et al., 2023; Anastassiadou et al., 2025). At its core, this process involves linking the specific use of a chemical to its environmental exposure and subsequently connecting that exposure to observable ecological changes or trends. However, establishing these connections is inherently complex. Chemicals are often used in multiple ways, and their concentrations vary across space and time. Once released into the environment, they can migrate within and between matrices, sometimes reaching areas far from their original emission point. Moreover, spatio-temporally explicit data on actual usage are often fragmented or unavailable, making it difficult to accurately trace exposure pathways. Transparent reporting of chemical usage is increasingly recognised as essential for interpreting monitoring data and enhancing the ecological realism of ERA (Bub et al., 2025). Yet, even when correlations between chemical use and measured environmental concentrations can be established, actual exposure to non-target organisms is influenced by additional factors, such as species-specific biology and behaviour. Finally, while ecological trends may coincide with environmental exposure to a stressor, demonstrating causality remains a significant challenge. This is due to the presence of numerous confounding variables, including resource availability, habitat quality, climate change, and disease dynamics (Anastassiadou et al., 2025). Despite these challenges, such integration is crucial and legally mandated for PPPs under Regulation (EC) No 1107/2009.

Robust protocols for integrating real-world data into prospective ERA can be effectively developed through structured collaboration among regulatory experts, scientists, and practitioners. Within Work Package 4 "*Monitoring and Exposure*", PARC activities already focus on environmental monitoring data and provide a solid foundation for this effort. Additionally, the JRC and other partners contribute valuable datasets generated through long-term environmental monitoring programmes. Building on these resources, a harmonised and systematic approach to standardising methods—such as sampling strategies, analytical techniques, data collection, and validation—is essential. Such coordination would strengthen the scientific basis for ERA, enhancing model reliability, ecological relevance, and alignment with evolving EU guidance and standardisation frameworks.

2.5. Update and modernise ERA approaches

To remain fit for purpose, ERA frameworks must keep pace with the latest scientific and technological developments, making use of new and emerging data sources. This calls for regular updates and modernisation of ERA approaches. For instance, new approach methodologies (NAMs)—including effect models—are increasingly available as *in silico* (computational), *in chemico*, and *in vitro* tools that can contribute to the replacement, reduction, and refinement of traditional animal-based testing in chemical risk and food safety assessments.

While NAMs for ERA have primarily been explored as alternatives to *in vivo* fish testing, they introduce alternative test systems that incorporate diverse model species and endpoints. As such, they may support assessments that better reflect the complexity of real-world scenarios (Di Nicola et al., 2023; Rattner et al., 2024; Baccaro et al., 2025). They support extrapolation of effects from controlled laboratory settings to field environments, and across multiple levels of biological organisation, from molecular and cellular responses to impacts at the population and ecosystem level. NAMs also facilitate cross-species extrapolation by identifying conserved biomolecular functions across species, helping predict susceptibility in untested organisms. Their ability to detect early biomolecular signatures of toxicological stress—well before observable ecological endpoints such as population declines or biodiversity loss—positions them as powerful early warning tools. Integrating NAMs into ERA enhances mechanistic understanding of toxic effects and contributes to more transparent, predictive, and scientifically robust risk characterisations. These efforts align with EU policy goals, including the Chemicals Strategy for Sustainability and the ambition to phase out animal testing. However, despite their growing scientific maturity, NAMs face persistent barriers to regulatory uptake. The lack of standardised protocols and formal validation hampers reproducibility and comparability. NAMs also lack historical datasets, making trend analysis and benchmarking difficult. Regulatory bodies often lack in-house expertise to interpret NAM outputs, which are nuanced and context-dependent rather than single-value metrics. Institutional inertia and uncertainty around interpretation further slow adoption. Overcoming these challenges is essential to unlock the full potential of NAMs and ensure that ERA frameworks evolve to be more forward-looking, ecologically realistic, and aligned with policy priorities.

In collaboration with PARC 6.4.2 "*Facilitate the regulatory acceptance and use of new methods*", the "Effects" project of PARC 6.4.4 explores the utility of NAMs for PPP ERA. It will benchmark prospective ERA methods (including NAMs) against environmental field monitoring data (retrospective ERA) and contribute to the European Commission initiative "*The roadmap towards phasing out animal testing for chemical safety assessments*" (EC, 2024).

