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Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA)

Final Roadmap Report

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Abstract

The European Partnership for next generation, systems-based Environmental Risk Assessment (PERA) is a strategic initiative launched by the European Food Safety Authority (EFSA). This initiative is in response to the recognition that the current ERA paradigm has "fallen out of step with scientific knowledge and progress" and the new policy and societal ambitions e.g. the EU Green Deal strategy to better safeguard the environment. As part of the initiative, EFSA commissioned the development of a roadmap to facilitate a transition to an integrated and cross-sectoral environmental risk assessment (ERA) approach. The PERA systems-based approach aims to connect relevant partners from various sectors across regulatory silos, promotes and facilitates the sharing of data and expertise, and improves efficiency and transparency of the risk assessment process. In this External Scientific Report, we present the PERA roadmap that comprises of a problem description (current state), a vision (future state) and a series of steps to move towards the vision (transition process). The PERA roadmap was developed after extensive desk research and multiple stakeholder interviews, that were used to identify partners, areas needing further development, challenges, blockers and collaboration opportunities. We designed a vision for next generation ERAs, initially focused on pesticides, based on the ideas of stakeholders and accounting for the identified strengths and weaknesses of the current ERA system. Workshops were held during which stakeholders were invited to comment on these draft concepts providing valuable feedback for further revision. The PERA vision is a visual framework for systems-based ERA, with a concentric circle model. Its core circle builds upon and strengthens current ERA processes by focusing on pesticide specific aspects useful for comparability and decreasing the assessment complexity of pesticides. The inner core circle is surrounded by a supportive circle of landscape scale ERA, that addresses ecosystems properties of generic relevance for all pesticides. These two ERA circles are in turn connected to surrounding circles representing the agricultural, ecological and production systems as well as the political, economic and social systems. To fully optimize the process these circles need to be interconnected with information feed-back loops. The vision and roadmap were designed to incorporate the strengths, knowledge and expertise of the current state into a new holistically framed systems-based ERA. Strategies for transition, as well as concrete projects to spark the transition process are proposed and include concrete and tangible steps in a holistic direction within the current regulatory framework.

Key words: Holistic ERA, Pesticides, Plant protection products, Systems-based ERA

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Executive Summary

In 2020, the European Food Safety Authority (EFSA) identified the need to develop a roadmap for action on "Building a European **P**artnership for next generation, systems-based **E**nvironmental **R**isk **A**ssessment (PERA)", referring to new scientific developments, societal demands and policy targets as drivers of change. EFSA calls for the implementation of a more integrated and cross-sectoral (also termed systems-based) approach to Environmental Risk Assessment, and recommended the establishment of a Partnership (PERA) to collaboratively design and facilitate the transition to a next generation ERA. EFSA envisions that this should be achieved by connecting partners, promoting the development of new tools and sharing data and expertise in order to improve the efficiency and overcome the currently fragmented regulatory landscape.

The transition to systems-based approaches in ERA is not constrained to single regulated substances, but aims at overcoming regulatory silos, whereby an array of regulatory ERAs are performed under different sectoral regulatory frameworks. However, to prioritize efforts and aid the establishment of PERA as pilot initiative, the work of this project focused on pesticides. Helping to determine the PERA roadmap, project outcomes include: 1) the refinement of the problem formulation, the mapping of relevant stakeholders (agronomists, risk assessors, managers, advisers, farmers, developers, consumers/society), their needs and activities relevant to the development of PERA and new ERA frameworks; 2) identification of areas requiring further development, and 3) challenges and blockers to the transition to a next generation systems-based ERA. To support PERA, further necessary aspects were identified that are focused on communication and cooperation/collaboration opportunities. The proposed roadmap also presents a strategic prioritisation of project proposals to spark the transition towards systems-based approaches in ERA.

Besides detailing the outcomes mentioned above, this roadmap report also contains in depth analysis of the current substance-by-substance ERA framework and sets out a holistic vision for a future systems-based ERA. The vision for PERA is an essential part of the roadmap since it outlines the goal and direction for the transition and is used to prioritise working areas for further development. The vision for PERA is based on the refined problem description, as outlined below, and incorporates input and feedback from stakeholders as well as the contracting authority (EFSA). The vision addresses concerns raised about the current ERA system, such as being complex and labour intensive, lacking realism in assessments and being disconnected from certain stakeholders e.g. from the agronomic and biodiversity conservation sectors. It also addresses concerns about a future systems-based approach, which are primarily related to increasing overall complexity and lack of a comprehensive definition for a system-based ERA.

To map the current ERA system and identify stakeholders directly and indirectly related to it, desk research and semi-structured interviews were undertaken to provide crucial insights. This was supported by network analysis, to identify relevant stakeholders in selected ERA processes, confirming the large number and diversity of stakeholders involved in the current ERA system. However, the analysis also highlights that several stakeholders, such as NGO's, consumer associations or farming advisories are not well represented in certain processes.

The analyses of the ERA development activities, such as research projects, method and guidance development, evaluation reports and monitoring campaign results, show that only a few stakeholder types currently work together. Some existing multi-stakeholder projects, however, are good examples for fostering cooperation as well as communication between different sectors.

The refined problem formulation also critically assessed the current tiered approach in ERA. This critique highlights several issues. The current ERA system does not account for the possibility of cumulative impacts over growing seasons or years, as most agricultural landscapes do not provide space for recovery. Also, long-term monitoring data indicates that the current ERA might not be sufficiently protective for the wider biodiversity. The current assumption that organism groups are protected individually leads to overlooking possible indirect effects resulting from organisms' interactions, as well

as failing to address risks to biodiversity in a holistic manner. Thus, the current ERA system does not necessarily fulfil its objective, to avoid unacceptable effects of PPP on the environment[1].

Overall, the current ERA system has a deficit of holistic, systematic and comparative evaluation of the ERA methodology. For example, testing and outcomes of the assessment are not checked against the entire data set (e.g., monitoring data) acquired during the ERA of different substances. In combination with the encouragement to develop more sophisticated tools to demonstrate a "safe use", details of unclear relevance are introduced in the ERA, which in turn add complexity and demand knowledge, time and resources. A possible driver for loss of trust in the current system might be that despite requiring more resources, ERA process do not prevent continuing environment issues of concern e.g. biodiversity losses.

The PERA project poses a number of framing questions to avoid transferring the problems from the current system into a new paradigm, focusing on more holistically framed ERA issues. The central question is: "*If we are to move into a new paradigm, which are the things that we don't want to bring into it?*" From the assessment of the current state and the (revised) problem formulation, the following proposals for a systems-based ERA are considered necessary: 1) a high-level shift in perspective from substance-by-substance and regulation-by-regulation to a holistic systems-perspective, and 2) an improved alignment across silos to other regulatory areas by adopting a broader perspective.

In a future state with a systems-based ERA, the *modus operandi* between stakeholders should be improved so that ERA integrates different systems and multiple disciplines of expertise to strive for new/alternative solutions and a sustainable management of agricultural production systems and agroecosystems (addressing interconnectivity and overbridging silos). Technical and scientific ERA methodologies should be improved by strengthening the feedback between prospective and retrospective risk assessments and capturing the combined impacts of pesticides and other ecosystems stressors at the agro-system level (addressing protectiveness and realism). Focusing on relevant factors and aspects in greater levels of detail for ERA will help to increase the comparability of data and assessments (addressing complexity, relevance, efficiency and harmonisation to overbridge silos).

The developed vision for a systems-based ERA and the holistic scientific reframing of ERA, as a core element of the transition towards the vision, emerges from the considerations above. It follows the intention to maintain the strengths and expertise of the current system and to increase its efficiency by expanding its application, starting with the current legal framework.

For addressing the impact on non-target organisms in an agricultural landscape within the context of pesticide use, other stressors need also to be considered. The new ERA process should benefit from lessons learned from existing ERA and capture the differences/comparability between PPP. Prospective ERA should be linked to monitoring, thus enabling the systematic retrospective evaluation of ERA appropriateness. As a result, the proposed vision for a systems-based ERA can be pictured as a concentric circular layered ERA process.

An inner circle represents a refined version of the current "substance by substance" assessment process. In a systems-based ERA, this process should be focused on comparing and thus distinguishing the impact of different PPPs, increasing comparability and decreasing the assessment complexity (internal benchmarking). Benchmarking ERA methods will be a driver for improved realism and focus on relevant aspects.

The surrounding circle supports PPP evaluations and provides ERA with aspects related to landscape and ecosystem levels, with longer time perspectives and integration of larger datasets addressing issues related to ecosystem properties currently submitted for substance specific higher tier assessment. This assessment layer considers e.g., multiple PPP applications and monitoring data. Handling these aspects mostly outside the single dossiers would improve consistency between assessments and reduce the workload. Also in this layer, benchmarking of ERA methods will be a driver for improved realism and focus on relevant aspects. Interconnectivity between the layers is essential and needs to be

[1] S. Leenhardt, L. Mamy, S. Pesce, W. Sanchez (2022). Impacts des produits phytopharmaceutiques sur la biodiversité et les services écosystémiques, Synthèse du rapport d'ESCo, INRAE - Ifremer (France), 124 pages. (in French)

systematically implemented, for example, as updated assessment factors or generic conditions for use addressing landscape properties.

A third circle illustrates improved interconnectivity to the agricultural eco- and production system. Here, issues related to generic biological and chemical monitoring and the assessment of the necessity of PPP intended uses are dealt with. By integrating the different layers, the efforts currently dedicated to the higher tier assessment are conveyed from the product-specific assessment to the integration of information from landscape and agricultural systems.

Finally, an outer circle represents the political, economic and social contexts. On the one hand, developments and decisions taken here will affect the specific ERA aspects. On the other hand, the use of the information produced during ERA will be valuable for more informed decisions and actions at the strategic level to better protect biodiversity. The holistic scientific reframing connecting areas of expertise and data, including other strategic EU-partnerships, is proposed as a key driver to facilitate such improvements.

The transition to a systems-based ERA and its implementation faces, like every change in paradigm, several challenges and blockers. In this project we have identified several key ones and propose ways to overcome them. This task, however, needs to be continued in PERA (the partnership). Overcoming these challenges and blockers can be partly achieved by the advancements of the proposed projects (see further down).

The proposed vision for the future ERA needs to be further developed and operationalised with concrete development steps among a broader range of stakeholders. Besides environmental and risk assessment aspects, it should also include socio-economic aspects, food production or ecosystem management. This roadmap provides a starting point for the development of a systems-based ERA, identifying its main components and interactions between them.

A potential blocker is the harmonization of processes, particularly when considering the variety of different regulations and the envisaged increased involvement of various stakeholders in a systems-based ERA. More complex ERA, by including stakeholders at the regional, national and European level, may be difficult to perform similarly for all companies and Member States. The integration of new concepts and data requirements in the systems-based ERA (e.g. for monitoring or consideration of the agricultural practice) have to be designed in a way that they are feasible, affordable and meaningful when considering differences at the national/regional level (e.g. sentinel or tiered monitoring with different intensities).

However, a crucial point in the future systems-based ERA will be to identify and address the most important uncertainties without increasing the overall complexity. Moreover, integrating more data from the field (e.g. exposure and effect data from monitoring) and calibrating the prospective, systems-based, risk assessment with such data will overcome a potential increase in uncertainty. Field data will ideally support the identification of driving factors for pesticide exposure and effects, improving ERA predictions and focus ERA on relevant aspects, thus keeping complexity under control.

Finally, the implementation of a systems-based ERA for PPPs should be legally framed. However, a substantial part of the proposed transformative change consists of a scientific reframing of ERA issues, a topic that *per se* does not necessarily imply changes in the legal framework. Still, procedures and responsibilities between stakeholders may have to be adapted for a full implementation of a systems-based ERA, implying the need for possible legislative changes. It is therefore suggested that the transformative change works with strategies tailored for different time perspectives: i) Short-term: search for opportunities to improve the current system by taking steps in the direction to holistic assessments and systems-based ERA within the current legal framework; ii) Long-term: align and proactively interact with long-term overarching legal development and implementation.

The roadmap outlines the most important factors for a successful management of the transition in a multi-stakeholder transformative process, these being: i) leadership for the participatory process, ii) early phase problem framing and reframing, iii) knowledge of change management.

A strong overarching leadership is needed to steer the scientific reframing, with strong mandate and incentives for driving the change process over time. These are considered necessary elements essential for a successful transition. Pilot groups who can work towards shared and achievable short-term goals need to be identified, in order to break down the transformative change towards the vision into achievable concrete steps. The identified projects have been scoped to fill different missions in a strategy for transformation towards the proposed vision of a systems-based ERA. There are three main themes and purposes of the project proposals:

- Overarching governance and leadership in the holistic scientific reframing of ERA (Project 1)
- Stakeholder engagement and partnership formation (Project 2)
- Research at the technical level exploring new solutions and developing new methods and tools (Projects 3-5)

The different projects have both long-term and short-term objectives, they are planned to run in parallel and to interlink.

Project 1 Development and implementation of systems-based approaches in ERA: this project has an overarching and integrative role in guiding the specific scientific and technical developments within projects 3-5 and is tightly linked to Project 2 (the development of the PERA partnership). The aim is to empower the transition to a systems-based approach in environmental risk regulation via a strategic and scientific governance. It sets out to ensure transparency and integrity of scientific contributions to systems-based ERA. Moreover, it aims at connecting science, data and knowledge from ERA to high-level EU strategies. It encompasses the integration of results from the projects 3, 4 and 5, providing different options at the strategic level to reduce ecosystem impacts of PPPs and to meet the Farm-to-Fork Strategy targets.

Project 2 Development of a PERA framework: this project is crucial for bringing together stakeholders and for building the PERA platform for systems-based ERA. It will focus not only on cooperation, communication, as well as conceptual and strategical developments, but also on the implementation of concrete steps for the PERA development (How is the platform/partnership built and how does it work? Who owns and who pays for it? Who is in control, and how is the PERA platform observed?)

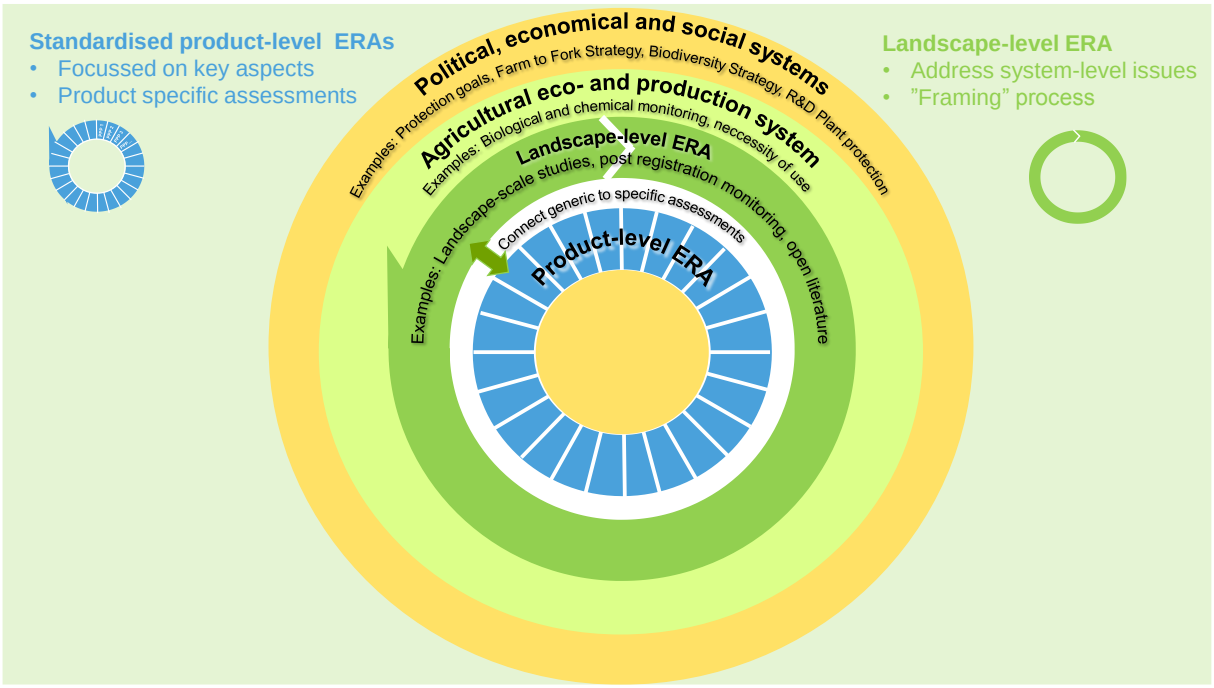
Project 3 Develop comparability between environmental risk assessments of PPP: this project will provide the scientific basis to shift the use of PPPs to more favorable environmental profiles, both by removing those with the highest impact and by facilitating market access of PPPs with a better environmental profile. This project will develop methods for improving comparability of environmental impacts between different PPPs.

Project 4 Combining pre- and post-registration data for prospective ERA of PPP: this project aims at combining the information from the prospective risk assessment and resulting decisions with the information from the real world, i.e. existing and new field observations in the field for all compartments and assessment areas. Critically reviewed environmental data will feed into projects 3 and 5 and will also connect to the agricultural eco- and production system.

Project 5 Holistic impact assessment in agricultural ecosystems: this project provides the basis for integrated assessments by developing regulatory applicable and relevant tools for systems-based risk assessments of PPPs and other chemical stressors. Mechanistic model development is envisaged as well as validation studies, in order to identify relevant scales for integrated system-level assessments. The scientific outcomes of this project will support reducing the use of PPPs in general and improving ecosystem resilience in agricultural production- and ecosystems.

The outlined strategy for the transition towards a systems-based ERA puts particular emphasis on **early prioritization of projects 1 and 3**, and to some extent on project 4. These projects contain opportunities for information synthesis from already existing data sources that can be used to improve the ERA work within the current legal framework and support existing ERA processes.

Graphical abstract (vision for a systems-based and holistically framed ERA)



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1. Introduction

In 2020, the European Food Safety Authority (EFSA) identified the need to develop a roadmap for "Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA)". A background Theme (concept) paper[2] by EFSA outlined new scientific developments, societal demands and policy targets[3] as drivers of change. The theme paper, thereafter referred as 'EFSA Theme paper for PERA', also envisioned the implementation of a systems-based approach to ERA.

