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Grant Proposal

PollinERA: Understanding pesticide-Pollinator interactions to support EU Environmental Risk Assessment and policy

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Abstract

PollinERA aims to reverse pollinator population declines and reduce the harmful impacts of pesticides. It addresses the call through four objectives: SO1 filling ecotoxicological data gaps to enable realistic prediction of the source and routes of exposure and impact of pesticides on pollinators and their sensitivity to individual pesticides and mixtures. SO2 developing and testing a co-monitoring scheme for pesticides and pollinators across European cropping systems and landscapes, developing risk indicators and mixture

exposure information. SO3 developing models for predicting pesticide toxicological effects on pollinators for chemicals and organisms, environmental fate, toxicokinetic/ toxicodynamic, and population models. SO4 developing a population-level systems-based approach to risk and policy assessment considering multiple stressors and long-term spatiotemporal dynamics at the landscape scale and generating an open database for pollinator/pesticide data and tools.

This will be achieved through developing knowledge and protocols for a broad range of toxicological testing, feeding to in silico models (QSARS, toxicokinetic/toxicodynamic, and population). Using a strong stakeholder co-development approach, these models will be combined in a One System framework taking a systems view on risk assessment and policy evaluation, including an international monitoring program.

The One System framework is based on EFSA's system ERA view, expanding on the tools used for bees to include butterflies, moths and hoverflies. The consortium partners are experts in the field needed for this development and are well-placed to facilitate the uptake of tools by European bodies to guarantee the project's future impact.

Expected impacts target Destination impacts of better understanding and addressing drivers of biodiversity decline, interconnected biodiversity research using digital technologies, and understanding the biodiversity and health nexus at the ecosystem level.

Keywords

Environmental toxicology at the population and ecosystems level, Pollinators, Pesticides, Sensitivity, Exposure, Mixture toxicity, Toxic load, Monitoring, Risk indicators, In silico model, TKTD, Population model, Landscape simulation, Policy impact, Systems-based

1. Excellence

1.1 Objectives and ambition

PollinERA addresses HORIZON-CL6-2023-BIODIV-01-1 Area B, moving the evaluation of the risk and impacts of pesticides and suggestions for mitigation beyond the current situation of assessing single pesticides in isolation on honey bees to an ecologically consistent assessment of effects on insect pollinators using a systems approach.

The European Green Deal, the EU biodiversity strategy, the EU zero pollution action plan, and the revised EU pollinators initiative all indicate the need to protect pollinators and address insect and pollinator declines. Plant protection products (PPP), AKA pesticides, have been identified as one of the primary triggers of pollinator decline (IPBES 2019). However, significant knowledge gaps and critical procedural limitations to current pesticide risk assessment (RA) require attention before meaningful improvements can be realised. The functional group is currently represented by only one species, the honey bee, which does not necessarily share other species' biological and ecological traits. Key areas that need focus include understanding routes of exposure and differential pollinator sensitivity to pesticides, the extent, and implications of exposure to multiple stressors (natural and artificial), and the system-level responses of populations and communities to pesticide use and agricultural management. The latter is crucial in designing effective mitigations that fit the local context and across policy instruments.

Recently, the European Food Safety Authority (EFSA) highlighted the need for a systems-based approach to the environmental risk assessment (ERA) of honey bees. EFSA's innovative strategy emphasises the need for a realistic approach to understanding the system-level effects of pesticides on honey bees (EFSA Scientific Committee et al. 2021). Subsequently, this idea has been extended to environmental risk assessment (ERA) in general (Sousa et al. 2022) and insect pollinators specifically, with the launch of EFSA's IPol-ERA project to create a roadmap to systems ERA for pollinators. The crux of the systems approach is to move the RA from a laboratory-based study to one considering the ecological system and spatial and temporal scales over which pesticide exposure and effects occur. The systems approach combines an improved understanding of PPPs' interactive, chronic and sublethal effects on pollinators (i.e., wild and domestic bees, butterflies, moths, and hoverflies) with their ecology, behaviour, and landscape context. It opens the way towards more environmentally friendly schedules of pesticide use across the EU by avoiding the combined use of chemicals for which significant synergistic effects on pollinators are found. This approach, therefore, is very well aligned with the ONE HEALTH concept, which is also part of the current strategic policy thinking.

Moving towards a systems-based ERA poses challenges. The *PollinERA* project divides these challenges into four main groups, each addressed by a specific objective (SO1-4, Table 1, Fig. 1). These objectives collectively relate directly to the 11 bullet points expected from Area B of the HORIZON-CL6-2023-BIODIV-01-1 topic, with the addition of social science components.

PollinERA is ambitious and could not be fully delivered within a project of this dimension, except for the fact that many of the building blocks have been provided by previous Horizon projects (see Table 2). All in silico approaches are advances on existing models (QSARs, TKTD and ALMaSS (Topping et al. 2003) population and landscape models, see descriptions of models below, under Specific Objective 3). Specific achievability is detailed in Table 1.

Specific Objective 1: Ecotoxicological knowledge gaps – Knowledge of the toxicity of pesticides for pollinators is severely lacking. Even though considerable data is available for the honey bee, wild bees, butterflies, moths, and hoverflies are not currently part of a regulatory testing scheme. Current tests focus on acute lethal tests, often missing critical sub-lethal or chronic effects. Extrapolation from a very limited number of species to the pollinator community is questionable. This challenge is exacerbated by the need to cover mixtures with additive, synergistic or antagonistic effects likely to vary between taxa. Some studies on bumblebees and solitary bees and ongoing Horizon projects (e.g., PoshBee) contribute to this data, including mixture effects, but these are few and far between. Even in the honey bee, there is little information about the effects of mixtures, and sub-lethal tests are not well covered.

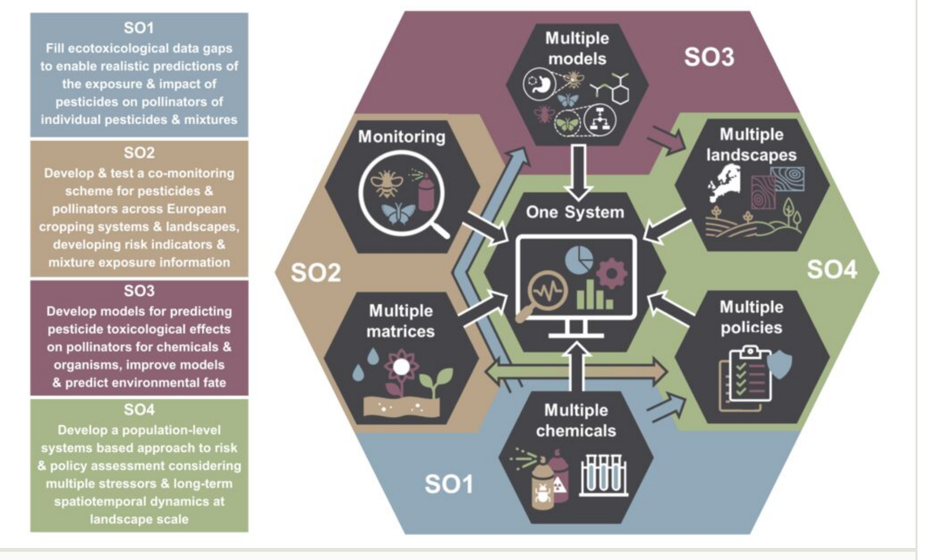

Figure 1. doi

The major components and relationships between *PollinERA* specific objectives, leading to the overall implementation of a framework (One System) for risk assessment and policy evaluation including a long-term monitoring scheme for pollinators and pesticides.

Table 1.

Specific Objectives (SO) of *PollinERA* (KPIs refer to Table 7).

Specific Objectives	
SO1	Fill ecotoxicological data gaps to enable realistic prediction of the source and routes of exposure and impact of pesticides on pollinators and their sensitivity to individual pesticides and mixtures. **Means of verification**: Reporting on the identification of pesticide sources, routes, and levels of exposure as well as acute, (sub)chronic and interactive effects of pesticides on pollinators representing different taxonomic groups. Completed toxicological testing protocols shared and ready as a foundation for eventual implementation by The Organisation for Economic Cooperation and Development (OECD) (KPI1). **Achievability**: The participating institutions have vast experience in insect ecotoxicology. New combinations of pollinator-relevant matrices and pesticides will be sampled and used, and new species representing more neglected groups will be tested in laboratory conditions. Developing protocols (Sgolastra et al. 2017, Mokkapati et al. 2022) will be the baseline for the extension to other pollinator groups.
SO2	Develop and test a co-monitoring scheme for pesticides and pollinators across European cropping systems and landscapes, developing risk indicators and mixture exposure information. **Means of verification**: Pesticide and pollinator co-monitoring scheme (PPCoMS) prototype and protocols made available through the EU Pollinator Hub (KPI2). **Achievability**: Partners already have national responsibility for separate pesticides and pollinators monitoring which could link to form EU-level monitoring. We leverage and connect these schemes, using case studies from three countries to ensure logistical tractability and provide actual implementation.

Specific Objectives	
SO3	Develop models for predicting pesticide toxicological effects on pollinators for chemicals and organisms, improve toxicokinetic/toxicodynamic (TKTD) and population models, and predict environmental fate. **Means of verification**: In silico models related to chemical structure implemented in VEGAHUB (platform for QSAR (quantitative structure-activity relationship) models) (KPI3a) and TKTD published on EFSA's TKPlate (Quignot et al. 2018) (KPI3b) and species model papers published in the FESMJ open collection (see 2.2.1) (KPI3c). **Achievability**: VEGAHUB already contains some models for pollinators, many of which were contributed by PollinERA partners. Partners have extensive TKTD and agent-based modelling experience, including model use in PPP regulatory contexts to provide a sound basis for model creation. Data tightly flows coordinated with SO1 will ensure data availability.
SO4	Develop a population-level systems-based approach to risk and policy assessment considering multiple stressors and long-term spatiotemporal dynamics at a landscape scale and generate an open-database for pollinator/pesticide data and tools. **Means of verification**: Documentation of the integrated systems ERA tools (KPI4) completed. Predictive ERA tools are co-developed and reality-benchmarked with monitoring data (KPI5; KPI11). **Achievability**: Early engagement of stakeholders in a co-development process where ERA knowledge needs for decision-making at different hierarchical levels are identified will start the process on the right path. Participating partners are very experienced with a long track record for developing complex software systems using tried and tested software protocols. Key landscape simulation building blocks have been developed in H2020 projects and are accessible. With an excellent experience in ERA science and governance/transition approaches, including extensive EFSA working group engagement and other participatory processes, we will ensure the integration of tools and the fit to regulatory/policy needs.

SO1 will address this challenge by

1. Detailing sources and routes of exposure among pollinators;
2. Characterising pollinator sensitivity to pesticides;
3. Assessing the impact (lethal and sublethal) of multi-pesticide exposures on selected pollinator species to detect possible deviations from the dose addition model (especially synergism and potentiation);
4. Assessing the impact of chronic exposure to pesticides (lethal and sublethal), where data reveals pesticide presence in the environment over long periods.

Beyond state of the art: SO1 will increase knowledge by testing a range of pollinator species for their sensitivity toward commonly used pesticides, predict intrinsic sensitivity across species and construct species sensitivity distributions (SSDs) for pollinators. It will create new protocols for mixture testing and a strategy for identifying key mixtures to create data for Toxicokinetic/Toxicodynamic (TKTD) models. It will also develop protocols for sub-lethal effects detection. Providing data on species sensitivity toward pesticides, frequency, and strength of interactions, obtained in uniform using standardised studies for the most important pollinator species in the EU, will be a significant step forward.

Specific Objective 2: Pesticide and pollinator monitoring scheme – Environmental pesticide and pollinator monitoring is needed to track their state change in the environment and to validate that *in silico* predictions comply with observations. The identity and concentration of pesticides in pollinator-relevant matrices over space and time need to be combined with pollinators' sensitivity (SO1) to track the spatiotemporal potential for toxicological impacts of pesticides in European landscapes. Pollinator exposure is dynamic and varies in space and time across multiple exposure routes, land management and environmental conditions – something that can be modelled (SO3-4) – but real-world data is needed to verify that the models are working. An EU pollinator monitoring scheme has been proposed (EU-PoMS, Potts et al. 2020). No standardised pesticide monitoring scheme exists for the matrices that pollinators are exposed to, and most suggested methods build on honey bees (e.g., the EFSA suggestion of a network of sentinel hives). How honey bee traits relate to other pollinators, especially those with different life histories, like butterflies, moths or hoverflies, is untested. In fact, pollinator risk indicators are not developed and thus constitute a significant gap in the toolbox for predicting the likely impacts of pesticide use.

SO2 will address this challenge by developing a pesticide and pollinator co-monitoring scheme (PPCoMS) based on:

- identifying potential high pesticide risk landscapes for monitoring, covering major European cropping systems and EU regulatory zones, and
- co-monitor pesticide contamination in pollen/nectar/water/plant/soil matrices and key pollinator groups (wild bees, butterflies, hoverflies, moths) at systematically selected sites and determine pesticide compound identities and concentrations.
- It will also develop pollinator pesticide risk indicators, useful for benchmarking and post-approval monitoring in the ERA process, and relate these to other commonly used pesticide risk indicators.

Beyond state of the art: Our design and testing of a workable co-monitoring scheme for pesticides and pollinators beyond honey bees in high toxic load landscapes with differing proportions of semi-natural areas and the development of pollinator pesticide risk indicators as part of a comprehensive ERA system will thus represent a significant step forward to track integration of pollinator conservation and pesticide regulation. We will provide significant steps beyond the ecotoxicological state-of-the-art by, alongside honey bee-collected pollen and nectar, also determining pesticide residues in other pollinator-relevant matrices (water, plant, soil) and-co-monitoring of pollinator communities.

Specific Objective 3: In silico models for chemicals and pollinator populations – These are four challenges.

1. To predict novel or untested pesticides' exposure and effects, separately and in combination. There are models for honey bees, but no models for predicting effects on other pollinators, and no read-across tools for pollinators have been reported.
2. Uptakes from multiple exposure routes and pesticides need to be combined and translated into organism effects using adaptable TKTD models for pollinators. These should represent different pollinator taxa without detailed physiological knowledge, but currently, TKTD models for terrestrial organisms are in their infancy.
3. Predicting population-level impacts, using models able to integrate the effects of landscape, climate, and agricultural management with ecology and behaviour to provide robust and descriptive models to indicate the effect of pesticides in space and time. Models exist for honey bee (ApisRAM), *Bombus terrestris* and *Osmia*

bicornis in ALMaSS. Still, these are the only pollinator models currently capable of integration in the proposed landscape simulation framework used by EFSA.

