



Roadmap for action on the environmental risk assessment of chemicals for insect pollinators (IPol-ERA)

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Abstract

Approaches integrating interdisciplinary perspectives are necessary to address current and future health and environmental challenges. Many policy initiatives have embraced more holistic approaches to tackle these challenges, e.g., the One Health concept, the Farm to Fork (F2F), Biodiversity and Chemical strategies within the European Green Deal and the global Sustainable Development Goals (SDGs). Insect pollinators are an excellent example of the One Health concept and have gained renewed focus through the EU Pollinator Initiative. Insect pollinators are essential for healthy diets by providing pollination services and maintaining biodiversity and healthy ecosystem functions. For this reason, they are part of the Environmental Risk Assessment (ERA) of chemicals, such as plant protection products (PPPs). However, an ERA of PPPs can align with and embrace these more holistic concepts and strategies by evolving towards a systems-based approach that recognises the diversity and the important role played by insect pollinators (e.g., pollination services for food security), as well as the variety of habitats and contexts they live in with their multiple stressors, and where PPPs may be used. A roadmap has been developed to determine the steps and actions needed to progress ERA methodologies and tools for insect pollinators. This roadmap is based on a review of the latest scientific knowledge, determining key areas for development to advance ERA, and identifying expertise and networks needed to foster progressive dialogue and public acceptance. The roadmap proposes several actions to generate the necessary knowledge to advance methodologies and tools within the current ERA framework, initially for chemical PPPs but extendable to other regulated chemicals. In addition, it outlines the actions needed to build the framework and the collaborative activities required to realise the transition to a systems-based ERA for insect pollinators by 2030.

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Key words: pollinators, pesticides, knowledge gaps, stakeholder engagement, systems-based ERA, monitoring, modelling

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Summary

In 2021, the European Food Safety Authority (EFSA) outsourced the development of a roadmap for action on the environmental risk assessment (ERA) of chemicals for insect pollinators (IPol-ERA), through a call for tenders. EFSA awarded the contract to a consortium led by Aarhus University.

A Theme (concept) paper, "Advancing Environmental Risk Assessment for Chemicals to better protect Insect pollinators" details EFSA's vision for the future of ERA for insect pollinators stating that: 'By 2030, the methodology followed for the ERA of chemicals across EFSA's activities will be further advanced to better safeguard the protection of insect pollinators (including wild and managed pollinators), their diversity, ecological functions and ecosystem services they provide, including pollination' (EFSA et al., 2022b). The Theme paper also envisions developing and implementing a systems-based approach to ERA (EFSA et al., 2022b). This roadmap provides recommendations on the actions and steps needed to achieve EFSA's strategic goal to ensure preparedness for current and future risk analysis needs and describes the processes necessary to advance the ERA of chemical pesticides for insect pollinators.

In line with EFSA's Theme paper, the roadmap addresses six interrelated **risk assessment development areas** (RADAs):

- 1. Engage towards a joint IPol-ERA partnership;
- 2. Assess ecological consequences of chemical effects on insect pollinators;
- 3. Advance hazard and exposure characterisation;
- 4. Advance risk assessment of combined exposure to multiple chemicals in insect pollinators;
- 5. Develop landscape-scale population-level based ERA tools that account for environmental stressors;
- 6. Develop and implement a systems-based approach and promote its use and uptake in a regulatory context.

In line with EFSA's tender specifications, the roadmap is structured around seven specific objectives:

- 1. Develop a protocol for problem implementation;
- 2. Map relevant activities and organisations for a joint IPol-ERA partnership;
- 3. Identify areas requiring further development;
- 4. Identify challenges and blockers;
- 5. Assess collaboration opportunities;
- 6. Prioritise working areas and possible partners;
- 7. Identify communication opportunities.

We used a 'vulnerability perspective' as a conceptual **(problem formulation)** frame to determine areas requiring further development and address challenges and identify opportunities associated with the ERA for insect pollinators. This approach enabled to consider four **areas requiring further development (IDAs):** (1) insect pollinator external exposure (addressing RADAs 1-5); (2) insect pollinator intrinsic sensitivity (addressing RADAs 1, 3 & 4); (3) insect pollinator population resilience (addressing RADAs 1, 2, 4 & 5); and (4) integrated ERA framework for insect pollinators (addressing RADAs 1, 4 & 6).

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IDAs 1-3 focus on the identification of knowledge gaps, the gathering of knowledge, and the development of methods and processes for ERA. IDA 4 focuses on bringing the developments in IDAs 1-3 into implementation and on advancing ERA through key aspects of communication, stakeholder networks and engagement.

A database of relevant **activities** and **organisations** was collated. Activities and organisations were classified according to the four IDAs and divided into categories for analysis. After an initial iteration, the database was created and analysed for data gaps. These gaps were then targeted using more focussed search strategies to determine if data gaps were real or were simply missed in the initial searches. Subsequently, network analysis was used to identify organisations having key structural roles (as hubs or connectors) in the collaboration network of organisations for each RADA.

Besides the database, stakeholder workshops and interviews were held to complement and expand the information gathered during desk research and provide stakeholder input to guide the development of the IPoI-ERA roadmap. These targeted interviews and workshops helped to gain further insights into the latest scientific developments/knowledge and explore 'actor' perspectives (encompassing views of experts and stakeholders) on potential **challenges** and **opportunities** for each of the four IDAs.

For each of the four IDAs, the following challenges and opportunities were identified:

- Insect pollinator external exposure: The development of exposure scenarios requires knowledge of the use of pesticides in time and space, including pesticide fate in various environmental compartments relevant for insect pollinators. Exposure scenarios should include socioeconomic metrics and be integrated with new developments, e.g., in Integrated Pest Management (IPM). These scenarios should also integrate knowledge on pollinator activity leading to exposure for all insect pollinator groups, and be informed by occurrence data derived from monitoring programmes (including post-market monitoring) and modelling for prospective risk assessment;
- 2. Insect pollinator intrinsic sensitivity: Development of toxicological testing methodologies and models to create standard approaches to data provision for the new ERA methods. It uses tools such as toxicogenomics to scale effects across pollinator groups and quantitative structure-activity relationships (QSARs) to predict the effects of novel compounds and chemical mixtures for which we have insufficient data. Toxicokinetic and toxicodynamic processes should be identified and modelling developed to feed the risk assessment process;
- 3. Insect pollinator population resilience: Development of approaches to assess population-level resilience to PPP use, including exposure scenarios in space and time, and relying on pollinator traits that affect vulnerability and recovery to generalise among pollinator species and groups. This provides the foundation for considering ecosystem functions for all bees, and socioeconomic aspects particularly relevant to honey bees. Coupling testing protocols from lab to field with landscape population-level models developed and tailored for ERA and pesticide and pollinator monitoring schemes, enables the assessment of chemicals (initially chemical pesticides) impact on pollinator populations and feedback to validate and iteratively improve the methods and tools;

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4. Integrated ERA framework for insect pollinators: The management of the developments from IDAs 1-3 aiming for centralisation, harmonisation and consolidation. Centralisation considers the governance processes associated with implementing advances in ERA, such as aligning with the underlying legal framework and administrative and decision-making processes. It addresses the need for centralised data access and formats and has the crucial role of implementing the communication plan for the iterative development of the new ERA methods. Harmonisation follows the implementation of the governance activities and broadly covers the participatory approach, incorporating stakeholder perspectives and co-development to promote a broad acceptance of the process. The harmonisation activities. These build on existing methods/procedures to implement the ERA, mapping knowledge and knowledge or tool gaps to drive the process forward to deployment.

To support the four IDAs, the roadmap provides 14 **project proposals** covering all the necessary aspects to transition from the current ERA to a systems-based ERA of chemical PPPs for insect pollinators. The project proposals could eventually be extended to other regulated chemicals.

The roadmap approach was designed to cover five key aims:

- 1. To keep to a 2030 timeline;
- 2. To have a phased ERA advancement
- 3. To be flexible to take account of changing funding and political contexts;
- 4. To cover all areas needed to advance ERA for insect pollinators;
- 5. To have a co-developed approach to roadmap implementation.

The roadmap includes a flexible timeline for implementing the project proposals, consisting of three project blocks, each delivering a product for possible implementation in ERA. **ERA Product 1** expands the current ERA under Regulation (EC) No 1107/2009 to integrate the landscape context and deliver more context-specific ERAs for honey bees, *Bombus terrestris* and *Osmia bicornis*, focusing on single pesticidal active substances. **ERA Product 2** implements a multiple-stressor (covering exposure to multiple pesticides along with non-regulated environmental stress factors) systems ERA for bees in general, and **ERA Product 3** implements a multiple-stressor systems ERA for insect pollinators.

The project proposals are designed to address different needs and thus have different time spans. Projects supporting ERA Product 1 have a shorter duration because they need to feed into future projects. One project has an overarching role and frames the other proposals. This project will lead and coordinate the roadmap implementation and manage communication and leadership, centralising resources and data access, harmonisation, consolidation, and implementation. Three projects are longitudinal, covering the entire roadmap period. These projects cover data frameworks, farming and landscape networks and data, and the provision of insect pollinator models for ERA. The remaining projects aim to gather knowledge and development of tools or processes.

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The overall timeframe for developing the different products depends on the timing of project initiation. To keep to a 2030 timeline, all projects need to be started in time for the final adoption by the stakeholders and the deployment of the new ERA advances; this requires a concerted effort to create project funding and expedite the roadmap implementation.

The **roadmap implementation** by 2030 is ambitious. Once in motion, the tight coordination of these projects and the information flow between them will be critical to succeed because it is impossible to design a feed-forward strategy within the available timeframe. The projects proposed as part of the roadmap are not solely within EFSA's remit. They encompass a wide variety of activities cutting across scientific and regulatory sectors that are intended to foster a broad array of ERA advancements for insect pollinators. Hence, a network strategy with multiple parallel activities and a carefully designed information flow is needed prior to initiating the roadmap. This process emphasises inclusive leadership, careful coordination, a stakeholder co-development process, and reflection and development throughout the timeline.

Overall, this roadmap report summarises the screening of all the activities and organisations identified as running or having run in the past, the efforts related to insect pollinators, and the ERA of chemical pesticides. Several knowledge gaps have been identified that will need to be covered to pave the way for transitioning towards a systems-based ERA for insect pollinators aligned with other more holistic approaches such as the One Health concept, the European F2F, Biodiversity and Chemical strategies and the global SDGs. Furthermore, the network analysis and the actors' insights gained from interviews/workshops suggest a significant gap in collaboration and communication between scientific and non-scientific organisations. It is crucial to foster greater engagement and coordination among all relevant stakeholder groups to comprehensively understand the challenges of creating a systems-based ERA. The roadmap proposes several actions to fill the identified gaps in knowledge, communication, and engagement whilst also integrating current knowledge.

These activities are primarily linked to leadership, project coordination, and communication within the roadmap implementation and are described as an overarching project. This project needs to be set in motion quickly if timelines for the roadmap are to be realised. In addition, a key conclusion of this report is that, to achieve a significant impact by 2030, it is important to initiate some of the projects in 2024 and to create a plan to implement the roadmap with the appropriate resources allocated for activities.

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1 Introduction

Approaches integrating interdisciplinary perspectives are necessary to address current and future health and environmental challenges. Environmental issues such as biodiversity loss, global warming, pollution, and emerging pathogens are major concerns of today and for future generations. Many policy initiatives have embraced more holistic approaches to tackle these challenges, such as the One Health concept linking human, animal and environmental health (Mackenzie and Jeggo, 2019; One Health EJP Project, 2020) and the global Sustainable Development Goals (SDGs). These holistic or systems-based approaches highlight the interdependence of humans with nature and the need for interdisciplinary collaboration locally, nationally, and globally (Box 1). Insect pollinators are a prime example of this interdependence, with their pollination services supporting agricultural and livestock production and cultural values; on the other hand, their population persistence is affected by agricultural intensification and the loss of semi-natural areas, as well as other multiple stressors. These are potentially numerous sources of stress, that often interact and impact habitats/organisms in complex and unexpected ways (e.g., climate change, invasive species and diseases). The European Commission (EC) has also put renewed focus on insect pollinators through their revised EU Pollinator Initiative. In addition, animals are viewed as sentinels and indicators for environmental health in the One Health concept (National Research Council, 1991) and bees and other insect pollinators are examples of such indicators (Kevan, 1999; Porrini et al., 2003; Schindler et al., 2013).

Box 1. Definitions of a systems-based approach.

Pesticide use and insect pollinators are embedded in socio-ecological systems, which makes it logical to have interdisciplinary perspectives (ecology, sociology, economics etc.) to handle these jointly (c.f. Folke et al., 2010). This can be done by applying a holistic/systems approach that deals with the 'whole' system rather than its 'separated components' (White, 1995). In general terms, a holistic/systems approach builds on the argument that the whole cannot be understood through any one component on its own without considering the interconnections within the entire system (Fang and Casadevall, 2011). Moving in this direction is suggested to be fruitful for Environmental Risk Assessment (ERA) to account for the interconnectedness between socio-ecological systems even when focusing on the single issue of a pesticide (Kapustka et al., 2010). Holistic approaches for ERA are being considered, although 'definitions' of what a systems-based approach entails do vary (e.g., EFSA et al., 2022b, 2022c; EFSA Scientific Committee et al., 2021; Sousa et al., 2022).

The European Partnership for next generation, systems-based Environmental Risk Assessment (PERA) takes a holistic view of ERA (Sousa et al., 2022) and formulated the following as a future vision of a systems-based ERA:

"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."

PERA was joined by a concept paper (EFSA et al., 2022c) that envisioned that ERA advancements included "*formulate ERA issues/problems and associated protection goals holistically; address the cumulative effects of multiple regulated substances/compounds or products and stressors; analyse upstream and*

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downstream life-cycle implications; evaluate a range of alternative solutions; involve a broad range of stakeholders; and use interdisciplinary scientific approaches.".

The IPol-ERA concept paper (EFSA et al., 2022b) brings up six development areas, in which the sixth "build on previous development areas and integrate their outcomes to contribute to the development of a more holistic ERA framework for insect pollinators that follows systems-based approaches" but do not provide further definitions of such an approach beyond the components of the development areas.

A practical definition was formulated by EFSA Scientific Committee et al., (2021), to cover the ERA of multiple stressors in honey bees and exemplifying that the system and its components are defined by the focus of the approach:

"A systems-based approach for the risk assessment of multiple stressors in honey bee colonies is composed of two core components, a monitoring system and a modelling system. The 'modelling' component refers to the ApisRAM model and the 'monitoring' component is related to sentinel hives and the surrounding landscape to a radius of 3 km around the hive as well as the broader EU landscape)"

It is also worth noting that the definition of risk itself may not be straightforward because of its multidimensionality and plurality in perspectives (Haimes, 2009). For this reason, a systems-based approach is proposed to handle such multidimensionality for effective risk assessment and management (Haimes, 2009). Haimes (2009) concludes that "we must understand, model, and define the complexity of risk, vulnerability, and resilience in a systemic way and through a methodical, theoretically-based systems approach, where the states of the system constitute the essence of the analysis."

Insect pollinators play an essential role in the maintenance of biodiversity, ecosystems' wellfunctioning and food security, and have multiple socioeconomic values, as a source of income, inspiration, and cultural value for society (Potts et al., 2016). However, a widespread decline of insect pollinators has occurred in recent years. Agricultural intensification at landscape levels (including the ongoing loss of semi-natural habitats, land-use change, and farming practices such as insecticide application) are suggested to be major drivers of the decline in flying insect biomass (Hallmann et al., 2017), the decline of populations (Powney et al., 2019), and diversity of insect pollinators, including bees (Biesmeijer et al., 2006; Potts et al., 2010). Non-target insect pollinators can be exposed to pesticides applied in agricultural production systems, potentially adversely affecting their health, the environment and society (Potts et al., 2016). Thus, a need to consider non-target insect pollinators in ERA for pesticides arises from the legislation itself (Regulation (EU) 1107/2009). Insect pollinators are fundamental contributors to ecosystem functioning and biodiversity maintenance and have a significant economic impact on the food chain production from a human perspective. In addition, insect pollinators can serve as indicators and bio-monitoring tools due to their ubiguity, and for some species, their ecology and life histories are well understood. Embracing a systems approach for ERA of chemical pesticides requires the evolution of the current system. In line with its strategic objective "to ensure preparedness for future risk analysis needs" (EFSA, 2021) in a fast-changing world, the European Food Safety Authority (EFSA) has issued several theme papers providing directions in readiness for future ERA requirements (Garcia-Vello et al., 2022; Sousa et al., 2022).

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In 2021, EFSA identified the need to develop a roadmap for 'Advancing the Environmental Risk Assessment of Chemicals to Better Protect Insect Pollinators (IPol-ERA)'. A Theme (concept) paper published by EFSA detailed its vision for the future pollinator Environmental Risk Assessment (IPol-ERA), stating: 'By 2030, the methodology followed for the ERA of chemicals across EFSA's activities will be further advanced to better safeguard the protection of insect pollinators (including wild and managed insect pollinators), their diversity, ecological functions and ecosystem services they provide, including pollination' (EFSA et al., 2022b). The Theme paper also envisioned implementing a systems-based approach for ERA of chemicals (EFSA et al., 2022b). The evolution of the ERA framework of chemical PPPs for insect pollinators will require consolidation, integration, and harmonisation of existing methodologies, as well as new methods and tools to support and iteratively advance established and functional ERA processes. In addition, ongoing dialogue with key stakeholders (e.g., risk assessors, managers and industry) will be fundamental to gaining a shared understanding, promoting knowledge exchange and fostering regulatory acceptance and uptake of a new generation of methodologies/tools and an evolving ERA framework.

In line with sectorial legislations, ERA methodologies focus on evaluating the risks of singleproducts in single-crops on groups of non-target organisms, with bees, particularly honey bees, as representatives of insect pollinators. For ERA to align with the One Health concept and help realise the ambitions of the Farm to Fork (F2F) Biodiversity and Chemical strategies within the European Green Deal, a number of advances are envisaged. ERA for insect pollinators should account for their biology, ecology, and context-dependency (e.g., due to variable environmental conditions) and various environmental stress factors (e.g., climate change, landscape) they are exposed to, in addition to chemical pesticides. Achieving significant advances requires the mobilisation of multiple disciplines and sectors, the consolidation and harmonisation of proven methods/tools, as well as the uptake of new knowledge and technologies that consider landscape scales for ERA to be operational, adaptive and effective in the long term.

European legislators have implemented the current ERA of chemical pesticides over more than thirty years, making it functional for pesticide authorisation and generating historically relevant ecotoxicological data, mainly focused on individual active ingredients and PPPs and for pollinators on how honey bees may be exposed or affected. Non-target organisms are protected within the current legal framework, and consideration is currently being given to evaluating pesticides on pollinator species other than honey bees. Developments observed in recent years in public health and environmental protection concepts, continued advancements of scientific knowledge and methods, as well as the availability of powerful contextual data (i.e., weather, landscape, farming practices, etc.) are factors that can enhance ERA for insect pollinators to address societal concerns better.

Consequently, this IPol-ERA roadmap explores how ERA of chemical PPPs for insect pollinators can be advanced, encompassing systems-based approaches and ensuring preparedness for future risk assessment challenges. Steps have already been taken to integrate more holistic visions for ERA of chemicals. The PERA roadmap detailed the requirements for developing a European partnership for next-generation, systems-based ERA, taking a broad 'lens' approach investigating multiple aspects of ERA processes, activities, and actors. The PERA roadmap report presented a conceptual vision and detailed several ideas to foster the transition to a systems-based ERA (Sousa et al., 2022). Many of these conceptual ideas provided a helpful framework

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for IPol-ERA. Several additional key documents and initiatives have framed the work of IPol-ERA, e.g., the ERA guidance for bees (EFSA, 2013) and its revised version (EFSA et al., 2023), documents related to setting Specific Protection Goals (SPGs) for bees and non-target arthropods (EFSA, 2016, 2015; EFSA et al., 2022a, 2021), and the EFSA scientific opinion on 'A systemsbased approach to the environmental risk assessment of multiple stressors in honey bees' (EFSA Scientific Committee et al., 2021), developed by the MUST-B working group. In developing and setting out a pathway for advancing ERA methodologies and encompassing holistic approaches for insect pollinators, it is acknowledged that detailing what a systems-based ERA will be is an on-going and iterative process of co-development involving multiple stakeholders/actors. The MUST-B scientific opinion is one reference point for referral, which recommended two interlinking core components for ERA, modelling and monitoring, to better account for complex interactions within socio-ecological systems, e.g., multiple stressors and multiple plant protection product (PPP) applications. However, the MUST-B systems-based view was focused on honey bees. In this report, we explore and expand on the concepts and principles it outlined, as well as consider other scientific opinions (Schäfer et al., 2019; Uhl and Brühl, 2019) to help guide the formulation of a roadmap to advance ERA for various insect pollinator groups, e.g., bumble bees, solitary bees, butterflies, hover flies. This report identifies and outlines key elements to advance ERA for insect pollinators that embrace systems-based approaches and determine potential linkages and connections that foster efficient interactions between multiple disciplines of expertise (addressing interconnectivity and overbridging silos). This work will also help to identify potential/new solutions that can add value by connecting elements that might not be connected today, further supporting the evolution of ERA of chemicals for insect pollinators.