In 2021, EFSA awarded the development of the roadmap for action on "Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA)" - lot 1 (reference number OC/EFSA/ED/2020/01), thereafter referred as the 'PERA project' in this report, to the University of Coimbra (Portugal) in consortium with the Swiss Confederation acting through Agroscope, replaced by the Federal Office for the Environment (FOEN), Switzerland; Swedish Chemicals Agency (KemI), Sweden; University of Gothenburg, Sweden; German Environment Agency (UBA), Germany; University of Osnabrück, Germany; Aarhus University, Denmark; Wageningen Environmental Research, The Netherlands.

Strongly anchored to the EFSA Theme paper for PERA (see Box 1 with scope and objectives described by EFSA), the overarching aim of the PERA project was **to build a roadmap for action providing a vision of a systems-based ERA and a strategic approach to transitioning towards that vision**, by addressing the following aspects:

1. Analysing the current ERA system and refining the problem formulation

2. Mapping relevant activities and organisations (stakeholders) for PERA and next generation, systems-based ERA

3. Identifying areas requiring further development

4. Identifying potential challenges and blockers to the transition

5. Proposing a series of multi-annual and multi-stakeholder projects, prioritising them and pinpointing cooperation/collaboration opportunities between different partners

As stated in the Theme paper for PERA, the strategy leading to PERA and to systems-based approaches in ERA is not constrained to single regulated substances, compounds or products but specifically aims at overcoming current "regulatory silos[4]". This can be achieved by harmonising approaches in the different regulatory ERAs and increasing interoperability. In light of prioritising working areas and piloting the establishment of PERA, EFSA suggested to focus the initial work on pesticides.

Therefore, besides fulfilling the objectives noted above, this roadmap report describes the current ERA system and a vision for the future ERA, focused on pesticides[5], as pilot substance group. It also identifies relevant activities and key stakeholders important for transitioning towards a next generation system-

[2] EFSA (European Food Safety Authority). Devos Y, Auteri D, de Seze G, Fabrega J, Heppner C, Rortais A and Hugas M, 2022. Theme (concept) paper – Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA). EFSA supporting publication 2022:e200503. 9 pp. doi:10.2903/sp.efsa.2022.e200503

[3] The Farm to Fork strategy for sustainable food, the Chemicals Strategy for sustainability towards a toxic-free environment, the Biodiversity Strategy for 2030 to protect and restore biodiversity, the Zero Pollution action plan to reach a toxic-free environment, the Circular Economy action plan to pave the way for a cleaner and more competitive Europe, and the EU Soil Strategy for 2030 for sustainable soil management

[4] European Commission, DG Research and Innovation, 2018. EU authorisation processes of plant protection products from a scientific point of view. Group of Chief Scientific Advisors, scientific opinion 5 (supported by SAPEA evidence review report No. 3). Brussels, 4 June 2018, Publications Office, 2018, https://data.europa.eu/doi/10.2777/71851

[5] Throughout the report, and unless specified otherwise, **the terms plant protection products ("PPP"), "product" and "product-level" apply to ERA issues both at the EU-level, for the approval process of active substances, and at the national level for the authorisation process of PPPs**. The same concepts, methodologies and guidance documents for ERA are used both for assessing at the EU-level the possible approval of active substances to be used in pesticides and at the national level in the authorisation of products with approved active substances, to ensure the harmonisation across Member States according to Regulation (EC) No 1107/2009.

based ERA. As part of this report, a number of strategic recommendations are provided along with multi-annual and multi-partner project proposals.

Box 1 - Scope and objectives of the "European Partnership for next generation, systems-based Environmental Risk Assessment (PERA)" (EFSA, 2022)

The purpose of PERA is to provide an overarching platform that:

- Facilitates the transition to next generation, systems-based ERA that addresses new policy targets and society needs;

- Connects relevant partners (e.g. national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society) from various sectors, across regulatory silos, and improves cooperation between these partners;

- Accelerates the development of new/complementary tools and methods, and the uptake of innovative tools and methods for regulatory ERA;

- Promotes and facilitates the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise, and the establishment of an EU-wide cross-disciplinary network of risk assessors and risk managers (e.g. community of practice);

- Improves efficiency and transparency;

- Overcomes the challenges of a fragmented regulatory/policy landscape.

1.1. Conceptual approach and actions taken to develop the roadmap

Considering the complexity of the project's objectives, it was deemed particularly relevant to refine the problem formulation by analysing the current state of regulatory ERA before commencing the development of future recommendations. An iterative double-diamond approach[6] was used (Figure 1**:** Conceptual approach chosen by the PERA-project team to address the project objectives by adopting the 'double-diamond' approach. The blue, green and yellow circles in the middle are a graphical representation of the preliminary vision developed for a future systems-based environmental risk assessment.) to identify, understand and address the problem, and to help design the roadmap for the transition to a new ERA framework. By learning more about the variables of the problem, the gathered information could then be filtered and elaborated on to develop a solution. This work culminated in a preliminary vision of a future ERA, which was developed as the result of collaborative work between the project team and external stakeholders.

The approach was applied to concepts and frameworks, both within the existing legal framework and potential new amended frameworks. The rationale behind this was to embark on a transformative process that would build a set of holistic methodologies on positive aspects of the current system as a solid base, whilst eliminating those methodologies which are no longer aligned with the desired new system. Transformation of the existing ERA methodology to a new holistic paradigm facilitates the process by retaining existing regulatory processes, its strengths as well as relevant data and expertise from the current system. This avoids the need for a complete overhaul and enables to implement the future desired state in small steps.

To this end, system maps of the current and future ERA states were developed. In this approach, the links between stakeholders and their activities are crucial elements. Important steps in this interactive and iterative process for developing the roadmap have been:

1. Semi-structured interviews: designed to identify possibilities for new constellations of collaborations, as well as perceived challenges and blockers for transitioning to a new systems-based ERA. Relevant interactions between stakeholders and potential partners were explored

[6] https://www.designcouncil.org.uk/our-work/news-opinion/double-diamond-15-years/

by asking stakeholders about their relationships to other stakeholders with whom they interact or could interact with, as well as about their expectations, perceptions of the current ERA framework and a transition to a new one. The information gathered in the interviews was coded with the software tool NVivo and analysed quantitatively and qualitatively to create visual representations of the main networks between different stakeholders (sociograms), hierarchical and heat maps interlining stakeholders and relevant topics under analysis, e.g., working areas requiring further development, strengths and weaknesses of the current ERA system and potential challenges and blockers to the transition to the new system. Stakeholders who were interviewed included: EU-level and national regulatory authorities (16 interviews), representatives from academia and research institutes (7 interviews), and representatives from industry, farmers associations and NGOs (6 interviews) (full list in Appendix A - Table A 1).

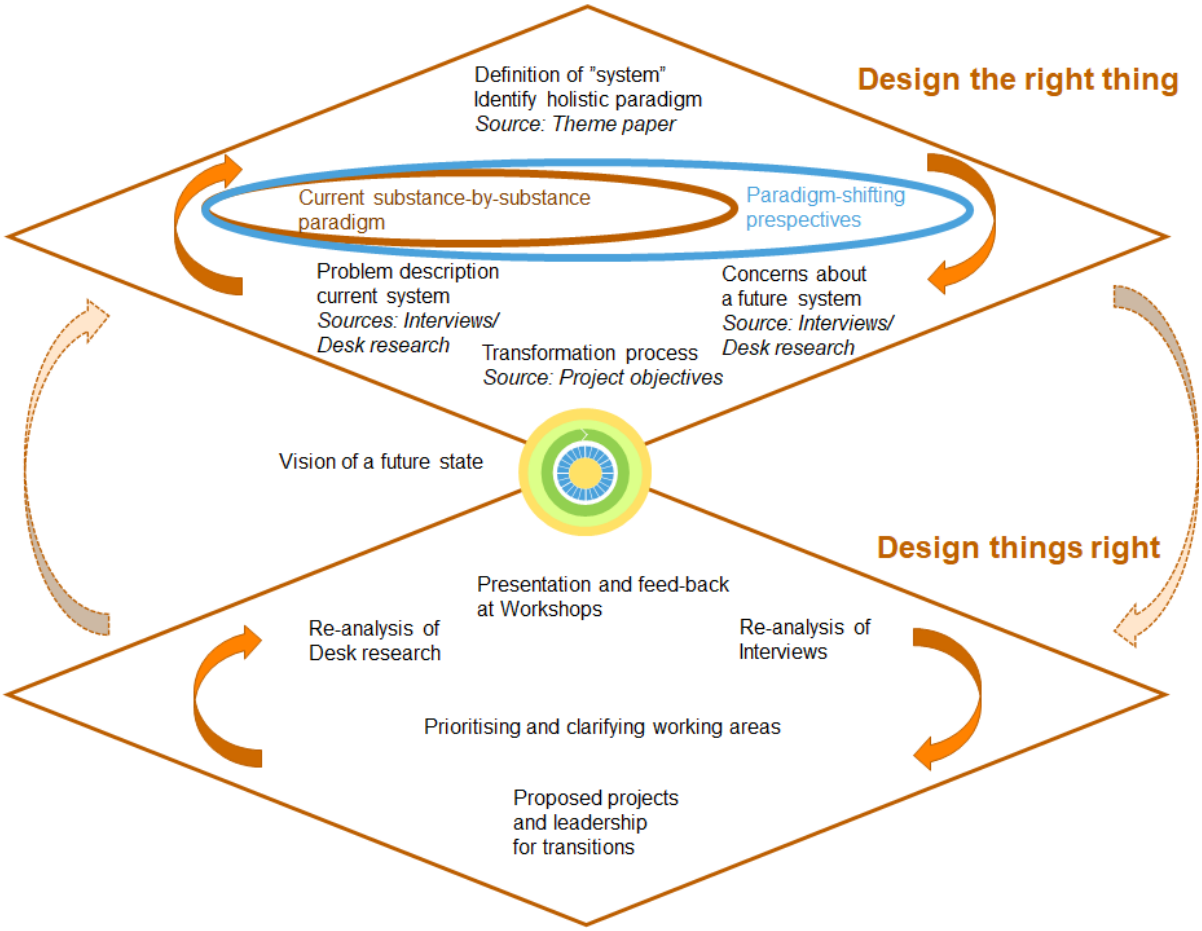

Figure 1: Conceptual approach chosen by the PERA-project team to address the project objectives by adopting the 'double-diamond' approach. The blue, green and yellow circles in the middle are a graphical representation of the preliminary vision developed for a future systems-based environmental risk assessment.

2. Desk research: conducted to collect information on multiple stakeholders and their activities (e.g., research and regulatory projects/programmes, reports) relevant for PERA, complemented by a search on the SCOPUS® (Elsevier) database for additional relevant scientific publications. The collected information was compiled in an internal database of stakeholders (institutions and contact persons) and activities. Stakeholders were coded according to stakeholder type and role in the ERA process and activities were coded according to the areas requiring further development, identified in the EFSA theme paper for PERA (see Box 2), and according to a

coding typology specifically developed for the project, embracing different categories considered relevant in a systems-based environmental risk assessment with a focus on PPPs (see Box 3). Network analysis tools were used to analyse data to find links between stakeholders/stakeholder types and activities/activity types, and between activities and activity types and areas requiring further development.

3. Workshops with invited stakeholders from different sectors: carried out to gain feedback and input for developing a future ERA. Participants at the workshops belonged to 25 organisations (full list in Appendix A - Table A 2) covering relevant sectors as identified in the interviews and in the desk research. The aim was to collect the first impressions on the vision of a systems-based ERA. The workshop employed different interactive tools to gain answers on several pre-established questions and carrying out a SWOT analysis on selected topics considered relevant for the implementation of a systems-based ERA. The aim was also to establish a community to support the roadmap for the transition to a systems-based ERA.
4. Development of conceptual models for a participatory discussion with the stakeholders on the current state and a vision for the future state of ERA approaches: the models outline, for example, how a holistic paradigm and broader scientific framing could be applied on existing data, expertise, and methodologies. Examples of such conceptual models in this report are Figure 2 (Current system), Figure 3 ("Vicious circle" of increasing complexity), Figure 4 (Future system) and Figure 5 (Vision for a systems-based ERA).

For the development of the roadmap, it was considered important to identify and define terms such as "holistic" or "systems-based". In this way, questions could be formulated regarding the possible paradigm shift needed to achieve the project aims. The PERA project team interpreted holistic framing of ERA issues from common definitions of the word holistic. Examples are "*elating to or concerned with wholes or with complete systems rather than with the analysis of, treatment of, or dissection into parts*"[7], and "*dealing with or treating the whole of something or someone and not just a part*"[8]. For ERA approaches, this would mean identifying the "whole" or the "system", to put the parts constituting a system into the appropriate context and to increase a systems-perspective by gaining knowledge on how the pieces are related to each other and form as a whole a system that is more than the sum of its parts. Adopting such a framing on the *existing* ERA processes could also increase knowledge on how parts of today's ERA approaches relate both to each other and to a future systems-based ERA. A new scientific framing of ERA at a higher organisational level would also be an opportunity to support the operationalisation of high-level EU strategies under the European Greed Deal, such as Farm to Fork and Biodiversity strategies.

For a future systems-based ERA to integrate, for example, effects of multiple stressors at landscape level, such a holistic framing would imply to scientifically address questions such as:

- How do impact levels of PPPs relate to and interact with other ecosystem stressors?
- How do different risk management options, such as risk mitigation measures or alternatives to PPPs, compare to each other and affect the impact level of PPPs?

For the existing methodologies and ways-of-working with ERA for PPPs, a holistic framing would imply focusing on questions such as:

- How do environmental impact levels of authorised PPPs assessed with current ERA methodology and data compare to each other?
- How do predictions in the prospective ERA compare to independent measurements in the environment?
- How do alternative methods to predict exposure and effects compare to each other?

[7] Merriam-Webster Dictionary
[8] Cambridge Dictionary

These questions and the resulting defined paradigm of a holistic approach to ERA were used as tools to analyse information from new perspectives and to develop a preliminary vision of a systems-based ERA. This vision could both: 1) meet the overarching goals outlined in the EFSA Theme paper for PERA and 2) also overcome the major problems with the current ERA system and concerns for a future system as identified by stakeholders and expressed in the interviews. The feedback received from the interviews and the outcome of the desk research was used to refine the problem description and proposed vision for a future ERA.

Based on these analyses, concrete steps of the envisioned transition to a future ERA were proposed. This included a strategic project for leading the transformative change, a proposal for establishing a partnership, as well as the development of concrete scientific-oriented projects for implementing a systems-based ERA.

Box 2 - Working areas as referred to in the EFSA Theme paper for PERA (EFSA, 2022):

The following non-exhaustive list of potentially interrelated working areas is proposed for PERA:

Short Title	Working areas from the EFSA Theme Paper for PERA
WA1: Overall system impact	Formulating ERA issues/problems and (specific) protection goals holistically to address overall system impacts
WA2: Environmental risks	Assessing environmental risks resulting from exposure to regulated substances/compounds or products at relevant levels of biological organisation (individual, population, community, ecosystem) and spatio-temporal scales
WA3: Mixture toxicity	Assessing cumulative environmental effects resulting from exposure to multiple regulated substances/compounds or products, and stressors
WA4: Efficiency of risk mitigation measures	Developing and designing tools and methods (including post-market environmental monitoring) for evaluating the efficiency of risk mitigation measures
WA5: Monitoring	Monitoring regulated substances/compounds, or products in different environmental compartments and matrices, and along the food/feed chain
WA6: pre/post registration data	Integrating of pre- and post-registration data of regulated substances/compounds or products, and other environmental monitoring, surveillance and pesticide/pharmacovigilance data
WA7: Alternative solutions	Comparing environmental risks of regulated substances/compounds or products with a range of alternative solutions
WA8: Harmonised ERA	Developing more coherent, harmonised and interoperable regulatory ERA approaches
WA9: Currency	Developing a common currency for the assessment of environmental impacts
WA10: Impact/sustainability assessment	Integrating regulatory ERAs in EU environmental impact and sustainability assessments, or policy assessments performed by relevant partners in the context of other regulatory frameworks/policies
WA11: Safe design	Developing and implementing the safe and sustainable by design concepts for regulatory ERA
WA12: Guidelines	Identifying areas where revised or new guidelines are needed for the ERA of future/new candidate (innovative, greener) regulated substances/compounds or products
WA13: Group assessment	Assessing groups/classes of chemical products for authorisation renewal based on the type of active substance, mode of action, and/or use
WA14: Transparency	Implementing the FAIR (findability, accessibility, interoperability, and reuse) principles for digital ERA data
WA15: Relevant projects	Building on relevant projects
WA16: Linkages with relevant partnerships	Building linkages with relevant/complementary partnerships (e.g. One Health platform, EU bee partnership, EU Partnership for the Assessment of Risk from Chemicals [PARC], EU Partnership for Biodiversity)
WA17: Related fields	Drawing on experience from related fields, including in non-EU jurisdictions

Box 3 - Overview of the identified Environmental Risk Assessment categories and respective sub-categories considered relevant for a systems-based approach with a focus on PPPs that were used to code the information on activities collected from the desk research.

Categories	Sub-categories
Agronomy	Plant breeding; PPP application techniques; PPP Alternatives/ IPM; Safe use of PPPs (e.g. filling and cleaning sprayer); Awareness, advice; Develop independent advisory services (prescription); Non-professional use
(Risk) Assessment (RA)	Identify key input data needed for predictions for prospective ERA; Ranking PPPs by comparable risk assessment; Identifying gaps in ERA (e.g. bats, Amphibians+Reptiles); Developing concepts for RA, Use of new methodologies and tools for hazard assessment; Linking prospective RA with retrospective monitoring; Mixture toxicity; Hazard-based versus risk-based
Ecosystem	Risk at landscape level; Mapping PPP exposure off-field; Mapping connectivity; Compensation areas: Protection goals
Harmonisation/cross linking	Legislations: Assessment methods; Data formats/Databases
Indicators	Trend analysis of PPPs use; Identification of Risk indicators for surface water or terrestrial habitats to analyze effects of management measures over time; Database for PPPs use (sales data); Mapping of risk indicators
Legislation	Improvement of legislations; Execution of legislations
(Risk) Management (RM)	Restricting the use of PPPs to those with lower environmental risk; Limiting the use of PPPs by subsidies (extensive production); Guiding the use of PPPs by imposing tax¸Point system to guide the behaviour of the consumer; Measures to compensate effects of PPPs in the field; Measures to increase biodiversity; Risk mitigation (efficiency and practicability)/IPM; Authorisation of PPPs
Monitoring	Concepting monitoring programs; Understanding input pathways; Identifying areas of concern; Chemical monitoring: Groundwater, surface waters, soil, sediment, biota; Biological/ ecological monitoring: Community analysis, Bioassays, effect directed analysis
Research & Development of PPP	Development/ selection of active substances, synergists, co-formulants; Design of active substances, synergists, co-formulants
Socio-economic aspects	How does the actual PPP risk assessment system influence society (with regards to consumption); Consequences of changes in the PPP risk assessment system to the society (with regards to risk perception, trust); Impact on farmers
Transparency	Transparency of all processes and decisions, decision bases in the context of legislations; Communication of the ERA process and results to the public using an easy language

2. Current state – Mapping and analysis of the current process for environmental risk assessment of PPPs

Before defining the needs for a systems-based ERA, the current regulatory ERA for PPPs and its context was analysed. For this, the strengths and weaknesses of the current system were evaluated from insights gained via the semi-structured interviews that took place with all selected stakeholders. Information from desk research was also used to identify existing links (i.e., collaboration between stakeholders). From the information collated, the current system was critically assessed to refine the problem formulation. In addition, feedback on the identified strengths and weaknesses of the current state of the ERA approach for PPPs was also collected from the workshop.

