

Practitioners' perspectives on EU environmental risk assessment for plant protection products

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Abstract

Prospective environmental risk assessment (ERA) is central to regulatory decision-making for plant protection products (PPPs) in the European Union (EU). Although the current framework is generally considered procedurally mature and harmonised, concerns remain about its efficiency, growing complexity, and capacity to reflect real-world environmental conditions. To explore these issues, this policy brief draws on a survey of regulatory practitioners across Europe and follow-up workshops organised under PARC in collaboration with PollinERA and SYBERAC. The survey collected responses from 114 practitioners, predominantly regulatory risk assessors, from 31 regulatory organisations across 25 European countries and all three EU PPP regulatory zones. Respondents generally considered PPP ERA effective in meeting formal regulatory requirements but expressed only moderate confidence in its ability to predict and manage environmental impacts of PPP use under real-world environmental conditions. They attached high importance to the scientific quality and societal relevance of their work, while identifying limitations in the ecological realism of current approaches. Practitioners also highlighted procedural complexity, the interpretative demands of guidance, fragmented data systems, limited opportunities to reuse information across dossiers, and increasing workload pressures as major constraints on assessment efficiency. Collaboration was viewed as essential for quality assurance, uncertainty management, and harmonisation. However, while collaboration was generally well established within organisations, it was reported to be less systematically embedded across organisations and Member States, limiting opportunities for harmonised interpretation, knowledge exchange, and collective learning. Taken together, the findings portray a PPP ERA system that is procedurally robust but increasingly challenged by operational complexity. Practitioners reported devoting growing effort to navigating guidance, managing fragmented information, re-assessing information, and conducting increasingly complex assessments, raising questions about whether greater complexity translates into better regulatory predictions or decisions. The findings point to the need for clearer ERA objectives and operational protection goals, stronger cross-organisational collaboration, and more proportionate, problem-driven assessment approaches. Together, these changes could enhance ecological realism, efficiency, and regulatory credibility while maintaining scientific rigour and legal robustness.

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Abbreviations

COVID-19	Coronavirus disease 2019
EFSA	European Food Safety Authority
ERA	Environmental risk assessment
EU	European Union
PARC	European Partnership for the Assessment of Risks from Chemicals
PERA	Building a European Partnership for next generation, systems-based Environmental Risk Assessment
PollinERA	Understanding Pesticide-Pollinator Interactions to support EU Environmental Risk Assessment and Policy
PPP	Plant protection product
SYBERAC	Towards a Systems-Based, holistic Environmental Risk Assessment of Chemicals
ZAPID	Zonal Authorisation Procedure Improvement and Development

Background and rationale

Environmental risk assessment (ERA) for plant protection products (PPPs) in the European Union (EU) is conducted under Regulation (EC) No 1107/2009. Active substances are first evaluated by a Rapporteur Member State and subsequently peer reviewed by the European Food Safety Authority (EFSA) and Member States before a decision on EU-level approval is taken. PPPs containing approved active substances are then assessed for zonal and national authorisation.

For a typical product use, such as a fungicide on winter wheat, the applicant specifies the intended conditions of use, including the crop, application rate, frequency and timing of application, application methods and techniques, and any specific use conditions. These parameters are used to estimate environmental exposure and assess risks to non-target organisms. Predicted environmental exposure is compared with ecotoxicological and ecological effect thresholds to determine whether the requirement of no unacceptable effects on the environment is met (Article 4(3)(e) of Regulation (EC) No 1107/2009). Assessments start with conservative (lower-tier) assumptions and may subsequently be refined using additional data, higher-tier studies, or risk mitigation measures. Following the zonal assessment, individual Member States decide whether the proposed use can be authorised at national level and under which conditions.

PPP ERA has been described as a comparatively mature regulatory science domain in the EU. This maturity reflects the progressive development of standardised data requirements, extensive and refined guidance, and formalised assessment and decision-making frameworks. Guidance, understood as non-binding regulatory documents that set out agreed principles, data requirements, methodologies, and interpretative approaches, has played a central role in supporting consistent implementation across organisations. Here, the term “*organisations*” refers collectively to public bodies involved in regulatory PPP ERA, including competent authorities, EU and national agencies, and other relevant institutions. Together, these elements have strengthened harmonisation, transparency, and legal robustness across Member States. At the same time, the cumulative expansion of data requirements and guidance has contributed to greater procedural rigidity, increasing the level of detail and complexity within the PPP ERA process and potentially constraining flexibility and adaptation in regulatory practice [9].

This highly standardised and increasingly complex process has raised concerns that regulatory assessments may, in some cases, prioritise procedural compliance over ecological relevance, place pressure on assessment timelines, and require substantial resources, in terms of personnel, expertise, time and analytical effort, without

commensurate benefits for environmental protection [9]. These challenges are exacerbated by fragmented data sources, unvalidated or overly conservative assumptions, and the continued expansion and periodic revision of data requirements and guidance intended to strengthen scientific robustness [1, 9].

At the same time, there is growing recognition that further tightening of authorisation criteria or reducing product availability may not, in itself, lead to improved biodiversity outcomes [1]. Such measures may also entail trade-offs, including delayed access to low-risk innovations and reduced crop protection options for minor uses [9]. Reflecting these concerns, ongoing EU policy discussions, including the European Commission's 2025 Food and Feed Safety Simplification Omnibus proposal [2], seek to improve procedural efficiency and reduce regulatory workload while addressing challenges identified through the ZAPID (Zonal Authorisation Procedure Improvement and Development) process [9].