4. In addition, there is the challenge of dimensionality caused by the need to consider combinations of stressors. Here cumulative assessment groups (CAGS) are used in human toxicology but are not yet defined for the environment.

SO3 will address these challenges by

1. developing open source *in silico* QSARs. These models will provide information on the uncertainty, the mode of action (MoA), and the mixture effects, for the parental compounds and their degradation products.
2. Developing robust generalised TKTD models and adapting and implementing these for the key pollinator taxa.
3. Develop new agent-based population models embedded in a dynamic landscape simulation to generate emergent population properties based on landscape and management scenarios. These models will exploit ALMaSS (as used by EFSA's honey bee model) to ensure compatibility with current activities and will include TKTD.
4. *In silico* models and knowledge of agronomic use of PPPs will be used to define ERA cumulative assessment groups, feeding to SO4.

Beyond the current state of the art: We will expand the range of QSARs available, develop robust generalised terrestrial TKTD models to integrate multiple exposure pathways and predict effects on survival and possible sublethal endpoints based on minimal experimental results. For population modelling, *PollinERA* partners are the developers of the bee population models within ALMaSS. They will use this expertise to create additional models covering the key non-bee pollinator groups, including TKTD models and the ability to model sublethal effects. Providing openly available models for these groups will be a significant step forward. The development of cumulative assessment groups for ERA will be a novel and major step beyond what is available now.

TKTD *describe the uptake distribution and potential transformation of a chemical (toxicokinetics, TK), and the processes that lead to impacts, such as changes in metabolism, growth, reproduction, and survival (toxicodynamics, TD). They provide the potential to integrate multiple exposure pathways/routes in a time-explicit way*.

QSARs *Quantitative structure-activity relationship models are regression models that relate the structure of a chemical to its effects (e.g., toxicity). They can be used to predict effects and to classify chemicals using machine learning to cope with large amounts of chemical data*.

Specific Objective 4: A population-level systems-based approach to pollinator ERA and policy evaluation – The challenge of moving towards an ERA for pollinators from single-product, single-use assessments requires the integration of many factors. There is considerable recent activity related to developing a systems-based approach to ERA including multiple stressors and landscape scale assessments. EFSA has commissioned two roadmap projects, and one, PERA, is now completed. However, no projects currently implement a systems-based ERA beyond EFSA's own ApisRAM development project. Expanding the scope of the ERA by defining an increased number of realistic worst-case scenarios to include and model multiple exposure scenarios and other anthropogenic and biotic stressors will be a challenge. Here we identify 4 key aspects:

1. ERA models must explicitly represent more physical and biological processes leading to high technical and data demands.
2. Ensuring representativeness and protectiveness of the assessment whilst improving connectivity and reusability of data, expertise and knowledge such as ERA outcomes.
3. A risk assessment scheme needs to be elucidated taking into account the new systems perspectives, without over-complicating the ERA process.
4. Stakeholders need convincing that the solution is fit for purpose and methodologies need to be validated for international regulatory recognition.

Additionally, the regulatory approach is characterised by subject and policy silos, with little consideration of synergisms that could be obtained through integral approaches across policy instruments and strategies that work on the same landscapes and systems (e.g., CAP, Water Framework Directive, Farm to Fork).

SO4 will address this challenge by

1. Integrating landscape simulation, population, and toxicological models into a common framework, including the necessary detail to define inputs/outputs to create a wide range of representative and worst-case scenarios. Done using the ALMaSS framework, already shown to be capable of handling this complexity. Drawing upon a variety of social science approaches (2-4).
2. Stakeholders' knowledge and experience will be used early in the tool design phase to ensure that the solutions are fit for purpose. Knowledge input from stakeholders includes how their decision processes work, their assessment and decision-making context, and the impact and scope of the decisions supported by ERA. A protocol for data flows between the monitoring and predicted toxic load to inform monitoring locations and validate and continuously develop the predictive tools will be developed using post-approval and existing monitoring.
3. Scenarios for ERA defined at the systems level (species, agricultural systems and landscapes, measurement endpoints, and suggested specific protection goals (SPGs), these being set by decision makers legally to define what needs to be protected, when and where). Landscape simulation modelling will include agricultural management, landscape features and dynamics, and pesticide fate for selected European countries, expanding on those currently available.
4. We will draw stakeholders into a co-development dialogue to map relevant decision contexts, key actors, scope, and mitigation measures for which landscape-level ERA would improve the decision basis. We will demonstrate cross-compliance and interaction with other pesticide and pollinator-relevant policies.

Beyond state of the art: PollinERA will build upon the EFSA roadmaps (PERA and IPol-ERA), and ApisRAM, to implement a first systems-based set of tools for pollinator ERA beyond honey bees. Extending the landscape simulation developed in H2020 EcoStack, PoshBee and B-GOOD, it will integrate with activities in PARC 6.4.4, which aims to implement short-term improvements within the current PPP ERA framework through knowledge from modelling and monitoring. Combining *in silico* models for predicting toxicological effects with agent-based population models and highly detailed landscape simulation will, for the first time, provide a set of tools to tackle multiple stressors in ERA and test management strategies to reduce pesticide use and reverse the pollinator decline.

1.1.1 Technology Readiness

TRL levels for all activities start at TRL2. Our aim in *PollinERA* is to develop all tools to TRL4-5. The final ERA system cannot go beyond TRL5 within the project since making this operational requires acceptance by regulatory authorities and member states. However, we will offer our *in silico* models to EFSA, to be included in the EFSA Knowledge Junction; this will be facilitated by the fact that partner IRFMN coordinates the sOFT-ERA project, funded by EFSA; which is aiming to develop *in silico* models to generate predicted values for the EFSA database OpenFoodTox. The ERA framework created based on ALMaSS will also be offered to EFSA through ongoing partner AU & UOS collaborations via EFSA PPR panel and the MUST-B working group.

1.2 Methodology

1.2.1 Overview

Our challenge is to select key species and pesticide combinations to test, whilst creating robust testing protocols, models, and frameworks and making these available to stakeholders, and filling relevant knowledge gaps. With this in mind, we take as broad a range of organisms into account in the toxicological tests as possible. We then focus on modelling the three bee species already defined by EFSA guidance, dipterans (hoverflies), and butterflies and moths. These chosen species represent the major groups of pollinators and will be modelled realistically. However, we will also make it possible to alter key characteristics to represent more vulnerable species (e.g., by reducing reproductive potential or dispersal ability). In this way, we can also provide flexibility to test vulnerable species identified in the future. In addition, we will pilot the co-monitoring of pesticide residues in pollinator-relevant exposure sources and pollinator communities across European cropping systems and landscapes to enable real-world validation and expansion beyond the indicator species. The systems ERA framework tools provided here will be developed from the building blocks already being used in Europe and will follow the roadmap project results from EFSA (PERA and IPol-ERA). Hence, the methodology will be familiar to EFSA and national risk assessors, which should ease future take-up of the tools.

Broadly speaking, the project methods structure is that SO1 feeds to SO2 through SO4, whilst SO2 and SO3 feed forward to SO4, which acts as an integrating hub (Fig. 1).

1.2.2 Specific Objective 1: Ecotoxicological knowledge gaps

To achieve SO1, we will determine how pesticide exposure, sensitivity, chronic impacts, and mixture toxicity varies among pollinator taxa, from these we will define focal species for ERA and test species for laboratory study. There are ca. 350,000 pollinator species worldwide and ca. 1,000 different commercialised pesticides. Considering these numbers, the test types (chronic vs acute, adults vs larvae) and their possible combinations, a critical issue is the selection of species and compounds to test. We have identified the following selection criteria:

a) Criteria for pollinator test species selection: The potentially most exposed species in the agroecosystems belonging to the three main pollinator groups (bees, dipterans, lepidopterans) will be selected. A special focus will be given to species that are commercially available or easily reared under laboratory conditions and that share ecological traits with or are phylogenetically close to the focal species (see SO3). We will evaluate routes and degree of exposure and pesticide sensitivity for at least seven species, and four species for chronic toxicological tests for single and combined substances. Relevant information on species vulnerability based on their potential pesticide exposure will be obtained from *PollinERA* results, literature, and IPol-ERA.

b) Criteria for pesticide selection: Pesticides with different modes of action and high occurrence levels in agroecosystems will be selected. A special focus will be given to new potentially dangerous compounds that are considered “safe for pollinators” with the current RA procedure. The mixture experiment will consider the most likely pesticide combinations in fields. We will test four different pesticides and a pesticide combination based on the information from other projects (e.g., PoshBee), stakeholder consultation (including IPol-ERA results) and exposure analysis.

Exposure routes and sources – By reviewing the literature the relevance of sources and routes of exposure for key pollinator groups (wild bees, butterflies, hoverflies, and moths) and sampling and analysing the most pollinator relevant matrices (pollen, nectar, water, plant, soil) will be determined. Sites for environmental sampling will be selected in conjunction with the monitoring in SO2. Samples will be collected in three countries, covering the three regulatory zones within the EU: Italy (southern zone; UNIBO), Poland (central zone; UJAG, INC-PAS) and Sweden (northern zone; ULUND). Pollen and nectar will be collected from honey bee foragers returning to sentinel hives following PoshBee protocols. The other matrices will be sampled in relation to expected important non-*Apis* routes and sources of exposure: water – small collections of standing water as potential habitat for saprophagous hoverfly larvae, plant – butterfly larvae host plants, and soil – nesting locations of ground nesting solitary bees. One partner, SLU, will screen and quantify pesticide concentrations to reduce variability (e.g., number of screened compounds and limits of detection) and use gas and liquid chromatography coupled with mass spectrometry (Knapp et al. 2023).

Pollinator sensitivity – The important step forward will be testing the range of pollinator species (‘a)’ above) for their sensitivity toward commonly used pesticides using standardised and uniform methods. Although not yet standardised, some protocols for wild bee pesticide testing are currently available in literature (Sgolastra et al. 2017, Mokkapati et al. 2022) and/or under ring testing by some international groups (e.g., COLOSS APITOX TF; ICPBR non-*Apis* working group), these test methods will be the baseline for their extension to other pollinator groups. Testing a range of pollinator species representing non-*Apis* bees, butterflies, hoverflies, and moths will enable us to construct species sensitivity distribution (SSD) curves for different pesticides. We will use data from the literature where it is available to augment the SSDs. Four laboratories will perform the tests (UJAG, INC-PAS, UNIBO, ULUND). Single compounds from ‘b’ above will be tested through contact and oral exposure to construct SSD profiles for pollinator species. For non-managed species, individuals will be obtained from the field, maintaining a balance between obtaining robust results and using a minimal number of animals. Specific biological traits of each tested species (e.g., body size, lipid content, hairiness, pH haemolymph, water content) will be characterised and correlated with relevant ecotoxicological endpoints to predict intrinsic sensitivity across species. This trait-based approach will also be useful for understanding the mechanisms of sensitivity concerning the toxicity processes, i.e., the TKTD.

Mixture toxicity – Despite the well-proven significant interactions between many toxic chemicals, mixture toxicity testing has never been introduced into ERA or registration procedures of pesticides (and other chemicals). Pesticides are commonly used in complex formulations, including combined multi-pesticide sprays or sequential exposure. Thus, pesticides representing different types (insecticides, herbicides, fungicides) and chemical groups and different modes of action, will be tested for the occurrence and frequency of significant interactive effects on selected pollinators representing different groups. The exposure to and impact of multi-pesticide exposure on pollinators is poorly studied. More data is needed to identify potential interactions that may lead to deviations from dose addition (potentiation, synergism, antagonism). The choice of interactions tested will be based on actual pesticide use in different crops and pedo-climatic zones as well as based on their co-occurrence and residue data obtained from past and ongoing or new monitoring studies (SO2 monitoring). Different life stages of the pollinator species will be tested where necessary based on exposure evaluation.

Sublethal and chronic laboratory tests – Testing will be done on pollinator species that are easily available and selected as model species. This approach will use oral exposure to mimic the prolonged exposure to pesticide residues in the field. The delayed effects on mortality, fecundity, development time, behaviour, etc., will be measured. Delayed effects are also known as time-reinforced toxicity. They are in the upcoming new bee guidance document for pesticide risk assessment (RA) by EFSA, suggested to be analysed by using a combination of chronic tests and TKTD models. The tests will also include combined treatments for pesticides commonly used in mixtures or sprayed next to each other in short intervals. When possible, pollinator exposure will be carried out according to international conventions for toxicity tests (e.g., OECD). Existing tests for the closest taxon will be adapted for species with no standard tests described.

Phototactic tests will be used to assess the sublethal effects on different pollinator species. Because phototaxy (positive or negative) is widespread in the animal kingdom, we expect to use this test as a standard and common method to compare sublethal effects between different pollinator species. In the laboratory, insect pollinators will be fed *ad libitum* with a syrup (with or without a sublethal dose of one or two pesticides) and then tested to assess their phototactic behaviour. The phototactic response will be quantified by measuring the time an insect needs to reach the light source inside a dark chamber arena. For recording, we will use an infrared camera connected to a laptop.

As the primary target of many insecticides is the nervous system, another possible sublethal effect can be changes in the respiration rate. The respiration rate may increase or decrease due to the direct toxic effect of an insecticide or may increase due to high detoxification costs. The respiration rates will be measured in selected pollinator species at sublethal concentrations, estimated based on bioassays performed earlier with SO1 toxicity tests.

Links to other SOs – The knowledge about the frequency and magnitude of exposure as well as interactive and sublethal (sub-chronic and/or chronic) effects on pollinators of the pesticides applied in mixtures, as a sequential application, or foraged concurrently in the landscape will allow control of pest populations while protecting the most important pollinators. This information feeds to SO4, cross-compliance. These data will allow the construction of more realistic models for ERA. Data on pesticide residue levels in pollinator relevant matrices and combined and sublethal effects of pesticides on selected pollinators will be further used in pesticide risk indicator development for pollinators (SO2) and predictive modelling using the TKTD and ALMaSS models (SO3, SO4).

1.2.3 Specific Objective 2: Pesticide and pollinator monitoring scheme

Sampling site selection and landscape toxic load mapping – Pesticide and pollinator co-monitoring is initially focused toward areas with high predicted toxic load of pesticides. Site selection for environmental sampling and co-monitoring will thus be based on landscape pesticide toxic load and cover major cropping systems in Europe and the three EU regulatory zones. Within Task 4.a, ALMaSS will produce a grid of the predicted pesticide toxic load and the extent of semi-natural areas over the three sampling regions (Italy, UNIBO; Poland, UJAG, INC-PAS; Sweden ULUND), with 6 sites selected in each region (Fig. 2). The sites will be selected in grid cells with high pesticide toxic load and will be centred on two cropping systems, arable (oilseed rape, annual; 3 sites per country) and fruit (apple, perennial; 3 sites per country), which previously have been identified as potentially of high pesticide risk for bees (Jonsson et al. 2022, Rundlöf et al. 2022). Sites within a crop and country will be distributed along a gradient of semi-natural habitat extent to provide useful landscape context variability for scenario validation in ALMaSS and potential for pesticide exposure and effect mitigation for pollinators (Park et al. 2015). Field inspections will be done to validate *in silico* outcomes for crops and landscape context.