A summary of the main findings from the desk research, interviews and workshop is given in the section below. This information was used to critically re-assess the problem formulation (see Section 2.2) and fine-tune the vision for this project.

2.1. Mapping of the current system: summary of results of desk research and interviews and feedback received from the workshops

The network analysis confirmed the large number and diversity of stakeholders that are involved in the current ERA system, with EFSA, DG-SANTE and different Member State authorities, as well as the PPP industry being well connected with each other. These institutions and stakeholders are well supported by different research institutions, from whom they receive information/knowledge on ERA related issues. However, sociograms, based on information collected by the interviews, also highlight that there are several stakeholders that are not involved or significantly represented in the current ERA process (these being, e.g., NGO's, consumer associations, utility/service providers or farming advisory/associations). As a result, expertise and opinions from these stakeholders are part of aspects that are not considered in the current ERA system.

The analysis of ERA related activities (especially emanating from the desk research), indicates that many of these are only connected to one or two stakeholder types. However, for a number of activities (e.g. the WATERPROTECT[9], PERIAMAR[10], INNOSETA[11] projects), the range of stakeholder types involved is very significant. These multi-stakeholder activities can be considered as good examples on how to best coordinate input from different stakeholders regarding the performance of the risk assessment and especially of the management of PPPs in the environment, and to foster communication between the different sectors involved.

The overall conclusion from the information collected via interviews supports the view that the weaknesses of the current ERA PPP system outweigh its strengths. Strengths of the current ERA process (e.g., clear and logic *modus operandi* and the comprehensive and harmonized data requirements) were identified by EU agencies, national authorities and EC Directorates General, whilst most weaknesses were identified by academia/research institutes, with national authorities and EU agencies highlighting just a few of them. Two relevant weaknesses that were highlighted for the current ERA process is that communication of risks to different sectors is limited (e.g., to farmers, general public), and that there is a lack of involvement of stakeholders from the agronomic and biodiversity conservation sectors in the process. In addition, it was also noted that a number of guidelines are outdated and that often the ERA results in the failure in complying with the overall regulatory goals by not being in line with several sectoral policies, and by being too simplistic (i.e., by not adopting a holistic approach – e.g., side/indirect effects and long-term effects are not considered; effects of using multiple PPPs and combined with multiple stressors are not considered; several organism groups are underrepresented).

The critical assessment of the current ERA system was described as triggering a *vicious circle* (see Figure 3 in the next section). This translates into more data being generated within the current paradigm which does not lead to comparable and protective risk assessments, nor to an increased trust in the process. This conclusion was supported by the majority of the experts interviewed as well as by the workshop participants (over 95% of participants voted 'yes' or 'partially' when asked whether they recognise the sort-of *vicious circle* in the current tiered-approach regulatory ERA).

2.2. Refining the problem formulation of the current paradigm

[9] WATERPROTECT - Innovative tools enabling drinking WATER PROTECTion in rural and urban environments (https://water-protect.eu/en)
[10] COST action Periamar: Pesticide Risk AssessMent fo Amphibians and Reptiles (PERIAMAR). https://periamar.com/
[11] INNOSETA - Innovative Spraying Equipment Training Advice (http://www.innoseta.eu/)

The original problem formulation is reported in the EFSA Theme paper for PERA and formed the basis for the considerations on the ERA process provided below.

The theme paper refers to the following challenges/shortcomings:

- Existing frameworks for the ERA of single substances/compounds or products are increasingly challenged and are claimed to have fallen out of step with scientific knowledge and progress;
- Existing ERA frameworks are not always in line with new policy targets and changing societal needs are demanding more sustainable solutions to protect the environment;
- Environmental policies in different sectors have developed in isolation and at different times, and are implemented by different institutions, leading to inconsistencies between different regulatory frameworks and potential policy gaps. Consequently, the need for more harmonised approaches in ERA across the EU that would comply with the one substance/one assessment principle has been reported;
- Existing ERA frameworks lack of a holistic framing of overarching issues, for example:
    - The cumulative effects of multiple regulated substances/compounds or products and stressors as existing in the environment.
    - Upstream and downstream life-cycle implications of risk assessment outcomes and subsequent risk regulations.
    - The existence of alternative solutions.
    - Transparency of the risk assessment schemes and outcomes and independency of assessment and decision taking needs to be further increased.

A conceptual illustration (Figure 2) of this problem description was developed to contrast against an envisioned future state where these problems have been overcome.

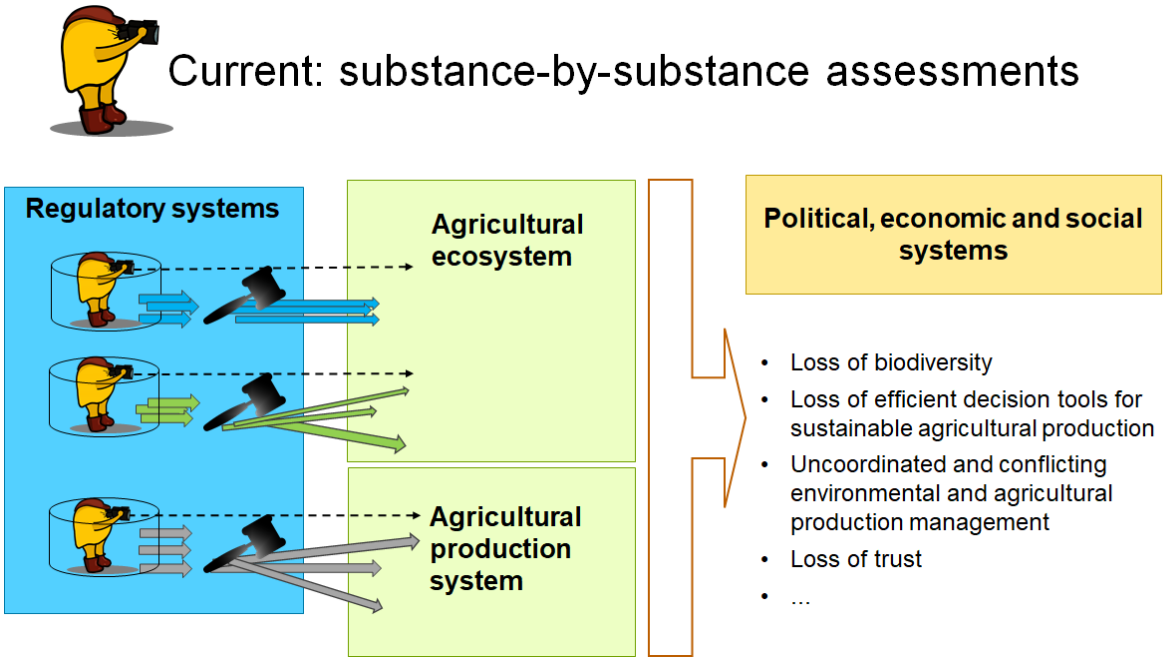

Figure 2: Conceptual illustration of the original problem description in the EFSA Theme paper for PERA. The figures with binoculars represent assessments in different sectors, which have developed in isolation and at different times, and are implemented by different institutions. This leads to inconsistencies between different regulatory frameworks. The agricultural system is not viewed as one system, but rather as an ecosystem or

a production system, depending on regulatory perspective. Communication and interconnectivity to, as well as trust from other societal system is in general in need of improvement.

2.2.1. Critical assessment of the evolution of the current tiered process

Pesticides are subject to a dual approval process, whereby active ingredients are approved at EU level and products subsequently authorized at Member State level. Individual substances are assessed in a so-called worst-case and tiered approach.

The underlying ideas of this approach are:

- Rapid identification of PPPs with a low risk based on a basic set of data
- Resource efficient by investing efforts where potential risks have been identified
- Management for single substances and single exposure routes
- Reduced animal testing by limiting testing to only few species (used as surrogate species)
- Consideration of uncertainties by use of trigger values defined for the first step of the assessment at EU level, the so-called uniform principles in Regulation (EU) No 546/2011[12]
- Harmonised approach laid down in guidance documents, but with sufficient room for expert judgement
- Clear separation of the mandates between risk assessors and risk managers
- The overarching legal framework is regulation (EC) No 1107/2009[13]
- All standard studies are submitted by the industry (notifier/applicant) according to regulation (EU) No 283/2013[14] and 284/2013[15]

New knowledge can be integrated as the guidance documents are routinely revised. However, currently EFSA has produced a number of statements and scientific opinions addressing new areas of concern, which have not been incorporated so far in amended or new guidance documents (e.g. Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods[16]).

The assumption on the worst-case character of the hazard and risk assessment procedure foots on the intention to employ ecotoxicologically sensitive test organisms (or with a known sensitivity), and to directly expose them in the laboratory to the investigated substance under constant/ standard exposure to be able to observe lethal and sublethal effects, if elicited at the tested exposure. Uncertainties are addressed by applying safety factors, or assessment factors, to account for the extrapolation e.g., from lab to field and/or to other species and/or life stages and/or sensitive endpoints. Most of the safety or assessment factors were derived from expert judgment. Scientific justification has partially been

[12] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175. http://data.europa.eu/eli/reg/2011/546/oj

[13] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50. http://data.europa.eu/eli/reg/2009/1107/oj

[14] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93/1, 03.04.2013, p. 1–84. http://data.europa.eu/eli/reg/2013/283/oj

[15] Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93/85, 03.04.2013, p. 1–68. http://data.europa.eu/eli/reg/2013/284/oj

[16] EFSA Journal 2015;13(2):3996

conducted in hindsight in the elaboration of guidance documents; however, the accuracy and protectiveness of the assessment factors are generally not fully validated towards real field conditions.

Assessments of possible risks arising from the intended uses of PPP are performed for different environmental risk assessment areas separately (individual groups of organisms and exposure routes). If this worst-case approach leads to an unacceptable risk based on the results of a rather small dataset, further data may be submitted in a tiered approach due to a so-called "unless-clause" in Regulation (EU) No 546/2011[17]. The rationale behind opening the assessment to further data can be sum up with PPP being "guilty till proven innocent". Following the authorization of many PPPs, the "unless-clause" has been interpreted as an opening for submitting virtually unlimited data. The originally resource-oriented tiered approach became a very resource-consuming process.

The goal of the current process is to make PPPs that meet the criteria for approval and authorisation available to the farmer in a timely manner. The tiered approach is based on a distinction between areas that need more attention and assessment areas with low risks for the environment. The tiered approach is designed in a way to rapidly separate the "bad guys" from the "good guys", leaving resources to more thoroughly assess the "bad guys" to make them into "good guys if managed properly".

The full effects of repeated or combined application of PPPs in an agricultural area has not been explicitly addressed in the current ERA scheme. The regulation (EC) No 1107/2009 stipulates authorisation criteria only for single PPPs. An authorised PPP shall have "no unacceptable effects on the environment" (Article 29 with reference to Article 4.3.e). The basic idea behind regulation (EC) No 1107/2009 is that it is acceptable to allow to bring agrochemicals with a potential harm actively into the environment. What has significantly changed since the development of this scheme is the agricultural landscape and production systems as well as consumers' expectations. Other stressors and the intensity of the production have increased due to anthropogenic actions. Furthermore, the increasing availability of long-term monitoring data on biodiversity shows that the "worst-case approach" is not sufficiently protective[18] and that the operationalization of the general protection goal "no unacceptable effects on the environment" appears to be very difficult.

A contributing factor for this is that currently defined specific protection goals (SPGs) may not be scoped with a sufficient level of holism but concentrate on assessing the impact of single uses on single organism groups. In reality, the protectiveness of a SPG may be dependent on landscape-related factors (e.g., proportion and distribution of agricultural fields and so called off-fields, coverage of single crops, etc.) currently outside the scope of the ERA and SPG definition processes. Although in the Commission's Regulation (EU) No 546/2011 acceptability criteria for *inter alia* effects on different organism groups are laid down, the general protection goal regarding "biodiversity and the ecosystem" in a holistic perspective has not yet been operationalized towards a specific protection goal.

2.2.2. Assumptions and framework for the current paradigm

The current assumption that organism groups are protected individually leads to i) neglecting possible indirect effects resulting from interactions between organisms and ii) omission to consider risks to biodiversity in a holistic manner.

If the risk assessment process has concluded that there are "no unacceptable effects", the information is not further used e.g. to differentiate between assessments of different PPPs, even if the risks of different PPP in reality might diverge.

Summarizing, under the following assumptions, a tiered approach based on worst-case would be suitable:

[17] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155/127, 11.06.2011, p. 1–49. http://data.europa.eu/eli/reg/2011/546/oj

[18] Topping CJ, Aldrich A, Berny P, 2020. Overhaul environmental risk assessment for pesticides. Science 367: 360-363.

- The worst-case approach with its assessment factors is conservative enough to cover impacts not explicitly assessed in the ERA schemes
- Adding "no unacceptable effects" from different PPPs in space or time really does not result in "unacceptable effects"
- The tiered approach itself and eventually submitted data generated under the current paradigm for the different tiers gives better informed risk assessments and decisions
- The "filtering effect" of a tiered approach towards areas displaying higher risks directs evaluation resources to the most relevant areas
- Assessing only those specific organism group(s) in the higher tier that showed high risk in the lower tier also covers effects on communities and interactions
- The burden of proof on applicants in combination with possibility to strategically choose refinement options does not create a bias in terms of gathering only specific data for a decision

However, some of the defining assumptions of the current paradigm are being challenged, in particular the first assumption above (see EFSA Theme paper for PERA and references therein). Thus, we explored the potential consequences of working under a paradigm for which one or more of the defining assumptions may not be valid.

There is a deficit of holistic, systematic and comparative evaluation of ERA methodology, testing and outcomes against monitoring results by using the entire data set acquired for all substances and ERAs. Besides the missing availability of data and/or data protection issues for different substances or products during assessment, a potential explanation for the missing evaluation of impacts is that the product-by-product approach, in combination with the worst-case assumption, results in a lack of incentives (i.e. the current ERA regime leads to a perception of the use of each approved and authorised PPP is "safe") for a holistic view on the current methodology (Figure 3).

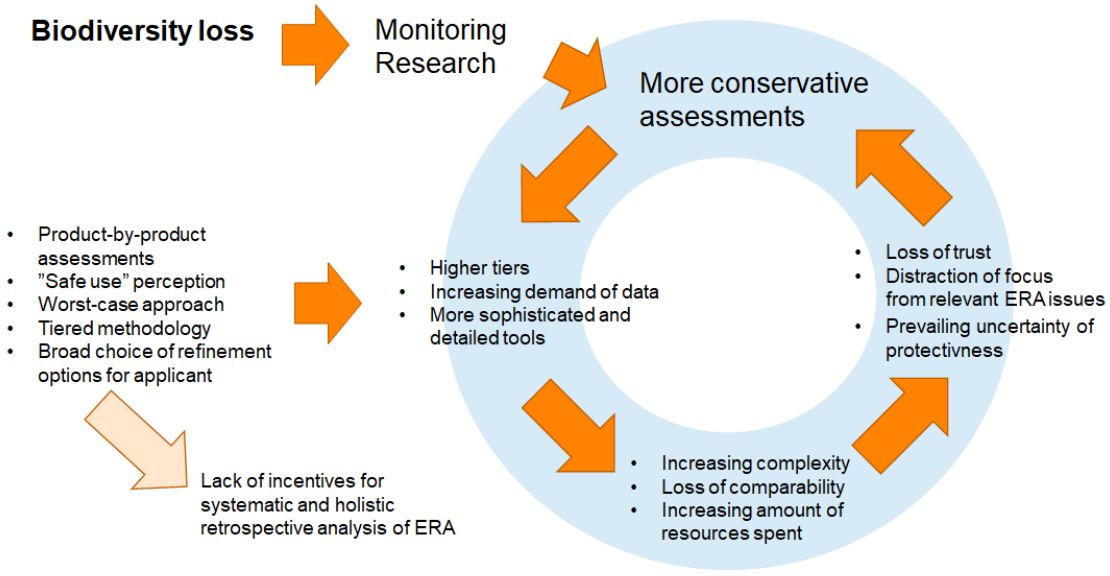

Figure 3: Illustration of how a lack of incentives for systematic and holistic analysis of the ERA methodology in combination with loss of biodiversity could lead to increasing complexity in the current tiered ERA system in a kind of "vicious circle".

The lack of systematic evaluation of ERA methodologies, in combination with the strong incentive to develop new and more sophisticated tools to demonstrate a "safe use", results in the introduction of details of unclear relevance into the process, which in turn gives a more complex process with regards to time and expert knowledge resources.

Few studies have been conducted to test the predictive capacity of ERA models and tools with varying degree of mechanistic detail against independent monitoring data. However, there is a pilot-study[19] in which the predictive power of simple one- and two variable equations for predicted surface water concentrations (PEC) was tested against multi-annual monitoring data from a representative agricultural area in Sweden. The study indicates that the correlation between the modelled PEC and measured concentrations is relatively good, even though the proposed calculation method was very simple in relation to the commonly used FOCUS[20] surface step 3 and 4 simulation models.

This lack of systematic evaluation of ERA methodologies also contributes to lack of comparability between assessments. Moreover, the tiered approach in combination with a highly variable choice of refinement options contributes to lack of comparability between assessment outcomes.

Drivers for loss of trust by citizens and stakeholders in the current system are e. g. the recorded losses of biodiversity and the prevailing uncertainty in the protectiveness of the current ERA. Also, by not covering environmental effects of PPPs at the landscape level, even though the ERA process requires more resources, data and tools, is a potential cause for loss of trust. A hypothesis is that such a cascade in turn triggers even more conservative assessments, which in turn requires generating more data, etc.