In response to these concerns, there is a need to better understand how the current PPP ERA system operates in practice and where opportunities for improvement exist [6, 8]. This policy brief draws on a cross-European mixed-methods study combining a survey and targeted follow-up workshops with regulatory practitioners, primarily EU- and Member State-level risk assessors involved in PPP ERA, to examine their perspectives on the functioning of the current system (Box 1).

The analysis was structured around four interrelated dimensions of ERA performance: *effectiveness*, *efficiency*, *collaboration* and *learning*. These dimensions were used as a pragmatic framework to synthesise practitioner perspectives and relate them to the priority areas identified in the PERA (Building a European Partnership for next generation, systems-based Environmental Risk Assessment) Roadmap commissioned by EFSA [1, 6]. *Effectiveness* refers to the extent to which ERA delivers reliable environmental protection (including biodiversity) through scientifically robust, fit-for-purpose assessments that meaningfully predict real-world risks. *Efficiency* focuses on whether these outcomes are achieved with a proportionate use of time, expertise and resources. *Collaboration* refers to the extent to which coordination, knowledge exchange, and shared understanding across organisations support consistent and harmonised regulatory outcomes. *Learning* refers to the extent to which PPP ERA systematically captures, retains, shares, and applies knowledge generated through assessments, monitoring, modelling, risk mitigation, and regulatory practice to improve future assessments, decisions, and environmental protection outcomes. Together, these dimensions provide a lens through which to examine current strengths, challenges, and opportunities for improving PPP ERA in the EU.

Practitioner observations

How practitioners understand the role of PPP ERA

In an open-ended survey question, respondents were asked to reflect on ERA and describe what they consider its key role. The survey responses on this question ($n = 102$) revealed several distinct and partly contrasting interpretations, indicating that ERA is understood and framed in different ways across the practitioner community. Some respondents emphasised ERA's role as a gatekeeping mechanism, primarily aimed at excluding hazardous substances from approval. Others emphasised ERA's role in supporting agricultural production and authorisation decisions, focusing on reducing risks to acceptable levels, in order to enable market access and practical use of PPPs by farmers. Some respondents also framed ERA as a protective instrument, intended to safeguard non-target organisms, ecosystems, and the environment through the identification and minimisation of risks. In contrast, other respondents viewed ERA mainly as a science-based process, designed to inform risk management decisions rather than to predetermine regulatory outcomes. Taken together, these responses point to divergent expectations regarding the purpose of ERA and suggest an underlying lack of consensus on whether it should primarily function as a regulatory gatekeeper, a benchmark for environmental protection, a decision-support tool, or a mechanism to support agricultural production by enabling the authorisation and use of PPPs. This plurality of interpretations may create a risk of interpretive fragmentation, whereby practitioners may apply ERA according to varying

Box 1 Methodological basis and practitioner engagement

This policy brief draws on a survey of regulatory practitioners conducted across the European Union (EU) in late 2024, complemented by targeted follow-up workshops. Both activities were undertaken under PARC (European Partnership for the Assessment of Risks from Chemicals; Activity 6.4.4), in collaboration with the Horizon Europe projects PollinERA (Understanding Pesticide–Pollinator Interactions to Support EU Environmental Risk Assessment and Policy), and SYBERAC (Towards a Systems-Based, Holistic Environmental Risk Assessment of Chemicals). The survey and workshops were conducted online using SurveyXact and Microsoft Teams, respectively. Data collection targeted regulatory risk assessors and managers directly involved in the environmental risk assessment (ERA) for plant protection products (PPPs) at EU and Member State level. Invitations were sent to national Competent Authorities under Regulation (EC) No 1107/2009, relevant EU-level agencies and regulatory expert groups involved in the peer review of active substances. Survey participants were recruited using established EU-level and national regulatory contact lists (approximately 400 contacts) and were invited to participate by e-mail. The survey was conducted in English, reflecting its use as the common working language in the EU regulatory PPP ERA context.

The survey focused on day-to-day regulatory experience with the PPP ERA system and comprised 18 questions (see Electronic Supplementary Material), not all of which were mandatory to complete. Survey topics were defined before data collection based on the ERA improvement areas identified in the PERA Roadmap and the objectives of the collaborating projects [1, 6]. Questions explored, among other topics, confidence in ERA outcomes, ecological realism (i.e., the extent to which ERA reflects real-world environmental conditions and ecological responses), procedural complexity and workload, and collaboration within and across organisations.

During analysis, the project team organised the survey findings into three interrelated performance dimensions: effectiveness, efficiency, and collaboration. A fourth, learning, was added after open-text survey responses and the workshop discussions pointed to a cross-cutting issue that the other three did not capture. These dimensions were developed inductively as a pragmatic framework for synthesising the results rather than as a predefined or exhaustive classification of ERA performance. Together, they provide insights into both the functioning of the current PPP ERA system and its perceived limitations.