Co-monitoring of pesticides and pollinators (PPCoMS) – Field monitoring for pesticides and pollinators (co-monitoring) borrows methods from current separate monitoring schemes. Following the method of the SPRING Minimum Viable Scheme Pilot within EU-PoMS, protocols will be implemented for transect surveys of 500 m, divided into 10 50-meter segments, to collect all bees, butterflies and hoverflies encountered within 1 m to each side and 2 m in front and up for bees and hoverflies and 2.5 m to each side and 5 m in front and up for butterflies while slowly walking along the transect during satisfactory weather. Non-collected pollinators are noted to the closest possible group on the EU-PoMS Transect Recording Form. The pollinator collection and recording are done to capture the pollinator populations and community at the sampling sites. The transect is walked back while counting and recording flower units in each of the segments using a 0.5 m^2 square to estimate local flower abundance and collection of plant material for pesticide residue analysis. Moths are surveyed and collected using special moth traps piloted within the Swedish Nat-PoMS. The sampling and survey, coordinated by ULUND, will be conducted by UNIBO (Italy), UJAG and INC-PAS (Poland) and ULUND (Sweden) to cover southern, central, and northern Europe as well as evaluate the inter-team feasibility of the protocols. Sampling and surveys are repeated twice to cover both previously identified high-risk pesticide periods (Knapp et al. 2023) and key pollinator activity periods (Arnberg et al. 2022). Collected pollinators are kept frozen until they are first identified to species in the laboratory and after that, pooled into a taxonomic group (wild bees, butterflies, hoverflies, moths) samples and sent for pesticide residue identification and quantification by SLU.

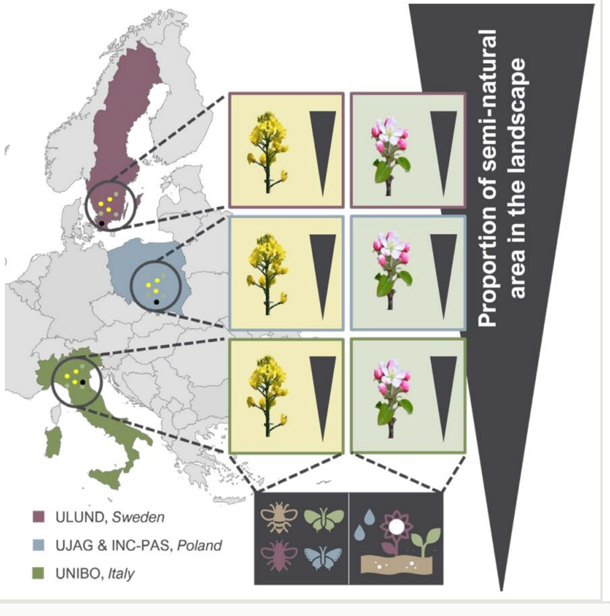

Figure 2. doi

The pesticide and pollinator co-monitoring and sampling covering pollinator relevant matrices, groups and cropping systems in three sampling regions in the EU zones (south, central, and north).

Pesticide screening and quantification – The laboratory at SLU will process environmental and insect samples from field locations based on their long experience in determining a large number of pesticides in bee-related matrices (Rundlöf et al. 2022, Jonsson et al. 2013). The laboratory is accredited according to Swedac 1208 ISO/TEC 17025 and has been running the national pesticide monitoring since 2002 with the aim to track long-term trends in pesticide residues in surface water and groundwater, later extended to sediment, air and precipitation. SLU will use liquid chromatography-tandem mass spectrometry (LC-MS/MS) and gas chromatography-mass spectrometry with negative chemical ionisation (GC- (NCI)MS) and methods development in SO1 & SO4.

Pesticide risk indicators for pollinators – There is no specific pesticide risk indicator for pollinators from which to indicate risk from information gathered by field monitoring. Hence, *PollinERA* will develop two such indicators, TWC_{mix} and PollSPEAR, which could be used along other more general pesticide environmental risk indicators such as pesticide (toxic) load and the EU Harmonised Risk Indicators. The toxicity weighed concentration of the pesticide mixture (TWC_{mix}) has been used by ULUND and SLU to track pesticide risk for bees among sites, matrices and pesticide active ingredients (Knapp et al. 2023, Jonsson et al. 2022, Rundlöf et al. 2022) and also applied in the PoshBee project. It is based on pesticide concentrations in bee-related matrices weighed by standardised toxicity data for honey bees (average of acute oral and contact lethal dose to 50% of the test population). In *PollinERA*, TWC_{mix} will be further used for non-bee-related matrices and related to pollinator species richness and abundance to evaluate its usefulness for pollinators also beyond bees. In addition, data on pollinator species sensitivity and traits (SO1 & SO3) will be combined with monitoring data on pollinator species abundance to develop a pollinator community-based pesticide risk indicator similar to the trait-based SPEAR (Species At Risk) indicator developed for aquatic invertebrate communities (Liess and Ohe 2005). We will attempt to improve on the SPEAR concept by following Rubach et al, 2010's suggestion to use mean species sensitivity of pollinators as the benchmark. The suggested indicator development is targeted towards pesticide risk and impact tracking which would provide tools for tracking the goal fulfilment of pesticide and pollinator related targets on reduce pesticide risk explicit within the strategies of the EU Green Deal.

Links to other SOs – The prediction of high pesticide toxic load mapping for site selection for the pesticide and pollinator co-monitoring relies on the ALMaSS landscape simulation (SO4). The co-monitoring will in turn provide empirical information on environmental pesticide exposure among pollinator taxa (SO1) and landscape context (SO4) as well as pollinator population densities (SO3). The development of pollinator pesticide risk indicators relies on pollinator exposure, sensitivity and trait information collected from the literature and produced in the laboratory (SO1) as well as *in silico* (SO3). The indicators are used to track outcomes of scenarios and policy related to pesticides and pollinators specifically (SO4).

1.2.4 Specific Objective 3: In silico models for chemicals and pollinator populations

SO3 includes development of three types of *in silico* models and one data analytical process. The model types are models to predict pesticide properties from their chemical structure (QSARs), models to describe the toxicokinetics and toxicodynamics of pesticides in pollinators (TKTD), and third, agent-based population models of pollinators in ALMaSS. The latter two feed as components to SO4, whilst the QSARS provide toxicological input for ERA evaluation. The data analysis produces a classification of pesticides into cumulative assessment groups, a necessary step to reduce the dimensionality of the problem for the ERA framework.

QSAR and associated approaches – To fill data gaps, *in silico* models that put into relationship the chemical structure and the activity (or property) to be calculated, QSAR models can be used. Their development will be based on these three main orthogonal methodological components:

- Quantitative structure-activity relationship (QSAR) models based on collections of experimental values, such as toxicity values; this method refers to the predictive models;
- Toxicological mechanisms, codified into rules such as structural alerts and physico-chemical properties; this method relies on the theoretical reasoning;
- Similarity tools to link experimental values of related substances within the read-across perspective; this method refers to the experimental evidence.

1. These three components will be combined into a weight-of-evidence (WoE) strategy, following the EFSA Guidance on WoE. Partner IRFMN will exploit data for a series of compounds to develop QSAR models. Multitask methods will be applied, addressing effects towards different species, which will exploit data even in a sparse data matrix for the lack of data. The honey bees' data will be the most numerous. The chemical information will be derived from the structure represented as Simplified Molecular Input Line Entry System (SMILES), in the case of models using the software programs CORAL (based on Monte Carlo statistical approach), SARpy and QSARpy (machine learning in house tools using fragments) (Carnesecchi et al. 2019; Carnesecchi et al. 2020a; Carnesecchi et al. 2020b). All these tools are available from the VEGAHUB website, developed in-house – www-vegahub.eu). Alternatively, molecular descriptors will be calculated using software such as Dragon 7.0 (Kode srl 2016) or PaDEL (Yap 2010) and used to develop models using support vector machines (SVMs), random forests, artificial neural networks (ANNs), deep learning, etc.
2. Using mechanistic reasoning to identify different species' sensitivity, based on the TK inputs derived from SO1 (Partner UOS), to cover the data gaps. This information will be linked to partitioning consideration and related to the different species biological traits. In this case, physico-chemical data, experimental or predicted using existing models (e.g., in VEGA), will be used to model toxicology among different species. Further features, related to active transport or toxicodynamic properties, will be addressed on a case-by-case basis, depending on the available theoretical information. In the case of the toxicodynamic properties, mode of action (MoA) will be used, extending the model already developed in VEGA for honeybees. Thus, these theoretical considerations will identify different behaviour compared to the honey bee's model; these deviations will be

represented by rules based on structural alerts and physico-chemical properties associated with the chemical structure of the substance to be evaluated.

3. Experimental values will be used with software in VEGAHUB such as ToxRead and VERA. These are software programs for read-across to provide toxicity evaluation for substances similar to those represented by the source ones. They use different similarity inputs: the overall structural chemical similarity, as in VEGA; the presence of relevant molecular groups; the physico-chemical similarity; the toxicological similarity, using structural alerts and MoA. A further similarity measurement based on toxicokinetics will be added to *PollinERA*.

These three components will be combined into a weight-of-evidence (WoE) strategy, following the EFSA Guidance on WoE. Existing models for the environmental degradation products, implemented in JANUS (available from VEGAHUB), will be used by IRFMN to provide information not only on the parental pesticide, but on its degradation products, while the VEGA model on mode of action can be used to group substances in a mixture.

Finally, the resulting models will be implemented in VEGA. Different technological solutions may be adopted to implement the models within other platforms, such as EFSA Knowledge Junction, OECD QSAR Toolbox, Danish (Q)SAR Database, AMBIT, ICE, etc. Docker solutions will be proposed in this case.

Definition of environmental cumulative assessment groups (CAGs) – This is a critical step to reduce the dimensionality of the problem down to several substance groups that can be followed in environmental matrices and simulated concurrently in the ERA framework tools. CAG definition requires a set of steps each refining the groups assigned to the individual CAG and draws on information across *PollinERA*. The first selection is based on toxicology and mode of action. Within VEGAHUB there is a model for the mode of action of pesticides, which will be useful to cluster substances. Molecules with similar modes of action and toxicological profiles will be combined for each focal species using data from SO1 and the in silico predictive models. These selections will be further refined by defining agricultural use (SO4) and environmental fate (SO1), and exposure of pollinators (SO1 & SO4). The result will be a set of CAGs that may be species and location specific but can be standardised to create comparable RAs across a wide range of pesticides and locations. The target here is to reduce the number of specific chemicals to be independently followed in the simulations from hundreds to 30-50 CAGs. The results of this analysis will be discussed with stakeholders (SO4) and once agreed will be implemented in the ERA framework.

TKTD modelling – To date, almost all TKTD modelling approaches have addressed aquatic species and one exposure route: uptake from the water. Nevertheless, one of the specific advantages of TKTD models in the context of the ERA of chemicals is that they can integrate several separate exposure routes and hence allow RA based on combined exposure routes. One first step towards using TKTD modelling for insects was recently made by suggesting the BeeGUTS model, which can account for two different exposure routes of chemicals for honey bees (*Apis*), i.e., via contact and oral exposure. Using BeeGUTS, it was possible to consistently describe experimental results of honey bee survival accounting for acute contact, acute oral, and chronic oral exposure with high accuracy using a single set of parameter values, and knowledge about the physiology of honeybees (e.g., honey stomach size). In *PollinERA*, we will develop robust generalised TKTD models integrating multiple exposure pathways without prior knowledge of detailed physiological characteristics. We will take advantage of ongoing project work within an EFSA-funded tender describing TKTD processes for non-target arthropods (AENEAS project), where the modified GUTS models are screened for their potential to integrate various exposure pathways. We will further optimise the structure of such pollinator-TKTD models and develop and provide robust and efficient methods to calibrate these models based on minimal experimental data while integrating machine learning techniques such as QSAR and read-across. The methodology will be applied to model the uptake and effects of various pollinator species, including hoverflies, butterflies, and moths. The result will be parameter sets for these pollinator species for a range of relevant pesticide compounds, together with the methodology that will allow to apply these models for further pollinator species and pesticides.

Population modelling – We propose to model four main pollinator groups, hoverflies (Syrphids), butterflies and moths (Lepidoptera) and bees (Apoidea) to cover the suggested groups for European pollinator monitoring (Potts et al. 2020). We define seven focal species for modelling using agent-based models in ALMaSS: utilising existing ALMaSS bee models (*Apis melifera, Osmia bicornis* and *Bombus terrestris*) and creating new models of species in the other pollinator groups. We plan to develop models for an aphidophagous (*Sphaerophoria rueppellii*) and a saprophagous (*Eristalinus aeneus, Eristalis tenax*) hoverfly species, a diurnal butterfly (*Maniola jurtina*) and a Noctuid moth (*Orthosia* sp.). However, the final choice to be informed by the recommendations of the EFSA IPol-ERA project when *PollinERA* starts. These models will include plasticity to represent the groups in Europe by re-parameterisation to represent the more sensitive species in the groups; they will integrate the TKTD models developed by the project into each individual modelled insect.

We propose a structured approach to create models for the new species. Each will first be scoped and designed using the new Formal Model approach (Topping et al. 2022), laying out the salient literature on the species and the intended design of the species models with equations for review. We will then implement the species models within the ALMaSS model in C++ using the OOP paradigm to allow for extensibility of code and easier maintainability, and document them using the MIDox approach that links documentation directly to the program code. Along with the implementation, the models will be calibrated against available ecological and behavioural data and knowledge on each species within the RA context (existing and from SO2). The models will also be parameterised to represent more sensitive species, allowing also to represent the target groups better. For example, the *Bombus* model could be parameterised to have shorter foraging ranges and smaller colonies, more similar to the common carder bee (*Bombus pascuorum*), a doorstep forager with small colonies.

The modelling will take a multi-stressor approach, taking account of the similarity of action, but of different exposure routes, to test multiple active pesticides. Single products will be tested but against a level of background exposure to other pesticides and stressors as found by monitoring (SO2). By incorporating TKTD modelling, the individual insect pollinators will be able to respond more realistically to the accumulated body burden of pesticides while also allowing recovery, rather than relying on probabilistic chances of death upon exposure. This will allow for a more realistic, and therefore a more refined, ERA.