1.1 Background and terms of reference as provided by the requestor

This contract was awarded by EFSA to:

Aarhus Universitet, Denmark, Universidade de Coimbra, Portugal, Lunds Universitet, Sweden, Instytut Ochrony Przyrody, Polskiej Akademii Nauk, Poland, Alma Mater Studiorum – Unversità di Bologna, Italy, BeeLife European Beekeeping Coordination, and Instituto Politécnico de Bragança, Portugal.

Contract title: Development of a roadmap for action on advancing the environmental risk assessment of chemical pesticides for insect pollinators.

Contract nr. OC/EFSA/ED/2021/01 - LOT1

Following EFSA's tender specifications, the contractor was requested to develop a roadmap for action for advancing the ERA of chemical pesticides for insect pollinators with a stated overall objective (Box 2).

Box 2: Objectives for Lot 1

 Development of roadmap for advancing the Environmental Risk Assessment (ERA) of chemical pesticides for insect pollinators

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The **main objective** of the roadmap for action for this lot is to identify recent relevant research and risk assessment developments that might need consideration when conducting environmental risk assessments (ERAs) of chemical pesticides for insect pollinators.

The roadmap also has to identify relevant ERA development needs for insect pollinators that require additional research input. This information must be relevant for consolidating, updating and harmonising methodologies for the ERA of chemical pesticides for insect pollinators, and for developing and implementing a systems-based approach for the ERA for insect pollinators.

To achieve this aim, the contractor was invited to address the following specific objectives:

- Objective 1: Develop a protocol for problem implementation;
- Objective 2: Map relevant activities and organisations for a joint IPol-ERA partnership, for advancing the ERA for chemical pesticides for insect pollinators and to transition to a next generation systems-based ERA for insect pollinators;
- Objective 3: Identify areas requiring further development;
- Objective 4: Identify challenges and blockers;
- Objective 5: Assess collaboration opportunities;
- Objective 6: Prioritise working areas and possible partners;
- Objective 7: Identify communication opportunities.

In line with EFSA's theme concept paper (EFSA et al., 2022b), the roadmap should consider six interrelated risk assessment development areas (RADAs) shown in Box 3.

Box 3: Risk assessment development areas (RADAs) of the "Advancing the Environmental Risk Assessment of chemicals to Better Protect Insect Pollinators (IPol-ERA)" Theme paper (EFSA et al., 2022b)

- 1. Engaging towards a joint IPol-ERA partnership;
- 2. Assessing ecological consequences of chemical effects on insect pollinators;
- 3. Advancing hazard and exposure characterisation;
- 4. Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators;
- 5. Developing landscape-scale population-level based Environmental Risk Assessment tools that account for environmental stressors;
- 6. Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context.

Building on (EFSA et al., 2022b) the overarching aim of the IPoI-ERA project was to build a roadmap for action for advancing the ERA of chemical pesticides initially, but extendable to other chemicals.

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2 Problem formulation

2.1 Conceptual framework

Protecting insect pollinators from the impact of PPPs requires considering their diversity and long-term (several years) population trends over landscape scales (spatial scales relevant for insect pollinators) to ensure population persistence and their ecological functions and services (EFSA et al., 2022a). However, this raises the practical question of assessing risks effectively among pollinator groups and species. We have therefore used a 'vulnerability perspective' to identify and tackle challenges associated with the ERA for insect pollinators. This perspective assumes that the most vulnerable species would have the highest likelihood of being affected by PPPs and thus covers the potential risk associated with other less vulnerable species (De Lange et al., 2010; Rubach et al., 2011; Schmolke et al., 2021). Species' vulnerability is at the core of the conceptual framework and was used to identify an initial set of development areas within IPol-ERA (referred to as IPol-ERA development areas, hereafter IDAs) for advancing ERA methodologies and transitioning to a systems-based ERA for insect pollinators (Figure 1**Error! eference source not found.**).



Figure 1: Overview of the areas requiring further development within IPoL-ERA (IDAs) to advance Environmental Risk Assessment (ERA) methodologies. Insect pollinators' vulnerability to PPPs, affected by their ecological and biological traits, underpins these IDAs.

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2.1.1 A guide to RADAs and related entities for reading the roadmap report

The relationship between development areas and the final roadmap is described in Figure 2. The **RADAs** (regulatory development areas), together with the **IDAs** (IPol-ERA development areas), were used to develop priority working areas (**PWAs**) which in turn were used to create the 14 project proposals that constitute the roadmap. These projects comprise the IPol-ERA Roadmap for developing three ERA products as a staged process towards a systems-based ERA for insect pollinators.



Figure 2: The relationship between development areas, working areas and projects in the IPol-ERA roadmap report.

2.1.2 IDA 1: Insect pollinator external exposure

Insect pollinator exposure occurs as their activity intersects with PPP presence in the landscape, with their levels resulting from patterns of PPP use and following fate dynamics (Sponsler et al., 2019). For example, a PPP-treated cropland, especially of intensively managed fruit and vegetable crops, can increase the amount and diversity of PPPs in the landscape (Böhme et al., 2018; Meehan et al., 2011; Nicholson and Williams, 2021). Likewise, crops are commonly treated several times with single or multiple compounds (often in a time-specific order) throughout a growing season with the same or different PPPs, resulting in sequential exposure to multiple compounds (Frische et al., 2018; Weisner et al., 2021). The concentration, identity, and frequency of these compounds in the environment will determine their potential to cause an effect on organisms (IDA 2). However, it is not until the insect pollinators encounter the PPP or environmental residues of a PPP that this toxicity becomes relevant. It is therefore important to understand both the contamination patterns of PPPs and the pollinator activity patterns resulting from their nesting, foraging, mating, and overwintering (Uhl and Brühl, 2019). Pollinator activity patterns are largely determined by ecological traits, which for bees include for example flight capacity and sociality (Kendall et al., 2022). Taking a trait-based approach, i.e., grouping species by their traits under the assumption that shared traits lead to common outcomes, has been suggested as a way forward to understand and predict variable outcomes of the intersection between PPPs and the diversity of non-target organisms (Rubach et al., 2011).

Insect pollinators, or more precisely flower-visiting insects, have a common need for pollen and/or nectar during some part of their life cycle but are otherwise diverse in their specific needs

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and life strategies (Ollerton, 2017). There is an emerging understanding of the importance of different exposure routes among some groups of insect pollinators (Boyle et al., 2019), but many questions remain (Sponsler et al., 2019; Uhl and Brühl, 2019). For example, how species' ecological traits, such as food and water requirements, nesting, egg-laying, overwintering, phenology, and foraging range, interact with their environment to drive PPP exposure (Sponsler et al., 2019). Furthermore, understanding how exposure through different media (e.g., pollen, nectar, plant material, soil, water, and air) relates to pollinator activity in different landscape contexts would be helpful for both pre-approval risk assessment and post-approval PPP residue monitoring. For example, an increased understanding of the methods to track how chemicals with different properties contaminate pollinator environments would enable exposure modelling for unexplored and not-yet-approved pesticides in the prospective ERA. Both pollinator traits and chemical properties are ways of generalising and predicting exposure (and effects) beyond the studied species and pesticides. Sufficiently evaluated (with environmental residue sampling methods and monitoring) pollinator exposure modelling could aid the identification of specific representative uses that could lead to the most exposure (amount, space or time-wise), and that would be followed up in effect evaluations. There is great potential for developing preapproval exposure assessment with increased matching to the relevant spatiotemporal scales of insect pollinator populations, from the source of PPP use to the organism target site (Teeguarden et al. 2016), as well as pesticide exposure mitigation opportunities (Baveco et al. 2016).

Insect pollinators may be exposed to PPPs if applied in areas where insect pollinators are active, such as flowering crops (Graham et al., 2021; Knapp et al., 2022; Rundlöf et al., 2015). However, PPPs can also drift and leach into the surrounding air, soil, and water to contaminate non-crop plants (Botías et al., 2015; Capela et al., 2022; Krupke et al., 2017; Wintermantel et al., 2020) or remain in the soil and contaminate succeeding crops (Simon-Delso et al., 2017). Thus, non-treated semi-natural areas that could provide refuge from PPPs or act as foraging areas could be a potential source of exposure if they are located close to intensively managed agricultural landscapes (David et al., 2016). Quantifying the occurrence, concentration, and identity of PPPs from insect pollinators, e.g., insect samples (Main et al., 2020; Ward et al., 2022), bee-collected pollen or nectar (Knapp et al., 2023; Main et al., 2020; Simon-Delso et al., 2017) or adsorbents outside (Ward et al., 2022) or inside honey bee hives (Murcia-Morales et al., 2020) are promising methods for estimating their **external exposure** at a landscape scale (i.e., covering their foraging range) and, thus, beyond contamination within a focal field (c.f. Zioga et al., 2020).

Species with narrower ecological niches (determined by ecological traits) are more likely to be sensitive to stressors in the landscape (Uhl and Brühl, 2019). For example, insect pollinators with smaller ecological niches may become disproportionately more exposed in intensively managed agricultural landscapes if forced to forage in contaminated habitats; this may be less of a problem for insect pollinators with a larger foraging range (Knapp et al., 2023). On the other hand, insect pollinators with larger niches may be more exposed (amount and number of compounds) regardless of landscape context (Knapp et al., 2023). This theory could be especially true for the honey bee *Apis mellifera*, a species that has a large foraging capacity (i.e., large spatial scales and long foraging season) and forms large and highly eusocial colonies that communicate profitable, albeit potentially treated, mass-flowering crop resources that they can store for extended periods (Sponsler and Johnson, 2017). Thus, an *A. mellifera* collected pollen-

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based PPP risk indicator is a promising metric for post-approval PPP monitoring in terrestrial systems (c.f. Milner and Boyd, 2017), even if it is still to be confirmed how well this species would cover exposure estimates for other insect pollinators.

In this context, the IPoL-ERA Development Fields (IDFs), considered within IDA 1 (Figure 3) are:

- a. **Pollinator activity.** How insect pollinators use habitats in the landscape for nesting, foraging, mating, overwintering, etc., resulting in spatial and temporal activity patterns;
- b. Pollinator traits. The ecological traits that affect pollinator behaviour in the landscape, e.g., their mobility and dispersal capacity, sociality, phenology, nesting location, host plants, or whether they are central place foragers (i.e., foragers departing from and returning to a central nest when foraging in the surroundings, rather than passing through an area or moving at random);
- c. **Pesticide use.** The spatial and temporal dynamics of PPP use, driven by, e.g., crops grown, pest pressure, availability of alternatives for pest control, social norms and values (e.g., cultural/regional/sectoral farming practices and traditions);
- d. **Pesticide fate.** The processes that convert PPP application rates to patterns of environmental contamination;
- e. **External exposure.** Patterns of insect pollinators' external exposure, resulting from the intersection of pollinator activity with PPP contamination;
- f. **Environmental exposure.** How the environmental context affects all components of external exposure, e.g., landscape heterogeneity, configuration, and composition over space and time, including potential foraging and nesting areas for insect pollinators, affecting pollinator activity. Likewise, how the amount and type of PPP-treated cropland affect the occurrence, concentration, and identity of PPPs encountered in the landscape, including exposure to multiple compounds over space (among different fields, crops and through drift to non-crop habitats) and time (from multiple applications and succeeding crops).

2.1.3 IDA 2: Insect pollinator intrinsic sensitivity

Even if insect pollinators experience similar external PPP exposure (IDA 1), intra- and interspecific trait variations may result in variable toxic effects (Beadle et al., 2019; Hayward et al., 2019; Rubach et al., 2011). These biological traits affect the bioaccumulation, biotransformation, and internal distribution of toxicants over time (toxicokinetics) to determine the internal concentrations of PPPs at target sites. These processes mediate the PPP effects (toxicodynamics), resulting in an intrinsic pollinator sensitivity.

Toxicokinetics begins with PPP uptake and is highly dependent on pollinator environmental pesticide exposure (IDA 1). It is affected by consumption (oral exposure), related to the proportion of contaminated food in their diet and absorption, and the proportion of contaminated material penetrating their cuticle (contact exposure). Some quantitative estimates of adult and larval honey bee food consumption are used to calculate oral exposure from PPP use (EFSA et al., 2023). However, these estimates may introduce uncertainty and potential inaccuracy when there is little systematic data to base such estimates on, even for common bee species such as *Bombus terrestris* (EFSA et al., 2022c). We know less about the biological traits that drive PPP

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excretion, but rapid elimination e.g., during metamorphosis, may reduce internal PPP concentrations (Kraus et al., 2014)

Furthermore, we know little about how PPPs are internally distributed and how different types of circulatory systems, the presence or absence of barriers separating the site of action from the rest of the organism, or characteristics of specific organs affect the distribution of PPPs in the whole organism (Rubach et al., 2011). Biotransformation is also critical to understanding toxicokinetics because some species can metabolise toxicants better than others, depending on their biological traits and chemical properties of the PPP (Rubach et al., 2011). Various enzymes and proteins are involved in de-toxification, adding complexity. However, these traits could be summarised into a species 'biotransformation potential' and analysed as a trait (Rubach et al., 2011). Once internal concentrations of PPPs reach organs and tissues, toxicodynamic processes may lead to damage, affecting the intrinsic sensitivity of insect pollinators. Here, the presence or absence of target sites (that relate to a chemical mode of action) and compensation mechanisms, including metabolisation, become essential. Whilst fundamental knowledge exists on compensatory mechanisms in some model species, their variability is not well known, and our understanding of toxicological traits is minimal (Ashauer and Jager, 2018; Rubach et al., 2011).

Tools such as toxicokinetic-toxicodynamic (TKTD) models (Alexander-Dann et al., 2018; Thomas et al., 2002) provide a methodology for linking biological traits to toxicity processes (Ashauer and Jager, 2018; Robinson et al., 2017). For example, these models have even been used to separate the impacts of food avoidance with toxic effects (Martin et al., 2022), which may help to explain how PPPs mechanistically interact with nutrition. Furthermore, there is a growing body of literature regarding the effects of PPPs in combination with additional unregulated, biotic, and abiotic stressors, such as parasites (Aufauvre et al., 2014). These results will provide insight into how the landscape context interacts with PPPs to affect insect pollinators. Nonetheless, empirical data on toxicokinetic and toxicodynamic processes for multiple PPPs in isolation and combination with other stressors is sparse, especially for non-bees, and highly variable between species depending on their life histories.

Toxicogenomics is another promising development for understanding the biological consequences of PPP exposure since species' intrinsic sensitivity to PPPs also has a genetic component (Haas et al., 2022; Thomas et al., 2002). This endeavour can be achieved by combining the power of multi-omics tools with the fast-growing availability of genomic, transcriptomic, and proteomic data for insect pollinators. Integrating multi-omics approaches with toxicological analysis (toxicogenomics) allows for a more mechanistic understanding of differential intrinsic sensitivity at the molecular level. Such methodological development offers great promise in an improved ERA framework. For example, using a combination of phylogenomics with omics and toxicology tools, Hayward et al. (2019) were able to decipher the molecular mechanism underlying the high intrinsic sensitivity of *Megachile rotundata* to certain insecticidal chemotypes F. Toxicogenomics could also explain the combined toxicity effects observed for mixtures under field conditions (e.g., Troczka et al., 2019), an essential prerequisite for realistic predictions of PPP effects. As a result, IDA 2 includes IDFs that help better define the intrinsic sensitivity of insect pollinators (Figure 3):

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- a. **Toxicokinetics.** How PPPs are absorbed, distributed, bio-transformed, and excreted over time.
- b. **Toxicodynamics.** How PPPs affect tissues, including their mechanism and mode of action.
- c. **Pollinator traits.** Traits modulating toxicokinetics and toxicodynamics, e.g., diet and consumption, life stage, nesting location, cuticula penetration, detoxification and biotransformation capacity, target site(s).
- d. Intrinsic sensitivity to single PPPs. How single chemicals (PPPs) affect an individual.
- e. **Intrinsic sensitivity to multiple PPPs.** How multiple chemicals (PPPs) affect an individual, i.e., antagonistically, synergistically, or additively.
- f. **Intrinsic sensitivity to multiple stressors**¹. How multiple chemicals (PPPs) and biotic, and abiotic stressors affect an individual, i.e., antagonistically, synergistically, or additively.

As far as points d, e and f are concerned, we consider lethal and sub-lethal endpoints under controlled experimental conditions (i.e., lab and semi-field studies).

2.1.4 IDA 3: Insect pollinator population resilience

Pollinator populations can be more or less resilient when facing environmental stressors, i.e., resist change, recover once impacted, shift between alternative stable states, or otherwise adapt to the new conditions (Crone and Schultz, 2021; Maebe et al., 2021; Oliver et al., 2015). Upscaling from individual effects to population effects requires understanding pollinator ecology, e.g., how species interact with their physical environment (Uhl and Brühl, 2019). Such intraand interspecific interactions affect pollinator population dynamics through population size and density variation, intrinsic growth rates, recovery potential, and species distributions (c.f. De Lange et al., 2010).

Species recovery potential depends on several often-correlated traits, including sociality, colony size, foraging capacity, and diet breadth. Interestingly, these traits also affect environmental exposure (IDA 1), although not necessarily in the same direction. For example, operating within a broader ecological niche allows a greater opportunity for recovery through recolonisation, which is affected by a species' ability to disperse and reproduce (Rubach et al., 2011). Generally, recolonisation can be considered 'external' recovery (Kattwinkel et al., 2015). Indeed, intra- and interspecific interactions may result in source-sink dynamics whereby individuals move into a habitat affected by PPPs (from a less or unexposed habitat), which may be mistaken for in-field recovery (UhI and Brühl, 2019). Migratory population dynamics are challenging to detect empirically; however, landscape-scale modelling approaches provide a promising alternative (Topping et al., 2015).

On the other hand, species' demographic traits, such as life span and survival, generation time, voltinism and the number of offspring, influence the population growth rates to result in population densities - 'internal recovery' (Kattwinkel et al., 2015). Whilst some PPPs may reduce pollinator densities through, for example, reduced fecundity (Baron et al., 2017), outcomes may vary in natural environments. For instance, sociality in bees may act as a buffer that allows the

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¹ Various sources of stress, that often interact and impact habitats/organisms in complex and unexpected ways (e.g., climate change, invasive species, and diseases)



loss of part of the workforce without losing their reproductive possibility, a buffer lacking in solitary species (Straub et al., 2015). This social buffering may explain why *A. mellifera* experienced no detectable adverse effects, compared to *B. terrestris* colonies that stopped growing and experienced reduced reproduction and *O. bicornis* that did not provision any offspring, from the PPP clothianidin, despite all three species being located at the same fields (Rundlöf et al., 2015).

The landscape context can moderate PPP effects through nutrition and pathogen presence (Siviter et al., 2021). For example, consequences of catastrophic events, such as drought or PPPs removing plant resources or directly affecting insect pollinators, can be mitigated by beneficial landscape contexts including woodland and other semi-natural habitats (Oliver et al., 2013; Park et al., 2015). Another example is that the local addition of flower resources in agricultural landscapes may alter the reproductive consequences of PPP exposure without reducing exposure (Rundlöf et al., 2022). Such context dependencies can be difficult to disentangle, but combining (semi-)field experimental, in silico and monitoring approaches can provide colony and population resilience data. Such approaches and data can be used to determine baseline conditions (normal operating ranges), which can be used to monitoring PPP effects and potential consequences to ecosystem functioning and services. Pollinator communities, the regional species pools that these are drawn from and the plant-pollinator networks they form are important parts of terrestrial ecosystems and contribute to food security. Pollinator communities and plant-pollinator networks rely on pollinator populations and by understanding the drivers of resilience in pollinator populations, models and methods can be developed to account for such resilience in ERA.

IDA 3 includes IDFs that help better define the elements contributing to pollinator population resilience (Figure 3):

- a. **External recovery.** Ability of pollinating insects to recolonise an area after PPP treatment, i.e., via dispersal.
- b. **Internal recovery.** Pollinator demographic capacity to recover within area after PPP treatment, i.e., via reproduction.
- c. Pollinator traits. The ecological traits affecting a species' ability to recover externally or internally, e.g., distribution, population size, reproduction strategy, generation time, mobility and dispersal capacity, sociality, life stages, life span, generation time, voltinism, phenology, density dependence, competition and other intra and inter specific interactions.
- d. **Environmental context (population sustainability)**. How the environmental context affects all components of pollinator population resilience. For example temperature, availability of food and nesting sites, and the amount and type of PPP-treated cropland affect a population's capacity to recover.
- e. **Population resilience.** Population trends over space and time, capturing the pollinator populations' ability to resist impacts and recover after these impacts.
- f. **Ecosystem function**. The translation of population-level effects to ecosystem function ecosystem services (pollination).