A clear and shared view seems to be missing within the current ERA system about which data and information are more important, and which are less important for the appropriateness of the risk assessment conclusions and the effective information of risk managers. This missing overview in turn appears to have impaired up to now an efficient governance of the strategic process development. Figure 3 illustrates some of the key aspects and effects of the current ERA.

The current methodology could be reviewed and amended by posing a number of paradigm-framing questions to spawn a more holistic perception of the regulatory ERA process. This is needed to avoid transferring potential flaws and caveats from the current system (as exemplified in Figure 2) into a new paradigm which is based on more holistically framed ERA issues, i.e., a scientific reframing as outlined in section 1.1 above (Conceptual approach).

In addition to the problem formulation in the EFSA Theme paper for PERA, and the findings of mapping the current systems (through interviews and desk research), this project revisited the problem formulation from a paradigm-shift perspective to answer the following question:

> "*If we are to move into a new paradigm, what are the things that we don't want to bring into it?*"

The section 3 below (Future state) addresses this question and provides suggestions on what to avoid in a new paradigm.

3. Future state – Proposal of basic concepts of a future systems-based environmental risk assessment

To clarify what the initial definition of the "system" and holistic framing of ERA issues could imply (see section 2.1.2. above), a conceptual illustration was developed to depict the differences between the current state (Figure 2, above) and a future desired state (Figure 4, below). The conceptual illustration highlights primarily two aspects: i) a high-level shift in perspective from substance-by-substance and

[19] Boström G, Jarvis N, Gönczi M, Kreuger J, 2019. A proposed new method for calculating predicted environmental concentrations (PEC) for plant protection products in surface water. Background report for the Swedish Pesticide Council 2019.

[20] FOCUS, 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.

regulation-by-regulation to a holistic systems-perspective, and ii) an improved alignment across silos with other regulatory areas by adopting a broader perspective.

As elaborated in section **Assumptions and framework for the current paradigm** (section 2.2.2.) above, the current lack of systematic evaluation of ERA methodologies also justifies a scientific reframing to find an appropriate level of detail in the assessments. Assessments and prospective ERA methodologies need to focus on aspects relevant for the decision-making context. Scientific methodology and independent validating data should be used to help determining what is less important and what is more important to focus on, and what is relevant for efficient and protective decision making, and thereby also avoid unnecessary complexity.

In a future state with a systems-based ERA, the *modus operandi* between stakeholders should be improved so that:

- Environmental risk assessments of PPPs are more integrated in system-level assessments, providing efficient tools for sustainable management for agricultural product- and ecosystems (addressing interconnectivity and overbridging silos)
- Multiple disciplines of expertise interact more efficiently, to find new solutions to support a sustainable development (addressing interconnectivity and overbridging silos)

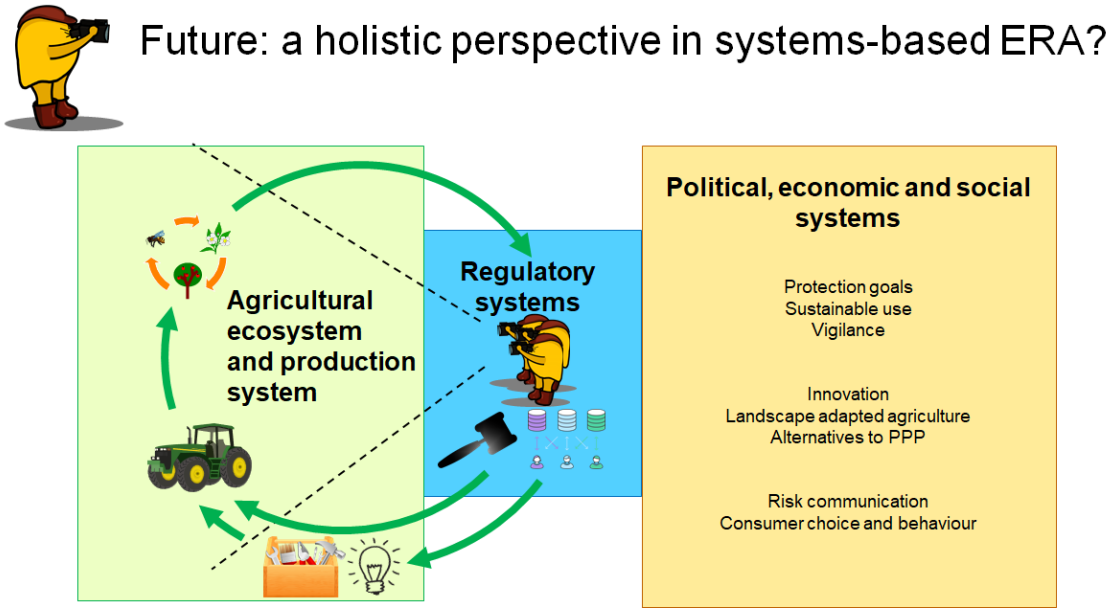

Figure 4: Conceptual illustration of an envisioned future state. The figure with the binocular has a broader perspective, assessments in different regulatory areas are more aligned and give the basis for more coordinated decisions, supporting the development of a sustainable agriculture. Data, assessments, knowledge and expertise are also made more accessible, as illustrated by the database icons, to support innovation and development of tools. The feed-back loop is also strengthened to ensure continuous learning and adaptability. Connection to systems such as political, economic and social are also improved.

Based on problem description in the EFSA Theme paper for PERA and the findings of the desk research (mapping and literature search), interviews, workshops and the holistic paradigm defining questions in Section 1.1 above, the areas that need amendments and improvements in the next generation ERA could be summarised as:

- Strengthened feedback loop (addressing protectiveness and realism)

- Capturing the combined impacts of PPP and other ecosystems stressors at the agro-system level (addressing protectiveness and realism)
- Comparability of data and assessment (addressing complexity, interconnectivity and overbridging silos)
- Focus on relevant factors and aspects of ERA (addressing complexity and relevance)
- Focus ERA issues on relevant processes levels, for example by focusing the product-by-product authorisation ERA to factors distinguishing PPPs from each other in terms of impact level (addressing efficiency and harmonisation)
- Improved agility to adapt to new policy targets, technical developments, and new scientific findings (addressing sustainable development)

The conducted desk research identified opportunities to increase interconnectivity in the new ERA state by (i) bringing together different research disciplines and areas of expertise and (ii) by incorporating knowledge of the agricultural production and the agricultural ecosystem.

The key aspects that should be included in the next generation systems-based ERA, as well as what to avoid bringing from the current ERA, are listed in Table 1.

Table 1: Key areas of the transition from the current regulatory ERA to a future next-generation systems- based ERA.

Current regulatory ERA	Future next-generation systems-based ERA
"Single substance" (one substance, one use) assessment in isolation	Consider impact of multiple PPP use on organisms in a realistic context, i.e., consider intensity of PPP use in a crop and ideally in a landscape context
Assumption for recovery potential	Consider the ecological status of populations, i.e., consider the source-sink dynamics
Single species assessment	Consider biodiversity, i.e., consider interaction between species and indirect effects of PPP
Detailed higher tier studies for individual species	Separate general ecological studies from PPP-specific assessments, i.e., consider impact of landscape structure and crop type on organisms.
Apparent equality of products based on the current "safe-use" authorisations	Address comparability of products, i.e., consider focussing on relevant aspects to conduct comparative assessment of PPP
Increasing complexity in the tiered approach	Focus on aspects driving the risk through systematic evaluation and simplification of ERA methodology
Detailed and highly specific predictive models	Design and use different model types according to purpose (e.g. improved mechanistic understanding; hypothesis formulation; predictions)
The real status of the environment for prospective ERA is not considered	Consider the use of monitoring data, i.e., strengthen feedback loop from retrospective assessments to improve prospective assessments (continuous learning)
Failing trust of the public	Consider engagement, i.e., communicate relevant information from assessments

3.1. Proposed vision for a systems-based ERA

Based on the input from desk research and interviews, a vision for a systems-based and holistically framed ERA was developed. As described above, the intention was to maintain the strength of the current system and to increase its effectiveness by expanding its application. The challenge was to define the range and boundaries of different relevant "systems", which could be integrated considering the current legal framework. However, the initial scoping discussion was not limited by the current legal framework as it is considered that the legal framework can be adjusted to reflect necessary scientific and social developments. Nevertheless, the proposed roadmap will start within the current legal system.

For addressing the impact on non-target organisms in an agricultural area in the context of PPP use, other stressors and activities need to be considered. Organisms are not only affected by PPPs (direct and indirect effects), but also by other anthropogenic (fertilisers, biocides, habitat destruction due to crop cultivation, etc.) and natural stressors (climate change, predation, food availability etc.), which may lead to an increase or compensation of PPP effects on non-target organisms. Therefore, conducting a PPP-ERA in isolation, without consideration of the agricultural eco- and production system, might not adequately assess the impact of PPP use. A further important starting point was that ERA is considered not only a legal requirement, but also a valuable process to gain information about potential impacts of PPPs prior to their actual use. In this sense, it was acknowledged that lessons learned from historical ERA, i.e., conclusions drawn from the analysis of previously conducted ERA for different active substances or PPPs, are currently not fully exploited. There is a lack of systematic retrospective evaluation of ERA methodologies. Furthermore, the information gathered in ERA (such as underlying studies and data, established list of endpoints, assessment methods and assessment factors used, as well as outcome of the assessments) is currently insufficiently integrated in other agronomic frameworks, which illustrates the need for a holistic framing by considering the political, economic and social system. Acknowledging that the reality cannot be fully reflected in ERA for a national authorization or the European approval of active substances, it was considered relevant to place more importance on the evaluation of the differences and comparability between PPP to reduce the impact on non-target organisms.

As a result of these reflections, a concentric circular layered approach is suggested, as can be seen in Figure 5.

The inner blue circle represents a refined version of the current "substance by substance" process involving ERA for individual PPP, as well the active substance evaluation at EU level. Each blue square would represent an ERA in an application dossier for a PPP (product level ERA). The ERA should be focused on aspects distinguishing the impact of PPPs from each other and thus increase the comparability of the assessment. Elucidating and assessing differences between PPPs aims to and could potentially decrease the complexity of the approval and authorisation ERA, especially if these assessments are developed in terms of standardisation and comparability. The blue circle would be focused on "internal" benchmarking focused on identifying and highlighting differences between PPPs. A fundamental idea here is to learn from previous ERA instead of conducting ERA of each PPP in isolation from each other (e.g., considering various datasets). Retrospective analysis of ERA should expand from evaluation of the individual assessments of different PPPs to evaluation of the prospective methods and tools used for all PPP ERAs. Thereby, conclusions of more generic relevance can also be made, and the ERA process and methodology as such can be improved.

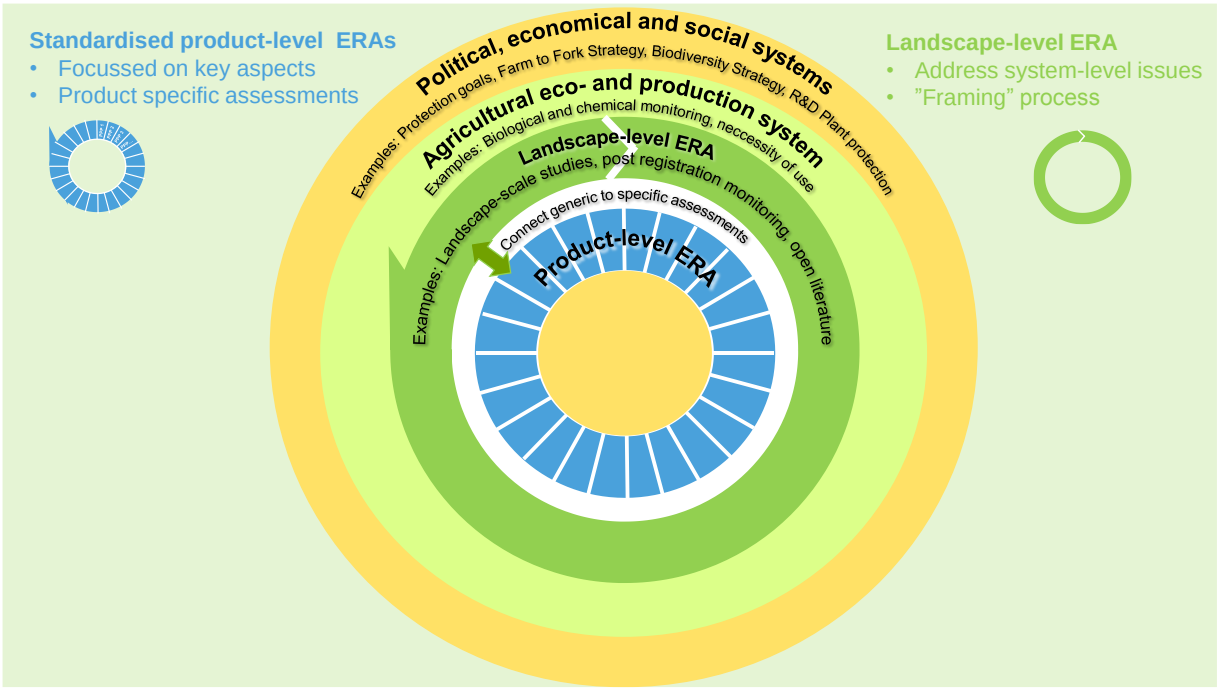

Figure 5: Vision for a systems-based and holistically framed ERA. This 'systems-based' approach focuses on ERA as holistic entity with interlinked component parts essential for the effective operation of the whole system. ERA is divided in the (active substance and) product-level ERA (blue circle), where product-by-product assessments will be conducted and a landscape-level ERA (dark green circle), where aspects affecting the impact of PPP and connected to the ecosystem are addressed in a general manner. These two levels are constantly feeding into each other illustrated by the arrow. ERA strongly interconnects to the agricultural eco- and production system (light green circle) by considering data from monitoring studies as well as specificities from production systems (orchards, vineyards, etc.). The system-based ERA is holistically framed by the political, economic and social system (yellow circles).

The surrounding dark green circle should be a supporting process for the inner blue circle. Aspects of the ERA related more to ecosystem specific issues could be handled partially outside the dossier-by-dossier process. Such assessments could then be done with longer time perspectives integrating larger sets of data and consider multiple stressors and multiple PPP applications. Examples of data and information to include in assessments at this level could be landscape-scale studies of interactive effects of PPP use and landscape management as well as other stressors. Environmental monitoring of effects and PPP residues could also be used as an information source, by evaluating data from dedicated post-registration monitoring as well as from existing monitoring programs, such as regional authorities work concerning the EU Water Framework Directive (WFD)[21]. Moreover, open literature could support the landscape-level ERA that is linked to individual PPP dossiers. With a holistic eco- and production system perspective at this level, conclusions and recommendations of generic relevance from open literature studies covering e.g. impact of actual use of specific PPPs may thus become more efficiently integrated into in ERAs for all other PPPs. Other potentially information sources link to this dark green circle are trends in indicators for biodiversity status.

Handling specific issues mostly outside the dossier-by-dossier process would reduce the workload and the risk that ecosystem issues are overlooked, which might be the case with the current higher tier methodology. The circular arrow built into the dark green circle illustrates that this should not be a static system, but a continuous loop striving for improvement through feed-back loops. Interconnectivity between the circles is essential and needs to be systematically implemented, in order to also deliver

[21] Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy

timely information for the ERA of PPP (e.g. regarding risk mitigation measures at landscape scale). The product-level ERA and landscape-level ERA could for example be interconnected by the landscape-level ERA supplying updated generic assessment factors to be used in the product-level ERA. Evaluation of monitoring data can deliver residue levels for substances present in the environment and identify upcoming risks. Another potential example is that generically applicable conditions for use could be developed based on assessments made at the landscape-level ERA. For example, such generic conditions for use could be a necessity to control overall use intensity of PPPs in sensitive areas or implement compensatory or ecosystem resilience improvements in specific areas.

A key driver for the development of the blue circle, part of and the surrounding dark green circle, would be new knowledge gained from the **scientific reframing** outlined in the Conceptual approach section (section 1.1). The holistically framed questions posed in this section aim to improve the understanding of how elements of the ERA system relate to each other, i.e. an improved system understanding in general. For the development of the blue circle part of ERA, this scientific reframing would translate to and be focused around questions like:

- Which factors discriminate efficiently between risk levels of different PPPs?
- How do new PPPs compare to previously assessed PPPs?

For the development of the dark green circle part, the scientific reframing would translate to and be focused around questions like:

- Which factors are more driven by ecosystem properties and hence more appropriately handled at a higher, more integrated level?
- How can regional aspects be considered in a national assessment?

The surrounding light green circle illustrates that the ERA should be better interconnected to the agricultural eco- and production systems. Focus of the evaluation should be biological and chemical monitoring data and the necessity of the intended uses. Information to interconnect both green circles more efficiently are post-registration monitoring and landscape management data. The two green circles are considered important to simplify the blue product-level ERA and achieve the desired increased realism in the prospective ERA. In a sense, by integrating the different levels, the efforts dedicated to the current higher tier assessment are conveyed from the product-specific assessment to the integration of information from landscape and agricultural systems. In this way, the efficiency will improve, and the current "vicious circle" (depicted in Figure 3) is avoided. By elaborating, analysing and integrating relevant data outside the product-level, the consistency and efficiency of ERA can be improved. The complexity of the landscape can be made operational by considering differences in the production systems, especially if these have a strong regional reference.

Finally, **the outer yellow circle** represents the political, economic and social contexts. The interaction with the political, economic and social system is seen two-fold, reflected by a yellow circle on the outside and inside of the graph. On the one hand, developments and decisions taken in the yellow circle will affect the PPP-ERA, on the other hand the use and integration of the information produced during PPP-ERA will be valuable for strategic decisions allocated in the yellow circle.

In the sections below, more specific information and areas to be considered for stepping towards the vision's circles are presented. Furthermore, in the project proposals (section 4.3) the necessary analysis and developments to address the identified areas are described in detail.

4. Transition process (how to attain the vision of a systems-based ERA) and the creation of the PERA partnership

An environmental risk assessment system, as the current system for PPPs, that has been developed over decades, cannot and should not be overturned. Its benefits and strengths should be preserved and transferred to a new system. Nevertheless, it is clear that a paradigm shift, not just a change, is needed to attain a systems-based ERA.