Links to other SOs – TKTD modelling will be used as a module within the species models in the ALMaSS simulation system (SO4). Integration of such a new module will require optimising the implementation of the TKTD modelling. We will hence further optimise the TKTD equations and methodologies to allow the most efficient and robust calculations of internal concentrations of a range of pesticides and their impact on pollinator species as modelled in ALMaSS. The QSAR models will be used in the ERA (SO4) too. Data to develop these models (TKTD and QSARs) comes from SO1. Definitions of CAGs feeds forward to SO4 and the ERA framework but also relies heavily on inputs from SO1.

1.2.5 Specific Objective 4: A population-level systems-based approach to pollinator ERA and policy evaluation

Simulation methods are designed to develop a spatial-temporally dynamic pesticide exposure and toxic-risk modelling tool for the pollinator systems based on ALMaSS. ALMaSS, often used to simulate pesticide effects (Ziółkowska et al. 2021), is a mature landscape-scale simulation system for investigating the effect of landscape structure and management changes on the population size and distribution of animals and environmental, economic, and agricultural consequences in agricultural landscapes. ALMaSS will provide the framework to host the pesticide application and fate simulation, which will be fully integrated into the spatial system providing modelling to toxic loads to support the ERA.

ALMaSS landscape modelling: A major part of the ALMaSS system is the environmental modelling (landscape) in which the agent models are placed. Through collaboration with H2020 projects (EcoStack, B-GOOD, and PoshBee) the fully working ALMaSS landscape models at the national or regional level are or will be soon available for 11 EU countries (Fig. 3) and can be adapted and (if necessary) upgraded to be used within the *PollinERA*. ALMaSS landscape models consist of spatial and temporal components, where the spatial component is a detailed raster map of spatial resolution of 1-m^2, and the temporal component allows capture of changes in vegetation patterns, and processes related to, i.e., farming activities, with a time step of 1 day. In these models, cultivable areas are described in more detail by delineating agricultural parcels and grouping these into farm units of different types. Such highly detailed models require data of sufficiently high resolution and quality. The methodology assumes (Topping et al. 2016) the use of detailed topographic databases (usually in scales 1:10,000 – 1:50,000) and IACS / LPIS (Integrated Administration and Control System / Land Parcel Identification System) data, particularly maps of LPIS reference (agricultural) parcels together with an agricultural register of crops cultivated in reference parcels and anonymised information on parcel owners. However, acquiring such data can be very time-consuming and costly for some countries. Therefore, in *PollinERA* existing landscape capability will be expanded only in those countries where ALMaSS simulation is already underway. These include the three countries used for monitoring and for which toxic load predictions will be used to determine optimal monitoring locations.

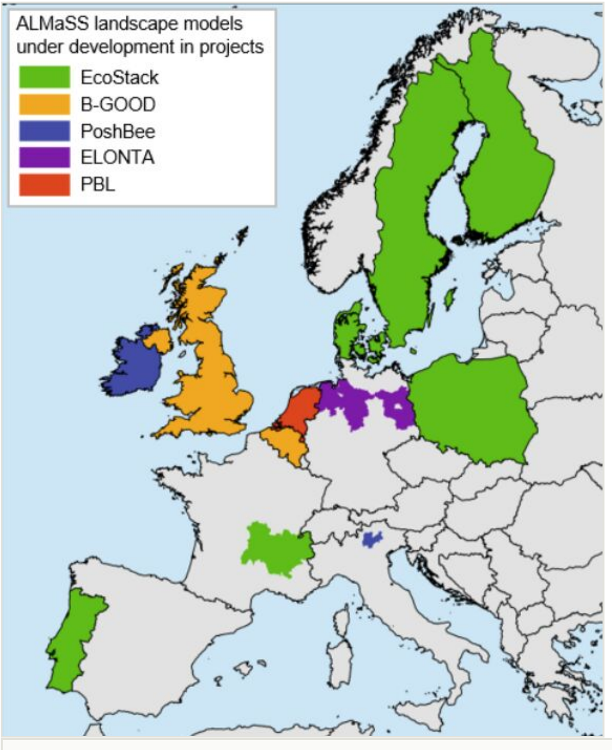

Figure 3. doi

ALMaSS coverage in Europe. All are now operational.

ALMaSS is an open-source open-science project hosted on GitLab, and is the main tool used and developed by the Centre for Social-Ecological Systems Simulation (SESS) at AU. It is an agent-based model system based on highly detailed simulation models (e.g., all bees in a colony as individuals making decisions every 10 minutes), a software engineering endeavour not to be confused with the typical simple agent-based models encountered in ecology. ALMaSS has seen use in regulatory RA to support policy evaluation for the Danish government, and, most recently, for the Dutch government to assess aspects of their agricultural sustainability policy. It can be used as a multi-criteria decision-making support by combining alternative options and goals in future scenarios, which can be compared and contrasted using objective metrics such as efficacy/cost. Key ALMaSS knowledge advances relate to the context dependency of results and the need to evaluate management/risks using a systems approach, fully dynamically integrating all significant factors. This is the basis of the new approach developed by the European Food

Safety Authority (EFSA) for ERA of bees, relying on ALMaSS simulation modelling to provide the honey-bee risk assessment model ApisRAM.

Landscape simulation for toxic load – Apart from the detail often used in ALMaSS models, what sets this system apart from others is that from its conception, it has utilised dynamic landscapes rather than static maps. Therefore, a very substantial part of the system is modelling the environment the pesticides will be applied into and their subsequent environmental fate. ALMaSS models can track the daily growth of vegetation, pollen and nectar resources, and the environmental concentration of multiple pesticides. Spatial relationships can be specified in ALMaSS for applying pesticides and their environmental behaviour in soil and vegetation, thus providing an excellent basis for developing a toxic load simulation. Pesticides are represented as substance concentration per $1m^2$ on vegetation surface, in soil or plant parts (pollen, nectar), which links to the environmental sampling and analysis in SO2. All are modelled with environmental decay rates that take weather into account. Supporting data will come from existing models for the environmental degradation products, implemented in JANUS (available from VEGAHUB), will be used by IRFMN to provide information not only on the parental pesticide, but on its degradation products. When cultivating a crop, initial concentrations are determined by applying the pesticide following normal agricultural practice. This application is determined by the agricultural system in place in a particular landscape and is thus location-specific. It can be overridden, however, for simulation of experimental scenarios (e.g., all farmers apply pesticides).

A key challenge here is expanding the capability to track multiple chemicals at this level of detail. This is only possible through cumulative assessment groups (from SO2), the application of well-designed data structures and the use of parallel processing in software design. Using these methods, we expect to be able to track 30-50 concurrent CAGs/ Pesticides. As well as feeding the ALMaSS population models, the landscape concentrations provide a separate output as spatial-temporal maps of toxic load for each landscape (for use in SO2 to guide the choice of monitoring landscapes).

Integration of the pesticide and non-regulated stressors will occur as a consequence of the impacts of management and climate modelled directly in the pollinator models developed. For example, direct mortality by farming actions such as cutting vegetation or sub-models for parasitoids, as appropriate.

Scenario generation methods – Scenarios will be developed to be relevant and replicable to all three traditional regulatory regions of the EU, represented by collaboratively developing scenarios in Sweden / Denmark (northern) Poland / Germany/ The Netherlands (central) and Italy (southern). Scenarios will also cover the Europe's main agricultural / cropping systems of Europe, i.e., arable, horticulture, fruit and oleaginous crops. The formulation of scenarios will require coordinated guidance between project experts and targeted stakeholder representatives of the project's two main user groups: namely

1. Risk assessors (in regulatory authorities and industry) - users of the tools and

2. Risk managers (at central EU level and national level). Input and feedback from these targeted end-users will be gained through a series of facilitated workshops / webinars held during the life of the project.

In addition, our end user engagement strategy, through a series of coordination meetings, will link *PollinERA* to other key projects engaged in the review and assessment of current RA guidance (e.g., PARC etc.). These activities will seek to bring together different viewpoints and explore a variety of ERA approaches, employing sound SSH (social science) approaches regarded as integral for effective transition management. This will further anchor the development of ERA tools and methods, formulation of scenarios, and impacts for policy on aspects of generic applicability, especially for higher-hierarchical-level decision contexts, highlighting the versatility, fitness-for-purpose, and applicability of project results.

Framework methods – This is the generation of the *One System* framework from the components combining all components of SO1-SO3. The toxic load relates to the hazard identified in SO1 combined with the environmental concentration through time of multiple pesticides. Toxic load provides a common currency for the combination of pesticide risks, allowing the effect of multiple pesticides to be directly combined. The sum of the combinations will be either dose addition or synergistic/antagonistic effects as predicted from SO1. Toxicological knowledge will feed to TKTD and exposure modelling. *In silico* predictive toxicology and agricultural usage information will predict combination effects and provide CAGs. The population-level RAs will access this information in space and time, driving TKTD models in individual pollinator agents simulated in the landscape. All will be integrated into ALMaSS-based landscape simulations for European countries using the pollinator population models, which will also bring in non-pesticide stressors, such as mortality due to farm management and parasites and diseases. Finally, a feedback loop based on monitoring will be specified to allow the adjustment of models, and to direct monitoring to critical locations. The models and procedures developed will be used with the *PollinERA* case studies (monitoring landscapes from WP4 and scenarios cases to demonstrate the tools across Europe) to develop and showcase the ***PollinERA One System***. A professional user interface will not be developed in the research project, but web-based user interfaces (e.g., using R and Shiney) will be provided so that users can test and evaluate the tools and provide access to the scenarios. The framework will then be ready to test regulatory and policy scenarios.

Policy impact methods – *PollinERA* is committed to contribute to the EU goal of reversing the decline of pollinators. This is done by mapping *PollinERA* key results and tools onto the intersection between the pesticide regulatory framework - Regulation EU 1107/2009 and Sustainable Use of pesticides Directive 128/2009, including its revision - and the pollinator focused biodiversity conservation initiatives – linked to and delivering on the European Green Deal and the fundamental Sustainable Development Goals (SDGs). Identifying these intersection nodes will facilitate the implementation of the revised EU Pollinator Initiative and the Restoration Law, contributing to achieve the targets established by the

Biodiversity 2030 and the Farm to Fork Strategies or understanding if those targets has been met. Specifically,

1. an integrated system for pesticide ERA will facilitate transformative change through maintained food production without degrading land or reducing pollinator biodiversity (SDG2/15);
2. pesticide risk indicators specific for insect pollinators and co-monitoring to set baselines, track the goal fulfilment of pesticide risk reduction and halting pollinator decline; and
3. pesticide mitigation actions that are trialled *in silico*, verified in landscapes and for potential integration as financially supported agri-environmental measures in the Common Agricultural Policy (CAP). Applying SSH approaches, authorities and other stakeholders will be engaged to define policy options that cover these intersection nodes, for possible implementation through the National Action Plans (NAPs).

To ensure the uptake of *PollinERA* advancements, the developments of the relevant regulatory frameworks will be continuously followed up through the PARC partnership (SLU, AU, UOS, ULUND) and by BEBC through monitoring of the decision-makers' discussions. See Table 8 for more detailed stakeholder coverage.

Interdisciplinary approach – *PollinERA* will take an interdisciplinary approach integrated through tool development. It uses multiple modelling approaches from chemical modelling to systems modelling together with laboratory experiments to generate knowledge and tools and uses social science approaches to co-develop these with stakeholders and to maximise impact.

1.2.6 Linkage to other national or international projects

The PollinERA project is closely linked to a number of international and national research and innovation projects and activities due to direct involvement of partners (Table 2). In addition, PollinERA will liaise with other activities and projects in this Horizon Europe Cluster 6 (Table 3) or in any project group suggested by the EC.

Table 2.

Links to relevant research and innovation activities in which *PollinERA* partners are involved.

Activity	Activity developments & linkage to *PollinERA*
IPol-ERA (2022-2023), OC/EFSA/ED/2021/01-LOT1	EFSA funded. Advancing the environmental risk assessment (ERA) of chemicals for insect pollinators. The project addresses current ERA challenges related to systems approaches and ensure preparedness for future challenges [**AU, ULUND, UNIBO, INC-PAS & BEBC**]. The **IPol-ERA** pollinator ERA database and final report will feed into *PollinERA*.

Activity	**Activity developments & linkage to *PollinERA***
EcoStack (2019-2024), GA 773554	H2020 funded. Development of ecologically, economically, and socially sustainable crop production strategies via stacking of biodiversity service providers and bio-inspired tools for crop protection, related to agricultural fields, in order to enhance sustainability of food production systems across Europe [**AU, UJAG & SLU]. EcoStack** plant protection strategy developments will link to *PollinERA* pollinator and landscape (Sweden) modelling.
B-GOOD (2019-2023), GA 817622	H2020 funded. Paving the way towards healthy and sustainable beekeeping in the EU through a collaborative and interdisciplinary approach. Developing and testing innovative tools to perform ERA according to the Health Status Index (HSI) [**AU, UJAG & PEN]. B-GOOD** provides integrative analyses performed using ALMaSS, incl. bee species modelling.
PoshBee (2018-2023), GA 773921	H2020 funded. Providing the first comprehensive pan-European assessment of the exposure hazard of chemicals, their mixtures, and co-occurrence with pathogens and nutritional stress for bees across two major cropping systems [**AU, SLU & PEN]. PoshBee** provides ALMaSS bumblebee species modelling and PPP residue data among matrices and bee species.
ApisRAM (2017-2021), OC/EFSA/SCER/2016/03	EFSA funded. Providing a model of a bee colony, following individual bees through their life cycle, and recreating their behaviour and decision-making [**AU & BEBC]. ApisRAM** provides ALMaSS honey bee modelling to *PollinERA*.
PARC (2022-2029), GA 101057014	HE funded. An EU-wide research and innovation partnership programme to support EU and national chemical risk assessment and risk management bodies with new data, knowledge, methods, networks, and skills to address current, emerging, and novel chemical safety challenges [**IRFMN, UOS, SLU & ULUND]. PARC** and *PollinERA* will feed into each other regarding ERA stakeholder engagement, and *PollinERA* will provide input to **PARC** for improving the current PPP ERA framework.
EUBP Platform (2022-2024), OC/EFSA/SCER/2021/09	EFSA funded. Implementation of the EU Pollinator Hub for harmonized data collection and sharing among stakeholders on bee pollinators, incl. the EU Pollinator Hub [**BEBC & ZIP]. EUBP Platform** will store data provided by PollinERA and take part in the exploitation of *PollinERA* results.