Survey questions combined closed-ended items (e.g., using five-point Likert scales measuring importance or agreement) with open-ended responses. This enabled comparison of responses across respondents, while also capturing more nuanced and contextualised perspectives. Survey data were exported to Microsoft Excel and checked for duplicates, completeness, formatting, and consistency of response identifiers. Open-text responses were retained verbatim, while blank responses and responses lacking sufficient substantive content for qualitative analysis were excluded. Qualitative data were analysed inductively using first- and second-cycle coding [5]. Initial codes were developed from recurring concepts in the responses and subsequently grouped into broader themes through an iterative process of comparison, discussion, and refinement among the project team. The resulting themes informed the qualitative findings presented in this policy brief. A high degree of convergence was observed across many responses; however, divergent and contrasting perspectives were retained and reflected where relevant. Closed-ended survey data were analysed descriptively.

In total, 114 responses were received from 25 European countries, representing 31 organisations across all three EU regulatory PPP ERA zones. Geographic coverage spanned all regulatory zones, with the Central zone most strongly represented (50%), followed by the Southern (24%) and Northern (13%) zones. A further 13% of respondents fell outside the standard zonal classification (e.g., EU-level or non-EU organisations not formally embedded in the zonal system but engaged in ERA activities). Participation was highest from Germany (24%) and France (17%), followed by the Netherlands (6%), Finland (5%), Sweden (5%), Austria (5%), and Switzerland (4%). Respondents were predominantly regulatory risk assessors involved in EU-level active substance evaluation and national-level PPP authorisation, with an even distribution across these two roles. Average professional experience was approximately ten years, indicating a highly experienced respondent group, with expertise primarily in ecotoxicology and environmental fate, often spanning multiple domains and across organisations with varying technical capacity. Only a small proportion of respondents reported holding a dual risk assessor/manager role, and just 2% identified primarily as risk managers, highlighting that the survey largely reflects risk assessors' perspectives rather than those of risk managers.

Survey findings were further explored in three half-day follow-up workshops, each involving approximately 10–15 participants and open to all survey respondents. Participation was voluntary and therefore self-selected rather than structured to achieve representation by organisation, Member State or regulatory zone. Participants contributed in their individual professional capacities, and their responses should not be interpreted as representing the official positions of their employing organisations.

The workshops were designed to deepen and contextualise emerging survey findings and to explore challenges relating to PPP ERA effectiveness, efficiency, and collaboration rather than to support comparisons between practitioner subgroups. A semi-structured format was used, whereby preliminary survey findings were presented before facilitated breakout discussions guided by survey-informed questions and optional probes, followed by plenary feedback and open discussion. Facilitators (members of the author group) encouraged participation while refraining from influencing the substantive content of the discussions.

Workshop discussions were audio-recorded. Participants were informed of the recording beforehand, and consent was obtained prior to the start of recording. It was reiterated that recordings would be accessible only to the project team. These confidentiality arrangements were intended to support open and candid discussion within a small and specialised professional community. For the present analysis, the primary data sources consisted of extensive anonymised notes prepared by dedicated note takers and outputs from participatory exercises, including Menti-meter responses. Audio recordings were not transcribed or systematically coded but were consulted where necessary to clarify the workshop notes. The anonymised notes and participatory outputs were subsequently reviewed collectively by the core project team.

Quantitative survey results were analysed descriptively, while open-text responses, workshop notes, and participatory exercise outputs were synthesised thematically. Survey-derived themes provided the initial framework for interpretation, while additional insights, qualifications, and contrasting perspectives emerging from the workshops were also considered. The combined analysis was used to identify recurring constraints, explanatory mechanisms, areas of agreement and divergence, and opportunities for improvement.

underlying logics. Such fragmentation can undermine consistency, predictability, and shared expectations in the assessment process, with implications for harmonised implementation across organisations.

Perceived effectiveness of PPP ERA: High commitment, limited confidence

When asked to rate what mattered most in their day-to-day work, survey respondents ($n = 114$) rated work quality highest (mean: 4.8 ± 0.5 (SD)). Other highly rated dimensions included the impact of their work (mean: 4.3 ± 0.8 (SD)) and adherence to guidance (mean: 4.3 ± 0.7 (SD)), whereas adherence to deadlines received lower ratings (mean: 3.7 ± 0.9 (SD)). In contrast, confidence in current ERA outcomes was more limited: agreement with the statements that ERA adequately predicts environmental impacts and that ERA procedures ensure the safety of authorised substances both averaged 3.1 out of 5 (mean: 3.1 ± 1.0 (SD) and 3.1 ± 1.0 (SD), respectively). These questions capture two related aspects of effectiveness: confidence in the predictive performance of ERA and confidence that regulatory decisions and risk management measures deliver environmental protection in practice. The similar, mid-range scores indicate only moderate confidence in both. This contrasts with the high ratings given to the quality and impact of respondents' own work, suggesting that practitioners distinguish confidence in their professional contribution from confidence in overall ERA outcomes. Workshop discussions linked this more limited confidence to challenges in capturing landscape context, mixtures and interacting stressors, indirect and long-term effects; uncertainty when extrapolating higher-tier assessments to field conditions, and the practical implementation of risk mitigation measures. These findings reflect practitioner perceptions and should not be interpreted as a direct evaluation of the predictive performance or protectiveness of PPP ERA.

Qualitative responses help to explain this gap. Survey respondents highlighted sustained time pressure and increasing regulatory complexity—stemming from expanding scope, greater technical intricacy, and rising analytical demand—as constraints on assessment quality, limiting opportunities for in-depth analysis, reflection, and collaboration. Some respondents also reported that conclusions related to unacceptable risks may be questioned or revisited at the risk management stage, a dynamic perceived as potentially undermining the evidentiary basis and credibility of ERA outcomes. Taken together, these findings suggest that reduced confidence in ERA effectiveness is driven less by a lack of professional commitment, and more by structural and organisational constraints inherent to the current system.