For a successful transition towards such a holistic ERA, e.g., for PPPs, it is important to implement a series of steps, both at operational and scientific/technical levels:

- Establish leadership to steer the transition process
- Engage stakeholders from different areas to commit to the common goal (develop a systems-based ERA), define and prioritise actions to take
- Improve collaboration with all relevant experts in the field of ERA and include other relevant experts that are not currently involved in the current ERA process (e.g., agronomists, farmers, NGOs), including their concerns early on in the ERA process
- Define and harmonize environmental protection goals
- Focus on the most relevant and overarching needs "to avoid getting lost in details" (scientific reframing of the ERA process) and identify small tangible steps in stakeholder forum, in order to integrate ecological knowledge and monitoring information and relate to landscape level, assessing effects holistically
- Engage pilot groups to take a new direction towards a holistically framed and systems-based ERA
- Build on the existing data of historical ERA to compare and rank PPPs
- Align and proactively interact with legal developments, anchored in the current legal framework, and their implementation

In this section, besides presenting a strategy towards the transition to a systems-based ERA for PPPs, including the activities to develop as multi-annual and multi-stakeholder projects (section 4.3), we also present a summary of the results from the interviews, desk research and participatory workshops regarding the areas that deserve further development for a successful implementation of a new system (section 4.1), as well as the identified potential challenges and blockers for this transition, and ways to overcome them (section 4.2).

4.1. Identifying areas requiring further development

The information gathered from the interviews, the desk research and the workshops support that the areas listed in Table 2 below need to be further developed, to ensure a successful transition and implementation of a systems-based ERA.

The areas are anchored in the working areas (WAs) described in the EFSA Theme paper for PERA (see Box 2 in section 1.1) as they are considered as highly relevant for the development of, and transition towards, a new systems-based approach for PPPs. Their links to the ERA categories developed by the PERA-project team (see Box 3 in section 1.1), as well to the circles of the proposed vision (see Figure 5) are also indicated.

Table 2: Areas requiring further development for a future system-based ERA based on information gathered from Interviews (I), Desk Research (DR), Workshop (W); relates to overarching themes from the different components of the proposed vision (see Figure 5)

Working areas	**Source**	**Overarching themes of proposed vision**[3-7]	**Developments needed** (*categories*, *sub-categories*, etc)	**Other elements:** connection[1] awareness[2]
Communication (new WA)	I, DR, W	Holistic reframing, coordination[3]	Participatory process of the risk assessment Improve stakeholders' engagement, awareness and advice, Improve communication	New area Awareness: high
Overall system impact (WA1)	I, DR, W	Holistic reframing, coordination	Needs in categories: *Harmonisation/ cross-linking,* *Legislation,* *Transparency* Needs in sub-categories associated with *Ecosystem* and *Socio-economic aspects*	Connection: medium Awareness: low
Environmental risks (WA2)	I, DR, W	Integrated assessment Focusing[5]	Needs in sub-categories associated with: *Assessment* (e.g. comparison/ ranking of PPPs, mixture toxicity and spray series, linking prospective/ retrospective risk assessment, development of ecological scenarios; currently connected to Key inputs for prospective ERA predictions) Currently connected to *Ecosystem* (Risk at landscape level) but needs for a more holistic perspective in terms of testing and evaluating	Connection: low Awareness: high
Mixture toxicity (WA3)	I, DR, W	Integrated assessment	Needs in sub-categories associated with: *Ecosystem* (Risk at landscape level), *Assessment* (mixture toxicity and spray series), *Monitoring* (chemical and biological monitoring)	Connection: medium Awareness: low
Efficiency of risk mitigation measures (WA4)	I, DR, W	Inter-connection[6]	Needs in sub-categories associated with: *Management* (measures for increasing biodiversity & for compensating PPP effects, improve planning and management of agricultural landscapes), *Indicators* (e.g., define clear indicators and thresholds for the desired level of protection promote risk mitigation measures, monitor aquatic and terrestrial effects of RMM over time, further adapt or improve the new ERA system)	Connection: low Awareness: high
Monitoring (WA5)	I, DR, W	Inter-connection	Needs in sub-categories associated with: *Monitoring*: developing concepts of monitoring programme, long-term monitoring, biological monitoring, *Indicators*: e.g., for different aspects of biodiversity, to better evaluate cumulative and/or combined effects, *Assessment*: better alignment between prospective and retrospective RA, feed-back	Connection: low Awareness: high
Pre-post registration data (WA6)	I, DR, W	Inter-connection Focusing		

			loop for using data into the registration process allowing its calibration	
Alternative solutions (WA7)	I, DR, W	Comparability[7]	Needs to connect knowledge in *Assessment* (ranking PPP by comparable RA) *Agronomy* (PPP alternatives, emerging fields of PPP application techniques, Awareness/ advice, Safe use of PPP), *Management* (Risk mitigation/ IPM and comparison to alternative crop protection) Bring interests of other stakeholders	Connection: high Awareness: medium
Harmonize ERA (WA8) (also linked to WA2 and WA6)	I, DR, W	Comparability Focusing	Needs in categories *Risk assessm*ent and *Monitoring*: to focus prospective ERA on risk driving factors and data with predictive capacity (based on retrospective ERA and monitoring) for more comparability, standardisation and reusability of data and assessments	Connection: medium Awareness: low
Common currency (WA9) (also linked to WA8 and WA7	I, DR, W	Comparability	Needs in category: *Socio-economic*s related to cost-benefit analysis (challenging due to lack of consistent data) Currently connected to sub-categories associated with: *Assessment (*Ranking PPP by comparable RA, Developing concepts for ERA), *Harmonization*, *Ecosystem*.	Connection: high Awareness: low
Impact/sustain ability assessment (WA10)	I, DR	Inter-connection	Needs in categories: *Harmonisation (*assessments, data formats and legislations) *Transparency (*overcome lack of transparency in current system) *Legislation* Needs in sub-categories associated with *Ecosystem* (more integration to improve crop and landscape management to decrease risks)	Connection: high Awareness: medium
Safe design (WA11)	DR	Inter-connection	Needs in categories: *socio-economic aspects* (e.g. Consequences of system changes to the society), *management* (e.g. use lower risk of PPP), *R & D of PPP* (e.g. design of a.s.)	Connection: high Awareness: very low
Guidelines (WA12)	I, DR	Focusing	Needs in categories: *Legislation (*currently connected to improvements and transparency), *Assessment* (currently connected developing concepts for RA but need for better integration and support)	Connection: medium Awareness: medium
Group assessment (WA13)	I, DR, W	Focusing	Needs in sub-categories associated with: *Assessment* (developing concepts for ERA)	Connection: medium Awareness: low

Transparency (WA14)	DR, W	Holistic reframing, coordination	Needs of considering: *Harmonisation (*data formats and assessments) and *Transparency* (in context of legislations and Communication, e.g. raising awareness and providing better advise for farmers)	Connection: medium Awareness: very low
Linkages with relevant partnerships (WA16)	I, DR, W	Holistic reframing, coordination	Needs in categories: *Harmonisation/ cross-linking, Legislation, Transparency.* Needs in sub-categories associated with *Ecosystem, Socio-economic related aspects*	Connection: medium Awareness: very low
Related fields (WA17) (see also new WA Communication)	I, DR, W	Holistic reframing, coordination		

[1] Connection to EFSA WAs (*high, medium low*) results from the mapping performed in the desk research
[2] The awareness about the different areas (*high, medium, low and very low)* results from the analysis of the 29 interviews (based on frequency counts an area/category was mentioned in the interviews)
[3] Holistic reframing, coordination: product level ERA, landscape level ERA and more specifically agricultural eco- and production systems and political, economic and social systems.
[4] Integrated assessment: product level ERA and landscape level ERA
[5] Focusing (reducing complexity): product and landscape levels ERA and agricultural eco- and production systems
[6] Interconnection: product and landscape levels ERA and agricultural eco- and production systems
[7] Comparability: product level ERA and agricultural eco- and production systems

4.2. Identifying potential challenges and blockers for the transition

Challenges and blockers for the transition to a systems-based ERA identified from the information collated through interviews, desk research and the workshops are presented below (Table 3).

Although it is not the aim of this project to provide a ready-to-use strategy on how to overcome the challenges and blockers, first suggestions are made below for each identified challenge and blocker. Overcoming these issues needs to be part of the project work in the PERA partnership.

Table 3: Identified potential challenges and blockers for the transition to a future system-based ERA based on information gathered from Interviews (I), Desk Research (DR), Workshop (W).

Challenge (C) or Blocker (B)	Source	Brief explanation	How to overcome it
Challenge: No comprehensive definition of the systems-based approach	I, W	No clear definition of a systems-based ERA, especially regarding socio-economic aspects, trade-offs between environmental protection and food production or ecosystem management.	The PERA project can be seen as a conceptual starting point for identifying the main parts and their interaction that should be taken into account for the development of a systems-based ERA. It will be then crucial to further develop the definition of a systems-based approach (e.g. revised protection goals, boundaries). The involvement of and increased exchange between different stakeholders is essential to create mutual understanding as well as to reveal ways

			and possibilities in which the various parts can be linked in a systems-based ERA (see activities from Project proposal 1).
Challenge: Communication	I, DR, W	Fostering communication among the broad range of stakeholders during the process of PPP development as well as approval/authorization and pre- and post-registration activities, including those stakeholders less involved in these processes, such as farmers, NGO's, environmental authorities). Improve exchange between ERA and agronomy, as farming systems and agricultural practices are currently only weakly represented in ERA, while the ERA of PPPs has a large impact on them (i.e. connect the light green circle to the inner blue and green circles in the vision for future ERA). Improve communication between agencies to align and harmonize the assessment between the different legislations (PPPs, Biocides, REACH) with the aim of implementing the same overall protection goals towards the "one substance, one assessment" goal.	The creation of the PERA partnership and the development of a holistic approach in a future systems-based ERA will trigger a number of new activities and tools (e.g., common databases) that should facilitate regular exchanges between different stakeholders e.g. those involved in pre- and post- registration processes (post-registration process including e.g. phytosanitary advice, monitoring, exchange with farmers). This will also enhance the transparency of processes regarding the assessment, management and use of PPPs. The increasing support of stakeholders from the agronomic sector (farmers, service providers) by regulators and risk managers via expert consulting, exchange of information or financial support, will enhance the development, authorization and use of PPPs with potentially lower risks to the environment. In the long-term, the improvement of the legal framework to be aligned with a systems-based ERA across regulatory silos will facilitate the interaction between stakeholders involved in different EU regulations and strategies.
Challenge and blocker: Complexity	I, W	Increase in complexity of the new systems-based ERA (when compared to the current ERA system) due to the involvement of new stakeholders and new levels (i.e. landscape level, agricultural practices, policy/ society, new areas of development).	The increased complexity caused by, e.g., implementing a landscape risk assessment and by improved stakeholder exchange, would be compensated by simplifying the ERA at the product level (the inner blue circle of the vision). Benchmarking studies against monitoring data has the potential to identify key predictors for environmental effects in order to ensure both protective and realistic assessments (e.g. adjusted assessment factors). The focus on simplified single tier and comparable data and methods is also the prerequisite to rank and compare the different PPPs (see project proposal 3). The efforts towards a uniform assessment of Non Taget Organisms will also potentially lead to a further simplification of the ERA across the various silos and, thus, enable a shift of

			resources towards a more integrative and holistic ERA.
Challenge: Increased uncertainty	I	The level of uncertainty is expected to increase with the increasing level of complexity due to the increased number of parameters to perform a more realistic and holistic ERA of PPPs.	As mentioned for the challenge and blocker "complexity", the simplification of the PPP ERA to simpler assessment (i.e. single tier) approaches at the active substance/product level (inner blue circle of the vision for future ERA) will improve comparability with a reduction of uncertainty. A potential increase in uncertainty should be also overcome by integrating more data from the field (e.g. exposure and effect data from monitoring) and calibrating such data with the prospective, systems-based risk assessment. The calibration with field data will support the identification of driving factors for PPP exposure and PPP effects, thus improve the efficiency of ERA predictions.
Challenge: Feasibility/ difficulties of implementation	I, DR	How to implement a systems-based ERA that goes beyond the effects of single PPPs and effects on single groups of organisms and focus on the risk of treatment regimens (multiple PPPs) incorporating also monitoring, crop management, and socio-economical aspects. Increase in time dedicated to completing an ERA for PPPs that will be protective for the environment.	Harmonised methods and freely and easily accessible databases (PPP properties, PPP use data, monitoring data, overview and assessment of PPP alternatives) need to be established with high priority. These are essential for e.g. comparing and ranking single PPP as well as treatment strategies. This will make the system more agile (see next challenge) Moreover, to ensure the feasibility and increase efficiency of the future systems-based ERA, the selection of sentinel organism groups/ communities in the field for monitoring or sentinel monitoring sites could be very useful.
Challenge: Agility of the new systems-based ERA	DR	Along with the development of the future systems-based ERA, it will be crucial to set mechanisms into place that enable e.g. the revision of existing guidance documents and the adaptation of the ERA, where and when necessary, as well as to give credit to new, generally recognized knowledge or the revision of thresholds values used in ERA according to findings in the monitoring programmes.	There are reasons why ERA should not be too flexible as this in turn could increase complexity, hamper comparability and reduce transparency. Nevertheless, mechanisms need to be improved to better incorporate generally accepted new knowledge in the future systems-based ERA. The use of post-registration data can play a central role to highlight potential shifts between the pre-registration assessment and the data from monitoring and PPP uses and, thus, the need to amend concepts for assessment and registration.
Blocker: Harmonization	I	Harmonization was considered as a blocker caused by an expected increasing complexity. A systems-based approach for PPPs might	A holistic, systems-based approach should ideally cover all regulations, and the largest possible overlap among them should be achieved resulting in the same

		result in a more difficult harmonization process due to the need to consider different regulations. More complex ERA (due to the inclusion of new levels of risk assessment and stakeholders at the regional, national and European level), may be difficult to harmonize across companies and member states.	principles to be applied. However, undoubtable differences will remain. Overcoming an increasing difference among regulations could be prevented by regular exchange and a potential transfer of approaches between regulations, when considered beneficial. This overarching view on the different regulations will be mandatory to harmonize across regulations. The integration of new concepts and data requirement in the systems-based ERA (e.g. for monitoring or consideration of agricultural practices) have to be designed as a prerequisite in a way that they are feasible, affordable and meaningful when considering differences at the national/ regional level (e.g. sentinel or tiered monitoring with different monitoring intensities in terms of number of sites or sampling spectrum).
Blocker: Legal framework	I	The current legal framework could, to some extent, pose constraints on the possibility to develop holistic approaches and systems-based ERA.	A substantial part of the proposed transformative change consists of a scientific reframing of ERA issues, a topic that per se does not necessarily imply changes in the legal framework. Regulation (EC) No 1107/2009 refers several times to "current scientific and technical knowledge" as a basis for assessments and decision making. The word "current" implies that adaptation of assessments and thereto associated decision making to scientific progress and development is a built-in function of the Regulation. Moreover, the Regulation also mentions the "Authority" (i. e. EFSA) as the actor accepting methods for assessments, implying a mandate. Still, procedures and responsibilities between stakeholders may have to be changed for a full implementation of a systems-based ERA, implying a dependence of the legislative changes. It is therefore suggested that the transformative change work with strategies tailored for different time perspectives: • Short-term: search for opportunities to take concrete and solid steps in the direction to holistic assessments and systems-based ERA within the legal framework. • Long-term: Align and proactively interact with overarching legal development and implementation.

4.3. Proposed strategy for transition and recommendations for next steps

This section outlines a proposed overarching transition strategy, as well as recommendations for next steps to spark the transition process, in the form of five multi-annual and multi-stakeholder projects. The proposed set of projects constitutes a comprehensive approach, with concrete steps towards a future systems-based ERA. However, they are not able to address all research and development needs outlined in this report. Thus, continuously aligning strategic and operative initiatives with other stakeholders, as well as research and development initiatives (e.g., Biodiversa+, Farm-to-fork strategy, PARC), is of essence for a future PERA partnership and a successful transition.

The proposed approach incorporates important factors for a successful management of the social learning and transition process in multi-stakeholder transformative change processes as advocated by Pahl-Wostl, 2010[22]:

- Leadership for the participatory process.
- Early phase problem framing and reframing, which will have a strong impact on the direction of the later stages of the transition.
- Classical change management knowledge with emphasis on communication and involvement (e.g Kotter[23]).

The ongoing transition process should be guided be these principles. This means that the vision for ERA needs to be further developed and operationalised, with concrete development steps among a broader range of stakeholders. Besides environmental and risk assessment aspects, it should include also socio-economic aspects, food production and ecosystem management.

The transition to a systems-based ERA includes a paradigm shift driven by a scientific reframing of ERA issues. The process requires clear and sustainable leadership to guide the scientific reframing, technical developments and stakeholder involvement. Ideally, a change of culture in and perception of ERA among the stakeholders would be achieved.

The transformative change towards the vision should continuously be broken down into achievable small steps giving short-term rewards for engaged stakeholders contributing to and implementing new ways of working. Pilot groups that can work towards shared and achievable short-term goals should be identified and backed-up with resources and sponsorship from relevant stakeholders. A strong overarching leadership, with mandate and incentives for driving the process of change over time, is paramount for a successful transition process.

Transitioning to a systems-based ERA for PPPs also needs to be legally framed. To some extent, the current legal framework could constrain the possibility to develop such approaches. However, a substantial part of the proposed transformative change consists of a scientific reframing of ERA issues, a topic that *per se* does not necessarily imply changes in the legal framework. Regulation (EC) No 1107/2009 refers several times to "current scientific and technical knowledge" as basis for assessments and decision making, implying a built-in regulatory function to adaptation of assessments and thereto associated decision making to scientific progress. Still, procedures and responsibilities between stakeholders may have to be adapted for a full implementation of a systems-based ERA, implying a potential dependence of legislative changes.

It is therefore suggested that the strategy for transition covers two different time frames: i) Short-term: search for opportunities to take concrete and tangible steps that, besides helping to improve the current ERA system, are aligned in the direction of holistic assessments and a systems-based ERA within the legal framework; ii) Long-term: align and proactively interact with long-term with overarching legal development and implementation.

[22] https://www.sciencedirect.com/science/article/abs/pii/S1462901110001073?via%3Dihub
[23] Kotter, J.P. 2012 Leading change. Harvard Business Press

Five high level recommendations for multi-annual, multi-partner studies or projects were developed to initiate the strategy for transformation towards the proposed vision. The projects are presented in the subsections below. These five project proposals suggest the first steps needed for building a partnership and transition towards a systems-based ERA.