Activity	Activity developments & linkage to ***PollinERA***
VEGAHUB (2022-2029) vegahub.eu	Platform that includes several *in silico* tools like VEGA (stand-alone application with 100+ QSAR models for physico-chemical, (eco)toxicological, and environmental properties) [**IRFMN**]. *PollinERA in silico* models will be implemented in VEGA.
sOFT-ERA (2022-2026), OC/EFSA/IDATA/2022/02	EFSA funded. Strengthening the development of OpenFoodTox (EFSA database) for substance evaluation and risk assessment. Developing *in silico* models to generate predicted values [**IRFMN**]. *PollinERA in silico* models will be included in the EFSA Knowledge Junction through **sOFT-ERA**.
BETTER-B (2023-2027), GA 101081444	HE funded. Understand the processes and mechanisms that apply in nature and to adapt modern beekeeping practices and decision making accordingly and using the benefits of advanced technologies [**AU & UJAG]. BETTER-B** will provide input to pollinator caring capacity and pollen and nectar modelling.
RestPoll (2023-2027), GA 101082102	HE funded. Pan-European collaboration to restore and connect wild pollinator habitats by strengthening society-wide capability to reverse wild pollinator decline and stabilise pollination services and their societal benefits [**ULUND & SLU]. RestPoll** will give input to empirical evaluation of pollinator supporting (flowers, nesting) and pesticide mitigation strategies.
Other relevant activities with *PollinERA* partner involvement	
Netherlands Environmental Assessment Agency (PBL) **Developing and application of a methodology to assess impacts of pesticides on key ecosystem services [AU & UJAG**] - National Science Center Poland (NCN) project 2015/19/B/ NZ8/01939 & UMO-2017/26/D/ NZ8/00606 [**UJAG & INC-PAS**] - Swedish research council Formas **MixToxBee** GA 2018-02283 [**ULUND & SLU**] – EFSA **TKPlate 2.0** OC/EFSA/SCER/2021/07 [**UOS**] – EFSA **AENEAS** OC/EFSA/ED/2021/02 [**UOS**] – EU **SPRING [AU & ULUND] - EFSA Bee Guidance Revision WG [ULUND & UOS**] – Swedish EPA and BECC **AirBeeSafe [SLU & ULUND**] – FP7 **STEP** GA 244090 [**AU, ULUND & SLU**] – EFSA **PERA** OC/EFSA/ED/2020/1-LOT1 [**AU & UOS**] – Umweltbundesamt (UBA) **JANUS FKZ 3716 65 4140 [IRFMN] – H2020 Safeguard GA** 101003476 [**ULUND, SLU & PEN**] – Umweltbundesamt (UBA) **ELONTA** Z 1.5-93 401/0064 [**AU & UJAG**] - Danish Environment Protection Agency (DEPA) **MUSBERA [AU, UJAG & INC-PAS] - EFSA PPR Panel [AU & UOS] – EFSA MUST-B WG [AU & UOS] - COLOSS APITOX TF [UNIBO & BEBC**]	

1.2.7 Gender dimension

The promotion of gender equality and the gender dimension in the Horizon Europe Research and Innovation Programme is addressed within the *PollinERA* project. The coordinator (AU), university and research institution project partners (UJAG, ULUND, UNIBO, UOS, INC-PAS, IRFMN, and SLU) all have gender quality plans implemented that undergo regular updates and amendments. Our NGO partner (BEBC) is represented by its female Scientific Director and Project Manager in this project. Furthermore, *PollinERA* confirms gender balance with the researchers of the consortium, comprised of 41% women and 59% men.

Table 3.

List of important national and international activities that are highly relevant and complementary to *PollinERA* with no connection to the *PollinERA* consortium.

Activity	**Activity developments & linkage to *PollinERA***
HORIZON-CL6-2023-BIODIV-01 Area A	HE funded. **Better understanding the routes of exposure of the wild fauna and flora to chemical pollution - Area A** of the topic where PollinERA answers Area B. Area A and B are linked as both areas are expected to assess the effects and impact of chemical pollutants, in particular the most dangerous substances from agriculture, on the condition of the biodiversity and ecosystems in natural environment and consequently on human health, and identify preventive and mitigation measures.
ICP-PR non-*Apis* W	The **ICP-PR non-*Apis* working group (WG)** is a subgroup of the ICP-PR Bee Protection Group, which serves as a forum for addressing challenges and uncertainties associated with protecting and enhancing the health of non-*Apis* bees and to provide a means of coordinating international research efforts within academia, government, and industry to develop suitable testing and evaluation methods for assessing exposure and effects of factors impacting bee health. This work links to the *PollinERA* SO1 & SO2.
INSIGNIA-Bee (2018-2021) & **INSIGNIA-EU** (2022-2024)	EU funded. **INSIGNIA-Bee**, the pilot phase of the INSIGNIA project, developed a guideline with protocols for the citizen-science-based monitoring of pesticides using honey bee colonies. The follow-up, **INSIGNIA-EU**, aims to design and test an innovative, non-invasive, scientifically proven citizen science environmental monitoring protocol using honey bee colonies for the detection of pesticides, microplastics, heavy metals, and air pollutants. *PollinERA* will integrate relevant honey bee-collected pesticide exposure data from the projects once available.
EFSA Knowledge Junction	A curated, open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments. *PollinERA in silico* models and raw data output will be stored on the **EFSA Knowledge Junction**.
EU Pollinator Information Hive	A platform for information on actions for conservation of wild pollinator species in the EU. It facilitates information, and collaboration between stakeholders. *PollinERA* will be registered in the **EU Pollinator Information Hive**, and thus link and explore collaborations.
INSPIRE Knowledge Base	Infrastructure for spatial information in Europe to create harmonised spatial data sets that can be used seamlessly in cross-border applications. *PollinERA* will integrate relevant geospatial data from the **INSPIRE Knowledge Base** to support modelling.
BISE	Partnership between EC & EEA. **Biodiversity Information system for Europe (BISE)**, a policy framework to protect biodiversity at the global, EU and national levels. *PollinERA* will establish a link and explore collaborations with the **BISE**.
SPRINT (2020-2025)	H2020 funded. Aims to develop a Global Health Risk Assessment Toolbox to assess impacts of PPPs on ecosystem, crop, livestock, and human health. *PollinERA* will engage with **SPRINT** having related activities and goals to benefit from and maximise the knowledge exchange.

PollinERA considers the insights to an inclusive analysis presented in Gendered Innovation 2 (European Commission, Directorate-General for Research and Innovation 2020). The project will include a gender dimension in the project activities, ensuring user acceptance of differences in biological characteristics and the social and cultural features of genders. AU will be in charge of gender considerations within the *PollinERA* consortium.

Operationalisation of the gender approaches will benefit the performance of the project team and, thus, the project. During the project, AU will ensure the assessment of interactions of all genders with the proposed solutions and potential gender differences according to Gendered Innovation 2. In *PollinERA*, potential gender differences in the project will be considered, particularly concerning WP5 & 6's interaction with stakeholders. *PollinERA* ensures that the group of relevant stakeholders will be complementary, considering their added value and their social, cultural, and societal background, including gender differences.

1.2.8 Open science practices

Open Science – all *PollinERA* protocols and results will be disseminated using an Open Science initiative to maximise impact and end-user engagement. All protocols developed will be described on the *PollinERA* website. The communication and dissemination WP includes significant representation from all partners to enable continuous scientific feed to the website. All program code will be available as open-source (GitLab) and all discoveries translated to easily understood news articles published on the website. Models relating biological, environmental, and physical-chem properties of chemical substances to their structure will be published on VEGAHUB. Full documentation of all models will also be provided in an easy to navigate format. This initiative is in addition to the normal open data principles of H-Europe. The project will also make use of the highly innovative Open Access journal Research Ideas and Outcomes (RIO) and Food and Ecological Systems Modelling Journal (FESMJ), where a special Open Science Collection for *PollinERA* is envisaged as well. In addition to conventional research papers, the journals welcome contributions documenting the entire research cycle, including data, models, methods, workflows, results, software, perspectives, and policy recommendations (see section 2.2. for details).

1.2.9 Research data management and management of other research outputs

Data management plan – A data management plan will be developed at the beginning of the project conforming to FAIR principles. Its aim is to ensure that the data is acquired, processed, and stored systematically and transparently and that it complies with formal and regulatory requirements. The data management plan will comprise the three major steps – data acquisition, data processing and data storage. It consists of a data governance framework, a plan for metadata management and a definition of the data pipeline. Partner BEBC will manage this process and will assist in the development of the relevant data models.

Data governance framework – A framework for data governance, consisting of a formal framework for the execution and enforcement of authority over the management of data and related assets, will be set up in collaboration with all *PollinERA* teams involved in data acquisition and processing. Such a framework is currently developed for the EU Pollinator Hub. It could be used as a basis for the development of procedures, dedicated work instructions and guidelines for the *PollinERA* project. In this framework it will be defined how and with which tools the teams will standardise, collect, and model data. If considered necessary, a standard business glossary with commonly defined and shared terms will be created and a procedure to update this dictionary will be established. Existing data standards will be collected based on data sampling and processing methods in order to solve conflicts such as ambiguity of concepts or different use of terms. Where necessary, legal requirements concerning the data will be addressed in the data governance framework. If the data should contain personal identifiable information, it will be ensured that the required consent to process this data will be tracked and executed throughout the data life cycle. Data ownership will be managed in the same way. Eventually, roles and responsibilities within the project with respect to data stewardship will be defined: responsibilities for data collection, maintenance, and modelling.

Metadata management – A plan for the management of metadata, necessary to describe the nature and purpose of datasets, will be developed for the *PollinERA* project. The metadata management plan will contain a procedure to collect a procedure to collect information on the origin of the data, the entities (individuals, organisations) responsible for standardisation, acquisition and processing (transformation, modelling, storage) of data, material and methods used for acquisition and processing (transformation, modelling, storage) data, quality standards applied (e.g., regulatory standards, internal standards, protocols and results for method validation).

Data Pipeline – A data pipeline will be defined, establishing how (through an existing upload module or through dedicated procedures) and by whom data will be integrated on the EU Pollinator Hub. Dataset reports will be created by the EU Pollinator Hub as part of the data integration process, containing a catalogue of the metadata and the results from data profiling (technical metadata) such as information of files, fields (names, types, length) and (if necessary) encoding. Unique and persistent identifiers are provided for datasets, providers, and files. Relationships within and between datasets are documented. Information on data integrity (completeness, accuracy, consistency across data files or datasets) as well as uniqueness, is provided. Data quality issues and the resolution of such issues are documented. The team of BEBC will set up and operate the data pipeline.

Open data and data storage – Research data and other outputs (metadata) of *PollinERA* will be integrated on the EU Pollinator Hub, an open data hub developed by a consortium led by BEBC and sponsored by the European Food Safety Authority (EFSA) which aims, among others, to establish a free-of-charge and automated service specialised in the standardised collection, processing and dissemination of pollinator-related data from validated sources. Some on EU Pollinator Hub will be stored within the EFSA knowledge junction in Zenodo. More structured data will be imported into the EU Pollinator Hub itself, transformed to the data model used by the platform, and stored within the MariaDB database server used by the Hub.

2. Impact

2.1 Project’s pathway towards impact

PollinERA’s overall strategy towards achieving impacts is shown in Fig. 4. The One System created in SO4, comprising the components developed in SO1-3 will be encapsulated in a proactive stakeholder engagement process in order to achieve medium and long-term impacts.

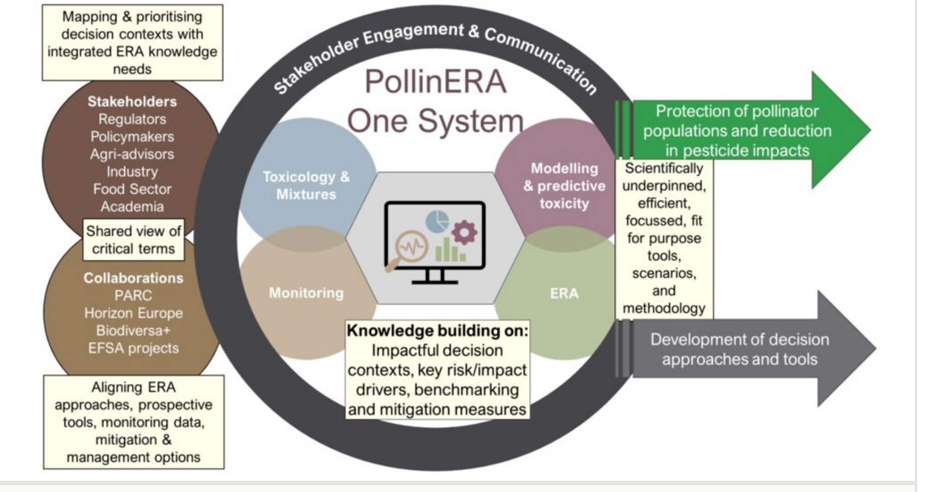

Figure 4. doi

PollinERA systems tools use and interactions with stakeholders leading to better protection of pollinators and improved decisions and tools.

2.1.1 Key project results leading to Outcomes

Important links to impacts and outcomes are indicated with references to Expected Outcome numbers (EOX), each linked to the specific objectives. The *One System* ERA and policy evaluation framework (KER6) entails a significant technological advancement that links complex models with data streams to create a systems tool. This tool is able to evaluate the impact of new and existing pesticides under realistic conditions, as well as the impacts of policy or management changes. It is supported by knowledge creation and scientific tool development and access.

Knowledge Creation – *PollinERA* creates new knowledge to support understanding the landscape-agriculture-pesticides-pollinator system. SO1 provides an understanding of sources and routes of pollinator pesticide exposure and the effects of such exposure among pollinators, both separately and as mixtures. Ecotoxicological knowledge is expanded on both exposure and effect, particularly in the direction of non-bee pollinators – as this is a major gap. This new ecotoxicological knowledge is used to support the development of TKTD models, for mechanistically linking environmental contamination to effects on pollinators (EO4), and for validating predictions of pesticide environmental fate and landscape toxic load (EO3). SO2 will expand the ecotoxicological insights by linking the SO1 environmental contamination of pollinator-relevant matrices (nectar and pollen as food, water where hoverfly larvae develop, plants that host butterfly larvae, and soil that wild bees nest in) to the contamination in insect pollinators (wild bees, butterflies, hoverflies, moths), their population densities and community. This will enable conclusions on links between pollinator community composition and pesticide exposure levels, as well as the potential for seminatural areas to mitigate pesticide-related pollinator loss and knock-on effects on food production (EO1, EO2). SO3 will generate knowledge on the likely behaviour of novel pesticides through modelling (EO3), and SO4 will generate systems-level knowledge of the effect by integrating toxicology, environmental fate, and exposure, with landscapes, pollinator ecology, and behaviour and management practices (pesticides, farming, biodiversity support, mitigation) (EO5).