In parallel, survey respondents articulated clear expectations regarding what a more effective ERA outcome should deliver. In open-ended responses, many respondents suggested a shift beyond single substance, product-by-product assessments towards approaches better able to account for multiple stressors, combined effects arising from the use of multiple products, indirect and long-term effects, and landscape context. While workshop participants acknowledged the regulatory and methodological challenges of operationalising such perspectives, many workshop participants agreed that ERA outcomes must be better aligned with real-world environmental conditions. Importantly, workshop discussions emphasised that effectiveness should not be equated with increasing analytical complexity. In this regard, workshop participants noted that higher-tier refinements may, in some cases, reduce confidence rather than increase it: when based on experimental studies, assessments can become highly representative of specific conditions, complicating extrapolation to other field situations; when based on modelling, uncertainties arise from the validation of model outputs against real-world conditions.

Across workshops, risk mitigation emerged as a central determinant of ERA effectiveness. Participants stressed, in their view, that environmental protection in practice depends less on increasingly refined assessment approaches, whether experimental or model-based, than on whether mitigation measures are realistic, enforceable, and adopted in the field. This led to calls for PPP ERA to be designed with greater attention to feasible risk mitigation options from the start, and for stronger interaction between risk assessors, risk managers, and end users (i.e., farmers). In this view, effectiveness depends on whether the assessment identifies decision-relevant risks and uncertainties and supports practical conditions of use and risk mitigation measures that can be implemented in reality. Additional technical refinement is valuable where it materially strengthens this decision basis, rather than as an end in itself.

Post-registration environmental monitoring was widely recognised by practitioners as a potentially important mechanism for strengthening the effectiveness of PPP ERA, particularly by providing feedback on ERA assumptions and the performance of risk mitigation measures. In open-ended responses, survey respondents viewed monitoring as valuable for identifying emerging issues, informing guidance development, and improving the link between prospective assessments and real-world outcomes. Workshop participants similarly described monitoring as a “reality check” for ERA, with particular relevance at system level, supporting learning, recalibration of assessment factors, and evaluation of whether protection goals are being met.

At the same time, survey respondents highlighted significant challenges to the systematic use of environmental monitoring data within PPP ERA. Limitations included difficulties with attribution, causal interpretation, and relevance to individual products, often exacerbated by the lack of reliable and harmonised PPP usage data. Respondents also pointed to the absence of coordinated monitoring and reporting frameworks defining what is monitored, how data are collected, and how results are shared across Member States. These issues were reinforced during workshop discussions, where participants emphasised that different types of monitoring serve distinct purposes and that, without robust usage information, monitoring alone cannot resolve product-level questions of causality.

As a result, feedback loops between prospective ERA, risk mitigation and environmental monitoring were not perceived as fully operationalised within current practice. Compared to monitoring-focused discussions, survey respondents in risk assessment roles generally viewed monitoring primarily as a strategic or contextual source of information, rather than as a routine mechanism for validating or systematically adjusting ERA outputs. This suggests that the potential of monitoring to function as a structured learning tool, linking assessment, implementation, and outcomes, remains underexploited.

Overall, a recurring view among participating practitioners was that strengthening feedback loops between ERA, models, risk mitigation, and environmental monitoring would be an essential step towards improving confidence in PPP ERA outcomes. Achieving this would require clearer objectives for monitoring, greater harmonisation of monitoring and reporting systems (including the systematic integration of PPP usage data), and more explicit integration of retrospective evidence into PPP ERA processes. Without such developments, the capacity of monitoring to enhance the real-world relevance of PPP ERA and support regulatory learning is likely to remain limited.

Perceived efficiency of PPP ERA: Rising complexity, diminishing returns

Alongside concerns about effectiveness, respondents identified efficiency as a growing challenge within PPP ERA. Guidance was widely recognised as central enabler of efficiency, as it provides legal certainty, structures assessments, and supports harmonised implementation across Member States. At the same time, however, respondents reported that the growing volume, fragmentation, and complexity of guidance has itself become a major source of inefficiency. Guidance was frequently described as outdated, rigid, and slow to evolve, with highly detailed and prescriptive requirements that are time-consuming to apply and, in some cases, constrain expert judgement and problem-driven assessment approaches.

Respondents further noted that applying guidance often requires substantial interpretation, contributing to variability across individuals, organisations, and Member States. This creates a recurring tension within PPP ERA: instruments intended to support consistency and efficiency may in practice also encourage conservative behaviour and divergent implementation. To navigate this complexity, practitioners reported relying on supplementary sources beyond core guidance, including precedent cases, informal exchanges, and expert judgement, to progress assessments.

This reliance on supplementary material reflects a broader feature of the regulatory landscape. Consistent with practitioners’ experience, survey respondents and workshop participants reflected on the proliferation of regulatory ERA outputs, such as draft guidance documents, statements, and scientific opinions. While these materials are

valuable, their operational use was perceived to vary across organisations, further shaping interpretation in practice. Although this aspect was not always raised explicitly in the survey, it aligns with workshop discussions on fragmentation and the challenges of integrating multiple, partially overlapping regulatory ERA documents into day-to-day workflows.