There are three main themes and purposes of the project proposals:

- Overarching governance and leadership in the holistic scientific reframing of ERA (Project 1)
- Stakeholder engagement and partnership formation (Project 2)
- Research at the technical level exploring new solutions and developing new methods and tools (Projects 3-5)

An overview of the structure for these individual project proposals is given in Figure 6. The different projects have both long-term objectives e.g. continued co-creation and engagement for a shared vision among stakeholders, and short-term goals e.g. the co-creation and implementation of small steps of technical/scientific development leading to short term benefits for the involved stakeholders while at the same time leading in a paradigm-shifting direction towards the vision.

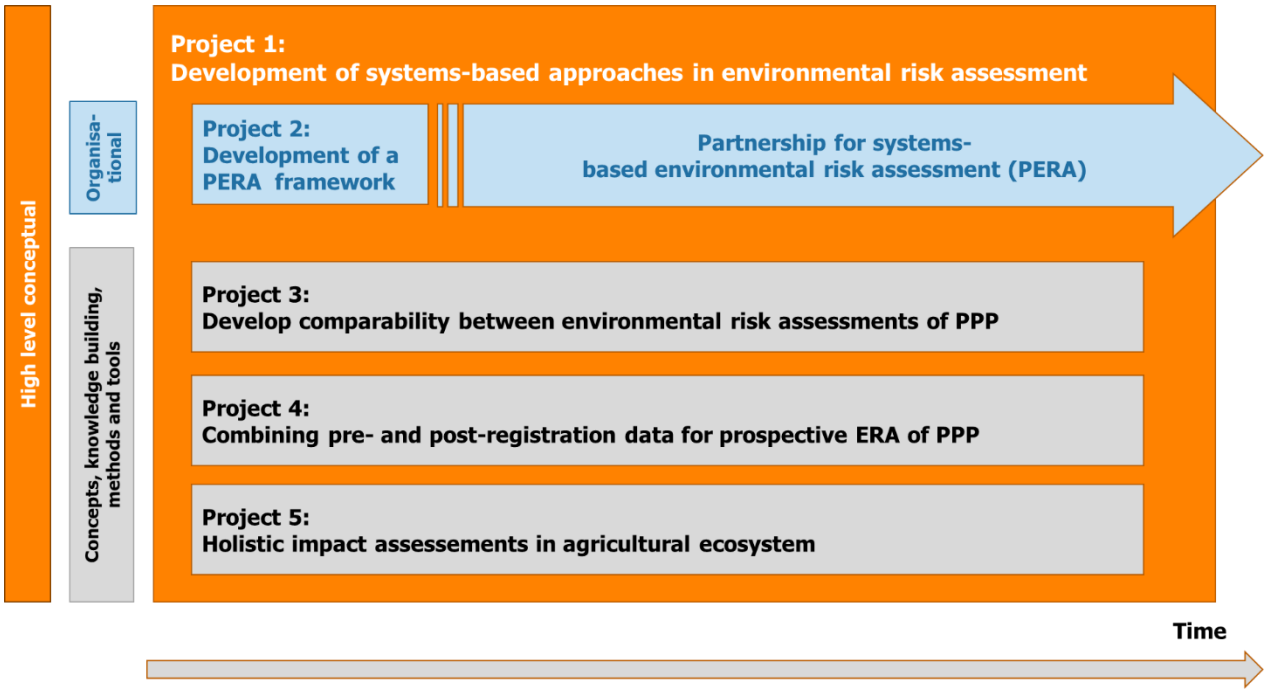

Figure 6: Outline of interrelation between proposed projects. Once project 2 is finished the ownership of the transformation process should be taken over by the Partnership PERA.

A detailed explanation of each project proposal is provided below following a logical sequence: Background, Scope, Objectives, Opportunities, Challenges, Expected impacts and Stakeholders involved. But in a nutshell, **Project 1** is designed to have an overarching and integrative role in guiding the more scientific and technical projects 3-5. The high-level scoping also creates a platform connecting science, data, expertise and knowledge in regulatory ERA (historic and future) to high-level EU strategies.

Project 2 is crucial for bringing together stakeholders and for building the PERA partnership for systems-based environmental risk assessment. It will not alone focus on conceptual and strategical developments, but also on implementation of concrete steps for the development of the platform/partnership, thereby solving questions like: How should be the platform/partnership be organised? Who owns it? Who pays for it?

Projects 3-5 are technical and provide the necessary knowledge basis for the scientific reframing and transition towards a holistic paradigm. **Project 3** is mainly focused on the transition towards the blue inner circle of the vision, by developing methods for improving comparability of environmental impacts between different PPPs but would also provide building blocks for integrated assessments developed in project 5. **Project 4** is focused on combining the information from the prospective risk assessment and resulting decisions with the information from the real world, on defining and providing the data for projects 3 and 5 and also on connecting to the outer circles of the vision, e.g. the agricultural eco- and production system. **Project 5** aims at developing regulatory applicable and relevant modelling tools for systems-based risk assessments of PPPs and other chemical stressors, thus supporting the reduction of PPP use in general and improving ecosystem resilience in agricultural production- and ecosystems.

An overview of potential arenas for collaboration on the different projects are given in Table 4.

The strategy outlined above puts particular emphasis on the **prioritization** and **early implementation of projects 1 and 3**, and to some extent of project 4. These projects contain opportunities for information synthesis from already existing data sources that can be used to improve the ERA work within the current legal framework and support existing ERA processes.

Table 4: Examples of potential arenas for collaboration and knowledge exchange. They are linked to the layered approach envisioned for a future systems-based ERA, as well as associated project proposals (see below) to develop and realise collaborative partnerships for transitioning.

	Collaboration arenas			
ERA Level	**Focus**	**Collaborators/ stakeholders**	**Desired outcomes and who might benefit**	**Project proposals**
Product level	benefit harmonization, standardisation of methodologies and PPP comparability	risk assessors, researchers (monitoring), agronomists (substitution assessments), decision makers, political scientists	simplification and focus of ERA, overview of risks of different PPPs for risk assessors and decision makers; improved predictability of approval/authorisation process for companies; focussing monitoring studies on high-risk PPPs for researchers; raising awareness and distinguishing between safe use for farmers/agronomists; targeted and scientifically supported basis for decisions at the strategic level	1 and 3
Landscape and agro-ecosystem level	assessment of multiple ecosystem stressors and risk mitigation measures at the landscape level, integrating agro-economic and ecosystem management	risk assessors, researchers (modellers, systems scientists), conservationists, farmers, risk managers, decision makers, political scientists	increased realism and targeted ERA for risk assessors; information about most effective type of mitigation and/or compensation measure for conservationists; information about the risk potential of PPPs on different fields and crops for farmers; information about acceptability of risks depending on crop and landscape structure for risk managers	1, 3, 4 and 5
Political, economic and social level	include societal perspectives, e.g. protection goals for ERA; connect data, knowledge and expertise to support strategic initiatives as Farm to Fork	risk managers, consumer association, farmers, risk assessors, decision makers, political scientists	increased toolbox to mitigate and communicate impacts of PPP for risk managers; raising awareness and supporting/enabling differentiated consumers choices; informed decisions about the choice for plant protection for the farmers; scientific basis for decisions at the strategic level	1, 2

4.3.1. Project proposal 1 – Development and implementation of systems-based approaches in environmental risk assessment

Background

The transition from a current fragmented regulatory view on protection targets to a systems-based approach requires a radical change of perspective in environmental risk assessment and management. To be able to scientifically reframe the assessment of risks to environmental targets from a systems perspective, a dedicated scientific leadership needs to be established. This project proposal centers on the overarching strategic transformation of governance required to bring about the change in perspective and to scientifically underpin the transition towards holistic environmental risk regulation.

Currently, environmental risk regulation is performed at a very specific and fragmented level, by targeting mostly the impact of single substances in single uses on single organism groups via single exposure routes at a single spatio-temporal scale. When taking the agricultural ecosystem as an example, direct and indirect effects on environmental protection targets result not only from simultaneous and sequential multiple exposure to e.g. different types of chemicals, but also from disrupted interactions between organisms. In addition, non-regulated products and agricultural measures and practices influence the extent of chemical impacts. For prioritizing the transformation efforts, focusing initially on pesticide environmental risk assessment (ERA) frameworks, offers the opportunity to understand how regulated products (here: pesticides) impact the environmental targets in a system, when applied under multiple realistic uses.

In order to advance the ERA of different regulated products, it is therefore not only necessary to further consolidate and innovate the single building blocks for conducting risk assessment. Implementing a holistic perspective on environmental protection is central to address the risks to targets as they are faced within the real environment. Moreover, emergent ecosystem changes, following chemical and non-chemical impacts, can only be identified and mitigated by switching the assessment standpoint from single stressors and organism groups to a systems perspective.

Several European and international strategies and allied legislations address the environment from a systems perspective, in order to overcome past policy issues leading to "fragmentation, overlaps, gaps and inefficiencies". Following on the example above, environmental protection targets in agricultural ecosystems are addressed by several legal frameworks as the Regulations to place products on the market, the pesticide Sustainable Use Directive, the Farm to Fork, Biodiversity and Soil Strategies with their follow up laws. Moreover, binding environmental goals and development targets for agricultural systems are also included in the Water Framework Directive and Habitats Directive. Streamlining and scientifically framing holistic protection goals by adopting a systems perspective on risk regulation is impellent and will allow to link ERA processes and outcomes to the wider environmental goals of the European Green Deal. Agricultural areas are suitable systems to explore and pilot the implementation of a systems perspective in ERA, starting with a focus on pesticides and strengthening their regulation, in view of including substances and compounds in further developments.

Scope

The scope of this project is to empower the transition to a systems-based approach in environmental risk regulation, via a strategic and scientific governance of the transformative change. This project will also guide and coordinate the proposed projects focusing on critical scientific aspects (3-5) and is tightly interlinked to project 2, the partnership for PERA.

Fulfilling the perspective change and implement a system's view in ERA is linked to several conceptual and practical challenges. It is proposed to prioritize the area of pesticides to pilot and advance the implementation of a systems-based perspective in ERA. This call focuses on the following main overarching goals:

- Implement a high-level governance strategy, to consequently advance systems-based approaches within the current existing frameworks - but also scoping to potential overall changes.
- Overcome scientific inconsistencies and streamline protection goal identification towards a holistic approach
- Set the high-level scientific boundaries to system approaches in environmental risk assessment and management considering societal and legal needs
- Deliver a general framework and perform a proof of concept, to demonstrate the feasibility and practical implementation potential of the developed system-based approach to environmental risk regulation

Objectives

The following specific objectives (organized in work packages, WP) should be achieved to reach the goals

WP 1: Overarching governance strategy and structure

I. Revise and build on the data and proposed vision for a systems-based approach, as outlined in this report. Develop a conceptual and methodological science-based governance strategy and structure supporting EFSA's leadership in the scientific framing of ERA approaches.

II. Prioritize high-level regulatory contexts particularly relevant for the transition to holistic protection goals identification based on a system's view and starting with pesticides and in close cooperation with the developing PERA.

III. Define binding feedback loop instruments to integrate scientific, social and legislative advancements into adaptive adjustments of the transformation strategy. Implement the links to the methods and tools for projects 3 to 5.

WP 2: Scientific bases for the definition of holistic protection goals

I. Characterize the protection aims implemented in different legislative and strategic frameworks at EU and international level.

II. Characterize divergences and commonalities in the scientific definition of protection targets in different legislative frameworks.

III. Scientifically streamline protection goals identification across legislation by identifying similar targets in the same ecological systems. As above, start with pesticides as group of chemicals embedded in agricultural (eco)systems.

IV. Explore and propose how the outcome of a system-based ERA (e.g. for pesticides, see below) can be linked to the status of protection targets in the field/indicators (see project proposal 4) and how the information derived from monitoring can be fed in agile ERA approaches.

WP 3: Systems science

I. Set the scientific boundaries to systems approaches in environmental risk assessment and management.

II. Define those systems components that need to be considered to reach a holistic approach as well as those system components with less relevance - in order to limit complexity and promote workable environmental risk assessment procedures.

III. Propose transdisciplinary and overarching systems definitions, e.g. for ERA in agricultural (eco)systems that can i) account for holistic protection goals and ii) serve as references for environmental risk assessment frameworks for different substances and stressors.

WP 4 System-based ERA framework and proof of concept

I. Propose a framework for systems-based environmental risk assessment, including those essential building blocks identified in the PERA project as well as conceptual advances of PERA/other partnerships (project 2) and the scientific outcomes of the projects on knowledge building and tools development (projects 3, 4 and 5; comparative assessment, integrate pre-post registration monitoring data and new tools for holistic assessments).

II. Design a proof of concept to demonstrate the feasibility and practical implementation potential of the developed framework on how to build and perform a system-based approach to environmental risk regulation. Give priority to pesticides and regulated products in agricultural systems for the proof of concept design.

III. Perform a proof of concept study, starting with environments far advanced in knowledge and data availability and based on legal framework in place (e.g. pesticides). Transfer concepts and approaches to other, less advanced systems components. Indicate where to adapt the strategy and governance to transition, if needed, regarding scientific and legal innovations and feed back to the Partnership for Environmental Risk Assessment (project 2).

Opportunities

The project which is called for gives the key opportunity to streamline the concept of systems-based environmental risk assessment approaches. Developing a general framework for system-based ERA will advance the interoperability of regulatory ERA procedures and consolidate outcomes across assessment areas.

The chance to scientifically underpin the definition of holistic protection goals would bridge across regulatory silos and lead to a harmonized understanding and integrated assessment of environmental protection targets.

Challenges

A major expected challenge is to install a governance for a general transition to a systems approach in ERA given the currently existing fragmented regulatory landscape and the resulting partitioning of remits and activities. Aligning the long-term goals across different regulatory areas and advise a stepwise but consequent approach will support leadership empowerment. Fostering scientific discussions, a continued development of the vision, reaching out for dedicated legal support and implementing the feedback from the wide spectrum of stakeholders involved in PERA, is expected to help overcoming challenges and blockers.

Expected impact

The project envisaged that main outcomes will be a streamlined approach to holistic protection goal definition and an overarching general framework to a systems-based ERA.

The proof of concept of the proposed framework for a systems approach in environmental risk regulation, based on pesticide ERA in agricultural systems, is expected to serve as reference and to further drive the implementation of system-based ERA across different regulatory areas. Finally, the project will enable to link ERA outcomes to the goals of the European farm-to Fork, Biodiveristy and Soil Strategies and the associated Regulation and Laws.

An example is given in Figure 7, which illustrates how holistic approaches to ERA in projects 3 and 5 respectively can provide different options at the strategic level to reduce ecosystem impacts of PPPs and to meet Farm-to-Fork targets.

Type of stakeholders involved

Environmental risk regulators, together with risk managers, social scientists and system scientists. Ultimately, strong involvement of PERA stakeholders to ensure regulatory relevant system boundaries.

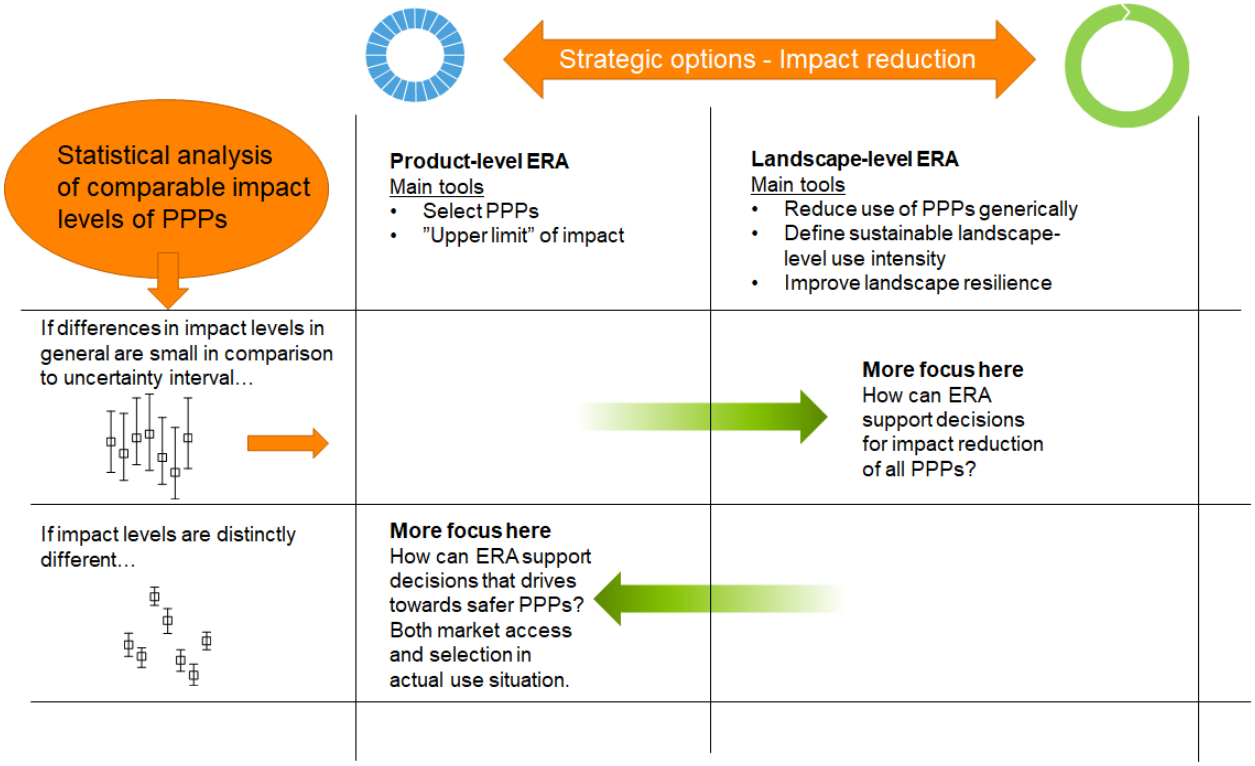

Figure 7: Illustration on how holistic analysis of PPP impact levels as provide scientific basis for strategic options to reduce impacts to meet Farm to fork targets. Project 1 could be a platform to provide strategic-level science and Project 3 could deliver concrete ERA information for strategic decision making.