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2.1.5 IDA 4: Integrated ERA framework

Advancing ERA for insect pollinators requires harmonising old and new methodologies and tools – consolidating on existing ERA methods (e.g., standard toxicity testing) with novel techniques and approaches (More et al., 2021; Schäfer et al., 2019). Novel techniques, sometimes referred to as new approach methodologies (NAMs) within the ERA context (e.g., Di Nicola et al., 2022; Escher et al., 2022), include toxicogenomics to predict intrinsic sensitivity among pollinator taxa (Haas et al., 2022) and *in silico* approaches to predict PPP effects on multiple species over large spatio-temporal scales (e.g. Ockleford et al, 2018) – essential for prospective risk assessment. Empirical data from IDAs 1-3 are needed to parameterise these models, and long-term exposure and effect monitoring data are ideally required to validate their output. Furthermore, centralising concepts, methodologies, and tools into an ERA framework will ensure compatibility across different ERA areas, facilitating trust and strong working relationships. As a result, IDA 4 includes IDFs related to the evolution of the risk assessment framework based on systems-based approaches (Figure 3):

- a. **Consolidation.** Taking existing elements of ERA (methods, protocols, and tools) to build and strengthen ERA in the long term when transitioning to a systems-based approach.
- b. **Harmonisation.** Aligning methods and tools (old and new) so they are compatible across different ERA arenas/countries/institutions, ensuring compatibility (e.g., ERA methods for PPPs and other chemicals).
- c. **Centralisation.** Harmonised data (e.g., from dossiers and monitoring), methods and tools are gathered into centralised, accessible environments, available to every actor to build trust and to avoid multiple assessments of one substance, i.e., an ERA platform that integrates different sources of data and tools (e.g., through EU Pollinator Hub or other ongoing initiatives).
- d. **Socio-economic values.** Evaluating the availability of data (e.g., economic and other 'social', less tangible costs and benefits i.e., mental health/food security) and ability to determine overall socio-economic values related to systems-based ERA, such as ecosystem services, PPP use, and perceptions/acceptance of a new ERA.
- e. **Concepts for systems-based ERA.** Conceptualising a systems-based ERA based on ecological theory, e.g., organismal concepts such as species vulnerability and focal species.

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Process

Outcome



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IPol-ERA Roadmap Report



Figure 3: Development Fields (IDFs) affecting Development Areas (IDAs): insect pollinators' external exposure, intrinsic sensitivity, population resilience, and achieving a systems-based ERA outcome. The IDFs are categorised as processes, moderating factors, and outcomes.

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3 Data and Methodologies

3.1 Mapping relevant activities and organisations

3.1.1 Desk research and construction of the IPol-ERA database

Databases and systems maps were used to collect, store, organise, and visualise the information needed to assess areas requiring further development and identify gaps, challenges and opportunities, and collaborations that help advance the current and future ERA methodologies for insect pollinators.

A variety of databases (e.g., PubMed, Web of Science, Scopus) and websites (e.g., Cordis; See Appendix A - IPol-ERA database, Table A1) were searched to collect data on ERA-related activities and organisations to feed the IPol-ERA database.

Activities and organisations were classified according to the four IDAs and the corresponding IDFs (Table 1). The IPol-ERA database was built in MS Excel (**IPol-ERA_database_EFSA_23-06-21.xlsx**) and designed to facilitate downstream system map analysis using R studio. The building process of the database was iterative and entailed different steps, depicted in Figure 4.

- The activities were arranged into five categories: 'research projects'; 'programs, partnership, initiatives'; 'scientific articles'; 'documents' and 'other' (for details, see Appendix A.1.1).
- The organisations were arranged into ten categories: 'intergovernmental'; 'European authorities'; 'national authorities'; 'regional authorities'; 'academia'; 'non-academic research centres'; 'industry'; 'farming/beekeeping associations'; 'NGO', 'other' (for details, see Appendix A.1.2).

Candidate search terms focusing on insect pollinators, PPPs, IDAs and IDFs were established based on expert knowledge within the IPol-ERA Team (Appendix A, Table A2). These keywords were used to establish the IPol-ERA database in an initial iteration. The database was reviewed to identify possible data gaps, and refined searches (targeted at specific IDFs) were conducted in the search engine Google in a subsequent iteration (Appendix A, Table A3). Activity and organisation codes are provided in Appendix A (Tables A4 and A5), along with metadata for activities (Table A6) and organisations (Table A7).

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Figure 4: Summary of the iterative data gathering approach to building the IPoI-ERA database. The left panel outlines the methods utilised to establish the database in the first phase. This entailed formulating search terms (keywords) and generating a list of preliminary sources. Subsequently, data on activities and organisations associated with insect pollinators, plant protection products (PPPs), and Environmental Risk Assessment (ERA) were obtained via website and literature searches, as well as drawing upon expert knowledge. Identified activities and related organisations were then recorded in the first iteration of the database (central panel). In subsequent data-gathering phases (right panel), the database was reviewed to identify possible data gaps, and refined searches (targeted at specific IDFs) were conducted. New data on activities and organisations were then added to update the IPoI-ERA database (central panel).

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Table 1: Classification of activities and organisations according to problem formulation IDAs and IDFs.

	PF	PROBLEM FORMULAION IPOL-ERA DEVELOPMENT AREAS (IDAS)									
		1. Pollinator external exposure	2. Pollinator intrinsic sensitivity	3. Pollinator population resilience	4. ERA framework						
		Pollinator activity	Toxicokinetics	External recovery	Consolidation						
		Pollinator traits	Toxicodynamics	Internal recovery	Harmonisation						
		Pesticide use		Pollinator traits							
ent	Developm	Pesticide fate	Pollinator traits	Environmental context (population sustainability)	Centralisation						
	ent Fields (IDFs)	External exposure	Intrinsic sensitivity of single PPPs	Population resilience	Socio-economic values						
		Environmental context (exposure)	Intrinsic sensitivity of multiple PPPs Intrinsic sensitivity of multiple stressors	Ecosystem function	Concepts for systems-based ERA						

3.1.2 Interviews

Interviews were conducted to expand and support information gathered in the IPoI-ERA database. Targeted interviews of experts² and stakeholders³ (collectively termed 'actors') were undertaken to gain further insights on latest scientific knowledge, from various scientific fields through interviews with experts, as well as exploring ideas on potential actions and challenges in advancing ERA methodologies through interviews with stakeholders. Potential candidates for interviews were selected from network analysis on organisational data gathered in the IPoI-ERA database and were prioritised following sector-specific expert knowledge (see Appendix B – Network Analysis). A total of 12 interviews were conducted with experts and 13 with stakeholders. All interviews were conducted in English. Although limited in number, the variety of interviewees was considered sufficient in providing a diversity of opinions/perspectives representing different sectoral interests. Interview guides for both experts and stakeholders used a series of open-ended questions to elicit responses on opportunities and challenges to advance ERA associated with the identified priority working areas (PWAs) described in Section 4.4. The interview methodology is summarised in Figure 5 and detailed in Appendix C – Interviews and Workshops along with the respective interview guides.

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² E.g., academics/scientists

³ E.g., authorities/ institutions, i.e., EU institutions, other EU agencies; NGOs and advocacy groups, i.e., charities, associations; business and food industry, i.e., pesticide manufacturer associations; and practitioners' associations, i.e., farming and beekeeping associations)



Figure 5: Interviews methodology (see Appendix C – Interviews and Workshops for details).

The expert candidates were selected to represent key scientific fields:

- Specific pollinator traits, behaviours and pathogens, genomics etc.
- Pesticides, chemicals, PPPs, neonicotinoids
- Ecotoxicology
- Entomology
- Ecosystem services, species interactions, landscape ecology, aquatic systems.
- ERA, emerging technologies, and risk assessment.

The main objectives of the expert interviews were:

- 1. Gain insights into scientific methodologies and knowledge of toxicity, pollinator traits, and ecosystem services to identify potential advancement opportunities.
- 2. Identify collaboration and communication pathways between researchers and research fields related to ERA, helping to determine collaborative opportunities and collective resources that can facilitate harmonisation e.g., open databases.
- 3. Identify challenges linked to knowledge gaps and compatibility between scientific developments and ERA procedures.

The stakeholder candidates were selected to represent and gain insights from key sectors involved in and/or with an interest in ERA for insect pollinators at European level (see Appendix C for the list of organisations).

- European Authorities/Institutions (e.g., Directorate-Generals)
- Industry (associated with pesticides or agriculture).
- Environmental NGOs & Advocacy groups (associated with pollinators).
- Practitioner Associations (associated with pollinators or agriculture).

The main objectives of the stakeholder interviews were:

- 1. Gaining opinions and perspectives on advancement opportunities identified in the Prioritised Working Areas (PWAs) (detailed in Section 4.4).
 - a. Environmental advancements such as additional focal species, context considerations and multiple compound assessment.
 - b. Procedural methodologies to interlink pre-assessment to post-authorisation and increase compatibility between assessment sectors, such as modelling tools and monitoring schemes that provide feedback data.
- 2. Establish potential opportunities and challenges for realising advancement opportunities from the perspective of the represented sectoral viewpoints.
 - a. Gain understanding of the diverse stakeholder objectives and goals for ERA developments.

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3.1.3 Workshops

Three online IPol-ERA workshops were held between 31st of May and 2nd of June. Each workshop followed the same format and was conducted in English. This series of workshops provided flexibility for the invited actors to attend a date convenient for them. In addition, it was anticipated that only a small number of participants could attend per workshop, better suiting the online format. Twenty-four participants registered, and a total of twenty-two actors attended across the three workshops.

Stakeholders were selected from organisations representing five key sectoral interests, primarily at European level:

- Authorities/institutions (e.g., EU Institutions, other EU agencies);
- NGOs and advocacy groups (e.g., environmental/wildlife charities, associations);
- Business and food industry (e.g., pesticide manufacturers' associations);
- Practitioners' associations (e.g., farming and beekeeping associations); and
- Academia (e.g., universities/research institutions).

The main objectives of the workshops were:

- 1. Share IPol-ERA vision for advancing ERA for insect pollinators in relation to three focal ERA development areas (detailed in Appendix C). These being:
 - a. Inclusion of additional focal species⁴
 - b. Consideration of context dependencies.
 - c. Advancement of the ERA Framework.
- 2. Gaining shared understandings, discuss challenges and identify collaboration opportunities to address and develop methodologies within the current ERA framework that could facilitate, in the long-run, the transition towards a systems-based ERA.

3.2 Identifying areas requiring further development, challenges, and opportunities

Initial insights regarding areas requiring further development, along with challenges and opportunities, were obtained by analysing desk research data collated in the IPol-ERA database (Appendix A - IPol-ERA_database_EFSA_23-06-21) and 'heatmaps' produced as part of this analysis. Heatmaps provided visualisation of the concentrations of activities in the IPol-ERA database, linked to IDFs within each of the four IDAs, as well as the key pollinator groups (honey bees, wild bees, butterflies, hover flies, moths, other insect pollinators). Higher colour intensity of the heatmap indicates a higher number of activities within each IDF and pollinator group. The database was prepared for analysis using R studio with the packages TidyR and dplyr. Database columns of interest (IDFs, main responsible organisation, partners, and pollinator groups) were split into separate columns for each value in a cell, e.g., partner cell containing five partners was separated into four rows containing each partner. The resulting tables were analysed using the PivotTable function in MS Excel to generate tables. Subsequently, heatmaps were generated using R studio with the packages reshape and ggplot2.

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⁴ Within interviews, 'focal species' was left open for interviewees to interpret and define within context of considering insect pollinator species selected for use within ERA.



3.3 Assessing collaboration opportunities, possible partners, and prioritising working areas

Identification and analysis of collaboration opportunities that could tackle future projects aiming to advance on ERA methodologies was done through a structured network analysis.

Through desk research and entries in the IPol-ERA database collaborations were identified within each of the four IDAs by linking organisations by their involvement in collaborative activities. These collaborations formed the basis for a network analysis of each of the six RADAs (Table 2). Only two activity categories 'Programmes, partnerships, initiatives' and 'research projects' (see Section 3.1.1) were selected for network analyses to connect organisations. These two activity categories were selected as network links since they were considered indicative of genuine collaborations/affiliations between organisations, rather than the other activity categories used in the database (i.e., 'scientific articles', 'documents' and 'other'). An additional activity category, named 'tools' was created in the database to link organisations. The 'tools' category served to classify whether identified activities involved potentially useful tools for risk assessment. This activity category was included for the network analysis as a key activity for both RADA 6 and IDA 4, which both concern the development of a systems-based ERA approach.



Figure 6: Visualisation of modular structures of collaboration networks, depicting the links (connecting line) between organisations (small circles) within and between 'modules' that represent collaborative communities of organisations (shaded large circles). Organisations (small circles) highlighted with red circles are hub organisations.

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Network analysis was implemented for each RADA to identify modular structures, i.e., to test if collaboration networks were compartmentalised into distinct sub-groups (modules) of organisations exhibiting a stronger collaboration among each other than with organisations in other modules (Figure 6). This analysis aimed to identify potential hub organisations, which have (relatively) many links and connectors to organisations within a module, relative to organisations having many links across different modules. Non-random modular structures of the RADA networks were documented, and key functional roles of organisations (nodes) were identified using a statistical approach, functional cartography of complex networks (Guimerà and Amaral, 2005; Guimerà and Nunes Amaral, 2005). See Appendix B for further details.

Table 2: Links between the Risk Assessment Development Areas (RADAs), as described in the (EFSA et al., 2022b) to the four IDAs (Table 1), and activity categories used for network analyses done separately for each RADA.

Risk Assessment Development Area (RADA)	IDAs	Activity categories
1. Engaging towards a joint IPol-ERA partnership	1, 2, 3, 4	Programs, partnerships, initiatives
2. Assessing ecological consequences of chemical effects on insect pollinators / pending NTA	1, 3	
3. Advancing hazard and exposure characterisation	1, 2	Research projects; Programs, partnerships, initiatives
4. Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators	1, 2, 3, 4	
5. Developing landscape scale population level based on Environmental Risk Assessment tools that account for environmental stressors	1, 3	
6. Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context	4 + Tools	

3.4 Identifying communication opportunities

The key actors for communication were selected from the list of organisations identified through network and database analysis. Based on expert judgment, organisations were classified as having high (marked as 1), medium (marked as 2), and low (marked as 3) priority for communication and engagement. This prioritisation also considered the geographical reference of the organisations, with European organisations considered to have a higher priority. Several identified priority actors have been involved in the development of the roadmap, either through

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interviews or participation in the workshops. These activities provided the first opportunity to disseminate and discuss proposed concepts and methodologies to advance ERA for insect pollinators amongst targeted actors (see Section 4.4). Further communication/dissemination activities e.g., international congresses and actions related to insect pollinators and ecotoxicology have been identified based on expert-knowledge (see Section 3.5).

4 Results

4.1 Mapping relevant activities and organisations

4.1.1 IPol-ERA database of activities and organisations

The IPol-ERA database contains a total of 383 unique activities, with 931 organisations involved. The number of activities distributed across the four IDAs and five categories is provided in <u>Table 3</u>.

The majority (259/68%) of the activities were classified as either 'scientific articles' or 'documents' and 103 activities (27%) were classified as 'research projects' and 'programs, partnerships, and initiatives', with most projects having finished (past) prior to 2022.

Among the 931 identified organisations, 313 (33.6%) are academic and 150 are National authorities (16.1%) (Figure 7).

Table 3: Number of activities by activity category in the database identified for each of the four IPoI-ERA Development Areas (IDAs). The total number of activities given in bold is unique for each activity category (i.e., activities were only assigned to a single activity category). However, activities can be related to multiple IDAs and hence counted within each IDA with totals given in brackets.

ACTIVITY CATEGORY	IDA 1. Understanding pollinator external exposure	IDA 2. Understanding pollinator intrinsic sensitivity	IDA 3. Understanding pollinator population resilience	IDA 4. Evolution of ERA framework	Total
Scientific articles	43	80	35	58	199 (216)
Documents	8	17	15	41	60 (81)
Research projects	24	20	34	38	71 (116)
Programs, partnerships	6	1	10	23	32 (40)
Other	4	1	1	16	21

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Figure 7: Number of organisations classified in the 10 organisations categories. AC: Academia; NA: National authorities; NGO: Non-governmental organisation; NAR: Non-academic research centre; Ind: Industry; FBA: Farming/Beekeeping association; EUA: European authorities; RA: Regional authorities; IG: Intergovernmental.

4.2 Identification of areas requiring further development, challenges and opportunities

The areas requiring further development, challenges and opportunities can be visualised in the heatmaps (Figures 8 & 9). These show the activity intensity within each IDF, as well as by pollinator group. A relatively high number of activities are attributed to most IDFs for both honey bees and wild bees. However, it should be kept in mind that the wild bee group covers many more species than the honey bee group. The other insect pollinator groups, such as hoverflies, show a limited activity intensity compared to bees. However, population resilience in butterflies is an exception to this pattern.

Colour intensity for 'scientific articles' (Figure 8) associated with IDA 2 ('understanding pollinator intrinsic sensitivity') is relatively strong, suggesting areas of established scientific knowledge, particularly related to honey bees as well as wild bees. However, the many 'scientific articles' related to toxicodynamics/toxicogenomics/toxicokinetics may reflect a broader body of work or knowledge related to these IDFs that may go beyond insect pollinators.

There were very few activities related to the socio-economic aspects of ERA for insect pollinators within IDA 4 ('facilitating a systems-based ERA'). It seems that scientific knowledge and activities are scarce when considering the socio-economic implications related to ERA for insect pollinators. Additionally, our data show that there may be a knowledge deficit in the IDFs 'insect pollinator traits', 'internal recovery', and 'external recovery' (IDA 3), as well as pesticide use, related to understanding insect pollinator external exposure (IDA 1; Figure 8 & 9).

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IDA 4 ('Evolution of ERA framework') was well-represented in the heatmaps (Figures 8 & 9). The volume of activities mapped within this IDA is likely a result of its broadness and our searches encompassing a variety of elements related to developing ERA methods and approaches. It would seem there is an encouraging degree of interest and scientific momentum and impetus to advance the current ERA of chemicals for insect pollinators and to move towards systems-based approaches. Several areas were identified and considered necessary to advance concerning the four-problem formulation IDAs defined in Section 3. These are described below and, as part of the project's iterative development process for the roadmap, were later integrated into the Priority Working Areas (PWAs) described in Section 5.4, as well as the identified challenges/opportunities for implementation described in Section 6.4.1.

For IDA 1 ('external exposure'), identifying and selecting a variety of focal species representing vulnerability across pollinator taxa is regarded as a fundamental building block, linking all IDAs. Developing and advancing toxicological approaches for new focal species (e.g., TK/TD, QSARs, OMIC tools, etc.) is important to better understand their intrinsic sensitivities (IDA 2). Also, promoting an understanding of the drivers and quantifying reproduction, mortality, and movement is crucial to assessing population resilience (IDA 3) of new focal species. Finally, the inclusion and integration of new focal species, tests, and models, etc. will require concerted effort and support from numerous organisations as part of a cohesive implementation of the roadmap and adoption of systems-based ERA approaches for insect pollinators (IDA 4). There are several key challenges to advance ERA for insect pollinators: the extent (level/detail) of scientific knowledge/data in relation to new focal species, difficulties in gaining required knowledge/data (e.g., methods and resources lacking), as well as effectively managing/reducing the dimensionality of assessments (e.g., no. species x no. PPP compounds x no. contexts) to ensure the development of ERA for insect pollinators.

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IPol-ERA Roadmap Report



4. Socio-economic values -	0	1	0	0	2	0	1	
4. Harmonisation -	0	6	0	0	5	0	2	
4. Consolidation -	1	7	2	1	8	1	7	
4. Concepts for systems-based ERA -	9	18	8	8	18	8	13	
4. Centralisation -	0	1	0	0	0	0	1	
3. Population resilience -	3	4	2	2	0	2	7	
3. Pollinator traits -	0	3	0	0	0	0	8	
3. Internal recovery -	0	2	0	0	0	0	7	
3. External recovery -	0	0	0	0	0	0	0	Activities
o 3. Environmental context (population sustainability) -	3	5	3	3	1	3	7	Activities
3. Ecosystem function - 2. Toxicokinetics - 2. Toxicogenomics - 2. Toxicodynamics - 2. Toxicodynamics -	5	7	5	5	1	5	9	- 15
2. Toxicokinetics -	0	7	0	0	1	0	4	
2. Toxicogenomics -	0	17	1	0	5	1	8	10
g 2. Toxicodynamics -	0	12	0	0	2	0	7	5
2. Pollinator traits -	1	16	0	0	1	0	11	
2. Intrinsic sensitivity of single PPPs -	0	12	0	0	1	2	15	0
2. Intrinsic sensitivity of multiple stressors -	0	11	0	0	1	0	6	1
2. Intrinsic sensitivity of multiple PPPs -	0	15	0	0	0	0	11	
1. Pollinator traits -	4	7	2	2	0	1	10	
1. Pollinator activity -	3	5	2	2	0	2	5	
1. Pesticide use -	0	3	0	0	2	0	0	
1. Pesticide fate dynamics -	3	7	1	1	2	1	5	
1. External exposure -	0	14	0	0	1	0	6	
1. Environmental context (exposure) -	3	9	0	0	2	0	5	
	butterflies	honey bees	hoverflies	moths	N.A.	other pollinator group	s wild bees	

Figure 8: Heatmap of activities categorised as 'scientific articles', within the IDFs grouped by the respective pollinator group. N.A. indicates 'scientific articles' not focusing specifically on insect pollinators but addressing pertinent aspects of ERA associated to IDFs.