Scientific Tool Provision and Accessibility – *PollinERA* aims at developing science-based tools to support sustainable development. Key tools developed or created by the project include the SO1 development of new protocols for toxicological testing of pollinators (KER1) (EO4). From SO2 the creation of a co-monitoring scheme for pesticides and pollinators is a key result (KER2) (EO1, EO2). From SO3 there will be the creation of a set of models from QSARs to predict chemical impacts based on their structure (KER3), through generic and specific TKTD models (KER4), and to agent-based pollinator population models in ALMaSS (including TKTD) (KER5) (EO3, EO4). All *PollinERA* tools, comprising the monitoring scheme and systems models will be backed by detailed documentation to provide easy access for researchers to further develop or use these tools. Analysis of where *PollinERA* tools might be used to bridge different policy instruments will help steer users to impacts (KER8).

2.1.2 Expected Outcomes (EO) set out in the call topic and the relevance of PollinERA

The expected outcomes are referred to in sequence below with the contribution of *PollinERA* highlighted. EO1-3 refer to knowledge creation, which is the main expected outcome of the call, while EO4-5 focus on implementation. **EO1: Routes of exposure, which link ecosystem and biodiversity dynamics to chemicals are better understood.** From SO1, *PollinERA* information will be stored in the EU Pollinator Hub and used by the scientific communities and international authorities (e.g. EFSA, ECHA) for developing guidance documents for insect pollinators. This guidance will be facilitated by *PollinERA*'s partner connections to these authorities. The *PollinERA* Pollinator and Pesticide Co-monitoring Scheme (PPCoMS) will constitute a tangible resource for several stakeholders (policymakers, decision makers, risk assessors, risk managers) to further understand the link between pesticide exposure and its consequences on functional biodiversity and pollination services. This links to **EO2: Issues raised by the contamination of biodiversity in the natural environment are better known** (SO2). Here *PollinERA* will contribute to identifying the most persistent and co-occurring pesticides in the fields and their level of accumulation in the environmental matrices that are relevant to different insect pollinators. *PollinERA* outcomes will provide a platform to develop a post-registration monitoring scheme to identify the actual impact of pesticides on biodiversity at the landscape level, to be used by policymakers to better target policy, and to evaluate if measures are working. From SO3, through predictive *in silico* approaches *PollinERA* will develop tools that **predict the fate of new chemicals of emerging concern (EO3)**. These tools will be used by public authorities for screening pesticide risk, as well as by industry to identify early on whether novel pesticides might raise concern.

Using the information from SO1-3 in SO4, *PollinERA* will address **EO4 (Toxicological and ecological impacts of contaminants are better understood and risk assessments for relevant highly exposed species are strengthened)** by identifying the most vulnerable/ exposed species, which could act as umbrella species for key pollinator groups provides critical input to the regulatory process and will dramatically affect the pesticide ERA guidance. In addition, the ecotoxicological protocols developed by *PollinERA* will be included as new tests/model species in regulatory ERA. Using the *One System* in SO4 we will address EO5 (Prevention and mitigation measures are identified and developed). We will contribute to identifying scenarios at high risk for pollinators and develop suitable mitigation measures by testing and identifying risk and mitigation scenarios useful in preventing ecological impact on insect pollinators. *PollinERA* outcomes will provide support for farmers, risk assessors and managers in their decisions simulating their consequences for pollinator health.

2.1.3 Main Impacts set out in the Destination and the expected contribution of PollinERA

Although *PollinERA* will contribute to all destination impacts to some degree we have identified three main areas where impacts will be most significant (Table 4).

Table 4.

Main Impacts set out in the Destination and the expected contribution of *PollinERA*.

Main Impact 1. ***Direct drivers of biodiversity decline will be better understood and addressed***	
• The systems approach using *PollinERA*'s *One System* for risk assessment will provide new understandings of interconnectedness in pollinator systems and change the focus from single-substances, lab-based assessments to landscape assessments including multiple stressors and pollinator taxa. • Use of the *One System* will direct focus to critical areas (pesticide use, type, and mitigation) and provide new biodiversity-supporting actions and measures based on scientific underpinning. • Use of *PollinERA* tools to support regulatory processes, including guidance, and for policy evaluation will directly use the knowledge to apply actions to reduce and reverse pollinator declines with biodiversity co-benefits.	
Scale and significance This impact covers a European spatial scale through regulatory and policy instrument effects. It will have a significant impact potentially changing the face of farming through subsidy schemes, promotion of integrated pest management and pesticide authorisation.	**Pathway Science & Society** Building from EO1 to EO5 new knowledge and tools are developed and exploited through KERs 1-6. Re-use in future projects and continued stakeholder engagement and communication, including training, leading to knowledge building and the development of valid decision contexts and tools that will be accepted and used by stakeholders. Strong *PollinERA* partner networks in European agencies promoting tools.

Quantification

- We expect that *PollinERA* tools will be used, and approaches adopted in at least four future EFSA regulatory guidance documents (pollinators, non-target arthropods, in soil, and birds and mammals) and adopted and used by all EU member states environmental protection agencies.
- At least one biodiversity-friendly management supported under CAP subsidy altered based on *PollinERA* outcomes.
- Reduction by 50% in the usage and environmental risk of pesticides and removal of those most damaging to pollinators.

Main Impact 2. *Interconnected biodiversity research and support policies, and processes at EU and global levels, making use of advanced digital technologies*

- *PollinERA One System* tools can be used as the core of a landscape scale simulation tool that works with systems and integrates policy objectives co-occurring in space and time in support of biodiversity and sustainability goals. Applications of the tools will facilitate interconnected systems and data working from local to national and European levels.
- Regulatory implementation of *PollinERA* tools (*One System, in silico* models, and SOPs) for pesticide approval guarantees a harmonised approach across the whole of the EU and ideally would influence global approaches (e.g., through OECD standards, influencing global EPAs).
- Uptake and centralised provision of systems-based tools (e.g., at JRC/EFSA) and access to interconnected open data including those provided by *PollinERA* through the European Pollinator Hub, would be used by authorities, industry, and civil society.

Scale and significance	Pathways Science & Technology
European to global spatial scale through maximising the use and re-use of data and promoting future development of tools in science and policy having major impacts on future development directions.	Building from EO4 & EO5 with an open science focus, and data sharing following FAIR principles using facilities with a long lifespan and/or European organisation support (e.g., JRC Knowledge centres European Bee Hub, VEGAHUB, TKPlate). Open-source models with strong documentation (KER7), and stakeholder engagement in co-development promoting the spread of knowledge and know-how.

Quantification

- Landscape-scale simulation using the *PollinERA One System* available for all 26 member states.
- Uptake of *PollinERA* tools and data by 50% of national policymakers implementing aspects of the Green Deal.

Main Impact 3. *Understanding the biodiversity and health nexus at the level of ecosystems, using the one-health approach, addressing drivers and trade-offs*

- The *PollinERA One System* forms a major component of the toolset used by authorities, industry, and civil society to address a holistic approach to biodiversity management through a better understanding of social-ecological systems.
- The *PollinERA One System* is used to address trade-offs associated with spatial segregation or integration of biodiversity in agricultural systems, as well as production-conservation trade-offs, thus altering the face of future European agricultural systems.
- Agricultural systems better support healthier food production and land management that improves societal well-being.

Scale and significance	Pathways Science, Technology & Society
Important impacts at the European level, affecting all consumers and agricultural producers either by changing behaviour (producers affected by policy/ pesticide availability/pollination services) or indirectly through improved food and environmental quality.	Building primarily from EO4 which implements the *PollinERA One System* (its use derives EO5), leads to a strong scientific underpinning of new approaches, centralized data and digital tool integration (Impact 2), and builds on the stakeholder engagement and communication through current and future projects e.g. PARC to further develop *PollinERA* approaches.

Quantification

- Uptake of *PollinERA* tools and data by 30% of decision-makers working with aspects of the EU biodiversity strategy.
- 30% percent of land dedicated to biodiversity, including pollinators, conservation by 2030.
- A small but measurable improved human well-being as a result of improved nature experiences and reduced chemical exposure.

2.1.4 Barriers conditioning impacts

Barriers to impacts primarily act on two levels, the implementation of the tools and tests (critical risks see Part A), and secondly to the uptake of the tools or access to resources, which if not successful, will largely prevent societal and economic impacts (Barriers Table 5).

Table 5.

Barriers to the expected outcomes and impacts conditioning *PollinERA* impacts.

Barriers and obstacles	**Mitigation measures**
Ensuring openness & longevity of access to resources e.g., data, protocols, program code & tools. (Low)	Following FAIR, Open Science principles and using established resource platforms (e.g. European Bee Hub, VEGAHUB, TKPlate, GitLab etc.) will ensure the accessibility and useability of the project's KERs within the project's lifetime and afterwards.
Gaining confidence in & demand for systems- & model-based risk assessment approaches amongst authorities and civil society (Low)	Project's stakeholder engagement and communication strategies (e.g., External Advisory Board) will facilitate the acceptance and confidence in systems- and model-based risk assessment approaches amongst targeted stakeholders. Confidence will be built upon foundations of co-development and transparency of protocols, methods, and models developed, as well as the scientifically robust evidence ERA approaches' merit in terms of improving process efficiency and effectiveness for the protection of pollinators.
Ensuring uptake of integrated systems ERA tools	Integrating accessibility and acceptance, dissemination and training activities will facilitate the uptake and usage of the projects data streams, protocols and models amongst targeted policymakers enabling them to benefit from these integrated systems tools.

2.2 Measures to maximise impact - Dissemination, exploitation, and communication

PollinERA works towards maximising its impact through its Key Impact Pathways (KIPs). The fulfilment of these pathways will be supported by the project's **dissemination, exploitation, communication, and engagement (DECE)** activities. A detailed **Plan for the Exploitation and Dissemination of Results (PEDR)**, including a **Communication Strategy (CS)** and an **Engagement Strategy (ES)** (Task 6.a), will be developed detailing how *PollinERA* will maximise the impact of its Key Exploitable Results (KERs) (see Table 6). The plan will support the fulfilment of the project's three KIPs, and will be produced by M6, and periodically updated whenever significant changes arise. The PEDR will serve as a roadmap throughout the project and will include appropriate monitoring tools as Key Performance Indicators (KPIs) (see Table 7). The achievement of KPIs will be monitored by the responsible parties in WP6, responding and adjusting as necessary, enabling the progress of KIPs to be measured and KERs quantified. To address the challenges of data access and sharing, rather than create our own data hub, which will fall out of use after the project is over, we tap into existing European platforms. In doing so, the project's data future usability will be ensured.

Table 6.

PollinERA Key Exploitable Results (KERs); KPI numbers refer to Table 7. Outputs generated during the *PollinERA* project which can be applied and create impact.

Ref	KER	Route to Exploitation	KPIs
KER1	Standard operating procedures (SOPs) for pesticide toxicological testing of different insect pollinator taxa	Contact ministries at Member States to bring protocols into OECD standardisation working groups. Make the SOPs available to researchers by depositing the protocols on the EU Pollinator Hub.	1
KER2	Co-monitoring scheme for pesticides & pollinators with pesticide risk indicators for pollinators	Contact MS authorities to explain the need for monitoring & the utility it provides to document that targets are met. Promote use of the scheme to EFSA & EC DGs.	2
KER3	Models for predicting pesticide toxicological effects on non-standard pollinators from chemical structure	*In silico* models for toxicity & effect prediction implemented & made available in VEGAHUB (www.vegahub.eu) for external use.	3a
KER4	Generic & specific TKTD models for pollinators	TKTD models deposited in EFSA's TKPlate & published in FESMJ enabling external use.	3b
KER5	New ALMaSS species models for butterflies, moths & hoverflies, including TKTD pesticide responses	Formal models & MIDox documentation published in FESMJ. Open-source code available for further development.	3c
KER6	Population-level systems-based approach to ERA & policy evaluation considering multiple stressors, detailed management, & long-term spatiotemporal dynamics	Provision of user-friendly software, courses, feedback sessions. Co-development workshops. Extensive documentation. Showcasing of results on *PollinERA* website.	4,5,6
KER7	Provision of open-source program code for all models developed	Open access via GitLab. Publishing in FESMJ & high-ranked scientific journals. Uptake by European authorities for standardising ERA models.	7
KER8	ERA & policy alignment report Deliverable 5.4	Contact through stakeholder network External Advisory Board, policy briefs, & website.	4,9,5

2.2.1 Plan for Dissemination, Exploitation, Communication and Engagement (DECE) activities

The planning of Dissemination, Exploitation, Communication and Engagement (DECE) activities in *PollinERA* is based on a methodology starting connected to the *PollinERA* planned actions and KERs above. These strategic elements aim to ensure that the DECE activities planned will focus on achieving real impact and supporting the project through adequate planning and execution.

Table 7.

PollinERA Key Performance Indicators (KPIs) with the target number of entities indicated.

Ref	Description with timings	Target	Impact
KPI1	New pollinator toxicological test SOPs described & deposited on the EU Pollinator Hub (M24-48)	12 SOPs	Provision of draft new standard tests will allow impacts of pesticides to be evaluated for new products. To be used by researchers & regulatory bodies around the World
KPI2	National protocols developed for pesticide & pollinator co-monitoring (M12-24)	3	Operationalise the monitoring for 3 countries as a proof of concept
KPI3a	QSARs for pollinators developed & deposited on VEGAHUB (M12-36)	7	Provision of models to allow prediction of pesticide effects on pollinators for novel products
KPI3b	TKTD models parameterised for pollinators & deposited on TKPlate & FESMJ (M12-24)	7 species, 10 compound	Refinement of effect modelling for pesticides & pollinators allowing more realistic predictions of impact
KPI3c	Documented ALMaSS pollinator models provided in FESMJ Formal Model & MIDox formats (M24-36)	4 models	Expansion of population modelling capability for systems ERA beyond bees (2 hoverflies, 1 butterfly, 1 moth)
KPI4	Documentation of ALMaSS models, landscape & species comprising the ERA framework (M36)	8 (7 species)	Scientific transparency & as building blocks for future developments of these or new models
KPI5	Co-development workshops held with stakeholders (M6,18,36)	3	Increase ‘buy-in’ of stakeholders for the *PollinERA* approach
KPI6	Scenario reports showcased on *PollinERA* website (M36-48)	9	Raise awareness of PollinERA & education on the effects of pesticides on pollinators & effects of management/mitigation
KPI7	Open-source program code available for *PollinERA* models (M36)	7	Scientific transparency & as an exploitable resource for developers
KPI8	Scientific journal publications based on project results (M9-48)	~30	Increase scientific knowledge & provision of potential pathways for innovation & research for EU funding programs & others
KPI9	A summary of policy-relevant results & recommendations provided from the project (M6-48)	16	Regulatory related audience are aware of activities & results to inform policy debates
KPI10	*PollinERA* website visitation rate	>3000	Outreach to non-technical stakeholders

Ref	Description with timings	Target	Impact
KPI11	Training & educational activities (M38-48)	4	Workshop & webinars used to generate awareness & acceptance of *PollinERA*'s new tools & approaches.
KPI2	Project conference session (M46-48)	1	Outreach to the scientific audience, profiling project results

Plan for the Exploitation and Dissemination of Results (PEDR) – *PollinERA*'s activities are policy and technically orientated, and thus 'Policy Briefs' (KPI9) will be targeted to disseminate results to the regulatory community related to chemical risk assessment and management from the pesticide, biocide and veterinary production areas, both at EU and national levels. Policy Briefs will outline analyses and recommendations for legislative initiatives associated to activities and results obtained by *PollinERA*. The dissemination of Policy Briefs is intended to raise awareness, foster the 'buy-in' and adoption of the project's new ERA tools and approaches amongst the wider regulatory community, and will be supported and benefit from project's engagement activities (KPI5) and training activities (KPI11). *PollinERA*'s scientific advances (knowledge and tools) will be disseminated to a variety of interested audiences, through the publication of scientific peer-reviewed articles (KPI8), as well as scientific outreach via *PollinERA* conference session at a major conference (KPI12).