4.3.2. Project proposal 2 - Development of a PERA partnership framework

Background

The identification of stakeholders and activities is an initial step for PERA, however a key component is establishing a framework for partnership(s) that can bring together diverse stakeholders, who can act as 'agents for change'. There is a need to provide them with mechanisms and tools that empower them, give them agency (ability to take action or to choose what action to take) and take responsibility as part of a transformative system that continues to co-create and progress towards a visionary and innovative system-based ERA.

Current ERA is embedded in fragmented regulatory/policy landscape and there is a need to bridge its development with other policy and regulatory initiatives / developments e.g. Farm-to-Fork, Biodiversity Chemicals strategies. In addition, the transition towards a system-based ERA needs to engage and align various actors participating in diverse sectors and disciplines, where often competing interests, perspectives and knowledge prevail.

Development of trust

It is widely recognised that an essential aspect of good governance, along with effective and sustainable regulatory processes is trust, founded on transparency that promotes shared knowledge, learning and understanding. 'Transparency Plus'[24] has been developed and promoted for chemicals policy and regulation. The concept extols those two pillars of transparency, beneficial for regulatory risk assessments, sustaining 'trust':

1. All information (data, methods and contexts etc.) is available to all concerned parties
2. The information used to make decisions is understandable to diverse audiences e.g. openly providing data and reasoning to support specific decisions.

Data and knowledge and its effective management and sharing (dissemination and exploitation) amongst diverse groups of stakeholders is an "indispensable support for creating transparent and shared understandings" of decisions, helping to dispel of misunderstandings and align perspectives.

Findings of the PERA project support this viewpoint and recommendations for Transparency Plus. There is a need for establishing a framework for effective knowledge management and stakeholder engagement, in order to foster the transition to a next generation systems-based ERA.

Fostering ownership and empowerment

Furthermore, the transition towards a system-based ERA requires stakeholders to understand their roles and take ownership, act and support change. Two aspects play a role here. The first one is the need for a concrete proposal to create the organizational infrastructure that supports collaborative partnerships to be convened or self-organized. Aspects to be covered are: to identify and propose mechanisms and platforms that support collaborations amongst relevant stakeholders, steered by effective leadership; to facilitate meaningful knowledge exchanges and cooperative activities; to provide sufficient financial funding, and, where appropriate, seamlessly integrate into current EU organizational structures. This will give partners a mandate and fundament to start building new networks and bridges and to strengthen the transition process.

A second aspect is that stakeholders, in order to decide on whether to endorse and participate in any transition, they need to understand their role and visualize how the new approach will work and how it will impact their spheres of work and business. Concrete scenarios need to be developed in a co-design process and at an early stage in the transition process. For example, what will be the impact on registration of products? What will be the impact on the work of a national risk assessor? Etc.

Scope and objectives

The focus of this project is on the development of an engagement strategy with the final aim to establish a partnership framework for future system-based ERA. A spectrum of strategic approaches should be considered, as there is no single pathway or approach to promote change and to create engagement.

The strategy can and should be built on the results and building blocks that were developed in the PERA project. The PERA database with relevant projects and organizations and the interviews conducted with relevant stakeholders are a rich source of information on stakeholders' perceptions on current and future ERA, that can be further explored and can inform the project.

The generic (long-term) strategy should be a concrete plan that is sufficiently flexible and able to align and link with other relevant ERA initiatives, PERA projects and policy agendas. This plan should include:

- a clear scope and the context of the stakeholder engagement, i.e. clearly establishing the reasons to engage stakeholders

[24] Carusi A, Wittwehr C, Whelan M. 2022. Addressing evidence needs in chemicals policy and regulation, EUR 30941 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-79-45889-0, doi:10.2760/9130, JRC126724.

- a clear strategy for identification of stakeholders to ensure effective representation. This includes the definition of stakeholder groups, reasons for engagement and potential benefits for engagement. The strategy may focus on core sets of stakeholders for knowledge management and engagement but should also consider the involvement of communities of practice (wider networks of related practitioners and interested parties).
- a clear assessment, analysis and prioritization of stakeholders as well as the level of engagement that is needed for a specific group of stakeholders (inform, involve, consult, collaborate).
- mapping of stakeholder characteristics, roles and contributions in the different stages of the PERA partnership.
- a selection of methods for engagement, appropriate for the engagement level of the specific group of stakeholders and timespan.
- identification and engagement of pilots for "partnerships of collaboration", whereby relevant stakeholders (practitioners and interested parties), who share common interests, can align on various goals and means to achieve these. Close collaboration with the other projects 1 and 3-5 is needed to identify specific pilot partnerships. In addition to working on concrete issues, participants will explore how specific steps and more general aspects of transitioning to a system-based approach, will impact their roles.
- a proposal for a concrete 'leadership entity' that provides the needed resources and governance infrastructure for PERA. This entity should inspire, coordinate, oversee and link activities within and between pilot partnerships. Means to foster ownership of issues and actions and to identify potential sources for funding, should also be outlined.

The strategy should further include:

1. A co-creation engagement plan on the development of scenarios for operationalization of a future system-based ERA. These scenarios should be acceptable to relevant stakeholders, including policy makers/ risk managers, product developers, farmers, agronomists, risk assessors. They should be embedded in and have a strong scientific backbone. The impact of these scenarios for different stakeholder groups and their roles should be assessed related to e.g. (i) registration procedures and decision making of regulated substances and products, (ii) farmers options for pest control, (iii) link to the legal framework, is there a need for changes?, (iv) transition to more sustainable agriculture, (v) inspection and control, (vi) international trade of commodities.
2. The development, set up and operationalisation of the infrastructure, to create a framework for knowledge management and actor engagement, that starts by integrating the work and outputs of the proposed PERA projects (P1-5). This framework should be adaptable and targeted for particular purposes that can foster knowledge sharing, dialogue and learning between diverse groups of interested parties. The framework should also take account and consolidate upon / with existing initiatives, strategies and platforms that promote integrated knowledge management and diverse stakeholder engagement e.g. EFSA's Stakeholder Engagement Approach and engagement principles (Authentic / Inclusive / Targeted). In addition, the design of the framework should have a 'user-centric' focus to ensure that the framework meets the requirements of the people it is aimed at.
3. A feasibility study on how to organise the exchange of data and align with other initiatives in EFSA or EU on open data and AI programs running at EFSA and partner organisations – provision of data, ownership and accessibility and usage sharing.

These developments should create the foundation for two interconnected frameworks that can enable transitioning to a systems-based ERA, through continued co-development of its vision and building blocks:

- A knowledge management system: that enables and promotes information availability, access and understanding
- A platform for partnership(s): that enables and promotes inclusive yet targeted stakeholder engagement

Challenges

This project specifically addresses the **communication and involvement of relevant stakeholders**, which was identified as one of the main challenges from the desk research. The engagement strategy should pay specific attention to the exchange and **communication with farmers**, being one group of stakeholders that is currently weakly connected to ERA.

The project furthermore targets to facilitate the **implementation of the new system-based ERA**, mentioned as one of the main challenges in the interviews. By starting a co-creation process, stakeholders will be given power to influence the process and together find solutions for practical implementation issues, as well as reaffirm / define their roles within a systems-based approach.

Expected impacts

The final (longer-term) project's outcome will be a consolidated partnership framework, which is based on a thorough understanding and analysis of PERA stakeholders and outlined in an engagement strategy. This framework will provide the foundation for active partnerships that can steer new generation RA vision and developments, as long as they are needed and in which Partnering stakeholders understand and help to define their roles.

The right knowledge management and engagement mechanisms can support shared understandings, among diverse groups with multiple perspectives, and furthermore build trust between partners and developments transitioning to a new generation RA, with partners willing to build upon existing effective processes whilst supporting innovative developments.

In addition, an infrastructure will be developed, implemented and operationalized, in order to foster knowledge sharing, dialogue and learning between diverse groups of interested parties.

Type of stakeholders involved

Lead by social / political scientists but involving key actors at EU / national level as part of user-centric design process.

4.3.3. Project proposal 3 - Develop comparability between environmental risk assessments of PPP

Background

This project aims to improve the comparability of prospective PPP ERAs relative to each other by developing a concept for ranking the PPP according to their risk potential. The identity, particularly of the highest-ranking PPP, will be validated with independent monitoring data. By ranking and exploring the outcome of ERAs with varying level of complexity and amount of data, an appropriate level of detail and precision in the prospective assessments can be achieved.

By links to project 5, EFSA WA2- "Assessing environmental risks resulting from exposure to regulated substances/compounds or products at relevant levels of biological organisation (individual, population, community, ecosystem) and spatio-temporal scales" is addressed in addition, supporting the development of relevant aspects of ERA to achieve a standardised systems-based approach.

There is an existing research initiative addressing aspects of this topic as part of PARC Activity 6.4.4. Although this PARC activity also aims for holistic assessments covering all risk areas, the project is currently focused on aquatic environment and would benefit from strengthening research capacity on the terrestrial side.

Scope

The scope of this project is to identify and focus on the relevant aspects in ERA, in order to achieve the realism of a systems-based approach without increasing complexity. A wealth of information is available from ERAs and monitoring, but has not been analysed to identify the relevant aspects and breaking away from the current circle of increasing complexity with new guidance and models.

This project would build further on and strengthen the research questions in PARC Activity 6.4.4 "Risk assessment to support and promote efficient overall protection of biodiversity", by further developing the following aspects:

- Scope to gather outcome of ERA to understand the requirements, implications and ultimately benefits of a common platform on environmental risk assessment.
- Consideration of monitoring data, to ensure protectiveness and development of a comparable ERA.
- Development of a range of comparable approaches for risk ranking, and evaluating these approaches by testing predictions against monitoring data.
- Consideration of the impact of uncertainty in ERA on the risk ranking.
- Use ranking approaches to evaluate effects of management measures on overall risk in a systems-based approach.
- Feasibility study for a publicly available risk ranking database.
- Strengthen the research for developing and integrating assessments, especially in the terrestrial environment, to achieve a holistic and comparable ERA.

Objectives

Research questions to answer with this project are:

- Which data is essential, and which should be omitted to improve the comparability of prospective ERA?
- Does rank order of PPPs change between different ranking approaches/methods?
- Does rank order of PPPs change, if also uncertainty interval for each ERA is considered?
- To which extent can impact levels of PPPs can be distinguished from each other considering uncertainty intervals (see conceptual framework in Figure 7)
- Which degree of precision in impact level for PPP is warranted for regulatory use, considering the uncertainty intervals of impact estimates and variability in the environment?
- Effect of MS specific conditions (mitigation measures) on rank order?
- Effect of agronomic context (PPP use) on rank order?
- Effect of aggregation and simplification on rank order?
- Could we have predicted the ranking of PPP observed in monitoring studies with the ranking of comparable ERA?

Potential data sources to be used in this project and research questions formulated above are data in the list of endpoints in EFSA conclusions (relating to toxicity – effects data, and physico-chemical properties – environmental fate data), national pesticide registries (use and agronomy – exposure data),

existing ERA methodologies and models, as well as data on monitoring av exposure and effects of PPPs in the environment.

Opportunities

Improving ways-of-working within the current paradigm and taking steps towards a new paradigm

Some examples and suggestions aimed to illustrate the required stepwise movement towards the envisioned systems-based ERA are given below.

Improving comparability between assessments can open new possibilities to validate effects of and strengthen the scientific basis for decision making. Individual authorisation decisions could be cross-checked against an overall risk map in a database containing ERAs for all authorised PPPs and lead to a more consistent management by grouping PPP. This could be seen as first step in a transition towards a streamlined product level ERA in the vision in Figure 5.

A database containing comparable risk levels of all authorised products could also serve as a tool for planning and risk-based governance of resources for evaluation of renewal dossiers. Evaluation resources in the renewal process could be directed towards the PPPs with high-risk ensuring an efficient use of resources.

Comparing ERAs supported with monitoring benchmarking can identify risk key driving factors across dossiers/products/active substances, across agronomical contexts and across varying environmental conditions in different member states. Such analyses can supply objective and transparent basis for improving harmonisation of data requirements for assessing risks for different compounds used in agricultural areas. This in turn would improve the basis for work-sharing among member states and efficient use of resources.

Contribution towards the vision

Improving comparability between ERA assessments has several potential benefits. Intra-comparability between PPP ERAs is a pre-requisite for creating inter-comparable building blocks to be used in integrated assessments of multiple PPP-applications and other stressors at the landscape level. The identification of PPP with higher risk in the ranking enables the evaluation of spray series with different PPPs. Further, a standardised tier could be developed in which the different PPP ERAs are benchmarked in the same way towards environmental exposure. This means that the environmental exposure does not have to be repeated in every dossier, reducing noise in the individual assessments.

Increased relevance and reusability of ERA data and expertise. Databases of comparable PPP ERAs can also be used for Open data initiatives, to make the information and expertise generated within the authorisation process available to other stakeholders. Examples are suppliers of IT-tools integrating ERA with other data to support local and landscape environmental impact and plant protection management by farmers. By passing on relevant information of the ERA to the farmer, he/she can better carry the responsibility transferred to him/her for a sustainable food production (connection to the agricultural eco- and production system level in the proposed vision). The current understanding of safe use, implying that all authorised PPP are equal, becomes differentiated. Comparable ERA also increases transparency and eases risk communication with the public (addressing political, social and economic level in the vision).

Challenges

A major challenge anticipated is engaging stakeholders, such as risk assessors and risk managers, that are fully overloaded with making the current system work. To ensure regulatory relevance, it is necessary to involve stakeholders already from the start, in the co-creation of a focused comparative ERA approach. To overcome this challenge, the project should include resources and planning also for an interactive co-creation approach and involving pilot groups of stakeholders to develop a first set of

proof-of-concept studies with alternative approaches to risk ranking. Feedback and questions from end-users need to be accommodated for the continued development work. Initially, input from the pilot group will be used, and in subsequent cycles a wider range of stakeholders need to be involved. Simplifications needed for this ranking approach to work, need to be based on scientific agreement for solid support. Therefore, the effects of the simplifications on the raking will be investigated in sensitivity analyses. Nevertheless, the reduction of a complex system to a simplified system may lead to concerns of a reduced level of protection or of missing important information. This can be overcome by continuous feedback from retrospective risk assessments.

Another challenge for the project is to balance between, on one hand, the overall objective of reducing complexity and focus on relevant aspects of the ERA, and, on the other hand, requirements of additions of data based on specific ERA contexts and scenarios. A way to handle this challenge would be to include participatory workshops, where specific data requirements are compared to each other and framed into a holistic context in expert group evaluation of impact for a holistic ERA level. Benchmarking against monitoring data and system noise analysis are potential tools in such evaluations.

Expected impact

Short-term: a database containing the outcome of all historic ERAs in a comparable format can support authorities responsible for evaluation and decision making with assessments prior to evaluation. Pre-evaluation assessments of dossiers could be supplied automatically based on input of GAP data and EU-level agreed endpoints. Such comparisons can also give a quantitative context on the relative impact of new data (changed endpoint). Furthermore, such information could be used to focus evaluation resources to dossiers for PPPs with the highest risk levels.

Long-term: Comparable and simplified ERAs based on environmental benchmark could potentially be introduced as a new tier (higher tier since it would include monitoring), to streamline ERA within the current regulatory context. Comparable PPP ERAs can be used as building blocks in landscape-context integrated assessments.

Type of stakeholders involved

Researchers, Environmental risk assessors, Risk managers, Social scientists, Legal expertise, IT-Systems architects.

4.3.4. Project proposal 4 - Combining pre- and post-registration data for prospective ERA of PPP

Background

In the current system ERA, the links between pre- and post-registration data are very poorly developed and for some parts of the system non-existent. Several recent field studies (e.g. Stehle and Schulz, 2015[25]; Liess et al., 2021[26]) are showing exceedances of regulatory thresholds, but there is no efficient system in place that enables to feed-back this information into the ERA.

Thus, there is a need to better link pre- and post-registration data. This could be achieved by comparing the expected exposure and effects from the prospective risk assessment with the observed field exposure and effects using evaluations that consider synchronized data on PPP concentrations and potential biological/ ecological effects in various agricultural landscapes. Such an integrated monitoring

[25] Stehle S, Schulz R, 2015. Pesticide Authorization in the EU—Environment Unprotected? Environmental Science and Pollution Research, 22, 19632–19647

[26] Liess M, Liebmann L, Vormeier P, Weisner O, Altenburger R, Borchardt D, Brack W, Chatzinotas A, Escher B, Foit K, Gunold R, Henz S, Hitzfeld KL, Schmitt-Jansen M, Kamjunke N, Kaske O, Knillmann S, Krauss M, Küster E, Link M, Lück M, Möder M, Müller A, Paschke A, Schäfer RB, Schneeweiss A, Schreiner VC, Schulze T, Schüürmann G, von Tümpling W, Weitere M, Wogram J, Reemtsma T, 2021. Pesticides are the dominant stressors for vulnerable insects in lowland streams. Water Research, 201, 117262

would act as an early warning system for divergences between predictions and the PPP exposure or biological effects detected in the field.

This project represents a key component for the transition towards and the establishment of a system-based approach by transitioning from the current ERA, considering a single chemical-crop combination to a more holistic ERA integrating landscape structures, multiple crops as well as combined and repeated PPP use. Besides, it will provide inputs to projects 3 and 5.

There are some research initiatives addressing related aspects in some parts of PARC, in particular activities under PARC 6.3 and 6.4 which could add, complement and connect to this current project. For example, one of the projects explores the differences between various regulatory frameworks that are aiming at protecting the same ecosystem; other projects aim at i) reducing the complexity by identification of the most relevant predictors for ERA and ii) quantifying effects of PPPs relative to other stressors through landscape risk assessment, that provide information on environmental impacts.

Scope

The scope of this project is to combine the information from the prospective risk assessment and resulting decisions (e.g. authorisation delivered with specific risk mitigation measures) with the information from the real world, i.e. existing and new field observations in the field for all compartments (e.g. terrestrial and aquatic) and assessment areas (i.e. aquatic, soil organisms, non-target arthropods and terrestrial plants, pollinators, aquatic organisms, birds and mammals, amphibians and reptiles, groundwater).

This information will be integrated in order to adjust and/or validate the predictions, so that the prospective environmental risk assessment of PPPs is improved.

The project must include all relevant aspects and the integration of data must be conducted in a synchronised and iterative way. This requires that the sentinel monitoring program implemented in agricultural landscapes is realistic in terms of feasibility and affordability in the different European member states. Particularly the monitoring of terrestrial compartments requires specific efforts for being developed and established.