2.6. Foster the transition toward a systems-based approach

A systems-based approach is proposed to advance the regulatory PPP ERA framework, as outlined by Sousa et al. (2022) and Axelman et al. (2024). This approach introduces a new way of working within the current regulatory framework, aiming to holistically interconnect and integrate knowledge, data, and expertise across disciplines, sectors and stakeholders. By applying systems thinking to ERA, the framework would become more cohesive and adaptive, enhancing the interplay between prospective (pre-market registration assessments) and retrospective ERA (post-market registration assessments) (Devos et al., 2022a, 2022b). The starting point involves identifying existing data, knowledge and expertise that can be integrated through cross-disciplinary collaboration to improve protectiveness, accuracy, and efficiency. Simultaneously, this approach enables the exploration and testing of new ERA concepts, guiding efforts to expand its scope to encompass ecosystem and societal relevance.

Core components of this new approach are explored in PARC 6.4.4 through interconnected case studies that pose novel research questions and foster cross-disciplinary collaborations. These studies integrate previously disconnected knowledge, data, and expertise, and are guided by stakeholder engagement and adaptive management principles. As systems-based ERA inherently promotes transdisciplinary collaboration, it supports the development of agile interfaces between the legally framed core regulatory processes, which must retain a degree of rigidity and independence, and the rapidly evolving landscape of scientific and technological innovation. Such interfaces are essential to ensure that regulatory science remains responsive and future-proof.

Currently, several EU research projects are exploring pathways to develop and implement a systems-based approach for ERA of chemicals, including PPPs. These projects include:

- PERA—*Advancing the ERA of plant protection products towards a system-based approach*
- PollinERA—*Understanding pesticide-pollinator interactions to support EU environmental risk assessment and policy*;
- SYBERAC—*Towards a systems-based, holistic environmental risk assessment of chemicals*.

Insights from PARC 6.4.4 have underscored the necessity for coordinated actions among these projects to ensure alignment, enhance complementarity, avoid duplication, and leverage synergies. This need has inspired the development of a cross-disciplinary initiative under PARC Task 2.2 "*Knowledge management and uptake into policy*" within Work Package 2 "*A common science-policy agenda*". The proposed project "*MIND (Map, Integrate, Network, and Drive)—A strategic and collaborative platform for "next-generation" risk assessment of chemicals*" aims to bridge the gap between science and policy by creating a common agenda and frameworks to foster the integration of knowledge and data from different scientific disciplines. This project seeks to establish an interdisciplinary platform for advancing knowledge-building and sharing, and collaboration on biodiversity protection. It is designed to strengthen synergies within PARC and with external initiatives promoting the development and implementation of "next-generation" ERA approaches, including NAMs and systems thinking. The project has two main objectives: (1) to create an overview of existing initiatives designed to advance ERA methodologies and research biodiversity (i.e., map existing efforts); and (2) to develop workable frameworks for cross-project collaborations and stakeholder engagement. This platform, along with its associated processes, will facilitate the governance of scientific coordination for systems-based ERA and transition from gaps and overlaps to synergies.

However, transitioning to a systems-based ERA approach presents several challenges (Sousa et al., 2022; Axelman et al., 2024). This paradigm shift introduces greater complexity by requiring the integration of diverse data sources (such as field studies and environmental monitoring data), engaging a broader and more diverse set of stakeholders (including not only regulators, risk assessors and scientists, but also farmers, NGOs, industry, and the public), and considering the interconnectedness of environmental, agricultural, and societal dimensions. Existing legal and regulatory frameworks are often designed for more linear and compartmentalised assessments, typically focusing on single chemicals in isolation. These frameworks may not be flexible enough to accommodate the holistic, cross-sectoral methodologies that a systems-based ERA demands. Therefore, a stepwise approach is essential for sustaining ongoing regulatory ERA processes, while enabling an effective transition. This means building on the strengths of the current ERA system, while progressively introducing, testing and evaluating more holistic and comparative methods. The goal of PARC 6.4.4 is to avoid unnecessary disruption and ensure that improvements are practical and supported by stakeholders. Achieving this, requires early and inclusive engagement with stakeholders, involving all relevant parties from the outset and fostering openness to co-shape the process. By taking this inclusive approach, the evolving ERA system can better reflect a range of perspectives, address real-world needs, and build trust and transparency. It also allows for the early identification of practical barriers and solutions, making the transition process smoother and more effective.