While such adaptive practices can improve efficiency at the individual level, they raise concerns regarding transparency, reproducibility, and the systematic accumulation of regulatory learning. Workshop discussions reinforced these observations and pointed to potential improvements, including better integration and cross-referencing of guidance and related outputs, clearer decision pathways, more interactive formats, and targeted training to reduce interpretative burden on risk assessors and help stabilise assessment practice across organisations.

Beyond guidance and interpretation, respondents pointed to a structural efficiency challenge within PPP ERA linked to data management and reuse. In the absence of shared data infrastructures and systematic mechanisms for reusing prior assessments, evidence is frequently re-assessed on a substance-by-substance basis and across dossiers, leading to duplication of effort and increased workload. As a result, potential efficiency gains from standardised requirements and guidance are not fully realised.

Concerns about diminishing returns also extended to modelling and refinement practices. Survey respondents and workshop participants emphasised that increasing model sophistication does not automatically translate into more robust regulatory decisions or improved environmental protection. While the scientific value of advanced models was not questioned, practitioners highlighted that greater complexity frequently increases workload and interpretative effort without changing regulatory conclusions. In this context, participants stressed the need for systematic “reality checks” linking model outputs to monitoring evidence (see above), in order to focus assessment effort on parameters that meaningfully influence risk. Complex models were described as resource-intensive, difficult to explain, and sometimes weakly connected to real-world outcomes, creating a risk that refinement effort is diverted away from the main decision-relevant uncertainties.

Collectively, these findings indicate broad support for fit-for-purpose modelling, understood as the use of models and refinements that are explicitly linked to regulatory questions and decision points, proportionate to the decision context, and sufficiently transparent to support communication with risk managers and stakeholders. Fit-for-purpose was not equated with simplification; rather, it was framed in terms of proportionality. Increased complexity was considered justified only where it delivered clear regulatory added value, such as changes in risk conclusions, improved realism, more effective risk mitigation options, or better alignment with retrospective evidence. Workshop participants identified benchmarking and feedback from monitoring as particularly promising mechanisms for determining when additional complexity is warranted and when simpler approaches can provide equivalent or superior decision support.

More broadly, survey respondents highlighted system-level efficiency constraints affecting PPP ERA, including ambiguously defined protection goals, the absence of clear procedural stopping rules (i.e., predefined decision points that determine when further refinement is no longer required), expanding data requirements over the course of assessments, and increasing procedural complexity. Respondents also noted an uneven guidance landscape: while some risk areas are governed by an expanding and partly overlapping body of guidance, other risk areas lack up-to-date or sufficiently developed guidance, creating challenges for harmonisation, consistency, and efficient decision-making. Taken together, these conditions translated into substantial operational burdens, including effort spent interpreting and navigating complex guidance, addressing areas where guidance is missing or outdated, re-assessing information that is difficult to reuse across dossiers, and pursuing higher-tier refinements or increasingly complex models that may not alter the regulatory conclusion. These observations point to diminishing returns, where additional assessment effort and detail may provide limited added value for regulatory decision-making while consuming resources that could be directed towards other assessments or addressing decision-critical uncertainties.

Collaboration in PPP ERA: essential, but uneven

Collaboration was characterised as a practical necessity for PPP ERA, reflecting the multidisciplinary integration required in assessments. Respondents emphasised a strong reliance on collaboration to complete assessments, particularly within their own organisations and teams, and highlighted its importance for quality assurance through peer consultation and second opinions. Internal collaboration was nearly universal and occurred frequently, including interaction across focus areas within organisations, among team members with similar expertise, and between ecotoxicology and environmental fate disciplines. This indicates that multidisciplinary exchange is embedded in routine assessment practice. However, respondents also noted that increasing procedural demands and time pressure often limit opportunities for exchange, thereby constraining the extent to which collaborative working can be fully exploited.

Collaboration was perceived to be strongest and more routine within organisations, while cross-organisational cooperation was more irregular and often informal or episodic rather than systematically embedded in workflows. Interactions across Member States, operational levels, and with external scientists were reported to depend heavily on individual initiative, availability, and existing personal networks. Engagement with risk managers, farmers, and other stakeholders was comparatively limited and typically occurred at specific procedural stages rather than throughout the assessment process. Respondents highlighted that collaboration serves different functions (e.g., quality assurance, harmonisation, workload sharing, problem-solving), which influences both its intensity and form.

Within this context, workshop participants pointed to examples where growing regulatory strain, particularly in terms of workload and resource pressure, has prompted deliberate organisational responses. In particular, some Member States (notably the Netherlands and Sweden) have strengthened internal collaboration by establishing small, interdisciplinary teams that meet regularly to discuss assessment progress, uncertainties, and emerging challenges. These arrangements were described as improving efficiency, shared understanding, and internal consistency, and were perceived as helping to address complexity through earlier issue resolution and collective judgement. As such, they were seen as potentially instructive examples of how collaboration can be more systematically embedded in national-level ERA practice.

Insights from the workshops further illustrated that well-functioning zonal collaboration for product authorisations can act as a powerful enabler of efficiency. Participants described how routine meetings, shared issue lists, and the codification of agreed solutions into zonal guidance reduce repeated interpretation and help stabilise practice across Member States. In contrast, active substance assessments were often characterised as lengthy, resource-intensive, and comparatively fragmented processes, with fewer opportunities for collaboration, shared learning, and convergence across organisations. Personal connections and mutual trust, often established through earlier in-person interactions prior to the coronavirus disease 2019 (COVID-19) pandemic, were repeatedly highlighted as enabling faster problem-solving than formal procedures alone.