There will be a focus on promoting access, visibility, and longevity of the project results with the project's strong emphasis on Open Science and usage of various established platforms (e.g., European Bee Hub, VEGAHUB, TKPlate, and publication of formal models, KPI1-4) for publishing all information, data, and results. A dedicated *PollinERA* topical collection of articles using novel publishing formats (M24) will be established in FESMJ. FESMJ is an innovative open access journal which facilitates the publication of models, datasets and software solutions in several areas (agriculture, food, social-ecological interactions, bioeconomy, natural resources, environmental sciences etc.). Novel types of articles (e.g., Formal Models) help documenting the outcomes of the full research cycle, including data, formal model papers, model validation studies, software, data analytics pipelines and visualisation methods. The topical collection will store and highlight the most notable project results, such as ecotoxicological knowledge gaps data sets, pollinator pesticide risk indicators, models for chemicals and pollinator populations, as well as a systems-based approach to pollinator ERA. Other project outputs (e.g., reports) will be available in the Research Ideas and Outcomes journal (RIO). In addition, the project will be registered / incorporated in the EU Pollinator Information Hive, INSPIRE Knowledge Base, and establish a link and explore collaborations with the Biodiversity Information system for Europe (BISE). These measures will enable exploitation of *PollinERA* outputs to a selected audience (see Table 8).

Communication Strategy (CS) – The main strategic objective of the CS will be to ensure that the *PollinERA* activities effectively reaches a wider audience and society as a whole, promoting the project and its results, generating awareness and interest. The communication will occur via appropriate means to translate activities into meaningful and tangible actions. A website will be the project's communication and dissemination hub, ensuring visibility of project activities and results (KPI10). The website will have intuitive navigation and up-to-date content, and will: i) ensure general dissemination of project goals, structure and results; ii) provide secure storage in online libraries; iii) provide community links with other related EU Horizon projects; iv) offer regular dissemination of news, events, broadcasting an active dialogue through the project's social network profiles.

The main outreach messages for *PollinERA* will focus on describing the beneficial impacts that the project results will have on insect pollinators, human health, and the environment. These messages will be targeted and tailored for general audiences, anticipated to be a broad variety of stakeholders potentially interested in our work, ranging from academia, field operators (such as beekeepers, veterinarians, farmers or farming advisors), environmental NGOs and naturalists, industry and their associations or citizens. All in all, we would like to target over 1-2 million EU citizens by the end of the project to improve their knowledge about the risks of chemicals to pollinators' health, become aware of the role and the importance of pollination and insects and ways to improve the risk assessment and management of chemicals on them. Supporting DCE activities will include accounts set-up on LinkedIn, Twitter, YouTube, Facebook with a target of ~50 posts / year / per account, +100 followers / year, >10,000 impressions / year.

Engagement Strategy (ES) – Complementing the project's PEDR and CS, particular attention will be paid to promote and foster the involvement of key European stakeholders to maximise the acceptance and uptake of project exploitation and engagement. We have identified policy related institutions as main consumers of *PollinERA*'s outcomes, some of which will play a special role, in the co-development engagement activities (e.g., members of its External Advisory Board). For the ES, a preliminary list of potential stakeholders is provided in Table 8, highlighting (*) those proposed as members of the *PollinERA* External Advisory Board (EAB), to be contacted when the project starts. A variety of European stakeholders will be actively engaged in the project to improve partners' expert capacity, oversee, or evaluate calibration/validation the tools proposed and quality of regulatory proposals. This engagement will be done through interactive thematic workshops and training sessions (KPI5 & KPI11). In addition, we will engage with projects having related activities/goals (e.g., PARC, SPRINT, BETTER-B, MUST-B or future Horizon Europe winning projects), aiming to benefit from and maximise the knowledge exchange with these projects throughout the duration of *PollinERA* project. Direct communication and information exchange with relevant Biodiversa+ projects and JRC Knowledge Centres is envisaged.

2.2.2 Intellectual Property Rights (IPR)

PollinERA will develop its Intellectual Property framework (IP) in connection with its Data Management Plan (DMP). Management of intellectual property and foreseen protection measures generated will be managed in compliance with the Consortium Agreement (CA), which will be signed at the beginning of the project. The CA will address background and foreground knowledge, ownership, protected third party components, and protection, use, and dissemination of results and access rights. The principles are:

- Background information and knowledge contributed to the project by each participant will be listed in the CA. This information will be provided royalty-free for the implementation of the project's tasks.
- Results shall be owned by the participant who generated them. Each participant will be responsible for ensuring fulfilment of their obligations under the Grant Agreement regarding results by planning with any third parties that could claim rights to them.
- Whenever results have been produced jointly, the ownership of the results will be shared among the participants who carried out the work. The terms to be agreed upon via a joint ownership agreement.
- Each participant will be responsible for examining possibilities to protect results that may be commercially or industrially exploited. Participants will ensure that adequate steps towards protection are taken prior to DECE activities, preventing unapproved public disclosure of results, models, tools, and data.
- Access rights to results will be granted on a royalty-free basis for further research and commercial exploitation.

Table 8.

List of stakeholders and target groups with main KERs and KPIs of interest listed. Stakeholders and actors <u>underlined</u> are selected for exploitation and engagement activities, in *italics* are groups targeted for dissemination. All audience groups including the public are included in the wider communication of the *PollinERA* project. Note. Stakeholders with * have been preselected to be invited as a part of the External Advisory Board (EAB).

Target audience	**Stakeholders & Actors**	**Specific Interest**	**Example/Name**
Policy related institutions	EU & national decision-making (risk management) authorities & institutions	Understanding pollinator health, resilience, chemical fate & effects on biodiversity & pollinators. KERs 1,2,6,8 KPIs 2,5,6,9,11	DG SANTE*, DG ENVI*, DG AGRI, European Parliament*, Permanent representations (EU), Member States, National Parliaments
	Public bodies involved in RA & surveillance	Relevant, high-quality data for RA. KERs 1,2,6,8, KPIs 2,5,6,9,11	EFSA*, ECHA*, EEA*, EMA (EU) & their national collaborators
	Intergovernmental organisation dealing with standardisation	Standardisation of protocols for toxicity testing & pesticide RA. KERs 1,2,8 KPIs 1,2	OECD*, FAO
Academia	*Research institutions & universities*	Relevant, high-quality data. KERs 3-7, KPIs 3,4,8,12	COLOSS (APITOX Task Force)*, ENSSER, IUCN (worldwide)

Field practitioners (agriculture)	Beekeepers & their associations	Following pesticide/pollinator RA, pollinator health, resilience, chemical fate & effects on biodiversity & pollinators. KPIs 1,2,6,10	EPBA* (EU), Apimondia (worldwide), COPA-COGECA (EU)
	Farmers & their associations	EFSA-consulted stakeholder. Understanding pollinator health, resilience, chemical fate & effects on biodiversity & pollinators. KPIs 2,6,10	COPA-COGECA*, IFOAM, European Coordination Via Campesina (EU)
	Farm advisors as veterinarians, agronomists, or companies (SMS) providing agricultural/environmental advice/services	Understanding pollinator health, resilience, chemical fate & effects on biodiversity & pollinators. KPIs 2,6,10	AVC, FVE, EUFRAS* (EU), World Organization for Animal Health (worldwide)
NGOs	*Environmental NGOs & conservation trusts*	EFSA-consulted stakeholder. Understanding pollinator health, resilience, chemical fate & effects on biodiversity & pollinators. KER6, KPIs 1,2,5,6,8,9,10	PAN-Europe*, BCE (EU), BugLife (UK)
	Consumer organisations	Understanding pollinator health, resilience, chemical fate & effects on biodiversity & pollinators, & impact on food production. KPIs 2,6,10	European Consumer's Organisation (BEUC, EU), Consumers (CI, worldwide), other national consumers' organisation
Industry	*Agrochemical companies & association*	Understanding the impact in pesticide authorisation process. KERs 1,2,3,6. KPIs 1,2,5,6,8,9,10	CropLife (EU)*
	Pharmaceutical companies & associations	Understanding the impact in veterinary medicine authorisation process. KPIs 2,6,10	IFAH (EU)
	Biocidal companies & their associations	Understanding the impact in biocide authorisation process KPIs 2,6,10	Biocides for Europe* (EU)
	Companies from the agri-food sector	Understanding the level of chemical contamination of foodstuffs. KER 2, KPIs 2,6,10	FoodDrinkEurope (EU)

2.3 Summary

The key elements of the impact section are described in Table 9.

Table 9.

Key elements of the impact section.

Specific needs	Expected Results	D&E&C measures
General gaps: Efforts by EU bodies to address pollinator decline and meet policy targets are hampered by a lack of data and available *in silico* tools for impact and risk assessment. ***Ecotoxicological Knowledge Gaps***: Knowledge gaps related to pollinator exposure and toxicology, predictive toxicology of new pesticides, and combination effects make the transition to an improved risk assessment difficult. ***Systems approaches needed***: Current approaches are often not integrative enough to cope with the complex agricultural system and the diversity of pollinators. Therefore, they cannot properly weigh alternative strategies for implementing policy/regulation goals. Systems approaches that integrate landscape contexts, agricultural practices, pollinator ecology, pesticide fate and toxicology are needed to develop a realistic, reliable, and transparent risk assessment.	***Knowledge***: Gaps filled including information on sources and routes of pesticide exposure for key pollinator groups, sensitivity of pollinators to different pesticides and combinations, support for ERA and TKTD modelling including chronic toxicity and sublethal effects of single and multiple chemicals. ***New and Improved Methods***: Pesticide testing protocols for non-bee pollinators, co-monitoring schemes for environmental contamination and pollinators, development of cumulative assessment groups of pesticides for ERA, prediction of toxicological effects of novel pesticides and mixtures for the protection of pollinator communities. ***ERA Toolset***: Population and landscape modelling and environmental scenarios for authorisation and landscape management of pesticides; a list of suitable organisms for RA, *in silico* tools for prediction of toxicity endpoints, and TKTD models. A development of risk indicators based on cumulative risk (toxic load), initial identification of harmful pesticides, and an Open Science curated resource for pollinators and pesticides data.	***Dissemination***: Scientific publications and conferences; specific publications targeting risk assessors and managers; technical and informative publications addressed to field practitioners and stakeholders. ***Communication***: *PollinERA* website, promotional brochures, posters, video presentations, newsletters, 'Policy Briefs' and social media messages addressed to different target groups. ***Engagement***: Provision of an online community hub as a networking platform and decision support tool, training and engagement workshops for risk assessors and managers, and interested audiences. ***Exploitation***: Stakeholders mapping, KER inventory, Preliminary and Advanced Exploitation Plans (considering starting and within project exploitation aims and newly developed exploitation pathways), utilisation of EC tools, consortium network driven exploitation activities and feedback collection from the market towards use of *PollinERA* tools.
Target groups	**Outcomes**	**Impacts**
Risk assessors and managers at international, European, and national levels will use the ERA toolset,	***Adoption of PollinERA toolset and methods***: Monitoring, testing, and *in silico* tools for ERA	***Scientific***: Changing general scientific focus to a pollinator-systems perspective bridging silos by

methods, and data to develop new regulatory approaches, including local context in their assessments, and design new pesticide mitigation measures. ***Policy makers*** (e.g., EC, national ministries, EP) will use the knowledge and data available through the Open Science approach to support new and existing policy actions, track pesticide related risks. ***Academia & Scientists*** will have access to new knowledge, methods, and software. Engaging with existing networks e.g. COLOSS APITOX TF to enlarge capacity for ring testing. ***NGOs and citizen associations***, the agrochemical and food industries, and farming associations will be able to use data, methods, and software to assess pesticide impacts. This will lead to a knock-on understanding of the effects of potential management changes on pollinators.	on insect pollinators validated by OECD and adopted by EFSA and Member States. Implementation of a systems approach for evaluation of pesticide impacts on wild pollinators to support Green Deal initiatives and targets, as well as risk indicators to track progress. ***Exploitation of knowledge***: Better understanding of pollinator/pesticide interactions and predictive toxicology used to support risk assessment, policy, and science by filling data gaps on pollinator ecotoxicology, and methods provision for future development. Results and methods feed into PARC & Biodiversa+. Forms the basis for a tool for ranking pesticides based on risk. Use of the *PollinERA One System* to identify and implement mitigation measures in agricultural systems and policies. ***Open Science***: Open access for toxicological and risk assessment data, methods, *in silico* tools, and protocols (Open Science). Linked to EFSA Knowledge Junction, JRC Knowledge centres, and EU Pollinator Hub.	understanding of the interconnectedness of the critical underlying drivers, including ecotoxicology, land management and mitigation, to better understand the declines of pollinators. Based on this better understanding and interconnected data, *PollinERA* models used in a fully functional systems-based assessment of the use of pesticides and policy evaluation, underpinning of the best use of pesticides. ***Societal***: Underpinning a Systems/One Health approach to provide a fair healthy and environmentally friendly food system that promotes pollinator recovery, ensuring food security and a clean environment. Implemented through innovative governance, this will provide transparency and trust through scientifically based balancing of trade-offs, identification of alternatives, and risk management. ***Economic***: Improved efficiency of public resource use for risk assessment, better pollination services for production, furthering IPM, improved use of farm subsidy system to support the Green Deal strategy, and improved predictability for the agrochemical industry development of new products.