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4. Socio-economic values -	8	11	7	7	7	11	
4. Harmonisation -	6	12	5	5	3	13	
4. Consolidation -	2	9	2	2	1	6	
4. Concepts for systems-based ERA -	2	3	1	1	1	3	
4. Centralisation -	5	5	4	4	3	4	
3. Population resilience -	16	6	8	9	3	19	
3. Pollinator traits -	1	3	2	1	1	5	
3. Internal recovery -	0	3	0	0	0	3	
3. External recovery -	0	0	0	0	0	0	Activities
 Barrier State (1998) 3. Environmental context (population sustainability) - 	4	9	3	2	1	14	Activities
3. Environmental context (population sustainability) - 3. Ecosystem function - 2. Toxicokinetics - 2. Toxicogenomics -	4	6	3	3	2	12	15
2. Toxicokinetics -	0	2	1	1	1	4	10
	0	2	1	1	1	5	10
2. Toxicodynamics -	0	3	1	1	1	6	5
0 2. Pollinator traits -	0	3	0	0	0	3	·
2. Intrinsic sensitivity of single PPPs -	0	1	1	1	1	2	0
 Intrinsic sensitivity of multiple stressors - 	1	5	1	1	0	5	
2. Intrinsic sensitivity of multiple PPPs -	0	8	1	1	1	6	
1. Pollinator traits -	1	5	0	1	0	4	
1. Pollinator activity -	4	8	3	4	2	9	
1. Pesticide use -	1	4	1	1	1	5	
1. Pesticide fate dynamics -	1	4	2	2	2	6	
1. External exposure -	0	11	1	1	1	7	
1. Environmental context (exposure) -	2	11	1	2	1	9	
	butterflies	honey bees	hoverflies	moths	other pollinator groups	wild bees	

Figure 9: Heatmap of activities categorised as 'research projects' and 'programs, partnerships, initiatives', within the IDFs grouped by the respective pollinator group.

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4.3 Assessing collaboration opportunities and possible partners

Collaboration opportunities were assessed by network analysis on each RADA (objective 5). An overview of the statistics of the analysed networks is presented in <u>Table 4</u>. Most organisations were linked by a single activity, with only 2.2%-5.7% of organisations (nodes) in each network being linked by multiple activities. Notably, the network for RADA 1, which is relatively large with 10707 links, does not contain any identified hub or connector organisation. The absence of connectors for the network of RADA 1 is likely because this network only includes the 'programs partnerships and initiatives' category, which comprises only 33 activities with many partners. In contrast, RADAs 2-6 networks include the 'research project' category, which has 71 activities.

Table 4: Summary data of the networks analysed for each RADA separately. "Nodes" represent the number of organisations involved in the network, "links" is the total number of links between organisations, links with n>1 are specific links between organisations, which are present more than once (i.e., are linked by more than one activity), % indicates the percentage of links with n>1 out of the total links, M modularity calculated with NetCarto. *Denotes statistically significant modularity (M), based on 100 randomisations (p(M) < 0.05). Hubs are organisations with a high degree of connections to other organisations within a given module, while connector organisations connect different modules within the network.

RADA number	Nodes	Links	Links with n>1	Modularity M	Modules	Hubs	Connectors
1	297	10707	235 (2.2%)	0.315*	6	0	0
2 and 5	344	5946	340 (5.7%)	0.551*	8	2	18
3	230	4232	151 (3.6%)	0.456*	7	0	6
4	564	15737	719 (4.6%)	0.465*	9	5	27
6	479	14484	594 (4.1%)	0.44*	9	5	5

No hubs were found in RADA 3, two hubs (INRAE, UMONS) were detected in RADAs 2 and 5, and five hubs (INRAE, UMONS, UFZ, UA and WUR) were found in RADA 4. A variable number of connectors were found in the different RADA networks, ranging from no connectors up to 27 (Table 5).

In addition to identifying hubs and connectors, we also ranked organisations within each network based on their total number of links. The top five organisations for each network are shown in Table 5, with the corresponding number of links. A link would be counted as a collaboration with another organisation per activity (e.g., if an organisation were part of an activity comprising 20 partners, the organisation would count 19 links from that activity).

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Table 5: Organisations with key structural roles for each of the RADA networks. Numbers in brackets represent the number of connections of the organisation. Hubs are organisations which are highly linked within their own modules, while connectors have relatively many links across modules. For organizations with many links, the top five organizations for each network are listed.

		RADA 1	RADA 2 & RADA 5	RADA 3	RADA 4	RADA 6
	Hubs	-	INRAE, UMONS	-	INRAE, UMONS, UFZ, UAAR, WUR	UFZ, Pensoft, INRAE, WUR, UAAR
	Тор 5	LIST (174)	INRAE, SLU	UAAR (175)	INRAE (418)	INRAE (366)
	Organisations with high link density (connections)	UFZ (162)	(213) UFZ (205) UAAR (190) UBERN (174) UREAD (171)	INRAE (165)	UFZ (399)	UFZ (362)
		SLU (161)		SLU (162)	UAAR (359)	UAAR (359)
		UTARTU (157)		UBERN (146)	SLU (344)	WUR (305)
				UFZ, UREAD	WUR (305)	SLU (303)
		FEA-FI, SWEPA, UINNK, ULUND (156)		(144)		
	Connectors	-	AgroDijon, HAO- DEMETER, MLU, NBC, SGGW, SLU, UASVM, UBERN, UBGDY, UCDAVIS, UCOI, UFZ, UCOI, UFZ, UGENT, UJAG, UKCEH, ULUND, UMIN, UAAR	INRAE, SLU, UBERN, UCDU, UAAR, WUR	Agroscope, BCE, BEEP-NL, BSOUR, CER- HU, COLOSS, CRA-W, FBA- SML, FLI, ITSAP, JRC, KUDK, MLU, NINA, NTU, Pensoft, RBINS, SCIPROM, SLU, UASVM, UBERN, UBOR, UJAG, UKCEH, ULB, ULUND, UVAL	MLU, SLU, UBERN, JRC, KUDK

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Acronyms: AgroDijon (AgroSup Dijon, Higher National Institute of Agricultural Sciences, Food and Environment), BCE (Butterfly Conservation Europe), BEEP-NL (BEEP foundation), BSOUR (BeeSources -Beekeeping consultancy), CER-HU (Centre for Ecological Research (Hungary)), COLOSS (Prevention of Honey bee Colony Losses), CRA-W (Walloon Agricultural Research Centre), FBA-SML (Finnish Beekeepers Association SML ry), FEA-FI (Finland's Environmental Administration), FLI (Friedrich Loeffler Institute (Germany)), HAO-DEMETER (Hellenic Agriculture Organisation), INRAE (French National Institute of Agronomic Research)), ITSAP (French Technical and Scientific Institute of Beekeeping and Pollination (L'Institut Technique et Scientifique de l'Apiculture et de la Pollinisation), JRC (Joint Research Centre), KUDK (Natural History Museum of Denmark), LIST (Luxembourg Institute of Science and Technology), MLU (Martin Luther University Halle-Wittenberg), NBC (Naturalis Biodiversity Center), NINA (Norwegian Institute for Nature Research), NTU (Nottingham Trent University), Pensoft (Pensoft - Science Publisher & Technology Provider), RBINS (Royal Belgian Institute of Natural Sciences), SCIPROM (Sciprom - science management & communication), SGGW (Warsaw University of Life Sciences), SLU (Swedish University of Agricultural Sciences), SWEPA (Swedish Environmental Protection Agency), UAAR (Aarhus University), UASVM (University of Agricultural Sciences and Veterinary Medicine of Cluj-Napoca (Universitatea de Științe Agricole și Medicină Veterinară din Cluj-Napoca)), UBERN (University of Bern), UBGDY (University of Burgundy), UBOR (University of Bordeaux), UCDAVIS (University of California Davis), UCDU (University College Dublin), UCOI (University of Coimbra), UFZ (Helmholtz Centre for Environmental Research), UGENT (Ghent University), UINNK (University of Innsbruck), UJAG (Jagiellonian University), UKCEH (UK Centre for Ecology and Hydrology), ULB (Free University of Brussels), ULUND (Lund University), UVAL (University of Valencia), WUR (Wageningen University & Research).

In the network analysis for RADA 1 (encompassing IDAs 1, 2, 3, 4 see <u>Table 2</u>), despite the absence of hubs and connectors, eight organisations link to many other organisations. The 'programs, partnerships, initiatives' were found to be linked through two non-academic research centres, namely Luxembourg Institute of Science and Technology (LIST) and Helmholtz Centre for Environmental Research (UFZ), and four universities, namely the Swedish University of Agricultural Sciences (SLU), University of Tartu (UTARTU), University of Innsbruck (UINNK), and Lund University (ULUND). Additionally, two national authorities from Finland and Sweden, Finland's Environmental Administration (FEA-FI) and Swedish Environmental Protection Agency (SWEPA), exhibited a high link density.

In general, the 'programs, partnerships, initiatives' are primarily linked through organisations located in Central and Northern Europe. Notably, some of these organisations, such as the Helmholtz Centre for Environmental Research (UFZ) and the Swedish University of Agricultural Sciences (SLU), serve as hubs or highly linked organisations in other RADAs (2-6). This implies that these organisations are a promising starting point for establishing a network of partnerships in the future, aimed at various objectives such as sharing data and expanding expert knowledge.

As per the categorisation outlined in <u>Table 2</u>, both RADA 2 and RADA 5 cover the same IDAs, specifically, 'understanding pollinator external exposure' (IDA 1) and 'understanding pollinator population resilience' (IDA 3). The focal areas investigated under these RADAs are broadly related to the ecological implications of using pesticides and their effects on insect pollinators, such as their impact on populations, ecosystems, and ecosystem services. Moreover, there is a focus on developing tools capable of evaluating the impact of pesticides on insect pollinators in a landscape context. The network analysis revealed that the collaboration networks of RADA 2 and RADA 5 consisted of a large module (96 organisations) in addition to seven smaller ones (with 4 to 66 organisations per module). Two French institutions, the French National Institute of Agronomic Research (INRAE, non-academic research centre), and the University of Mons

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(UMONS, academia), were hubs of the large module, and thus may be considered as key organisations involved in these topics and potentially capable of advancing them. Additionally, four major universities with 171 to 213 links, namely, Swedish University of Agricultural Sciences (SLU), Aarhus University (UAAR), University of Bern (UBERN), University of Reading (UREAD), and one non-academic research centre, the Helmholtz Centre for Environmental Research (UFZ), were identified as having many activities related to these topics. All these organisations, except for UREAD, were classified as connectors, linking the large module to other modules.

RADA 3 covers two IDAs, namely, 'Understanding pollinator external exposure' (IDA 1) and 'Understanding pollinator intrinsic sensitivity' (IDA 2). This area focuses on advancing the characterisation of exposure and hazard by examining the type of exposure and the resulting effects. The network analysis did not identify any hubs for RADA 3, suggesting that the relevant activities are not centralised and may be spread across various institutions. However, we did identify six connectors for this RADA, which includes five academic institutions, namely, Aarhus University (UAAR), the Swedish University of Agricultural Sciences (SLU), the University of Bern (UBERN), University College Dublin (UCDU), and Wageningen University & Research (WUR), as well as a non-academic research centre, the French National Institute of Agronomic Research (INRAE).

The analysis of RADA 4, which focuses on advancing the risk assessment of combined exposure to multiple chemicals in insect pollinators while addressing all IDAs, revealed a certain degree of overlap between organisations identified as hubs or connectors in the analyses of RADAs 2, 3, and 5. We identified a total of five organisations serving as hubs in this RADA, including the French National Institute of Agronomic Research (INRAE), the University of Mons (UMONS), the Helmholtz Centre for Environmental Research (UFZ), Aarhus University (UAAR), and Wageningen University & Research (WUR). Additionally, we identified 27 connectors, of which 17 were research institutions, four industry, two national authorities, one 'farming/beekeeping association', one NGO, and two 'other'.

The findings of the analysis for RADAs 2, 3, 4, and 5 suggest that the identified hub and connector organisations are not specific to a single RADA but rather represent centres of national and international collaboration (e.g., France, Sweden). Given that most of these institutions are engaged in different RADAs, they have the potential to foster collaboration and understanding across various areas, which is essential for advancing in the current risk assessment for insect pollinators aiming at a transition towards a systems-based ERA. This is also reflected in the analysis of RADA 6, which focuses on the development and implementation of a systems-based approach, and its promotion in a regulatory context. The identified hub and connector organisations in RADA 6 overlap with those previously listed, except for Pensoft, (Science Publisher & Technology Provider), which is the only entity representing the industry category.

In summary, academic institutions and non-academic research centres are extensively represented across the RADAs. No organisations from the intergovernmental, European, or regional levels were identified as key organisations for RADAs 1, 2, 3, 5 and 6, although two national authorities (Finland's Environmental Administration-FEA-FI and Swedish Environmental Protection Agency-SWEPA) were organisations with high link density connectors in RADA 1. Furthermore, industry engaged in the production of PPPs are missing among structural key organisations in the RADA collaboration networks. Finally, beekeeping or agricultural



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associations and NGOs are also not represented as hubs and rarely as connectors. This suggests a significant gap in collaboration and communication between scientific and non-scientific organisations or an artefact of the methodology followed, given that initiatives bringing together stakeholders are comparatively underrepresented in our database. To achieve a more comprehensive understanding of the IDAs facing the transition to a systems-based ERA, it is crucial to foster greater engagement and coordination among all relevant stakeholder groups. The network analysis results reveal a set of key organisations that emerge as hubs with a high number of links across the RADA networks. Among these organisations, Helmholtz Centre for Environmental Research (UFZ), Swedish University of Agricultural Sciences (SLU), and French National Institute of Agronomic Research (INRAE) are identified as being key organisations across four or more networks (Table 6). It should be noted that this only represents involvement without the level of involvement within each activity. The number of links (collaborations) highly depends on the involvement in large multi-partner activities. Table 6 presents some of the largest activities (by number of partners involved) for each of the three aforementioned organisations. The organisations' involvement in those large activities is likely a contributing factor to their importance in the results of the analysis. Moreover, this observation highlights their extensive experience working on large projects that address multiple IDAs, which positions them well for future collaboration opportunities.

Potential stakeholder groups are likely to provide relevant contributions to advancing ERA and assist the transition into a systems-based methodology for insect pollinators, as outlined in <u>Section 6.3.</u>

INRAE	SLU	UFZ
ALARM	ALARM	BioAgora
PARC	E-BMS	E-BMS
PoshBee	Ecostack	PARC
PURE	PARC	PoshBee
	PoshBee	SAFEGUARD
	SAFEGUARD	STEP

Table 6: Key organisation and their activities. Activities listed represent the highest number of partners for the respective organisation.

ALARM (Assessing large-scale environmental risks with tested methods);

BioAgora (Bio Knowledge Agora: Developing the Science Service for European Research and Biodiversity Policymaking);

E-BMS (European Butterfly Monitoring Scheme,

Ecostack (Stacking of ecosystem services: mechanisms and interactions for optimal crop protection, pollination enhancement, and productivity);

PARC (European Partnership for the Assessment of Risks from Chemicals);

PoshBee (Pan-european assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);

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PURE (Pesticide Use-and-risk Reduction in European farming systems with Integrated Pest Management); SAFEGUARD (Safeguarding European wild pollinators); **STEP** (Status and Trends of European pollinators).

4.4 Priority working areas

Through desk research (Sections 3.1, 3.2), a lack of information/knowledge was identified regarding several aspects of each development area stated in the problem formulation (Section 2). This analysis formed the basis for establishing an initial set of working areas for advancing ERA for insect pollinators. Subsequently, extending on the initial 4 IPol-ERA development areas (IDS), a number of priority working areas (PWAs) considered pivotal for further development were identified from heatmaps (Figures 8 and 9), as outlined in Table 7 (PWAs 1-6). An additional 4 priority working areas were identified through expert evaluation (PWAs 7-10, Table 7), complementing PWAs 1-6 and encompassing aspects fundamental to all other areas.

These priority working areas reflect *initial proposals* for 'current' and 'future' developments for advancing ERA methodologies for insect pollinators. These developments are envisaged as steppingstones for incorporating systems-based approaches. Current developments, considered attainable in the short-term (3-5 years), focus on protecting insect pollinator communities already taking a 'systems-lens' approach, with Apis mellifera, Bombus spp., and Osmia spp. as model species. It integrates local context, geography, biota, agricultural systems, landscape structure, and weather using representative landscapes across Europe. The system should be up to date, accounting for changes in agriculture, land use, and climate to assess the long-term effects of current or prospective use. Additionally, the system should incorporate a realistic assessment of worst-case scenarios of single pesticide use. Future developments, representing likely longer-term advances (3-7 years) focus on extending the protection of vulnerable species across various pollinator taxa, i.e., an extended set of focal species. Furthermore, these developments extend the scope of interest to encompass the broader landscape context, spanning from local to national and European scales. They emphasise current assessments of agriculture, land use, and climate. However, they focus on the combined impacts of active ingredients and formulations in mixture combinations, reflecting real-world conditions and multiple exposure routes within organisms over time.

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Table 7: The priority working areas (PWAs) are divided into two development arenas regarding insect pollinators that are currently being considered under ERA revisions and future ERA where a wider group of insect pollinators is considered.

PWAs	Current ERA (3-5 years)	Future ERA (3-7 years)
1. Pollinator taxa & focal species	Focusing on bees only to determine the utility of <i>Apis mellifera</i> , <i>Bombus</i> sp., and <i>Osmia</i> sp. as starting points for choosing focal species, and identifying candidate species for other pollinator taxa	Evaluation of species chosen in light of ongoing method and tool developments, data availability, feedback from stakeholders and monitoring
2. Pollinator traits	Following the identification of focal species candidates, the development of knowledge on the general biological and ecological traits of insect pollinators, as well as in relation to pesticide exposure and impact should be started	Continued updating knowledge of the ecotoxicological and ecology and behaviour of the focal species to plug gaps and reduce uncertainty
3. Pesticide use	Comprehensive understanding of the use of pesticides in terms of target pest(s), crop(s), quantity, frequency, timing, location, and specific chemical composition and mixtures, across temporal and spatial scales to allow exposure prediction	Creation of semi- automatic/systematised data collection, collation, and integration of pesticide use information to ensure data is up-to- date and relevant
4. External exposure	Defining exposure scenarios by describing when, where and how bees are exposed to PPPs (e.g., orally, by contact with contaminated matrices) for <i>Osmia</i> and <i>Bombus</i> and relevance for other pollinator taxa	Generating and collecting data on exposure scenarios for insect pollinators other than bees
5. Intrinsic sensitivity	Focusing on knowledge for <i>Osmia</i> and <i>Bombus</i> , whilst developing protocols and techniques for non-bee pollinators and PPP mixtures	Using the methods developed to provide comprehensive data on intrinsic sensitivity to chemicals and mixtures for all insect pollinator candidate focal species.
6. External and internal recovery	Definition of protocols for testing population resilience (i.e., resistance and recovery), implementation for bee and butterfly species and relevance for other pollinator taxa	Implementation of population resilience protocols in support of PWA8 model development and validation
7. ERA context- specificity	Expansion of information on pesticide use to include other relevant environmental and management contexts (e.g., land use and landscape	Definition of data needs and formats as well as scenarios for ERA (full systems approach). Creation of semi- automatic/systematised data collection,

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	composition, climate, farming practices, etc.). Definition of data needs and scenarios for ERA (short-term)	collation, and integration of information to ensure data is up-to-date and relevant
8. Modelling	Further development and validation (through a combination of monitoring and lab to field methods) of bee and butterfly species models for ERA, linkage to scenarios and definition of baselines, measurement endpoints, and the interpretation of results	Development of models for new focal species, including free-flying insect pollinators, validation, and use. Definition of SPGs and related measurement endpoints for these species Continued testing and updating of bee models
9. Monitoring	Specification and integration of monitoring schemes, departing from the current grassland butterfly monitoring scheme and the suggested EU pollinator monitoring scheme, combined with pesticide residue monitoring ⁵ . Implementation in a network across EU representing the Southern, Central and Northern regulatory zones	Expansion of the monitoring scheme to include EU wide coverage and integration of the data in IPol-ERA.
10. ERA framework	Development of a functional ERA framework for bees, including landscape context and pesticide use, but focussing on single-substance ERA	Development of a full systems-based approach framework including feedbacks between monitoring and modelling, and the full range of focal species in a multi-stressor context

4.5 Identifying communication opportunities

From desk research, we identified a list of organisations involved in the different RADAs with the potential to contribute to IPoI-ERA (Section 2.5). The full list of organisations (n=931) is provided in Appendix A Table A5, and it details the organisation type, level, part of the world where it is active and their websites. We found organisations representing diverse sectoral interests and governance levels operating in different parts of the world, but primarily European.