Importantly, collaboration was not viewed as undermining professional independence. On the contrary, survey respondents consistently described it as supporting informed judgement, robustness, and confidence in assessments. Across both survey responses and workshop discussions, there was strong consensus that better resourced, more structured, and more systematic collaboration would improve efficiency, consistency, transparency, and trust in PPP ERA outcomes. Workshop participants emphasised that such collaboration should be seen as part of the regulatory infrastructure of PPP ERA, rather than as an informal or optional add-on.

Building a learning-oriented PPP ERA system

Across the workshops, participants drew attention to a broader issue that extends beyond issues of effectiveness, efficiency, or collaboration. They pointed to a more fundamental limitation of the current PPP ERA system: its limited capacity to function as a cumulative, learning-oriented regulatory system. While large volumes of data

are generated, evaluated, and discussed over time, these outputs are not systematically consolidated, reused, or fed back into future assessments in a structured manner.

A recurring theme was the fragmentation of regulatory knowledge. Data relevant to ERA (e.g., study results, endpoints, metabolite assessments, model outputs, rationale behind regulatory conclusions) appear to remain distributed across dossiers, static documents, and organisation-level systems. This fragmentation makes it difficult to trace how past evidence has informed decisions, to compare conclusions across assessments, or to build on earlier judgments in a transparent and reproducible manner. As a result, learning remains largely local and case-specific rather than embedded at the organisational level.

Workshop participants also highlighted limitations in the governance and stewardship of models and methods. Although modelling tools are central to PPP ERA, their regulatory implementation is often characterised by parallel evaluation, inconsistent evaluation practices, and limited shared ownership across organisations. This reinforces a situation where effort is repeatedly invested in scrutinising similar tools or refinements without generating a shared and durable knowledge base that could support future assessments or methodological evolution.

In the absence of integrated infrastructures for data and knowledge reuse, risk assessors rely heavily on informal memory, internal notes, precedent awareness, and ad hoc exchanges to navigate recurring issues. While such practices enable the system to function in practice, they remain inherently fragile: they rely heavily on individual expertise that is difficult to document, are insufficiently embedded in organisational memory, and are vulnerable to staff turnover, which undermines the retention of tacit knowledge and continuity over time. Workshop participants stressed that this affects not only efficiency and consistency, but also the system's ability to demonstrate learning and improvement over successive regulatory cycles.

These limitations were seen to directly constrain the operationalisation of feedback loops discussed in earlier sections. Without structured mechanisms to link environmental monitoring results, modelling assumptions, and past regulatory decisions, feedback remains diffuse and largely qualitative. Knowledge that could be mobilised to improve and update guidance, adjust refinement strategies, or define/revisit protection goals is generated, but it is not systematically captured or translated into decision frameworks. In this sense, monitoring and retrospective evidence exist *alongside* ERA rather than being embedded within it as drivers of adaptive change.

Workshop discussions therefore framed the challenge not as a lack of scientific expertise or regulatory intent, but as a gap in system design. Workshop participants emphasised that transforming PPP ERA into a genuine learning system would require deliberate investment in shared data infrastructures, clearer ownership of methodological tools, and governance arrangements that embed reuse and reflection at the organisational level. Without such changes, PPP ERA risks remaining a sequence of technically robust but largely disconnected case assessments, with limited capacity to accumulate insight, adapt to emerging evidence, or demonstrably improve over time.

Scope and interpretative considerations

Several limitations should be considered when interpreting the findings. First, the results reflect practitioners' perceptions and experiences and do not constitute a direct evaluation of the predictive performance or regulatory effectiveness/efficiency of PPP ERA outcomes. The survey relied on self-reported information, meaning that responses depend on individual judgement and willingness to disclose. Moreover, as the responses were interpreted and analysed by the authors, the findings are inevitably shaped by author judgement and may therefore be subject to interpretive bias.

Second, respondents were recruited through non-randomised channels and invited to provide anonymous reflections based on their professional experience. As a result, the findings are not statistically generalisable and reflect the views of the participating sample rather than the full population of regulatory risk assessment practitioners. In addition, the use of Likert-scale questions may have simplified complex practices and judgements, potentially obscuring nuances that characterise day-to-day regulatory work.

Third, the survey was administered exclusively in English, which may have resulted in differences in how questions were interpreted by respondents with varying English language proficiency. This may have affected the consistency and precision of some responses.

Finally, the geographical distribution of respondents was uneven, with a small number of Member States contributing a comparatively large share of responses. Although all regulatory zones were represented, the sample was not designed to be geographically representative. Country and zonal distributions should therefore be viewed as descriptors of participation only and not as a basis for comparisons between countries or zones. This imbalance may have influenced the overall emphasis of the findings and should be considered when interpreting broader conclusions. Similarly, the synthesis of follow-up workshop discussions reflects the perspectives expressed by participants and may give greater prominence to issues that were particularly salient during the discussions.