The comparison of existing and definition of new indicators based on monitoring and PPP use data will enable to follow up the trend of PPP exposure and related effects over time. In addition, indicators will support controlling the efficiency of mitigation measures.

As mentioned in project 3, a wealth of information is available from ERAs and monitoring activities, especially in the aquatic ecosystems. However, it has not been analysed yet in a way that could lead monitoring results and information to flow - in a feedback loop – back to the prospective ERA system. This would enable in project 4 to iteratively check and improve the level of protection achieved through adjustments of the systems-based methodology and management practices.

Objectives

- Contributing to the development of a database that includes all existing monitoring/ surveillance/ sentinel data of PPP exposure and related biomonitoring from aquatic and terrestrial ecosystems (link to PARC WP 4.2 and PARC WP 7 – FAIR data). The database should further include and provide actual PPP use patterns to better assess and predict PPP exposure and effects in agricultural landscapes.
- Defining (i) the integration of monitoring data and (ii) assessing the possibilities as well as limits of what can be assessed using monitoring data (e.g. links between PPP exposure and ecological effects, efficacy of mitigation measures) for the systems-based ERA. This also includes the level of overall PPP exposure and biological/ ecological effects (i.e. environmental impact) in representative/typical agricultural landscapes.

- Developing a concept for a sentinel/ monitoring program considering different assessment areas and harmonized across different regions and MS.
- Comparing the environmental impacts observed at landscape level and the predictions in the PPP ERA regarding exposure and ecological effects.
- Assessing if the divergences between observed and expected effects can be analyzed according to the landscape attributes (and RMM) and the specificities of the PPP risk assessment and if possible, divergences can be addressed and overcome (e.g. accelerated consideration of new data and approaches).
- Developing a concept for the consideration of retrospective PPP use data, in order to characterize crop and region specific treatment regimes and, hence, better predict PPP (site specific) exposure and related effects in the field for a systems-based approach.
- Evaluating existing or creating new indicators using monitoring data, PPP use data and other PPP related data from the ERA (e.g. physico-chemical properties, ecotoxicological data). These indicators should serve to display trends on PPP loads and effects over time as well as to evaluate RMM at different spatial levels (e.g. national level vs farm/ field level).
- Evaluating how could ERA and tools be developed in order to provide essential as well a realistic information for a system -based approach by using monitoring and PPP use data.
- Adapting/ changing some procedural aspects so that the feedback of post-registration data to the registration system is faster enabling for adjustments, e.g. in case of threshold exceedances.
- Addressing mixtures of PPP by analyzing monitoring data with PPP use. This aspect is linked to PARC, especially the activity 6.4.1. that will 'Develop risk assessment and management methods for chemical mixtures.' While in PARC 6.4.1, the approach will be rather conceptual (e.g. linking between legislations, analyzing the scale of the issue), the approach in this project will be more focused on the empirical assessment of PPP combinations in agricultural practice and different environmental compartments.

Opportunities

Improving ways-of-working within the current paradigm while taking a step in a new direction

- Improved ERA by calibrating pre-registration prediction with post-registration data including exposure and effect monitoring as well as reported PPP use data. PPP Exposure as well as effects resulting from realistic PPP application patterns and the interaction with environmental stressors that is characterized with monitoring data allows a more holistic assessment of PPP impacts on the environment. In addition, the identification of drivers for PPP exposure and PPP effects will be improved.
- Establishing and harmonizing a powerful management tool for the implementation/control of mitigation measures.

Contribution towards the vision

- Improved calibrated ERA has several potential benefits. It should help to focus prospective ERA predictions on factors that have predictive power for environmental risks/impacts (what is the predictive power of prospective ERA methods of varying mechanistic level of detail (evaluation of predictions versus monitoring)). Indeed, there is a large amount of process details and data in the assessments of unclear relevance for the assessment and management of environmental impact. The relevance of input parameters that improves effectiveness of ERA should be evaluated.

- Increased relevance of ERA data and expertise is also beneficial. Databases for PPP ERAs can also be used for open data initiatives to make the information and expertise generated within the authorization process available to other actors. Examples are suppliers of IT-tools integrating ERA with other data to support local and landscape environmental impact and plant protection management by farmers.

Challenges

Including proposed actions to address challenges

- Monitoring data regarding PPP exposure capture the result of multiple, repeatedly treated crops, different sources (i.e. PPPs, biocides, veterinary pharmaceuticals) and entry pathways (i.e point sources, diffuse sources). Also, observed ecological effects in the field are caused by a multitude of environmental or chemical stressors. Therefore, the challenge will be to identify monitoring data and design monitoring campaigns that can unravel as best as possible agricultural pesticide exposure and effects from the co-existence of confounding factors in terrestrial and aquatic ecosystems. As well, the interpretation of monitoring data can be challenging when the agricultural context is not available.
- Factors confounding with PPP exposure might vary for different landscapes, regions and MS, what needs to be addressed for example by mapping confounding factors according to the finding from existing, suitable monitoring data.
- Identification of suitable reference sites for biological monitoring is a challenge as there are hardly any "pristine" agricultural landscapes without PPP treatment in Europe and multiple anthropogenic stressors often co-appear with exposure to PPPs.
- Synchronized monitoring of PPP exposure and effects is feasible in aquatic systems, but assessment for mobile organisms in terrestrial ecosystem might be very challenging and less established (or at least poorly established). The focus on selected terrestrial organism groups as indicators might help to overcome this aspect. Lack of flexibility of procedures in the current authorisation system impairs fast adaptations in case of emergencies/ exceeded thresholds. Tools or mechanisms need to be put in place to improve the agility to adapt to new conditions.

Expected impact

Benefits to end-users and plan to involve end-users and affected stakeholders in scoping and implementation plans.

The main impacts include an efficient management tool to:

- Identify upcoming risks, e.g. hot spots for management (e.g. regions with high PPP risks and effects),
- Control the mitigation measures,
- Deliver information on the status of the system to be assessed,
- Provide feedback to the ERA on the fulfilment of protection goals, e.g. evaluate the success of national action plans for PPPs use,
- Deliver inputs to the renewal of products/active substances assessments, adjusting the prospective RA.

Type of stakeholders involved

Authorities at European/ National/ regional level: environmental risk assessors and risk managers

Farmers/ Farmers associations (PPP use data)

Researchers (Academia/ Research centers), IT experts

4.3.5. Project proposal 5 – Holistic assessments of fate and potential impact of chemicals in agricultural production systems

Background

The current organisation of ERA of chemicals in separated silos provides the grounds for complicated but still not fully consistent procedures for the calculation of exposure and corresponding risks of pesticides and other chemicals.

Currently available research suggest that landscape context and structure indeed can affect the resilience of ecosystems to impacts of PPPs. However, comprehensive knowledge as sound basis for incorporation in a regulatory context is still lacking.

A stepwise and integrative process is suggested bringing together different fields of expertise in hypothesis driven research with the overarching objective to develop methodology and ultimately tools for implementation in a regulatory context. This process needs to consider the balance between model development and validating studies. An integrated approach to knowledge-building has also the potential to bridge across silos in the research community.

This proposal is set out to define and implement a holistic multicompartment model representation of agricultural production systems and landscapes that allows to analyse emissions, transport, fate, exposure and effects of pesticides and other chemicals that occur in agricultural production systems, and to integrate model development in a landscape context in a consistent way, for example by using information from research initiatives such as Biodiversa+. Developing assessment tools and methodology will ultimately need to aim for simplified and holistic methods focused on aspects of ERA relevant in a regulatory decision-making context.

Scope

This project is about development of regulatory applicable and relevant tools for systems-based risk assessments of PPPs and other chemical stressors. Mechanistic model development in combination with validation studies by linking to other strategic research initiatives in the EU will be used to address the two following overarching research questions:

1. Development of regulatory feasible assessment methods and tools focusing on the aspects of ERA relevant for the regulatory and risk management context.
2. Identify relevant scales for integrated system-level assessments. Relevant spatial and temporal scales, as well as relevant ecosystem levels for exposure and effect assessment need to be identified, to capture impacts of PPPs and other stressors in agricultural landscapes. The identification of scales also need to consider the relevance for ecosystem and agricultural production management, for example taking into account efficiency and availability of landscape structure risk mitigation measures.

Objectives

- Identify and implement strategic connections to relevant research initiatives such as Biodiversa+ and other similar initiatives
- Identify relevant available mechanistic modelling tools and the needs to amend/integrate those
- Integrate and amend existing modelling tools if necessary to meet overarching objectives
- Apply models to explore relevance and applicability of different scales (temporal, spatial, ecological) for integrated assessments of PPP impact considering the regulatory and agricultural context

- Apply models to scope hypotheses to be tested in landscape-scale studies, including the identification of key risk drivers for use in regulatory decision making
- Develop tools and identify potential additional data requirements (PPP-specific or eco-system specific) for implementation in regulatory context, in technical collaboration with projects 3 and 4.

Opportunities

This project aims for providing the opportunity to bridge across the existing silos between different parts of current regulatory risk assessment of PPPs, and ultimately also across other regulated chemicals and other stressors with relevance in agricultural production systems. It would also contribute with essential elements of landscape-level ERA.

Challenges

One major challenge of this project is the need to integrate with the other ongoing projects in the roadmap to PERA. There are several existing strategies and research activities that this call should link to and seek coordination with:

- Technical coordination with project 3 risk ranking and project 4 on monitoring data.
- Agricultural case-studies integrating impact assessments as defined in PARC 6.4.4
- Research initiatives focused on protecting biodiversity in agricultural landscape, such as Biodiversa+

Another major challenge is to avoid development of unnecessary complexity with the required approach. Here, objectives of this on the definition and implementation of holistic, systems-based ERA tools should always aim to support the transitions. Identification of small steps to co-create a systems-based ERA should be done in coordination with project 1 in this report. An example is to use the results from modelling scoping studies to identify and exemplify potential risk drivers in various landscape scenarios and use these as concrete topics in stakeholder engagement projects.

Expected impact

The expected impact of a project following this call to provide a system of tools that integrates all relevant parts of regulatory risk assessment of PPPs and is based on processes, data and risk drivers of relevance for prospective and protective. This model system will at the same time include also agronomic practices and other stressors, and will, in that way, contribute to the transition to a systems-based risk assessment. Based on the development in close connection to the evaluation of monitoring data from landscape scales and initiatives such as Biodiversa+, trust of involved stakeholders and regulatory relevance will be achieved.

Type of stakeholders involved

Such a research project needs to be developed by scientists and technical experts from different disciplines. Communication and stakeholder involvement, which would involve also risk managers and societal interest groups, will be organised in coordination with project 2.

5. CONCLUSIONS

The vision for PERA (initially focused on ERA for PPPs) is an essential part of the roadmap since it outlines the goal and direction for the transition and is used to prioritise working areas for further development and guided development of the proposed projects. This vision addresses stakeholders' main concerns with the current ERA system, such as complexity and labour intensity, lack of realism in assessments and a disconnect of the current ERA with certain stakeholder groups e.g. from the agronomic and biodiversity conservation sectors. It also addresses stakeholders' concerns about a future systems-based approach, which are primarily related to increasing overall complexity of the process and a lack of a comprehensive definition for a system-based ERA. The analysis also highlights that several stakeholders, such as NGOs, consumer associations or farming advisories are not well represented in the ERA process.

From the assessment of the current state and the (revised) problem formulation, two key conditions for a systems-based ERA are considered necessary: 1) a high-level shift in perspective from substance-by-substance and regulation-by-regulation to a holistic systems-perspective, and 2) an improved alignment across silos from other regulatory areas by adopting a broader perspective.

In a future state with a systems-based ERA, the modus operandi between stakeholders should be improved so that ERA integrates different systems and multiple disciplines of expertise. This cooperative effort should strive for new/alternative solutions and the sustainable management of agricultural production systems and agroecosystems (addressing interconnectivity and overbridging silos). Technical and scientific ERA methodologies should be improved by strengthening the feedback between prospective and retrospective (monitoring) risk assessments, capturing the combined impacts of pesticides and other ecosystems stressors at the agro-system level (addressing protectiveness and realism). Future ERA process should incorporate lessons learned from the current ERA system and capture the differences/comparability between PPP. Focusing on relevant factors, aspects and level of detail for ERA, will help increase the comparability of data and assessments (addressing complexity, relevance, efficiency and harmonisation to overbridge silos).

The PERA vision is a visual framework for systems-based ERA, with a concentric circle model. Its core circle builds upon and strengthens current ERA processes by focusing on pesticide specific aspects, useful for comparability and decreasing the assessment complexity of pesticides. The inner core circle is surrounded by a supportive circle of landscape scale ERA, that addresses ecosystems properties of generic relevance for all pesticides. These two ERA circles are in turn connected to surrounding circles representing the agricultural, ecological- and production systems as well as the political, economic and social systems. To fully optimize the process, these circles need to be interconnected with information feed-back loops. The vision and roadmap were designed to incorporate the strengths, knowledge and expertise of the current ERA state into a new holistically framed systems-based ERA.

The transition to a systems-based ERA considers areas identified as requiring further development and its implementation faces, like every change in paradigm, several challenges and blockers. In the PERA project we have identified several key ones and proposed ways to overcome them. This task, however, needs to be continued in PERA (the partnership), and can be partly achieved by implementing the proposed projects.

It is suggested that the transition should encompass two different time frames: i) Short-term: search for opportunities to take concrete and tangible steps that, while helping to improve the current ERA system, are aligned towards holistic assessments and a systems-based ERA within the legal framework; ii) Long-term: align and proactively interact with long-term with overarching legal development and implementation. However, for a successful transition, a strong overarching leadership is essential for the scientific reframing, along with a mandate and incentives for driving the change process over time. These aspects are reflected on the prioritization of the project proposals as shown in Table 5.

Table 5: Overview of how the proposed projects cover the working areas originally proposed in the EFSA Theme paper on PERA. Colors indicate different levels of prioritization for project implementation, from first (dark green) second (medium green) and third (light green) level of priority. Details of project proposals can be seen on section 4.3.

EFSA WA/PERA project proposal number (1 to 5)	1	2	3	4	5	Proposed clarification of crucial components of the EFSA WAs, based on the analysis of the Current state and developed Vision
WA1: Overall system impact						Assigning ERA issues to relevant process levels; substance-level ERA, and landscape-level ERA respectively
WA2: Environmental risks						Develop focus of prospective ERA on risk driving factors and data with predictive capacity based on retrospective ERA and field-validating monitoring; landscape/ecosystem-related ERA issues (WA 2) Need to define ecological scenarios for ERA For this WA a distinction is also proposed between the scoping for, and develop assessment methods for relevant scales landscape-scale ERA, respectively
WA3: Mixture toxicity						
WA4: Efficiency of risk mitigation measures						
WA5: Monitoring						Integrate monitoring of actual use of PPPs
WA6: pre/post registration data						Develop focus of prospective ERA on risk driving factors and data with predictive capacity based on retrospective ERA and field-validating monitoring; substance-related and landscape/ecosystem-related ERA issues
WA7: Alternative solutions						
WA8: Harmonised ERA						Develop focus of prospective ERA on risk driving factors and data with predictive capacity based on retrospective ERA and field-validating monitoring; substance-related ERA issues AI to explore and understand drivers of variability in current ERA process
WA9: Currency						
WA10: Impact/sustainability assessment						Map and assess strategic options for biodiversity impact reduction (generic PPP use/intensity reduction, reducing/banning PPPs with highest risk, enhance resilience in landscape)
WA11: Safe design						
WA12: Guidelines						
WA13: Group assessment						
WA14: Transparency						
WA15: Relevant projects						
WA16: Linkages with relevant partnerships						
WA17: Related fields						
Development area (Communication)						Improving communication and raising awareness and providing better advise for farmers

Appendix A – Institutions that were interviewed and that participated in the workshops

Table A 1: Complete list of the interviews conducted by PERA-project team according to stakeholder type

Actor type	Institutions interviewed
European Commission (DGs)	• EC DG Agriculture and Rural Development (AGRI) • EC DG Health and Food Safety (SANTE) • EC DG Environment (ENV) • EC DG Joint Research Centre (JRC)
European Agencies	• European Medicines Agency (EMA) • European Environment Agency (EEA) – Interview 1 • European Environment Agency (EEA) – Interview 2 • European Food Safety Authority (EFSA) • European Chemicals Agency (ECHA)
National Authorities	• Dutch Board for the Authorisation of Plant Protection Products and Biocides (CTGB) • French Agency of Food, Environmental and Occupational Health and Safety (ANSES) • German Federal Office of Consumer Protection and Food Safety (BVL) • Benaki Phytopathological Institute (BPI) • UBA Umweltbundesamt Germany • Swiss Federal Office for Agriculture FOAG • Swedish Chemical Agency (KEMI)
Intergovernmental	• Organisation for Economic Co-operation and Development (OECD)
Associations	• CropLife Europe • European Farmers European Agri-Cooperatives (COPA-COGECA) • Lantbrukarnas Riksförbund
NGOs / Networks	• Pesticide Action Network Europe (PAN-Europe) • Friends of the Earth FOE Europe
Academia / Research Institutes	• (UBC) Institute for Environmental Research, RWTH Aachen University • University of Koblenz/Landau • Swiss Federal Institute of Aquatic Science and Technology (EAWAG) • Institute of Agroecology-agroecology.science • Lund University • Project SPRINT – WUR • Project WATERPROTECT - VITO

Table A 2: List of organizations that participated in the two workshops organised by the PERA-project team

Actor type	Institutions interviewed
European Commission (DGs)	• EC DG Research and Innovation (RTD) • EC DG Health and Food Safety (SANTE) • EC DG Environment (ENV) • EC DG Joint Research Centre (JRC)
European Agencies	• European Food Safety Authority (EFSA) • European Chemicals Agency (ECHA)
National Authorities	• Danish Environmental Protection Agency (DK-EPA) • French Agency of Food, Environmental and Occupational Health and Safety (ANSES) • Benaki Phytopathological Institute (BPI) • Swiss Federal Office for the Environment (FOEN) • Belgium Federal Public Service Health, Food Chain Safety and Environment • Swedish Chemical Agency (KEMI) • The State Plant Service under the Ministry of Agriculture of the Republic of Lithuania
Industry	• BASF SE • Corteva Agriscience • BAYER AG • Syngenta • ADAMA
Academia / Research Institutes	• Agroscope • University of Koblenz/Landau • Lund University • Swedish University of Agricultural Sciences • The University of Sheffield • UFZ - Helmholtz Centre for Environmental Research • Wageningen University & Research