The full list of organisations can be taken as the potential audience for communication and engagement. However, an initial prioritisation of organisations is used to indicate/suggest the most relevant organisations to engage, based on expert evaluation of their competence to contribute to advancing ERA for insect pollinators (Appendix A Table A5).

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⁵ <u>https://food.ec.europa.eu/plants/pesticides/sustainable-use-pesticides_en</u>



In addition, several international events have been identified that could provide visibility, showcasing advances in ERA for insect pollinators (<u>Table 8</u>).

Table 8: International events that could be used to disseminate and provide visibility for the proposed developments to advance ERA for insect pollinators.

Event	Date	Frequency	Торіс	Link
Apimondia congress	September	Every two years	World beekeeping congress covering several topics related to bees and insect pollinators	https://www.apimondia.org
SETAC Meetings	Varies	Annually	Ecotoxicology	https://setac.org
European Insect society congress	September	Every four years	Entomology	
World Bee Day	20 May	Annually	Conservation of bees, insect pollinators and beekeeping	<u>https://fao.org/world-bee-day/</u>
Eurbee	Early September	Every two years	European apidology conference	
EU Pollinators Week	Varies	Varies	Awareness raising about the actions done for pollinator protection	
International Congress of Entomology	Varies	Every four years	Entomology	https://www.icecouncil.org/
International Commission on Plant Pollinator	Varies	Varies	Promotes & coordinates research on relationships between	https://www.icppr.com/

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Relations (ICPPR)			plants and pollinators.	
Territorial Entomological societies (America, Australia, Brazil, Russia, etc.)	Varies	Varies	Entomology	Access to them via the International Congress of Entomology Council <u>https://www.icecouncil.org/societi</u> es The Ento meetings: <u>https://www.royensoc.co.uk/event/ento</u>
etc.)				https://www.royensoc.co.uk/event/ento 23/

4.6 Actor insights

This section summarises the insights gained from interviewees and participant inputs at the workshops, which explored views on the ERA of PPPs for insect pollinators, potential development areas of ERA methodologies and identification of potential challenges and opportunities. These are the opinions and perspectives expressed by the people interviewed and those who participated in workshops, and not those of the IPol-ERA project team. Their views were based on their experiences of sector-specific involvement with ERA, but they also reflect 'perceived' issues and challenges with the current ERA of chemical PPPs, as well as possible future developments. The prominence of many of these existing perceptions (both positive and negative) are important for consideration in future engagement and communication activities. The perspectives expressed by interviewees and workshop participants (henceforth referred to as 'actors'), serve as a foundation for their understanding of current and future challenges and provide a baseline for identifying opportunities to address them. Insights gained from both interviews and workshops were analysed and reported below in relation to the PWAs (Section 4.4), used to outline initial proposals for the IPol-ERA roadmap for advancing ERA for insect pollinators.

4.6.1 Additional focal species

The insights and perspectives outlined below relate to PWAs, 1 Pollinator taxa & focal species, 2 Pollinator traits, 4 External exposure, 5 Intrinsic sensitivity and 6 External & internal recovery.

The inclusion of additional focal species for ERA of chemical PPPs was considered beneficial by almost all interviewees whilst many, particularly experts, considered it a necessity. However, many actors also remarked upon the potential challenges of including additional focal species. Foremost were the challenges of knowledge gaps and lack of data and/or data accessibility e.g., species ecology/distribution for non-bee pollinators. Determining the criteria for selecting additional focal species and ensuring they are representative of taxonomic groups was another challenge, associated with generating sufficient knowledge on proposed species. Many actors emphasised that selection should be based on the vulnerability concept, whilst others expressed that selection of the focal species should reflect species mainly associated with agricultural areas, in accordance with their variability across agricultural landscapes in Europe. Actors also viewed it as necessary to develop standardized test protocols that are practical, adaptable, and

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representative of the real world. In addition, some actors expressed a need for streamlined mechanisms for faster development of testing protocols when integrating additional focal species. Moreover, many actors perceived it necessary to expand the temporal scales of test protocols to include assessment of exposure impacts over extended time periods.

These perspectives are particularly relevant for the PWAs, and projects devoted to generating knowledge on species traits, intrinsic sensitivity, population resilience and developing data frameworks and guidance documents. The divergent views, e.g., determining selection criteria for focal species, will need to be addressed when engaging diverse actors of different sectoral interests, in the co-development and implementation of the roadmap (Section 5.2).

4.6.2 Landscape-level assessments

Of relevance for PWAs 3 Pesticide Use, 4 External exposure, 6 External and internal recovery, 7 ERA context specificity, and 8 Modelling, where actors' perspectives on the contexts of PPP usage were explored in relation to ERA advances moving towards landscape-scale assessments.

Most actors stated that risk assessments should be at a landscape-level, many of whom further remarked on the benefits of incorporating modelling/simulation tools in ERA. Many actors viewed model developments as necessary to achieve a more realistic assessment of landscape- and population level effects of pesticides, as well as a tool to assess the effect of multiple stressors and impact of multiple exposures, also over extended time periods.

How risk varies across the landscape and how the assessment of risks can be targeted to tailor risk mitigation were considered as key components of landscape-level assessments. Perceived benefits of landscape-scale assessments aided by simulation tools were 1) the potential ability to assess the effects of exposure to multiple pesticides (e.g., tank mixes and sprays series) and 2) to identify potential targeted mitigation efforts for specific landscapes/areas and species. Despite these potential benefits many actors noted several challenges in moving to landscapescale assessments and how this might be achieved in practice. There were differing views on the potential to develop comprehensive landscape descriptions across Europe. Some actors deemed it a challenge but necessary while others saw it as unfeasible and too resource demanding in relation to the potential benefits. Simulation tools/models were universally expressed as a beneficial and practical tool for ERA, though not without implications. Main considerations expressed revolved around validating the accuracy of a model and providing sufficient guidance for end-users on using it as well as interpreting the model outputs. Recurring sentiments expressed were that models should be developed by independent scientists and would need to be complex enough to resemble real-world dynamics, yet practical and widely accepted for ERA usage. Additionally, some actors raised issues about the usage/resilience of large complex models and ensuring they are universally available, standardized, and interoperable, with several recommending taking modular approaches.

These actor insights are relevant for consideration when implementing several of the proposed projects (Section 5.2) related to model developments and usage guidance documents etc. Opinions and challenges perceived by actors provide valuable insights for strategic engagement of actors to ensure model developments are fit-for-purpose and widely accepted.

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4.6.3 Monitoring schemes

Several knowledge and data gaps were identified through desk research (Section 4.2) and are of relevance for PWAs 3 Pesticide Use, 4 External exposure, 6 External and internal recovery, and 9 Monitoring. During interviews and workshops, monitoring schemes were discussed as means to gain data and how these might link pre-assessment and post-authorisation procedures e.g., assessments of PPP exposure and longer-term pollinator population trends.

Multiple actors viewed the setting-up of an advanced monitoring scheme, not merely to account for the presence of species but also their health, as a necessary tool to advance the assessment of multiple stressors and pesticide use. However, many queried how monitoring schemes could account for the presence of species, as well as their health. Furthermore, many actors considered that linking centrally coordinated monitoring schemes for insect pollinators and PPP usage would benefit illuminating correlative connections between PPP use and impacts on pollinator populations. The monitoring and assessment of multiple compounds were viewed as necessary for better and fully understanding PPP impacts.

When considering potential links between post-authorisation and pre-assessment procedures, almost all actors viewed monitoring as a useful tool to validate and improve the predictions of the ERA process and assess the efficacy of risk mitigation measures (broadly discussed to encompass various definitions, while mostly discussed within the realm of the 1107/2009 policy). Furthermore, monitoring was pointed to as a tool to assess the efficacy of policy/regulation implementation and intended impacts, and thereby effectively connecting different regulatory silos. Additionally, many actors hypothesised the benefits of integrating monitoring data in a 'feedback loop' of communication, feeding into ERA methods/tools evaluation. Moreover, some actors expressed the importance of pollinator monitoring data informing the process of defining specific protection goals. Particularly, the advanced monitoring of the health status of different focal species could be utilised prior to adopting an ERA guidance document. Many actors saw a need for aligning monitoring data, and environmental contamination of matrices pollinators can be exposed to, where models could facilitate the interlinking of pre- and post-authorisation procedures.

4.6.4 Future ERA developments

A variety of opinions and perspectives were expressed about how ERA for insect pollinators could potentially evolve, and these views are pertinent in regard to developing systems-based approaches as part of a future ERA framework for insect pollinators (PWA 10).

Most actors stated that although there may be perceived increases in complexity for impact assessments when moving to a systems-based ERA, these should not hamper the speed of the decision-making processes. In addition, PPP application procedures should be adaptable to integrate novel scientific- and technical advances (e.g., use of "-omics" methods, use of drones for PPP application). Therefore, it was considered crucial by many actors to address potential gaps between scientific capabilities and regulatory capacity for effective risk assessment and mitigation of environmental concerns. Many actors noted a significant gap in collaboration and communication between scientific and regulatory developments could be enhanced by targeted bridging the gap between scientific and regulatory developments could be enhanced by targeted collaborative activities.

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Increased complexity of procedures hampering the speed of decision-taking processes, especially for placing new substances/products on the market, were a concern for several actors. However, many of these actors deemed the interlinking of regulatory regimes as well as the integration of models and use of monitoring feedback as an important and feasible mechanism to diminish these concerns.

The majority of actors expressed a need for an overarching risk assessment which considers all the different substances under different uses, and a need for bridge-building across different regulation sectors. Many acknowledged the existing efforts to increase the compatibility, i.e. One Health, but noted particular challenges of addressing divergent data requirements, nonharmonized procedures, and different acceptability criteria between different regulatory regimes, i.e., pesticides and biocides. All actors regarded the establishment of a stakeholder network as an important approach for collaboration on data generation ensuring synergies and harmonisation across sectors.

While many actors expressed a need for change, they emphasised that it should not diminish the complexity-level of current ERA procedures, considered necessary for robust assessments. Nor should it create additional work and resource requirements in the long term. 'Change' was expressed in terms of advancements, harmonisations and streamlining procedures to ensure effective assessments. Many actors recognised the need for investing resources in the short term, but prioritised resources and commitment to establishing stakeholder partnerships and networks for co-development. These collaborations were regarded as important for fostering knowledge exchanges to ensure usability/acceptability of new ERA methodologies and tools, accounting for the procedures specific to various sectoral frameworks.

The actors' perspectives detailed above are mainly concerned with policy and regulatory developments, however these perceptions are of significance for PWA 10 when considering a future ERA framework and projects designed to facilitate the development of systems-based methodologies and tools. These insights highlight prominent challenges, opinions, and perspectives that will need to be considered within several of the proposed projects (Section 5.2) but primarily addressed through ongoing engagement and communication (See Section 5.4). Opinions expressed by actors, although often rather critical, did indicate a high level of constructive engagement and willingness to collaborate in advancement activities as well as potential actor investment in co-creating and implementation activities.

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5 IPol-ERA roadmap for action

There is an established body of scientific knowledge of relevance for many aspects of ERA for insect pollinators, particularly for honey bees and the population resilience of some butterflies and wild bees. However, our analysis has highlighted that there are still considerable 'knowledge gaps', which are likely to hinder the advancement of ERA from extending to and protecting the breadth of insect pollinators found in Europe. Scientific and technological advances provide new opportunities to advance ERA methodologies for insect pollinators e.g., OMICs. These advances and the implementation of new methodologies and tools will need consideration to foster a progressive risk assessment system for insect pollinators. Engagement and collaboration will be important, fostering co-development and adaptation between key stakeholders/actors to ensure new developments and changes are fit for purpose and widely accepted. Several consultations/platforms already relate to the ERA of pesticides for bees (e.g., EU Bee Partnership). These could be extended/aligned, bringing together relevant stakeholders/actors in various collaborative endeavours to progress ERA for wild insect pollinators.

The foundations are there to pave the way to construct a progressive system for insect pollinators to ensure their future protection and the health of the environment and society. We have identified the following **four pillars** to foster the evolution of the current system. These pillars support the development and implementation of the roadmap to advance ERA for insect pollinators, encompassing systems-based approaches and methodologies:

- 1. **Coordination** to instigate and guide proposed projects (see Section 5.2), helping to steer and utilise advances in scientific knowledge, as well as the development of ERA methodologies and tools;
- 2. **Knowledge building** to fill identified gaps and pilot actions to combine the building blocks into an operational system;
- 3. **Engagement**: (1) engage with key stakeholders/actors to facilitate roadmap implementation, co-developing ERA methodologies and tools, as well as prioritise actions to take; (2) engage and inform experts from relevant disciplinary fields related to ERA, e.g., agronomy, farming, ecology, environmental protection;
- 4. Definition of the **roadmap framework** for implementation involving significant management (well-planned engagement, communication and leadership) to aid (1) definition and establishment of the building blocks of ERA; (2) definition and harmonisation of specific protection goals for insect pollinators (e.g., additional focal species); (3) Verification that new developments are fit-for-purpose, align with current regulatory regimes and gain wide acceptance by regulatory authorities and other key actors/stakeholders, e.g., industry.

Below, we present a strategy for advancing the current ERA for insect pollinators, initiating the transition to a systems-based ERA for chemical pesticides. This strategy includes several proposals for activities that can begin a transition to a more holistic approach, with fundamental building blocks in place by 2030.

• <u>Section 5.1</u> outlines considerations for leadership and coordination of the process and the context in which the roadmap is proposed.

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- <u>Section 5.2</u> details a strategy and a series of activities (project proposals) to build the necessary scientific knowledge base and incorporate technological/methodological advances.
- <u>Section 5.3</u> identifies participants (stakeholders/actors) important to engage in partnerships/collaborations to co-develop and foster ERA advances for insect pollinators, along with suggested engagement and communication plans.
- <u>Section 5.4</u> outlines the implementation process/timeline for the roadmap framework, as well as several potential challenges and opportunities for implementation.

5.1 Coordination and leadership

Advancing ERA methodologies and tools within the current regulatory regime ERA and transitioning towards a systems-based approach involves consideration of the broader regulatory environment governing the risk assessment of chemicals to ensure the continued protection and health of insect pollinator populations. Numerous actors from various administrative and nonadministrative sectors will need to collaborate to generate and share knowledge to advance ERA for insect pollinators spanning various governance levels (European, national, and regional). We have outlined several project proposals considered necessary to generate the scientific- and technical knowledge that embraces systems approaches to evolve ERA methodologies and tools (Section 5.2). These project proposals are not solely within EFSA's remit and/or restricted by EFSA's operational activities as the EC's science advisory body for risk assessment across the food chain. They encompass a wide variety of activities cutting across regulatory sectors that are intended to foster a broad array of ERA advancements for insect pollinators. These projects can be sponsored by EFSA or other funding programs (e.g., BiodivERsA, Horizon Europe, etc.). The roadmap relies on network strategy with multiple parallel activities and a carefully designed information flow. This process emphasises inclusive leadership, careful coordination, a stakeholder co-development process, and reflection and development throughout the timeline in order to support and implement anticipated ERA advances and their use in regulatory contexts.

Considering the diversity of actors potentially contributing to the building blocks of advancing ERA, we suggest establishing a core coordination and steering group of European institutes i.e., EC (e.g., DGs, JRC), along with other EU agencies (e.g., EFSA, ECHA) that would provide the necessary administrative, enabling, and adaptive functions (Figure 10). These functions would foster collaborative and dynamic partnerships through which innovative outcomes can emerge (Uhl-Bien, Marion et al. 2007). The administrative function would focus on planning, managing and aligning project proposals and their outcomes, as well as determining and allocating sufficient resources to achieve roadmap goals. The enabling function would focus on capacity building for intersectoral groups and partnerships. These partnerships should strengthen opportunities for cooperation between scientific actors (Section 5.3.2), institutional actors (Section 5.3.3) and field practitioners (Section 5.3.4), as well as build links between relevant and complementary partnerships (e.g., One Health platform, EU Partnership for the Assessment of Risk from Chemicals [PARC]). This enabling function would catalyse the conditions that facilitate the flow of knowledge and innovative outcomes into regulatory contexts that emerge as part of the adaptive function where learning and innovation are fostered through the diversity of proposed projects and collaborative interactions.

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Considering the wider socio-economic context when implementing the IPol-ERA roadmap, the transition towards systems-based approaches for ERA of chemicals is also relevant. Indeed, biodiversity and PPPs cover different stakeholders' interests and ultimately raise political and societal debates. To ensure the stable progression of the roadmap, the formalisation of its implementation under the remit of a designated institution or body would be of considerable benefit.



Figure 10: Representation of the coordination and leadership, providing administrative, enabling, and adaptive functions, considered necessary for engagement of different sectoral actors for co-developing and implementing ERA advances following the IPol-ERA roadmap.

Approach to the implementation of the IPol-ERA Roadmap

In this section, we present the project proposals considering the priority areas for further development (PWAs). They focus on advancing ERA methodologies within the current system and on transitioning to a future systems-based ERA for insect pollinators. The approach for implementing the roadmap to the point where products can be handed to the relevant bodies for regulatory implementation is based on balancing five intentions:

1 Keeping a 2030 timeline: We have not yet defined a fixed timeline for the implementation of the roadmap but since there is a general wish to implement ERA changes to support Green Deal goals for 2030, we have given and indicative and flexible timeline of 2024-30 as the fastest timeframe in which the IPol-ERA roadmap could be achieved.

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2 A phased ERA advancement: A staged process is desirable to ensure a smooth transition to a systems ERA. To this end, three ERA products for regulatory implementation will be delivered throughout the roadmap timeline. This builds on existing processes and knowledge on bees to develop early-stage products quickly whilst generating the knowledge to develop the final product for all pollinators. These are identified as ERA Products 1-3.

3 Flexibility to take account of changing funding and political contexts: Since the roadmap suggests a process that operates over a long timeframe and is costly, it is possible that the funding and political framework could change. In this case, the strategy would be robust and able to adapt to a changed timeframe.

4 Coverage of all areas needed to advance ERA: The roadmap plan covers all the areas identified as challenges for the implementation of the systems-based ERA for insect pollinators.

5 Proposal for a co-developed implementation: Co-development and stakeholder engagement are core concepts in the IPol-ERA roadmap. This is handled together with coordination in an encompassing activity.

The project proposals form a connection between the IDAs identified previously in the project and the implementation of the IPoI-ERA roadmap defined as a separate project (#no 14), described in <u>Section 6.4.2</u>, (Figure 11). The implementation largely focusses on communication and governance, whilst the other projects focus on key longitudinal activities or knowledge building to support the intrinsic sensitivity, exposure, and population effects.



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Figure 11: Overview of the systems-based approach. Policy decisions are in bold. This overview shows the links between IDAs 1-4 and the projects developed to fill gaps and develop the tools and methods, and the coordination and management of the IPol-ERA developmental process (IPol-ERA GO). Note that this is an iterative process.

Figure 12 shows the timeline with three interlinked yet distinct products of the roadmap: ERA Products 1-3.

- ERA Product 1 (Improved Context for bee ERA) occurs under the bee guidance implemented under Regulation (EC) No 1107/2009 and considers the use of models and their implementation for use in ERA in 2026, according to current EFSA timelines. This implementation will extend the context of the current ERA to include broader landscape information in terms of farming, landscape structure and resource availability. It is envisaged that ERA Product 1 will use models for *Osmia* and *Bombus* in the same way. This therefore requires further development and testing of these models for use in ERA (see project 13);
- ERA Product 2 (Systems-ERA for Bees) broadens the scope to include a system view with multiple regulated stressors for bees (which may include bees other than Apis,

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Bombus and *Osmia*). ERA Product 2 leverages what we know about the bees and ERA to move quickly to a more advanced and holistic ERA for this well-worked group;

• ERA Product 3 (Systems ERA for Insect Pollinators) is the implementation of the systems-based ERA for insect pollinators, i.e., including the non-bee groups. This product is the final product, but is based on many project outcomes, and those projects start at the beginning of the timeline. We consider the 6-year timeframe optimistic for all data and knowledge to be collected, but possible.



Figure 12: Building towards a systems-based approach for insect pollinators through the production of three staged products. Product 1 is an expansion of the current risk assessment approach to include landscape context and non-regulated stressors (farming systems, diseases, weather), but under the current bee guidance. The second product implements a systems-based approach with multiple stressors and products for bees. The third product implements a full systems-based approach for insect pollinators, using the vulnerability concept to define focal species and methodology for all insect pollinators. Although the final product for all pollinators is at the end there are multiple project outcomes building towards this from the beginning of the timeline, including work on non-bees.