Conclusion and recommendations

The survey and workshop findings depict a PPP ERA system that is procedurally mature and widely valued by practitioners, yet increasingly strained in day-to-day regulatory practice. Participating practitioners broadly recognised PPP ERA as essential for regulatory decision-making and environmental protection in the EU. At the same time, they expressed only moderate confidence in the system's ability to predict and manage real-world environmental impacts and raised concerns about its proportionality. They also highlighted growing challenges related to procedural complexity, workload, fragmented knowledge, ecological realism, and limited opportunities for systematic learning, knowledge sharing, and feedback across assessments and organisations. Collectively, these constraints were perceived as limiting the system's ability to deliver ecologically meaningful protection under real-world environmental conditions.

Importantly, these challenges were not framed primarily as a lack of commitment, expertise, or scientific rigour. On the contrary, practitioners demonstrated a strong professional ethic, placed high importance on the quality and impact of their work, and expressed broad support for harmonisation across Member States. Reduced confidence in outcomes was instead linked to structural characteristics of the PPP ERA system itself, notably how problems are framed, how complexity accumulates over time, how uncertainty is managed, and how regulatory knowledge is retained, shared, and reused.

Across discussions of effectiveness, efficiency, collaboration, and learning, a common message emerged: PPP ERA is largely doing the *right things*, but not always in the *right way* or at the *right level*. Practitioners generally called not for greater detail or refinement, but for a recalibration of the system toward greater clarity, proportionality, ecological relevance, and cumulative learning.

Drawing on the survey and workshop findings, the authors propose a strategic rebalancing of PPP ERA. The recommendations below reflect recurring concerns and improvement opportunities identified by practitioners, combined with the authors' interpretation of their implications for future regulatory practice. Specifically, the findings point to seven priority areas for action: (1) clarifying ERA objectives and operationalising protection goals; (2) introducing greater ecological realism in a selective and proportionate manner; (3) modernising guidance to better support judgement and usability; (4) strengthening PPP ERA as a system-level learning framework through improved data, and modelling governance; (5) strengthening monitoring and feedback loops; (6) investing in capacity and knowledge management; and (7) reinforcing structured collaboration across organisations and Member States (see Table 1). Collectively, these priorities address two overarching themes identified in the study: the need for greater clarity regarding the purpose and objectives of PPP ERA, and the need for stronger collaboration across the regulatory system. Greater clarity regarding the aims of ERA would provide a more consistent basis for assessment and decision-making, while enhanced collaboration would support shared interpretation, learning, and implementation across organisations. As many of the identified challenges transcend organisational and institutional boundaries, implementation will require coordinated action among the actors involved in PPP

Table 1 Author synthesis of practitioner findings: priority areas for strengthening the environmental risk assessment (ERA) of plant protection products (PPPs)

Practitioners' findings	Priority area	Core recommendation
<i>Collaboration:</i> Divergent expectations regarding the purpose of ERA; knowledge that could be mobilised to define/revise protection goals is not systematically captured <i>Efficiency:</i> ambiguously defined protection goals <i>Effectiveness:</i> Moderate confidence that ERA adequately predicts environmental impacts and that ERA procedures ensure the safety of authorised substances; many respondents suggested a shift beyond single substance, product-by-product assessments <i>Efficiency:</i> greater complexity frequently increases workload and interpretative effort without changing regulatory conclusions <i>Efficiency:</i> The growing volume, fragmentation, and complexity of guidance has itself become a major source of inefficiency; applying guidance often requires substantial interpretation, contributing to variability across individuals, organisations, and Member States <i>Collaboration:</i> codification of agreed solutions into zonal guidance helps stabilise practice across Member States <i>Efficiency:</i> In the absence of shared data infrastructures and systematic mechanisms for reusing prior assessments, evidence is frequently re-assessed on a substance-by-substance basis and across dossiers <i>Learning:</i> regulatory knowledge is fragmented, with data relevant to ERA distributed across dossiers, static documents, and organisation-level systems; modelling tools are subject to parallel evaluation, inconsistent evaluation practices, and limited shared ownership across organisations <i>Effectiveness:</i> Monitoring is described as a “reality check” for ERA, but there are difficulties with attribution and a lack of reliable and harmonised PPP usage data; feedback loops between prospective ERA, risk mitigation and environmental monitoring are not perceived as fully operationalised <i>Learning:</i> monitoring and retrospective evidence exist alongside ERA rather than being embedded within it <i>Effectiveness:</i> Sustained time pressure limits opportunities for in-depth analysis, reflection, and collaboration <i>Collaboration:</i> growing regulatory strain in terms of workload and resource pressure <i>Learning:</i> risk assessors rely heavily on informal memory, internal notes, precedent awareness, and ad hoc exchanges, which are vulnerable to staff turnover	Clarify ERA objectives and operational protection goals Ecological realism (proportionate expansion) Guidance design and usability System-level learning and data reuse Monitoring and feedback loops Capacity and knowledge management	Clarify the objectives of ERA and translate them into operational, ecologically relevant protection goals, specifying what is protected, at which biological level, and over which spatial and temporal scales Broaden ERA beyond single-substance paradigms selectively, using problem-driven approaches to address mixtures, cumulative exposure, landscape context, and indirect and long-term effects only where decision-relevant Modernise ERA guidance with clearer decision pathways, stopping rules, and better integration across documents; support proportional use of expert judgement through targeted training Develop system-level overviews and shared, interoperable data infrastructures, enable partial automation of routine assessment steps, and strengthen governance of models and evaluation practices Systematically link environmental monitoring to ERA as a feedback mechanism to recalibrate assumptions, update guidance, and identify emerging risks, supported by improved data governance Invest in staffing, specialist expertise, training, and organisation-level knowledge management systems as core elements of ERA quality