To navigate the challenges of transitioning to a systems-based ERA approach, PARC 6.4.4 places particular emphasis on implementing immediate, practical measures within the existing legal and regulatory frameworks. This includes improving communication, harmonising data formats, integrating available environmental monitoring data, and piloting new comparative assessment tools. Alongside these short-term actions, there is also a need to pursue long-term policy and regulatory reforms that will support the full adoption of systems-based methodologies. This would require aligning the legal framework with the needs of holistic ERA, developing new guidance and standards, and fostering harmonisation across sectors and regulatory domains. By focusing first on practical, actionable steps, PARC 6.4.4 aims to ensure that progress is both feasible and supported by stakeholders, while also laying the groundwork for more comprehensive changes in the future.

It is important to note, however, that an effective transition to a systems-based ERA approach ultimately requires strong leadership, clear governance, and a shared vision to guide change (Sousa et al., 2022). Breaking the process into manageable steps—such as initiating pilot projects under PARC 6.4.4 and achieving early successes—can help build momentum and strengthen stakeholder confidence. These broader elements of leadership and governance extend beyond the direct remit of PARC but are essential for ensuring lasting and meaningful change.

3. Conclusions

Research projects are ongoing in the EU to advance the ERA frameworks for chemicals, including PPPs, towards a systems-based approach. Among these projects, PARC 6.4.4 plays a distinctive role by exploring novel scientific avenues (including case studies) to simplify and accelerate ERA methodologies and regulatory processes, increase ERA's ecological realism, improve its responsiveness to regulatory needs, and ease the transition towards a systems-based approach to PPP ERA.

Concrete examples of a systems-based approach in PARC 6.4.4 include: (1) incorporating environmental monitoring data to calibrate and refine predictions against monitoring observations/field data and focus on relevant model parameters; (2) improving ERA comparability to enable cross-substance comparison and ranking; (3) enhancing the understanding of the combined impact of PPP use and other stressors; and (4) strengthening collaboration among actors within and across regulatory frameworks. To this end, a strategic alliance has been established with the Horizon Europe projects PollinERA and SYBERAC, creating synergies in stakeholder engagement and the co-development of systems-based ERA. Although the current work is primarily centred on PPPs, the concepts and tools developed are designed to be adaptable to other categories of regulated chemicals including emerging ones.

PARC 6.4.4 is designed to bridge the gap between research and regulatory science by clarifying regulatory needs and delivering scientific and technological advancements that support the continuous improvement of ERA in the EU. Therefore, the research conducted under PARC 6.4.4 focuses on developing novel approaches and tools aimed at creating a more streamlined and protective PPP ERA that can be effectively integrated into a regulatory context. PARC actively involves risk assessors, risk managers and regulators in shaping and reshaping priorities. This level of involvement is uncommon and underscores PARC's commitment to integrating regulatory perspectives throughout the research process, ensuring that outcomes are not only scientifically robust, but also practically applicable within regulatory frameworks.

PARC 6.4.4 is strategically positioned as a central case study for systems-based ERA, serving as a hub that interconnects projects and stakeholders both within and beyond the PARC initiative. By fostering collaboration across disciplines and sectors, PARC 6.4.4 mobilises and contextualises essential knowledge to advance chemical ERA, particularly for PPPs. This activity promotes a shift toward more integrated approaches, benchmarked against monitoring evidence, that reflect ecological complexity and long-term environmental impacts. A key objective is to support the regulatory uptake of project deliverables, especially those addressing conceptual and long-term regulatory needs. Through iterative stakeholder engagement, co-creation forums, and targeted workshops, PARC 6.4.4 seeks to expand its reach across the EU, building a collaborative and resilient partnership for systems-based ERA that is designed to endure beyond the lifespan of PARC and other ongoing projects.

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Funding

Funding was received from the European Union's Horizon Europe program under the grant HORIZON-HLTH-2021-ENVHLTH-03–01. This specific grant supports the European Partnership for the Assessment of Risks from Chemicals (PARC), which aims to enhance chemical risk assessment and management across the EU.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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