We have defined a set of 14 project proposals to cover knowledge acquisition through to ERA implementation (Figure 13).

- Projects 1,2 and 13 are longitudinal projects supporting the implementation by provision of data frameworks, farming and landscape context, and models;
- Projects 3-12 are primarily scientific projects aimed at strategic aspects of knowledge gathering, and tool or process development to support the ERA targets in Phases 1-3;
- Project 14 (<u>Section 5.4.2</u>), designated as IPol-ERA GO, is an encompassing activity that guides the roadmap development for all projects.

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Project proposals 3-12 are separated into four groups depending upon which ERA Product they feed (Figure 13). The first group of projects has a shorter timeframe because they should be completed by 2028 at the latest. The other projects have no specified timeline as it will depend on when they are initiated, and which other projects begin at the same time. Optionally, projects 5, 6 and 7 can be combined with projects 9, 11 and 12 respectively in case a full plan for implementing ERA Product 3 is initiated. Note that if ERA Product 3 were to be targeted to 2030, all longitudinal projects 8-12 by 2030. Hence, the timeframe is indicated with some flexibility.

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IPol-ERA Roadmap Report



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IPol-ERA Roadmap Report



Figure 13: Key relationships between projects proposed products ERA development suggested (green arrows). IPol-ERAGO encompasses all activities, and *, ** and *** indicate that projects could be combined or run separately depending on the timeline chosen. This timeline may be shorter if projects are started earlier but also may be longer if implementation and stakeholder agreement are not forthcoming or projects are delayed for any reason.

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5.2 Project proposals for development of the knowledge base

The 13 projects described below cover all the PWAs, needed knowledge and tool generation for successful development of the ERA products leading towards implementation of a systems ERA for insect pollinators. For each project key objectives are given, along with data gaps and RADA's addressed, and associated EC strategies and other projects that maybe linked with each project. The list of linked strategies and projects are examples, and not comprehensive as other unidentified projects could be of relevance. Further details for each of these project proposals are provided in Appendix D.

5.2.1 Project proposal 1 | *IPOL-ERA-FRAME* – Data framework

This project proposal aims to establish a framework to advance ERA methodologies to address current ERA needs and start addressing future ones. It aims to contribute to the data sharing and centralisation infrastructure required for incorporating the multidisciplinary dimension of the required data to advance ERA methodologies. The project seeks to support existing data hubs at various levels, expand data acquisition efforts to encompass local, national, and European perspectives, and establish a comprehensive system that facilitates easy retrieval and reusability of data for diverse stakeholders. It should coordinate with similar efforts under e.g PARC and with any future projects under PERA.

Advanced ERA for insect pollinators would consider information on land use and landscape composition, climate, farming practices, etc., to fully understand the risks of chemical pesticides on different taxa. Consequently, implementing a data-intensive framework integrating multiple sources must encompass several steps, including identifying data requirements, strategising data acquisition and management, conducting a data hunting phase, and establishing or supporting existing data hubs (e.g., EU Pollinator Hub). But mainly, centralising access and making available the scattered data so that scientists and risk assessors can use them to develop research and models, and risk assessors and risk managers have easy access to field monitoring exposure and impact data. The engagement of institutional actors can help the development of the data framework that will contribute to the future implementation of IPoI-ERA (Project 14: IPoI-ERA-GO).

At an early stage, this project aims to enhance data acquisition, management, curation, standardisation, and centralisation within ERA framework primarily related to bee species. At a later stage, the focus shifts towards data related to other taxonomic groups of insect pollinators other than bees.

The key objectives are:

- 1. To provide support for infrastructure development and human resources to existing data hubs involved in data acquisition, management, curation, and standardisation;
- 2. To broaden data acquisition efforts to include local, national, and European contexts, ensuring a comprehensive dataset for the system-based ERA framework;
- 3. To support data standardisation and centralisation to enable easy retrieval and reusability for various purposes within the ERA approach.

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This project could use tools/approaches already developed or proposed by Bersani et al. (2022) on the 'Roadmap for actions on artificial intelligence for evidence management in risk assessment' (Bersani et al., 2022).

The outcome of this project will be a centralised and harmonised data platform where the different actors involved in pesticide risk assessment and management can find any relevance data, methodology or tool to implement the further advancement of ERA for insect pollinators.

What data gaps are addressed?

- Definition of data needs for current ERA framework (foundation for the system-based approach).
- Data acquisition and standardisation in the current ERA framework (foundation for the system-based approach).
- Provision of support and resources to existing data collection hubs (e.g., EU Pollinator Hub).
- Establishment of new data collection hubs to address the data requirements.

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.
- RADA 6 Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context.

Potential links with examples of EC strategies and other projects:

- Towards an Implementation of the EU Bee Partnership Platform for Harmonised data Collection and Sharing Among Stakeholders on Bees and Pollinators (EFSA OC/EFSA/SCER/2021/09)
- BGEMS (Butterfly GEnetics Monitoring Scheme)
- B-GOOD (Giving Beekeeping Guidance by cOmputatiOnal-assisted Decision making)
- ORBIT (Taxonomic resources for European bees)
- SAFEGUARD (Safeguarding European wild pollinators)
- DECIDE (Delivering Enhanced Biodiversity Information with Adaptive Citizen Science and Intelligent Digital Engagements)
- IoBee (Beehive health IoT application to fight Honey Bee Colony Mortality)
- `Roadmap for actions on artificial intelligence for evidence management in risk assessment'

5.2.2 Project proposal 2 PUFA-NET – Pesticide use and farming practices

In order to provide the context for regulatory ERA, this project proposal aims to address the limited availability of data on land management practices, specifically focusing on pesticide application. The goal is to establish a thematic network of experts across the EU that represents each country/EU region, including, e.g., Advisory Farming Centers or Farming Associations. This network will facilitate the collection of comprehensive data on realistic pesticide use, including quantity, frequency, co-occurrence, timing, and location. Information on when, where, and how

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chemicals are applied is the first step to quantify exposure and co-exposure levels for insect pollinators. Considering current regulatory developments, such data should be made available by Member States and centralised at EU level in the future, in line with the provisions of the Regulation on Statistics of Agricultural Inputs and Outputs (EU Regulation 2022/2379)(Statistics of Agricultural Inputs and Outputs, 2022). However, it is uncertain if the level of detail publicly available will fulfil risk assessment needs in terms of data accuracy.

This project is linked to engagement activities of project 14 (IPol-ERA GO) to improve the data collection process with sensitisation (e.g., institutional engagement, communication on benefits and good data collection practices/standards).

The key objectives are:

- To establish a thematic network of experts across the EU that represents each country/EU region to facilitate collection, knowledge sharing and secure access to existing European and national datasets e.g. the CAP IACS⁶ data;
- 2. To develop a comprehensive inventory of the PPPs, active ingredients and mixtures of these applied in each crop and identify the most likely pesticide combinations to be assessed for their potential synergistic effects;
- 3. To assess land and farm management practices in representative landscapes to provide data for other areas of the ERA enhancement, e.g., *in silico* tools;
- 4. To establish an automatic system that can be updated regularly by the thematic network to ensure a consistent, and up-to-date collection of data;
- 5. To develop guidelines and standards to facilitate automatic data collection.

What data gaps are addressed?

 Undertake the collection, centralization, systematization, management, storage, and dissemination of high-resolution data pertaining to pesticide use at field level across all agricultural ecosystems.

Which RADA's are addressed?

- RADA 3 Advancing hazard and exposure characterisation.
- RADA 5 Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors.
- RADA 6 Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context.

Potential links with examples of EC strategies and other projects:

- PROTECTS (Protecting terrestrial ecosystems through sustainable pesticide use)
- iMAP project (Integrated Modelling platform for Agro-economic and resource Policy analysis);
- ALMaSS (the Animal Landscape and Man Simulation System);
- Quantifying exposure and effects of pesticides on bee to inform the integration of pollinator and pest management;
- SUSPOLL (Sustainable Pollination Services in a Changing World);

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 ⁶ Common Agricultural Policy Integrated Administration and Control System

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- Integrated pest and pollinator management in insect pollinated crops;
- CDPR (California Department of Pesticide Regulation): PUR (Pesticide Use Record)
- EU Pollinators Initiative;
- Farm to Fork Strategy.

5.2.3 Project proposal 3 BEE-EXPOSURE – Exposure scenarios for bees (Osmia spp. and Bombus spp.)

This project proposal aims to establish exposure scenarios for *Osmia* spp. And *Bombus* spp., like those developed for *Apis mellifera* currently by the EFSA MUST-B working group. Considering the diverse traits and activity patterns of insect pollinators, their co-occurrence with pesticide application will result in varying levels and routes of exposure. By accomplishing the objectives described below, this project aims to provide valuable insights into pesticide exposure dynamics of *Osmia* spp. And *Bombus* spp., contributing to more comprehensive ERA for these insect pollinators.

The key objectives are:

- 1. To gather data on exposure routes and exposure levels for *Osmia spp*. and *Bombus spp*. Through laboratory, semi-field and/or field testing, including data from monitoring studies focused on field exposure;
- 2. To develop representative landscape scenarios to accurately predict exposure levels for *Osmia* spp. And *Bombus* spp. Using *in silico* methods;
- To standardise methods for sample collection and pesticide screening, while exploring more cost-effective and efficient alternatives to standard residue analysis (e.g., HPLC-MS);
- 4. To validate the predicted levels of exposure with field pesticide monitoring data.

What data gaps are addressed?

- Defining exposure pathways for non-Apis bees.
- Environmental residues and exposure estimates for non-Apis bees.
- Further development and validation of bee models for ERA.
- Development of landscape scenarios representative of EU landscapes.
- Start to develop a co-monitoring for pesticides and insect pollinators.

Which RADA's are addressed?

- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.

Potential links with examples of EC strategies and other projects:

- PoshBee (Pan-European assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);
- B-GOOD (Giving Beekeeping Guidance by cOmputatiOnal-assisted Decision making);
- Ecostak (Stacking of ecosystem services: mechanisms and interactions for optimal crop protection, pollination enhancement, and productivity);
- BayÖkotox (Ecotoxicological Evaluation from substances in our environment);

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- DELETE (DEveloping Landscape Ecotoxicology in Terrestrial Ecosystems);
- MixToxBee (Exposure and effects of pesticide mixtures on bees);
- POLBEES (Risk assessment for honeybees and osmie bees of exposure to systemic pesticides and nutritional stresses via pollen, bee bread and osmie bread);
- INSIGNIA-EU (Preparatory Action for Monitoring Environmental Pollutions Using Honey Bees);
- ALMaSS (the Animal Landscape and Man Simulation System);
- ApisRAM Formal Model Description;
- EFSA project OC/EFSA/PREV/2023/02;
- EFSA project OC/EFSA/PREV/2023/03.

5.2.4 Project proposal 4 -BEE-POP-ERA - Landscape/population ERA for bees (*Apis mellifera*, *Bombus* spp. and *Osmia* spp.)

This project proposal aims to give the first step towards the development and implementation of landscape-scale population-level ERA for insect pollinators. Currently, detailed models are being developed for *Apis mellifera*, *Bombus* spp. and *Osmia* spp., which can soon be used to perform simulations under different environmental scenarios. This enhances the contextual information that can be used. Thus future environmental scenarios can include, e.g., weather, parasite/predator incidence, food availability for insect pollinators and landscape management practices, including the use of pesticides. After the models are evaluated and agreed, this extra context in ERA will allow the creation of an intermediate step between a full system-based ERA for multiple stressors (covering exposure to multiple pesticides along with non-regulated environmental stress factors) and the current regulatory ERA framework, by testing one active ingredient but including as many as possible non-regulated environmental stress factors to represent pollinator population resilience more accurately.

The key objectives of this project are:

- 1. To integrate the developed bee models and environmental scenarios under the same framework;
- 2. To develop and implement an ERA framework for the interpretation of models' outputs and apply them to the regulatory framework of pesticide authorisation, for example by setting SPGs based on simulations outputs.

What data gaps are addressed?

- Advancing on methodologies under the current ERA.
- Advancement of simulation tools.
- Integration to create an ERA framework.

Which RADA's are addressed?

- RADA 5 Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors.
- RADA 6 Developing and implementing a system-based approach and promoting its use and uptake in a regulatory context.

Potential links with examples of EC strategies and other projects:

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- PoshBee (Pan-european assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);
- B-GOOD (Giving Beekeeping Guidance by cOmputatiOnal-assisted Decision making);
- Ecostak (Stacking of ecosystem services: mechanisms and interactions for optimal crop protection, pollination enhancement, and productivity);
- ApisRAM Formal Model Description;
- ALMaSS (the Animal Landscape and Man Simulation System);
- EFSA project OC/EFSA/PREV/2023/02.

5.2.5 Project proposal 5 BEE-POP-RESIL – Colony and population resilience in bees

This project proposal aims to investigate bee population resilience, covering different bee species. When insect pollinators are exposed to environmental stressors (covering exposure to multiple pesticides along with non-regulated environmental stress factors) above a certain threshold, it can lead to the disruption of their normal operating range. After exposure, the population recovery may be regulated by internal (demography) and external (recolonisation) processes. Such mechanisms are still poorly understood for most insect pollinators. Considering the need to advance ERA methodologies under the current framework, colony and population resilience must be better understood, focusing on bee species currently suggested for ERA (i.e., *Apis mellifera*, *Bombus* spp. and *Osmia* spp.) first.

The key objectives are:

- 1. To develop protocols to measure the internal and external recovery of focal bee species (*Apis mellifera*, *Bombus* spp., *Osmia* spp.) considering their relevant biological and ecological traits;
- 2. To use a set of local landscapes representing different national and European level areas, to determine the population resilience (internal and external recovery) of bee pollinators;
- 3. To use the data generated from the project to validate the simulation outputs of the *BEE-POP-ERA* project (project proposal 4). This will involve comparing the modelling predictions with the observed population recovery patterns in the tested landscapes.

What data gaps are addressed?

- Advancing on methodologies under the current ERA.
- Definition and development of protocols for testing population resilience, implementation for bee species.

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators;
- RADA 3 Advancing hazard and exposure characterisation;
- RADA 5 Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors.

Potential links with examples of EC strategies and other projects:

• Behavioural and molecular responses to pesticide exposure in bumblebees.

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5.2.6 Project proposal 6 BEE-TOX-MIX – Toxicological effects of pesticide mixtures on model bee species

This project proposal aims to advance our understanding of the intrinsic sensitivity of bee pollinators to combinations of pesticides, with a focus on *Apis mellifera*, *Bombus* spp., and *Osmia* spp. The knowledge gained will contribute to the further development and standardisation of testing protocols for chemical mixtures. The project will involve the development of mixture prediction tools and the establishment of laboratory assessment protocols for evaluating the toxic effects of pesticide mixtures on bees.

The key objectives are:

- To develop mixture prediction tools building on existing methods (e.g., QSAR, computational toxicology tools, read-across, toxic unit models) for predicting interactions between pesticides in mixtures;
- 2. To develop, ring-test and standardise laboratory protocols with the ambition to refine current protocols (e.g., OECD, ISO) for the assessment of the toxic effects of pesticide mixtures on bees. Different exposure routes (e.g., acute vs. chronic, oral vs. contact), and diverse endpoints (e.g., physiological, behavioural) will be considered to comprehensively understand the derived effects. The project will account for common pesticide combinations found at environmentally relevant concentrations, including intentional and unintentional mixtures encountered by insect pollinators during foraging. Typical farming practices in terms of pesticide use patterns and spray series (Data from the PUFA-NET project; project proposal 2; Section 6.2.2) will also be integrated into the project. Moreover, potential interactions that may lead to deviation from dose addition (synergism, antagonism, potentiation) as well as potential dose-dependency and non-monotonic toxicity will be investigated.

What data gaps are addressed?

• Understanding of the intrinsic sensitivity of bee pollinators following exposure to combinations of pesticides by utilizing Mixture Prediction Tools and laboratory testing.

Which RADA's are addressed?

- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.

Potential links with examples of EC strategies and other projects:

- EU Environmental Scenarios for Risk Assessment (ERA) of Non-target Organisms' (Ref. No. OC/EFSA/PREV/2023/02;
- Revised guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) (https://doi.org/10.2903/j.efsa.2023.7989);
- PERA (Building a European Partnership for next generation, systems-based Environmental Risk Assessment);
- BayÖkotox (Ecotoxicological Evaluation from substances in our environment);

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- BEESYN (Identification of the impact of chemical products on honey bee mortality in Belgium, bearing in mind the interactions of these products with other plausible causes of mortality);
- EcoStack (Stacking of ecosystem services: mechanisms and interactions for optimal crop protection, pollination enhancement, and productivity);
- FIT BEE;
- MixToxBee (Exposure and effects of pesticide mixtures on bees);
- MUST-B (MUltiple STressors in Bees);
- POLBEES (Risk assessment for honeybees and osmie bees of exposure to systemic pesticides and nutritional stresses via pollen, bee bread and osmie bread);
- PoshBee (Pan-european assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);
 - 5.2.7 Project proposal 7 | *IPOL-FOCAL-SPEC* Focal species selection and testing

This project proposal aims to identify focal species candidates for regulatory ERA, based on their biological and ecological traits. It involves a literature review and testing phase, including laboratory, semi-field, and potentially field tests. The focal species selection will either build upon previous research results (EFSA OC/EFSA/PREV/2023/02 (Arena and Sgolastra, 2014; Schmolke et al., 2021), or on the results from systematic literature review. The primary objective is to determine the biological and ecological traits that influence the vulnerability of pollinator groups (social bees, solitary bees, butterflies, moths, flies) to pesticides. This project is the initial step towards advancing ERA with the project *CAKE-ERA-TRAIT* (project proposal 8; Section 6.2.8) and requires subsequent validation of the obtained results.

The key objectives are:

- 1. To identify and characterise vulnerability traits within the main pollinator groups;
- 2. To select species from each pollinator group, according to their relative vulnerability to pesticides for testing purposes;
- 3. To perform laboratory, semi-field, and potential field tests to identify the most sensitive and vulnerable traits. A single pesticide approach is proposed but with pesticides having different modes of action.

What data gaps are addressed?

- The project will fill the gap regarding the biological and ecological traits of pollinators that influence their sensitivity and vulnerability to pesticides.
- The project will fill the gap regarding understanding of the specific vulnerabilities and sensitivities of different pollinator groups (social bees, solitary bees, butterflies, moths, hover flies).

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 3 Advancing hazard and exposure characterisation.

Potential links with examples of EC strategies and other projects:

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- EU Environmental scenarios for ERA of non-target organisms (OC/EFSA/PREV/2023/02);
- SAFEGUARD (Safeguarding European wild pollinators).

5.2.8 Project proposal 8 | *IPOL-ERA-EXPOSURE* – Pesticide exposure of insect pollinators across landscapes

This project proposal aims is to establish a co-monitoring scheme that measures pesticide exposure levels in relation to pollinator activity, ideally building on already ongoing pesticide and pollinator monitoring activities and initiatives (e.g., EU-PoMS). It seeks to quantify the occurrence, concentration, and identity different types of pesticides, as well as the type of exposure (e.g., contact or dietary), to enhance our understanding of exposure scenarios and their implications for insect pollinators. Additionally, the project aims to investigate exposure through various media (e.g., pollen, nectar, plant, soil, water, prey (e.g., aphids), and air) in different landscape contexts to facilitate chemical read-across based on properties, validate ERA predictions, and improve post-approval pesticide residue monitoring.

The key objectives are:

- 1. To establish a comprehensive sampling network across various climatic areas and common landscapes throughout the EU. This network will enable the collection of data representative of different regions and agroecosystems;
- 2. To characterise exposure scenarios to identify the locations where insect pollinators are exposed in ecosystems, such as soil, flowers, and other relevant matrices. Determine the type of exposure, including contact and dietary exposure pathways;
- 3. To generate risk indicators that reflect the exposure levels of insect pollinators to pesticides. These indicators will contribute to the assessment of potential risks and inform decision-making processes.

What data gaps are addressed?

- Measure pesticide exposure over space and time: how much? (Pesticide quantity or concentration), where? (Where exposure occurs in the ecosystem), in what form? (Individually or in combination), how? (By which routes the exposure takes place), and when (Temporal patterns)?
- Validate pesticide use data and predict exposure using simulation tools.

Which RADA's are addressed?

- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.