Table 1 (continued)

Practitioners' findings	Priority area	Core recommendation
<i>Collaboration:</i> Collaboration is strongest and more routine within organisations, while cross-organisational cooperation is more irregular and often informal or episodic; well-functioning zonal collaboration can act as a powerful enabler of efficiency, whereas active substance assessments are comparatively fragmented; collaboration is not viewed as undermining professional independence	Structured collaboration	Strengthen structured cross-organisational collaboration at EU level, building on successful zonal practices while preserving professional independence

ERA. Consistent with the transition strategy outlined in the PERA Roadmap [6], progress will depend on a combination of strategic leadership and sustained collaboration across the PPP ERA system.

Taken together, these recommendations point towards a more purposeful PPP ERA system: one that is guided by clearer objectives and protection goals, proportionate in analytical effort, better aligned with ecological reality, and capable of learning from regulatory experience. Such a recalibration could strengthen both environmental protection and regulatory credibility without undermining scientific rigour or legal robustness.

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Data availability The survey questionnaire is provided in the Electronic Supplementary Material. Individual survey responses and workshop records are not publicly available because participants came from a small specialised professional community and detailed responses may be indirectly identifiable. De-identified supporting data may be made available by the corresponding author upon reasonable request, subject to participant consent, confidentiality obligations, applicable data-protection requirements, and, where appropriate, a data-sharing agreement.

Declarations

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Use of AI tools The authors used Microsoft Copilot, OpenAI ChatGPT, and Anthropic Claude to assist with English-language editing, rephrasing, and improving the clarity and readability of selected sections of the manuscript. All AI-generated suggestions were reviewed, verified, and edited by the authors. All conceptual development, scientific interpretation, and conclusions were developed by the authors. The authors take full responsibility for the accuracy, integrity, and final content of the manuscript.

Ethics approval and consent to participate This study was based on an anonymous survey and follow-up workshops involving practitioners undertaking day-to-day work in PPP ERA and regulatory practice. Participation was voluntary, and informed consent was obtained from all participants prior to their involvement. Workshop participants were informed in advance that discussions would be audio-recorded, and their consent was confirmed before recording began. Access to the recordings was restricted to the project team. Survey responses and workshop findings were analysed and reported in aggregated or anonymised form, without attributing views to individual participants or their employing organisations. According to applicable institutional and national guidelines, the study did not require formal ethical approval.

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References

1. Axelman J, Aldrich A, Duquesne S, Backhaus T, Brendel S, Focks A, Holz S, Knillmann S, Pieper S, Silva E, Schmied-Tobies M, Topping CJ, Wipfler L, Williams J, Sousa JP (2024) A systems-based analysis to rethink the European environmental risk assessment of regulated chemicals using pesticides as a pilot case. *Sci Total Environ* 948:174526. <https://doi.org/10.1016/j.scitotenv.2024.174526>
2. European Commission (2025) Proposal for a regulation of the European parliament and of the Council amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No 1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements. Strasbourg, 16.12.2025 COM(2025) 1030 final. 2025/0410 (COD)
3. PARC—Partnership for the Assessment of Risks from Chemicals (2026) PARC homepage. <https://www.eu-parc.eu/>. Accessed 2 May 2026
4. PollinERA—Understanding pesticide–pollinator interactions to support EU environmental risk assessment and policy (2026) PollinERA homepage. <https://www.pollinera-horizon.eu/>. Accessed 2 May 2026
5. Saldaña J (2016) The coding manual for qualitative researchers, 3rd edn. SAGE, London
6. Sousa JP, Aldrich A, Axelman J, Backhaus T, Brendel S, Dorronsoro B, Duquesne S, Focks A, Holz S, Knillmann S, Pieper S, Schmied-Tobies M, Silva E, Topping CJ, Wipfler L, Williams J (2022) Building a European partnership for next-generation, systems-based environmental risk assessment (PERA). *EFSA Support Publ* 19(8):58. <https://doi.org/10.2903/sp.efsa.2022.EN-7546>
7. SYBERAC—Towards a systems-based, holistic environmental risk assessment of chemicals (2026) SYBERAC homepage. <https://www.syberac.eu/>. Accessed 2 May 2026
8. Williams JH, Bordon A, Bednarska A, Pinto A, Martins CAH, Henriques D, Sgolastra F, Knapp J, Loureiro J, Sousa JP, Gócs K, Marcussen LK, Rundlöf M, von Post M, Castro M, Mølgaard N, Simon N, Capela N, Thomsen P, Casqueiro R, Magagnoli S, Holz S, Castro S, Dupont YL, Filipiak Z, Topping CJ (2023) Roadmap for action on the environmental risk assessment of chemicals for insect pollinators (IPol-ERA). *EFSA Support Publ* 20(11):EN-8431. 99 pp. <https://doi.org/10.2903/sp.efsa.2023.EN-8431>
9. ZAPID (Zonal Authorisation Procedure—Improvement and Development) (2024) Workshop report on the Zonal Authorisation Procedure—Improvement and Development (ZAPID) Braunschweig, 5–7 December 2023. Available at: https://food.ec.europa.eu/plants/pesticides/authorisation-plant-protection-products/workshops-and-grants_en

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