Potential links with examples of EC strategies and other projects:

- SPRING (Strengthening Pollinator Recovery through Indicators and monitorinG);
- SPRINT (SUSTAINABLE PLANT PROTECTION TRANSITION);
- PoshBee (Pan-european assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);
- INSIGNIA-EU (Preparatory Action for Monitoring Environmental Pollutions Using Honey Bees);

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- BayÖkotox (Ecotoxicological Evaluation from substances in our environment);
- DELETE (Developing Landscape Ecotoxicology in Terrestrial Ecosystems);
- MixToxBee (Exposure and effects of pesticide mixtures on bees);
- POLBEES (Risk assessment for honeybees and osmie bees of exposure to systemic pesticides and nutritional stresses via pollen, bee bread and osmie bread);
- AirBeeSafe (Pesticides in the air-pollinator exposure along an agricultural intensification gradient);
- B-GOOD (Giving Beekeeping Guidance by cOmputatiOnal-assisted Decision making);
- AENEAS (Advance ERA of non-target organisms, OC/EFSA/ED/2021/02);
- Policy/strategies: Farm to Fork Strategy, EU Pollinator Initiative, EU Pollinator Monitoring
- Calls: "HORIZON-CL6-2023-BIODIV-01-1".
 - 5.2.9 Project proposal 9 *IPOL-POP-RESIL* Population resilience of non-bee species

This project proposal aims to establish methodologies for evaluating the population resilience and recovery of insect pollinators following pesticide exposure in agroecosystem. By understanding the factors influencing population resilience, such as internal and external recovery, this project aims to contribute to the development and validation of modelling approaches for ERA (e.g., POLL-MODEL project).

The key objectives are:

- 1. To develop methodologies based on the BEE-POP-RESIL project to assess the population resilience and recovery of insect pollinators. These methodologies should consider the focal species identified in the other projects, e.g., IPOL-FOCAL-SPEC project;
- 2. To use a set of landscapes that represent diverse EU agroecosystems across the EU, to assess the population resilience (internal and external recovery) of focal insect pollinators.

What data gaps are addressed?

• Implementation of population resilience protocols in support models development and validation.

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 5 Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors.
- RADA 6 Developing and implementing a system-based approach and promoting its use and uptake in a regulatory context.

Potential links with examples of EC strategies and other projects:

- ALARM (Assessing large-scale environmental risks with tested methods);
- LIFE PollinAction (Actions for boosting pollination in rural and urban areas);
- PollinatorWatch;
- SAFEGUARD (Safeguarding European wild pollinators);
- SPRING (Strengthening Pollinator Recovery through INdicators and monitorinG);

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- AIPP (All-Ireland Pollinator Plan);
- PoMS (UK Pollinator Monitoring Scheme);
- Biodiversity and Ecosystems Programme.

5.2.10 Project proposal 10 | CAKE-ERA-TRAIT – Continuing Advancement of Knowledge on focal species and their traits for effective ERA of pesticides in insect pollinators

This project proposal aims to expand and update our understanding of the biological and ecological traits that affect insect pollinators vulnerability to pesticides. By conducting comprehensive testing and broadening the scope of traits, this project aims to reduce uncertainty and fill knowledge gaps in the ERA of pesticides for insect pollinators. This project is a continuation of the 'Advancing ERA of pesticides in insect pollinators through biological- and ecological traits-based focal species selection (IPOL-FOCAL-SPEC)' project, but with a special focus on other insect pollinator taxa.

The key objectives are:

- To use existing data as a foundation (e.g., IPOL-FOCAL-SPEC project), conduct laboratory, semi-field, and field studies on additional species that exhibit relevant biological and ecological traits. In addition to the previously studied pollinator groups, novel taxa should be considered, e.g., beetles or thrips;
- To expand the range of biological and ecological traits across a range of pollinator taxa and establish vulnerability factors for: (i) external exposure, (ii) intrinsic sensitivity, (iii) demography, and (iv) recolonization capabilities;
- 3. To understand how the environmental context affects trait-based vulnerability;
- 4. To assess the impact of pesticides on ecosystem services provided by all selected species, encompassing, e.g., pollination or pest control and evaluate trade-offs/ synergies between pest control and pollination services.

What data gaps are addressed?

- The project will fill the gap regarding understanding of the specific vulnerabilities and sensitivities of different pollinator groups (social bees, solitary bees, butterflies, moths, flies, beetles, thrips).
- The project will fill the gap regarding the ecosystem services provided by focal species.

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 3 Advancing hazard and exposure characterisation.

Potential links with examples of EC strategies and other projects:

• EU Environmental scenarios for ERA of non-target organisms (OC/EFSA/PREV/2023/02).

5.2.11 Project proposal 11 | *TOX-POLL-GUIDE* – Develop protocols for laboratory testing and predict toxicological effects of pesticide mixtures on focal insect pollinators

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This project proposal aims to enhance our understanding of the intrinsic sensitivity of both nonbee and bee pollinators to pesticide mixtures. It is a continuation of the 'Developing protocols for laboratory testing and predicting toxicological effects of pesticide mixtures on model bee species (BEE-POP-RESIL)' and profits from the lessons learnt during it. It focuses on developing innovative techniques and protocols to predict the toxic effects of pesticide mixtures on nontested pollinator species. The ultimate objective is to achieve ring-tested and standardised testing protocols to predict the toxic effects of pesticide mixtures on noncurrently tested pollinator species. The project aims to integrate OMICS techniques (genomics, transcriptomics, metabolomics, etc.) into ERA, allowing for the prediction of intrinsic sensitivity in non-model species (tier 0 assessment), which could feed to project 7 (focal species selection). The project should investigate potential interactions (synergistic/antagonistic) and non-monotonic toxicity.

The key objectives are:

- 1. To integrate OMICS Techniques:
 - a. Standardisation and validation of OMICS assays specifically designed for focal species selected in other projects;
 - b. Establishment of best practices for generating, storing, curating, processing, normalizing, and interpreting OMICS data to ensure data reliability and comparability.
- 2. To develop laboratory protocols:
 - a. Adjustment of existing protocols to develop laboratory assessment methodologies for evaluating the toxic effects of pesticide mixtures on focal species (non-bee pollinators). Key aspects to consider include species-specific exposure routes (acute vs. chronic, oral vs. contact), diverse endpoints (lethal and sub-lethal), and investigate commonly encountered pesticide combinations at realistic environmental concentrations.

What data gaps are addressed?

- Using the developed methods to provide comprehensive data on intrinsic sensitivity for all insect pollinators candidate focal species.
- Understanding of the intrinsic sensitivity of focal species following exposure to combinations of pesticides by utilizing, among others, OMICS and laboratory testing.

Which RADA's are addressed?

- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.

Potential links with examples of EC strategies and other projects:

- EU Environmental Scenarios for Risk Assessment (ERA) of Non-target Organisms' (Ref. No. OC/EFSA/PREV/2023/02;
- Revised guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees); https://doi.org/10.2903/j.efsa.2023.7989;
- 'Building a European Partnership for next generation, systems-based Environmental Risk Assessment (PERA);
- BGE (Biodiversity Genomics Europe);

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- ERGA (European Reference Genome Atlas).
 - 5.2.12 Project proposal 12 | *REVISE-ERA* Re-evaluation of focal species for implementation of system-based ERA

This project proposal aims to conduct a comprehensive re-evaluation of previously selected focal species to determine their suitability for pesticide risk assessment in the context of pollinator protection. It builds upon all projects (Figure 13) and employs a combination of monitoring and simulation tools to achieve its objectives. It is to some extent a synthesis of knowledge before final focal species are chosen for the full systems approach.

The key objectives are:

- 1. To implement monitoring schemes covering all EU member states to re-evaluate the previously selected focal species (i.e., considering their usefulness for ERA, if they are good surrogates for the system in terms of vulnerability, relevance, ease of use, etc.);
- To use appropriate simulation tools to assess the suitability of selected species for pollinator protection in agricultural areas, considering different exposure scenarios, landscape context, spatial-temporal variation, and the combined impacts of multiple chemical stressors and other stressors;
- 3. To incorporate ecological interactions between focal species and other organisms contributing to ecosystem services into the modelling framework. The modelling framework should encompass interactions with different species, e.g., other beneficial predators like parasitoid and predatory insects. This integration will provide insights into the broader implications of pesticide effects on multiple species and ecological dynamics in agroecosystems.

What data gaps are addressed?

- The project using monitoring data and simulation tools will fill the gap regarding suitability of previously selected focal species for ERA.
- The project aims to fill gap regarding ecological interactions between pollinators and other organisms providing ecosystem services upon exposure to pesticides. It will be done by incorporating these interactions and evaluating their effects on the focal species and ecosystem services.

Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.
- RADA 6 Developing and implementing a system-based approach and promoting its use and uptake in a regulatory context.

Potential links with examples of EC strategies and other projects:

- EU Environmental scenarios for ERA of non-target organisms (OC/EFSA/PREV/2023/02);
- ABLE (Assessing Butterflies in Europe);
- eBMS (European Butterfly Monitoring Scheme);
- EMBAL (European Monitoring of Biodiversity in Agricultural Landscapes);

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- EuMon (EU-wide monitoring methods and systems of surveillance for species and habitats of Community interes);
- EuropaBON (Europe Biodiversity Observation Network: integrating data streams to support policy);
- MAMBO (Modern Approaches to the Monitoring of BiOdiversity);
- PoshBee (Pan-european assessment, monitoring, and mitigation Of Stressors on the Health of BEEs);
- PURE (Pesticide Use-and-risk Reduction in European farming systems with Integrated Pest Management);
- SPRING (Strengthening Pollinator Recovery through INdicators and monitorinG)
- EuropaBON (Europe Biodiversity Observation Network: integrating data streams to support policy);
- OBServ (Open Library of Pollinator Biodiversity and Ecosystem Services).

5.2.13 Project proposal 13 | POLL-MODEL – Develop systems-based models for new focal species

This project proposal aims to develop a systems-based model for new focal species. Since the development of these models requires a considerable amount of time and effort, these should only be developed after the selection of the appropriate focal species. Furthermore, this step requires a deep understanding of insect ecology and behaviour. Thus, the successful project should be aided by a multidisciplinary team of researchers with a deep knowledge of insects' traits, ecosystems' interactions and the modelling skills to integrate these biological traits into the simulation system.

This project aims to consolidate and use data generated within various proposed projects. Specifically, it builds on the landscape context provided by the IPOL-ERA-FRAME and PUFA-NET projects, while drawing upon the knowledge acquired from the IPOL-FOCAL-SPEC and CAKE-ERA-TRAIT projects regarding pollinator sensitivity and vulnerability. Additionally, the project incorporates modelling techniques developed in the ADV-BEE-ERA projects.

The key objectives are:

- 1. To gather data on focal species organisms' ecology and behaviour to select the most important traits to include in the model by creating a group of experts or desk research;
- 2. To develop models for each new species, including non-bee taxa;
- 3. To validate the new models with data from representative landscapes;
- 4. To support the definition of SPGs by providing methods, simulations and data, and evaluate the impact of pesticides or any other decision-making affecting the environment of insect pollinators on the capacity of the focal species to perform their ecosystem services, and related measurement endpoints for these species.

What data gaps are addressed?

• Development of models for neglected insect pollinator taxa, their validation and use. Definition of SPGs and related measurement endpoints for these species.

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Which RADA's are addressed?

- RADA 2 Assessing ecological consequences of chemical effects on insect pollinators.
- RADA 3 Advancing hazard and exposure characterisation.
- RADA 4 Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators.
- RADA 5 Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors.

Potential links with examples of EC strategies and other projects:

- STEP (Status and Trends of European pollinators);
- The Insect Pollinators Initiative;
- ALARM (Assessing large-scale environmental risks with tested methods).

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5.3 Engagement

5.3.1 Actors

The network analyses and desk research have identified many key actors with the potential to collectively advance ERA for insect pollinators (Section 4.3). In this section, we have categorised potential partners into three main actor groups based on their involvement in pesticide risk assessment and authorisation procedures. These actors will have different roles and contribute different knowledge during the implementation of the roadmap:

- 1. Scientific experts and knowledge hubs;
- 2. Institutional authorities, including risk assessors and managers (at different levels of governance);
- 3. Field practitioners, including industry and civil society.

We consider that engaging with a broad range of representatives from these actor groups is necessary to align understandings of proposed developments (e.g., new methodologies, tools and systems-based approaches), foster co-development of a progressive ERA framework, and help prioritise and fine-tune actions as part of implementing the roadmap. Engagement is vital to ensure that methods and tools developed are considered fit for purpose by end-users and society.

5.3.2 Scientific experts and knowledge hubs

Scientific experts and knowledge hubs will help establish key concepts and methodologies and provide the data necessary to advance ERA for insect pollinators. Our network analyses identified different scientific experts and knowledge hubs who could best contribute to advancing ERA methods and tools in relation to the six RADAs (see <u>Table 2</u>).

Several knowledge hubs have been identified in each of the RADAs (Section 4.3, Table 5). The French National Institute of Agronomic Research (INRAE, France) and University of Mons (UMONS, Belgium) seem to be the best placed to provide knowledge about RADA 2 'Assess ecological consequences of chemical effects on insect pollinators / pending NTA' and RADA 5, 'Developing landscape-scale populations level ERA tools that account for environmental stressors'. In addition, other research organisations showed a high number of connections, meaning that they are involved in many related activities, where the Swedish University of Agricultural Science (SLU, Sweden), Helmholtz Center for Environmental Research (UFZ, Germany), and Aarhus University (UAAR, Denmark) are the three best placed (Table 5).

INRAE is also a knowledge hub for RADAS 4 'Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators' and RADA 6 'Developing and implementing a systemsbased approach and promoting its use and uptake in a regulatory context'. RADA 4 knowledge hubs are also UMONS, UFZ, UAAR and, Wageningen University (WUR, the Netherlands), most of which are also hubs for RADA 6, together with Pensoft (Bulgaria). Among these institutions they cover the first posts in the ranking of academic organisations best connected with ongoing or past initiatives. RADA 1 'Engaging towards a joint IPol-ERA partnership' is less concentrated, most likely because academic or research organisations are less involved in partnership development. Still, the Luxembourg Institute of Science and Technology (LIST, Luxembourg),

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UFZ, SLU and University of Tartu (UTARTU, Estonia) seem to be the best connected to activities involving partnerships for ERA. Like RADA 1, academic expertise covering RADA 3 'Advancing hazard and exposure characterisation' seems to be more scattered in Europe. Yet, again UAAR, INRAE, and SLU seem to be connected with the largest number of initiatives.

However, when determining the ideal individuals with the expertise and knowledge to help advance ERA for insect pollinators, the situation is complicated. Often key individuals are affiliated to several academic institutions or sometimes move between them, so targeting particular individuals/institutions can be difficult. For this reason, we have suggested a set of competencies or profiles for scientific experts who could assist and guide implementation of the roadmap (Table 9).

Table 9: List of profiles for scientific experts with the potential to assist in advancing ERA methods and tools for insect pollinators. Topics are linked to some of the identified Priority Working Areas (PWAs).

Торіс	Competences or scientific expertise profiles
Pollinator taxa & focal species	Competence in taxonomy and ecology of insect pollinators or access to a network of insect pollinators taxonomists.
Pollinator traits	Competence in ecology of different taxa of insect pollinators or access to a network of scientists with such a knowledge.
Pesticide use	Competence in agronomy, agriculture, integrated pest management and crop production or access to a network of experts on these topics.
External exposure	Competence in pesticide use, their environmental fate, and insect pollinators traits or access to a network of experts on these topics.
Intrinsic sensitivities	Competence in toxicology of insects or access to a network of experts on these topics.
External and internal recovery	Competence in ecology of insect populations or access to a network of experts on these topics.
Modelling	Competence on modelling, artificial intelligence and machine learning or access to a network of experts on these topics.
Monitoring	Competence on field monitoring of insects and environmental pollutants or access to a network of experts on these topics.
ERA framework	Competence on regulatory aspects of pesticide authorisation and risk assessment or access to an expert network on the topic.

5.3.3 Institutional actors, including risk assessors and managers

PPP risk assessors and managers at the national and European levels are key actors and endusers. We suggest they are involved early in the roadmap implementation to actively co-develop aspects of relevance and benefit to them.

Key institutional actors were identified based on desk research and expert knowledge. Following the One Health logic and considering the transversal nature of insect pollinators visible in the F2F, Biodiversity and Chemical strategies and the SDGs, we suggest involving a variety of related institutional actors with different functional roles: e.g., responsible representatives managing information related to agriculture and farming practices (including pesticide use and its alternatives), environmental monitoring (including biodiversity and chemical monitoring), research, and risk assessment and management of other regulatory frameworks (including, for example, biocides or veterinary products). We suggest integrating European and national efforts

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in gathering, standardising and centralising data about these topics (such as IACs, EU-POMS, INSIGNIA-EU, etc., Appendix A - IPol-ERA database, Table A5).

Table 10: List of institutions that could be involved in the advancement of ERA methodologies.

Organisation name	Organisation level	Already participated in the roadmap? If Yes, how? ^{(I)(w)}
EC - DG Sante	European	Yes; I, W
EC - DG Agriculture and Rural Development	European	Yes; I, W
EC - JRC	European	Yes; I, W
EC – DG Environment	European	Yes; I, W
EC – DG Research and Innovation	European	No
European Chemical Agency	European	Yes, I, W
European Environmental Agency	European	Yes, W
European Food Safety Authority	European	Yes, W
European Parliament	European	No
Presidency of the EU or PAFF members (Member States)	National	No
National Risk Assessors	National	Yes; W
European Reference Lab (Bee Heatlh)	European	Yes; W

(I): Interview(W): Workshop

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5.3.4 Field practitioners, industry and civil society

Field practitioners, industry, and civil society have also been identified as important actors for the successful development and implementation of the roadmap. We identified numerous actors at different governance levels of relevance but prioritised several organisations as key to being involved in implementing the roadmap. These organisations were selected based on expert knowledge and are detailed in <u>Table 11</u>. These organisations represent the interests of industry commercialising PPPs, field practitioners such as farmers or beekeepers, and environmental NGOs following pesticide impacts or insect pollinator conservation. Appendix A - IPoI-ERA database (TableA5.xlxs) contains the list of all organisations identified in desk research with a likely interest in roadmap implementation and potentially contributing to the process.

Several representatives of organisations listed in <u>Table 11</u> have already contributed to the development of the roadmap, either through individual interviews (Section 4.1.2) or by providing feedback in the thematic workshops (Section 4.1.3). We suggest maintaining their involvement in the implementation of the roadmap. In addition, we identified several ongoing research projects that can contribute to the IPol-ERA roadmap. Some of these projects are at an early stage of development and have not progressed sufficiently to share data or results. However, given that the roadmap is meant to cover several years, we suggest engaging with coordinators of ongoing and future research projects which can provide relevant knowledge.

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Table 11:Identified field practitioners, industry, and civil society representatives with
potential to contribute to advancing current ERA and transitioning to systems-based ERA.

Organisation name	Organisation type	Organisation level	Already participated to the roadmap? If yes, how? ^{(I)(w)}
Apimondia	Practitioners' associations	World	Yes; I
BCE - Butterfly Conservation Europe	NGO & Advocacy Grp	European	Yes; I, W
BeeLife European Beekeeping Coordination	NGO & Advocacy Grp	European	Yes; W
Copa-Cogeca	Practitioners' associations	European	Yes; I, W
CropLife	Industry	European	No
ELOO - European Land Owners Organisation	Practitioners' associations	European	No
EPBA - European Professional Beekeepers Association	Practitioners' associations	European	Yes; W
ESA - European Seed Association	Industry	European	No
IBMA – International Biocontrol Manufacturers Association	Industry	European	Yes; I, W
PAN-Europe	NGO & Advocacy Grp	European	No(a)
Pollinis	NGO & Advocacy Grp	National	Yes; I, W
Relevant EU research projects(b)	Research project	European	No

(I): Interview

(W): Workshop

(a) Participated in the framework of PERA, where they were interviewed.

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(b) Participation of representatives of research projects like: B-GOOD, PoshBee, Safeguard, Insignia, EU-POMS, Sting, etc.

5.3.5 Communication and engagement plan

5.3.5.1 COMMUNICATION

The IPoL-ERA roadmap takes a holistic approach to advance methodologies that address current regulatory developments (e.g., One Health concepts, EU Pollinator Initiative, the F2F, biodiversity and chemical strategies and SDGs) and future needs of the ERA of chemical pesticides for insect pollinators. However, the term 'holistic' is difficult to grasp and subject to various interpretations (See Section 1.1, <u>Box 1 Definitions of a systems-based approach</u>). For this reason, we suggest it would be important to generate visual educational materials explaining such concepts and the building blocks and steps in the roadmap's implementation process, e.g., infographics, simplified videos, and factsheets. Ideally, dedicated information packages would be created for targeted audiences and managed/coordinated by the proposed leadership structure in collaboration with the steering committee.

Novel information disseminated about potential ERA advances and the evolution of the framework would need to evolve in parallel with the implementation of the IPoI-ERA roadmap. In the beginning, educational material will need to be produced, and the content of publicly available information should evolve in parallel with developments and roadmap activities, providing updated information on the process (projects, events, achievements, etc.).

Actors identified above already have an interest in advancing ERA of insect pollinators, and they would be the primary audience of the communication and engagement activities. However, the number of organisations interacting/associated with the ERA of chemicals for insect pollinators is much larger, as can be seen in Appendix A.5. This extended list of organisations is a potential audience, mainly for communication purposes.

5.3.5.2 ENGAGEMENT

Establishing collaborative networks and communities is based on bringing people together. We suggest several types of events (workshops, demos, webinars, etc.) will need at a European level to annually build links between the IPol-ERA leadership structure and actors/stakeholders identified above. We suggest an engagement plan that aims to build an **IPol-ERA Community of Practice** (COP), which can continue and evolve beyond the successful implementation of the roadmap. Ideally, the events would be organised to coincide with existing sectorial events (some examples in <u>Table 8</u>). In addition to established events, we suggest a series of specific IPol-ERA events, ideally organised annually at the EU level.

The aim of these events would be to:

 At an early stage, to inform participants and, through them, the wider public about the existence of the IPoI-ERA roadmap as a means to evolve ERA for chemical pesticides, as well as collect information and promote knowledge exchange. Especially, press representatives could be invited wherever possible and/or press releases might be developed and distributed where applicable;

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- To build professional and social bonds that foster trust within the IPol-ERA COP both at EU and national levels;
- To collect existing IPol-ERA-related data and information and to identify additional research/innovation needs to the ones identified here and build to cover them;
- To engage practitioners by 'training' them on the concepts, working logic, and methodological implementation;
- To exchange knowledge, discuss, and provide guidance.

The implementation of the roadmap and advancing the ERA framework for insect pollinators is a long-term process with 2030 a stated target for EFSA. The roadmap's communication and engagement plans should span the duration of this process.

These plans can be divided into four phases:

- Setting up the scene, discovering, understanding and learning the concepts, building blocks, methodologies, etc., and making sense of the needed evolution, gaps, and processes;
- Co-development, whereby participants actively contribute to events and processes, and follow up activities (projects, regulatory developments, data gathering, etc.) happening in parallel;
- 3. Accelerating the implementation of a *proof of concept* (PoC) of the ERA for insect pollinators;
- 4. Following up on the implementation and contributing to fine-tuning to make the PoC operational, followed by a wrapping up initiative when the IPoI-ERA is in place and running optimally.

The first set-up phase may require a more intensive calendar to put initiatives in motion and create interest and willingness to engage and contribute. In contrast, the follow-up and codevelopment phases can be less intense but sufficient to maintain interest. However, increasing the rhythm of events and communications again would be beneficial when accelerating the PoC implementation phase. After the finalisation of a PoC, work should continue at a slower pace to embed the operationalisation of the framework. In practice, we suggest, for example, 4 interactive workshops during phase 1, 2 during phase 2, 3 during phase 3 and 2 during phase 4.

The organisational setting of the events must be engaging and inclusive, using training techniques leading to co-development, exchange of information, brainstorming and dialogue, e.g. Liberating structures (<u>https://www.liberatingstructures.com/</u>) or the JRC (Catana et al., 2021), alone or in combination. As far as possible, workshop programmes should include networking and social breaks. By doing so, an involving atmosphere can be created to align understandings and promote ownership of the work to be accomplished.

The participant composition of the workshops does not need to be the same each time. Indeed, different actors play different roles in the process and would require dedicated sessions to contribute. We suggest that at least one annual event would be dedicated to individual stakeholder groups: (1) institutional actors, (2) scientific experts and knowledge hubs and (3) field practitioners, industry and civil society. However, it would be important that the three

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groups attend at least one annual event to foster networking and knowledge exchange. Ideally, at least two of these events require the physical meeting of participants every year.

We also suggest a strategy to identify individual actors who can act as advocates of the IPol-ERA roadmap at different geographic levels, to aid the dissemination of IPol-ERA roadmap activities and developments.

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5.4 IPol-ERA Roadmap management framework for implementation.

The roadmap coordination and stakeholder engagement is described as a project that overarches all the others and includes significant management between projects. Since the development of a feed-forward process where each project is finished and feeds results to the next would result if a very long timeline, it is necessary to start projects in two blocks (Figure 13). This means that the information flow between these project blocks and within the block is managed by Project 14 IPol-ERA GO. Since planning for so many large and complex projects to start simultaneously is unlikely to succeed in practice, this puts much emphasis on the coordination activity in the encompassing project. This project operationalises three key aspects identified in IDA 4: centralisation, harmonisation, and consolidation. The project achieves this primarily through well-planned communication and leadership throughout the roadmap implementation stage. This project must therefore manage the key challenges and opportunities identified in the creation of the roadmap.

5.4.1 Challenges and opportunities for the transition

Advancing ERA methodologies/tools and creating a framework to support the implementation of these methodological evolutions is regarded as a major undertaking. One objective of the project was to identify potential challenges and opportunities for implementing the roadmap. This section outlines these challenges/opportunities identified through desk research and stakeholder input gained via interviews and workshops. These potential obstacles to advancing ERA for insect pollinators are considered from the 'vulnerability perspective' outlined in the problem formulation, whereby insect pollinators' vulnerability to PPPs, is affected by their ecological and biological traits and the requirement for evolving risk assessment framework that facilities the protection of all insect pollinators.

Project proposal outline in section 5.2, and suggested partnerships and engagement plan (section 5.3) address these challenges and are intended to deliver mechanisms and necessary 'know-how' (knowledge) to overcome potential obstacles and create opportunities for advancing ERA of chemical pesticides.

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Table 12: Identified potential challenges and opportunities for advancing Environmental Risk Assessment (ERA) and implementation of roadmap related to areas requiring further development (IDAs) and linked to Risk Assessment Development Areas (RADAs), based on information gathered from desk research, interviews, and workshops. **Focal species** selection underpins all advances in ERA methodologies.

IDAs for advancing ERA from `Vulnerability perspective	Links to RADAs	Challenges/opportunities
1. External exposure		 There is insufficient data available on pesticide use and residues for defining exposure pathways, for chemicals and mixtures, for focal species and traits, including methods development
	RADAs 1-5	 Limited extent of scientific knowledge on pollinator traits among pollinator taxa and how these relate to vulnerability, including how exposure of the selected focal species cover other species
		3) The large volume of work required to prioritise, develop and implement methodologies for exposure assessment (environmental fate, occurrence of multiple chemicals).
		4) Dealing with the dimensionality of what is considered vulnerable and 'how many' focal species are optimal for ERA of insect pollinators (e.g., no. species included x no. compounds considered x no. scenario contexts, and mixtures considered)
2. Intrinsic sensitivity	RADAs 1, 3 & 4	5) To provide basic toxicology tests across focal species (acute, chronic, sublethal)
		6) To extend and integrate standardised protocols for insect pollinators for toxicological testing for chemicals and mixtures (e.g., OECD / EFSA), leading to the development of advanced toxicological approaches and tools e.g., TK/TD, QSARs, and OMICs.
		7) An extensive data foundation needed for testing, modelling and decision-making, balancing sufficiency and manageability (dimensionality issue see '4' above). Ecological and toxicological data is lacking or limited for many pollinator species, especially non-bee species.



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3. Population resilience	RADAs 1, 2, 4 & 5	 8) It is difficult to quantify reproduction, mortality, and movement, and their drivers, for focal species as well as the practicality and difficulty of field measurements to determine and rank vulnerability, indirect effects and mitigation possibilities (methods, resources) 9) The large scale and complexity of the approaches to, and the generation of data for, verifying and validating spatio-temporally explicit pollinator population and food web models that capture multiple stressors, recovery processes and species interactions (data, dimensionality), accounting for indirect effects. 10) Lack of standardized monitoring of insect pollinators and PPPs over sufficient spatio-temporal scales to follow up regulatory decisions and model predictions (resources)
		 11) Difficulty in the selection and agreement of a set of focal species representing vulnerability across pollinator taxa 12) The scale of work required to develop tests and models for focal species for integration of these into ERA-framework (standardisation and harmonisation). 13) Complexity of model evaluation and determining the model detail needed and uncertainty accepted when defining models.
4. Integrated ERA framework	RADAs 1, 4 & 6	14) Linking different components e.g., data, models and monitoring, ensuring access, interoperability of data, models and monitoring as well as recognising data ownership and sensitivity issues (e.g., GDPR).
		15) Building awareness and trust by fostering multi-stakeholder partnerships/collaborations for co-development, knowledge sharing and implementing effective communications to engage and inform stakeholders, align perspectives, as well as `benchmarking' to ensure new developments are `fit-for-purpose'.
		16) Ensuring sufficient resources for coordination, engagement, and funding of roadmap activities, whilst not creating excessive administrative burdens.

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5.4.2 Project proposal 14 - IPol-ERA GO

In the long term, improving ERA methods and tools and integrating systems-based ERA approaches for insect pollinators will require planned and coordinated actions. Risk managers and assessors from Europe and national member states will need to discuss and fully understand the requirements of new methodologies/tools and possible new regulatory procedures. In turn, possible new requirements must be conveyed, discussed and accepted by the broader set of actor groups (defined in Section 5.4), collectively establishing the building blocks of an advanced ERA. Effectively managing the proposed projects and collaborative partnerships will be vital for sharing and promoting knowledge, expertise, methods and data as well as foster constructive dialogue.

This project relates to the roadmap management framework for coordination and leadership (section 5.1) to initiate the management and administrative, enabling, and adaptive functions needed to establish proposed projects and partnerships successfully. These coordination and leadership functions will be necessary to achieve the deployment of a systems-based pollinator ERA in the European regulatory framework at the end of the roadmap period. Unlike the projects defined above, IPoI-ERA GO focuses on the practical implementation of the methods, tools and concepts developed by the other projects in the EU Regulatory context. These methods, tools, and infrastructure will manage the process efficiently, facilitating communication and collaboration with the actors involved (section 6.3). As a result, this project requires organizational resources with personnel who can coordinate the activities involved in the roadmap; it also needs those with fund-raising possibilities and networks of experts of different profiles. The team must include people who can bring all actors together in a co-development process over the roadmap period.

Considering the preparatory work needed to achieve the goal of implementing a systems-based ERA framework, IPol-ERA GO will need to start generating the required knowledge and creating the supportive network as soon as possible to advance in the ERA before the 2030 target. However, this horizon is likely too ambitious, as some of the knowledge/advancements needed may take longer (see Section 4.2).

IPol-ERA GO is meant to evolve iteratively with the processes and projects enforced during the length of the roadmap. However, there are three stages of activities that can be identified with different objectives:

Stage A key objectives:

- 1. To establish the coordination and leadership (managerial organisation) that will steer decision-making and collaborative efforts (e.g., project proposals) throughout the roadmap implementation (section 5.1).
- 2. To create the IPol-ERA network with whom to communicate and engage (Section 5.3) and expand it along the duration of the roadmap if necessary.
- 3. To manage and implement the communication and engagement-related actions to achieve a common understanding of the nature and elements of the system-based ERA, motivating the shift to this approach and co-create with the actors the future ERA of insect pollinators.
- 4. To bring decision-making assistance into the other projects whenever needed.

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5. To raise funds to implement the knowledge-forming and tool development projects.

Stage B key objectives:

- 1. To consolidate the roadmap processes and development, including launch of projects, and overseeing engagement, partnerships, and communication activities.
- 2. To continue assisting the decision-making of other projects.
- 3. To develop a feasibility study following the accomplishment of Project proposal 6 (BEE_RES_GUIDE) to evaluate different dimensions of the practical implementation of a systems-based ERA for bees, exploring the consequences for society, economy, legislation, etc. Of the practical implementation of a systems-based ERA for insect pollinators. The institutional actor group will be key to co-shape the approach and evaluate, discuss and adapt, if necessary, the regulatory framework to accommodate the systems-approach ERA for insect pollinators. Risk managers and assessors would require extensive discussion to align concepts and approaches to ensure the correct interpretation of ERA outcomes.

Stage C has a single objective:

1. To accelerate the practical implementation of the systems-based ERA so that it is ready to use by all actors involved in the risk assessment and management processes.

What data gaps are addressed?

This project will facilitate the coordination and delivery of all other projects to ultimately
address all data gaps. It will also address legislative approaches and the identification of
regulatory and societal challenges and opportunities, including costs (incurred in
implementing the framework) and benefits (pollination, yield, human health, etc.).

Which RADA's are addressed?

• Since this project overarches all the others, all RADAS are addressed.

Potential links with examples of EC strategies and other projects:

• This project is intended to foster, build links and establish partnerships with relevant actions, initiatives, and projects in the field of insect pollinators and pesticide risk assessment.

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Glossary

Active substance – any chemical, plant extract, pheromone or micro-organism (including viruses), that has action against 'pests' or on plants, parts of plants or plant products. Before an active substance can be used within a Plant Protection Product in the EU, it must be approved by the European Commission.

Centralisation – harmonised data, methods and tools gathered into a centralised accessible environment, available to every actor to build up trust (e.g., EU Pollinator Hub, etc.).

Concepts for systems-based ERA – conceptualising a systems-based ERA based on ecological theory, e.g., organismal concepts such as species vulnerability, ecosystem vulnerability, focal species, such as service providing units.

Consolidation – taking what works well in existing ERA (methods, protocols and tools) and to unify and build upon them to strengthen ERA in long-term, when transitioning to systems-based approach.

Ecosystem function – translating population-level effects to ecosystem function (pollination) – ecosystem services.

Environmental context (exposure) – understanding how the environmental context affects all components of external exposure. For example, landscape heterogeneity, configuration, and composition over space and time, including potential food and nesting areas for pollinators, will affect pollinator activity. And the amount and type of pesticide-treated cropland affect the occurrence, concentration and identity of pesticides encountered in the landscape. This includes exposure to multiple compounds over space (between fields) and time (from multiple applications).

Environmental context (population sustainability) – understanding how the environmental context affects all components of pollinators' population resilience. For example, temperature, availability of food and nesting sites, and the amount and type of pesticide-treated cropland - affects a populations' capacity to recover.

External exposure – exploring patterns in pollinators' external exposure.

External recovery – pollinator's ability to recolonise following stress.

Focal species – insect pollinator species selected for use within ERA.

Harmonisation – aligning methods and tools (old and new) so they are compatible across different ERA arenas / countries / institutions, ensuring compatibility and enabling them to work together (e.g., ERA methods for PPPs and other chemicals).

Intrinsic sensitivity of multiple PPP – characterising the effect of multiple chemical (PPP) stressors, i.e., antagonistic, synergistic, and additive.

Intrinsic sensitivity of multiple stressors – characterising the effect of multiple chemical and unregulated, biotic and abiotic stressors.

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Intrinsic sensitivity of single PPPs – characterising the effect of single chemical (PPP) stressors – standard ecotoxicological tests.

Internal recovery – species' demographic traits, such as life span and survival, generation time, voltinism and the number of offspring, that influence the population growth rates to result in population densities.

Multiple stressors – sources of stress that often interact and impact habitats/organisms in complex and unexpected ways (e.g., climate change, invasive species and diseases).

Pesticide use – finding when and where pesticides are applied in the landscape. This could include common farming practices.

Pesticide fate dynamics – understanding the processes that result in patterns of contamination.

Plant Protection Product (PPP) – pesticides that protect crops or desirable or useful plants. They contain at least one active substance. They may also contain other components including safeners and synergists. EFSA is not responsible for assessment of PPPs, only active substances. The assessment of PPPs is done by the member states, but the PPPs are part of EFSA's remit.

Pollinator activity – pollinator activity patterns in the landscape.

Pollinator traits (1) – ecological traits that affect pollinator behaviour in the landscape, e.g., their mobility and dispersal capacity, sociality, phenology, nesting location, host plants, or whether they are central place foragers (i.e., foragers departing from and returning to a central nest when foraging in the surroundings, rather than passing through an area or moving at random)

Pollinator traits (2) – traits modulating toxicokinetics and toxicodynamics, e.g., diet and consumption, life stage, nesting location, cuticula penetration, detoxification and biotransformation capacity, target site(s).

Pollinator traits (3) – ecological traits affecting a species' ability to recover externally or internally, e.g., distribution, population size, reproduction strategy, generation time, mobility and dispersal capacity, sociality, life stages, life span, generation time, voltinism, phenology, density dependence, competition and other intra and inter specific interactions.

Population resilience – population trends over space and time.

PPP mixture – a mixture of two or more Plant Protection Products (i.e., a mixture of multiple products, each of which may consist of one or more active substances and additives).

Socio-economic values – evaluating the availability and ability to determine the socioeconomic values related to systems-based ERA, such as ecosystem services, pesticide use, and perceptions/ acceptance of a new ERA.

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Toxicokinetics – factors affecting the absorption, distribution, biotransformation, and excretion of pesticides. Toxicogenomics should be included in this challenge.

Toxicodynamics – factors affecting the mechanism and mode of action (e.g., damage).

Abbreviations

AgroDijon	Higher National Institute of Agricultural Sciences, Food and Environment
BCE	Butterfly Conservation Europe
CAP	Common Agricultural Policy
CER-HU	Centre for Ecological Research, Hungary
COLOSS	Prevention of Honeybee Colony Losses
СОР	Community of Practice
CRA-W	Walloon Agricultural Research Centre
DG	Directorate-General
DG Agri	Directorate-General of Agriculture and Rural Development
DG Envi	Directorate-General of the Environment
DG Research	Directorate-General of Research and Innovation
DG Sante	Directorate-General of Health and Food Safety
E-BMS	European Butterfly Monitoring Scheme
EC	The European Commission
ECHA	European Chemical Agency
EEA	European Environmental Agency
EFSA	European Food Safety Authority
ELOO	European Land Owners Organisation
EPBA	European Professional Beekeepers Association
ERA	Environmental Risk Assessment
ESA	
	European Seed Association

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IPol-ERA Roadmap Report



FEA-FI	Finland's Environmental Administration
FLI	Friedrich Loeffler Institute Germany
GDPR	General Data Protection Regulation (EU)
HAO- DEMETER	Hellenic Agriculture Organisation
IACS	Integrated Administration and Control System
IBMA	International Biocontrol Manufacturers Association
IPol-ERA	Environmental Risk Assessment of Chemicals for Insect Pollinators
IDA	IPol-ERA Problem Formulation Development areas (Areas Requiring Further Development)
IDF	IPol-ERA Development Fields (components within IDAs)
INRAE	French National Institute of Agronomic Research
IPM	Integrated Pest Management
ISO	International Organization for Standardization
ITSAP	French Technical and Scientific Institute of Beekeeping and Pollination (L'Institut Technique et Scientifique de l'Apiculture et de la Pollinisation)
JRC	Joint Research Centre
LIST	Luxembourg Institute of Science and Technology
MLU	Martin Luther University Halle-Wittenberg
NBC	Naturalis Biodiversity Center
NGO	Non-Governmental Organisation
NINA	Norwegian Institute for Nature Research
NTU	Nottingham Trent University
OECD	Organisation for Economic Co-operation and Development
PAN-Europe	Pesticide Action Network, Europe
PoC	Proof of Concept
PPP	Plant Protection Products

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PWA	Priority Working Areas
RADA	Risk Assessment Development Areas (EFSA)
RBINS	Royal Belgian Institute of Natural Sciences
SDG	Sustainable Development Goals
SLU	Swedish University of Agricultural Sciences
SPG	Specific Protection Goals
SWEPA	Swedish Environmental Protection Agency
ТКТД	toxicokinetic-toxicodynamic
UFZ	Helmholtz Centre for Environmental Research
WUR	Wageningen University & Research.

Acronyms (projects)

ALARM	Assessing Large-Scale Environmental Risks with Tested Methods
BEEP-NL	BEEP Foundation
BioAgora	Bio Knowledge Agora: Developing the Science Service for European Research and Biodiversity Policymaking
Biodiversa	Database that compiles information about past and current funding programs on biodiversity in Europe (including thematic and blue sky programs, grants, fellowships and studentships), research organisations, and project leading researchers active in biodiversity research
BSOUR	Beesources - Beekeeping Consultancy
EcoStack	Stacking Of Ecosystem Services: Mechanisms and Interactions for Optimal Crop Protection, Pollination Enhancement, And Productivity
EUPoMS	EU Pollinator Monitoring Scheme: Develop a Cost-effective Core Scheme for Essential Pollinators
INSIGNIA-EU	Citizen Science Investigation for Pesticides in Apicultural Products: Environmental Monitoring of Pesticide Use through Honey Bees
IPol-ERA	Environmental Risk Assessment of Chemicals for Insect Pollinators
MUST-B	Develop A Holistic Approach to The Risk Assessment of Multiple Stressors in Honeybees

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IPol-ERA Roadmap Report



PARC	European Partnership for The Assessment of Risks from Chemicals
PERA	The European Partnership for Next Generation, Systems-Based Environmental Risk Assessment
PoshBee	Pan-European Assessment, Monitoring, And Mitigation of Stressors on The Health of Bees;
PURE	Pesticide Use-And-Risk Reduction in European Farming Systems with Integrated Pest Management
SAFEGUARD	Safeguarding European Wild Pollinators
SCIPROM	Science Management & Communication
STEP	Status And Trends of European Pollinators

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