3. Quality and efficiency of the implementation

3.1 Work plan and resources

PollinERA is organised in 7 WPs (see Part A). These are arranged in 5 WPs aimed at developing a population-level systems-based approach to pesticide risk assessment of pollinators considering multiple stressors and long-term spatiotemporal dynamics (WP1-5), and two (WP6-7) on communication and dissemination, and project management, respectively. Each WP has a leader with specific expertise to achieve the goal of that WP. The WP leader is supported by contributing partners. The specific objectives SO1-4, will be achieved through the WP structure (Fig. 5):

3.1.1 Gantt and Deliverables

The Fig. 6 Gantt chart collates the *PollinERA* deliverables (see Part A) together with the task timelines and milestones (see Part A).

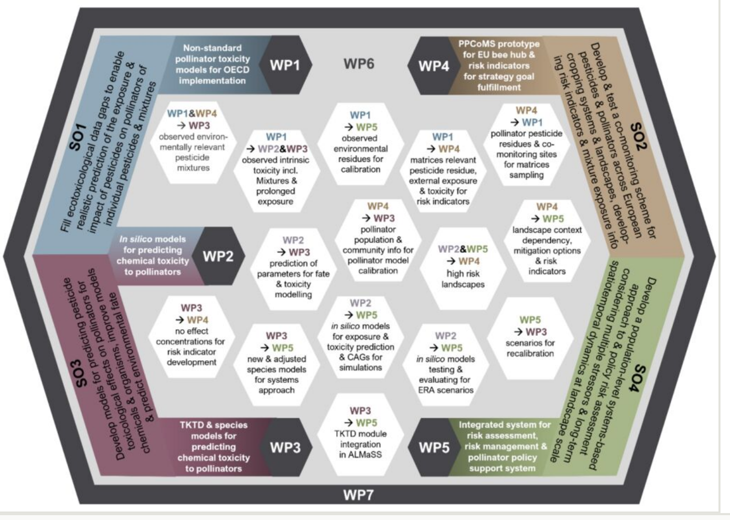

Figure 5. doi

WP1-5 (black hexagons) main activities (white text) linked to SOs (coloured bars to the sides). WP relationships (white hexagons) describe linkage from one (or two) WP(s) to others with an arrow. WP1-5 are all connected to WP6 which is communication, dissemination and exploitation (grey, background hexagon) & WP7 which is project management.

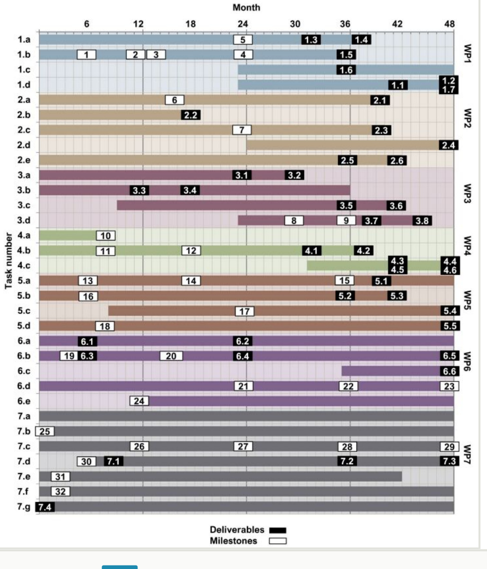

Figure 6. doi

Gantt chart showing the overall plan for implementation of deliverables and timelines. The coloured bars in the chart depict the timing of the tasks. The timeline (in months) is given on the top x-axis, task numbers on the left y-axis, and WP numbers on the right y-axis. Deliverables (black squares) and milestones (white squares) are indicated by their number in task bars at their due time.

3.2 Capacity of participants and consortium as a whole

3.2.1 Consortium as a whole

The PollinERA consortium is comprised of 11 partners, of which six are universities, two are research institutions, two are SMEs, and one is an NGO.

The consortium partners were chosen with care each to fulfil key roles in the project addressing the project objectives. Most of the partners have experience from participation in H2020 projects and have worked together on previous or current research projects, which is beneficial to the partner workflow of PollinERA (see Fig. 7).

Figure 7. doi

Visualisation of past & present collaborations between *PollinERA* partners. Collaborating partners are indicated by partner number at activity (dark hexagon). Funding bodies acronyms are indicated with underline, & project names are included below. Task force (TF), panel, & working group (WG) activities are indicated in italics. *PollinERA* partners in blue are universities, red are research institutions, green is an NGO & brown are SMEs.

3.2.2 Partner roles and experience

Partners work broadly integrated across the project but with key specialised experience grouped to the specific objectives (see Table 10), representing SO1 (UJAG, ULUND, UNIBO, INC-PAS & UOS), SO2 (UJAG, ULUND, UNIBO, INC-PAS & SLU), SO3 (AU, UJAG, UOS & IRFMN), and SO4 (AU, UJAG, ULUND & BEBC). The SME partners (PEN & ZIP) are specialists in communication and dissemination activities, and database development and management, respectively.

PollinERA partners come from a wide geographical area (Fig. 8) and from different areas of expertise.

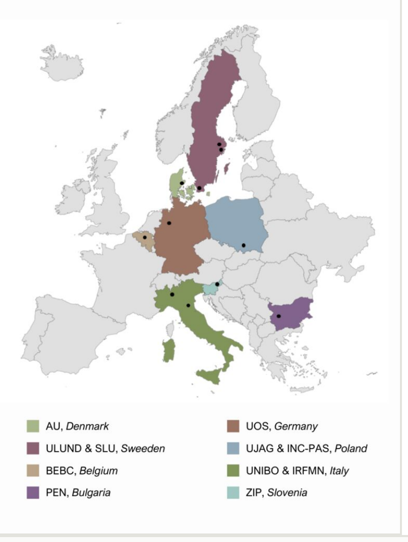

Figure 8. doi

Map of nationality of partners in the *PollinERA* consortium.

The contributions of partners to the major SO sub-tasks are shown in Table 10. Most partners contribute across the project, and their key expertise is listed below.

Table 10.

PollinERA partner competence matrix related to the main aspects of the Specific Objectives (SOs).

SOs	Competences	AU	UJAG	ULUND	UNIBO	UOS	INC-PAS	IRFMN	BEBC	SLU	PEN	ZIP
SO1	Exposure routes and sources		X	X	X	X	X			X		
	Pollinator sensitivity		X	X	X		X					
	Mixture toxicity		X	X	X	X	X					
	Sublethal and chronic laboratory tests		X	X		X	X					
SO2	Sampling site selection and landscape toxic load mapping	X	X	X	X		X			X		
	Co-monitoring of pesticides & pollinators scheme (PPCoMS)		X	X	X		X					
	Pesticide screening and quantification		X							X		

SOs	Competences	AU	UJAG	ULUND	UNIBO	UOS	INC-PAS	IRFMN	BEBC	SLU	PEN	ZIP
	Pesticide risk indicators for pollinators			X	X	X				X		
	Defining cumulative assessment groups (CAGs) for ERA	X	X	X				X				
SO3	*In silico* models							X				
	TKTD modelling					X						
	Population modelling	X	X			X						
	Pollinator ecology	X	X	X	X		X					
SO4	Landscape simulation for toxic load	X	X			X						
	Framework methods	X	X									X
	Scenario generation methods	X		X		X						
	Policy impact methods	X		X		X			X		X	
	Systems-based approaches	X	X			X						

Aarhus University (AU) coordinates *PollinERA*. The coordinator is Professor Christopher John Topping who leads the SESS centre. He is a deputy coordinator for H2020 EcoStack, and in the project management group of H2020 B-GOOD, as well as a partner in H2020 PoshBee, and coordinator of the EFSA bee simulation modelling project, ApisRAM, and the ELONTA project. He is also editor in chief of the FESMJ, which will be used to provide a platform for model dissemination, and vice-chair of the EFSA PPR panel. The coordinator will be supported administratively by the project office, and scientifically by all *PollinERA* partners on a day-to-day basis. The project office comes from AU's Research Support Office management team and has considerable experience of Horizon project management. The Research Support Office contains a broad range of administrative, clerical, and financial experience, drawing support from AU Contracts, Finance and Legal Departments. The coordination group is further assisted by the SESS Centre Administrator who is experienced in supporting Horizon projects.

AU also has a major role in SO3 & SO4. The SESS team have extensive experience of developing large-scale simulation models as well as leading multi-disciplinary projects, including the EFSA's IPol-ERA project. The core of the *PollinERA* framework for systems ERA will be based around ALMaSS, developed by the coordinator over 25 years, and now forming part of the toolbox used by EFSA for pollinator risk assessment (ApisRAM). The team has very strong programming and modelling and expertise. From a social science and humanities (SSH) perspective, James Henty Williams (AU) also provides key support and management experience for the multi-actor approach to H2020 projects (WP leader in

B-GOOD for multi-actor approach), as well as EFSA funded projects (e.g. EFSA PERA and IPol-ERA) and will bring this experience and expertise in developing and facilitating workshops, undertaking interviews and establishing active forums for knowledge exchange, all contributing to WP5's stakeholder engagement activities. SESS has access to multiple higher performance computing resources available for use by *PollinERA*.

The project management is complemented by WP6 Communication, Dissemination and Exploitation led by **Pensoft Publishers** who support communication and dissemination activities for the entire project. Moreover, the team will contribute to the stakeholder mapping process and will assist the organisation of various workshops and other events. In addition to supporting WP6, PEN will also contribute to WP7 Project Management. PEN has been providing science communication for over 30 projects, they are a science communication expert, and also a science publisher. They have published more than 1000 books and e-books. PEN is well-known among academics worldwide with its technologically advanced peer-reviewed Open Access journals. The company is actively developing new tools, workflows, and methods for text- and data publishing, dissemination of scientific information and technologies for semantic enrichment of an articles' content.

WP6 is supported by **BeeLife European Beekeeping Coordination, BEBC**. As chair of the EU Bee Partnership (stakeholder group centralising pollinator related data), participant to European Commission stakeholder advisory committees (DGs Agriculture, Santé and Environment) and ecotoxicologist engaged in the evolution and implementation of pesticide RA and management on bees since 2009, Dr. Noa Simon Delso has vast knowledge of the regulatory framework, related institutional and external stakeholders, and policies related to the topic. She also follows the European policy developments impacting pollinators, e.g., F2F, CAP, Natural Restoration Law, SUR. Thus, not only will she strongly support the engagement and exploitation activities in WP6, she will also assist the regulatory and policy-related activities in WP5. She is the coordinator of the EU Pollinator Hub initiative that she develops with colleague Dr. Michael Rubinigg, plant physiologist and data science expert in data curation, standardization, and quality management. Dr. Rubinigg peer reviews the data integrating the EU Pollinator Hub and assists Gregor Sušanj (ZIP) in the architecture of the EU Pollinator Hub, by defining data acquisition standards, procedures, and validation. Given Dr. Rubinigg's expertise, he oversees the Data Management Plan (DMP) (Task 7.d). The Hub will be connected to the *PollinERA* exploitation activities as it enables the FAIR data principles that governs the project and integrate *PollinERA* data with data from other projects and initiatives.

Jagiellonian University (UJAG) Team is led by Professor Ryszard Laskowski, an ecologist and ecotoxicologist with broad experience in studying effects of trace metals and pesticides on invertebrates and microbial-mediated soil processes. He has (co)authored 6 books and over 120 peer-reviewed papers and book chapters. In 2012-2018 he was a member of EFSA's Scientific Panel on Plant Protection Products and their Residues. PI in 20 major research projects, including 5 EU-funded, listed among 2% of most influential scientists in the world (Stanford University & Elsevier 2021, 2022). Researchers engaged published broadly on different aspects of ecotoxicology and, more recently, landscape models, including experience with ALMaSS and pesticide simulation. The studies cover the effects of a variety of inorganic and organic pollutants (especially pesticides) on soil microbial processes, soil-dwelling and epigenic invertebrates as well as pollinators and other arthropods. The team is expert in acute bioassays and chronic tests, using different exposure routes, such as topical, oral, spray, or coated glass assays. The laboratories are equipped with, among others, HPLC MS/MS, GC MS, three AASs, Potter tower, Micro-Oxymax respirometer, and high-quality walk-in climatic chambers.

Lund University (ULUND) is leading the work on developing and trialling a pesticide and pollinator co-monitoring scheme and pesticide risk indicators specific for insect pollinators. The leader is Dr. Maj Rundlöf, with nearly two decades of working and publishing extensively on insect pollinators in agricultural landscapes and exposure and effects of pesticides on bees. She is member of the EFSA working group Bee guidance revision and Biodiversity Theme leader within the Strategic Research Area Biodiversity and Ecosystem services in a Changing Climate (BECC). She has participated in several European projects (e.g., STEP, PoshBee, PARC) and coordinated national projects (e.g., DELETE, on developing landscape ecotoxicology for bees, and MixToxBee, on pesticide mixture exposure and effects on bees for monitoring and ERA). Dr. Lars Pettersson, responsible for the Swedish butterfly monitoring scheme and pollinator scheme piloting and partner in the SPRING project supporting the implementation of the EU-PoMS, and Dr. Lina Herbertsson, with expertise on sublethal effects of pesticides on bees and pollination services and partner in the iENT project on neuroenvironmental toxicity of pesticides to pollinators.

Institute of Nature Conservation of the Polish Academy of Sciences (INC-PAS) has extensive experience in testing the acute and chronic effects of pesticides and their mixtures on solitary bees' and other NTAs' survival, physiology and biochemical markers and is leading the work on mixture effects. The leader is Dr Agnieszka Bednarska who specialises in ecotoxicology with the main interest in the effects of stressors (including, but not limited to pesticides) and their interactions on life history traits and physiology of invertebrates (including insect pollinators), and their consequences for the population level. She participated in a number of research projects founded by the main Polish public bodies (NCN projects) being PI in 4 of them and international projects (e.g., MUSBERA, EcoStack, CREAM - Mechanistic Effect Models for Ecological Risk Assessment of Chemicals, NoMiracle - Novel Methods for Integrated Risk Assessment and Cumulative Stressors in Europe), covering different exposure routes and both laboratory- and field-based studies. She has co-authored 40 peer-reviewed papers in international journals and serve as Associate Editor in Ecotoxicology journal. She is employed as an assistant professor at Institute of Nature Conservation, Polish Academy of Sciences (full position) and Institute of Environmental Sciences, Jagiellonian University (part time). Some of the facilities necessary to run the experiments and/or chemical analyses are shared with UJAG, making the two teams highly compatible and interoperable.

Mario Negri Institute (IFRMN), the WP2 leader, is a non-profit research organization with major activities in drug research. Dr. Emilio Benfenati, head of the Department of Environmental Sciences, has a long experience in toxicity and environmental modelling. He coordinated and participated in tens of European and international projects, like sOFT-

ERA (an EFSA-funded project with the aim to develop *in silico* models to generate predicted values for the EFSA database OpenFoodTox) and JANUS (a German UBA-funded project with the aim to develop a prioritization system for environmental assessment), in particular. He is the author or co-author of more than 500 papers (including models to estimate the toxicity towards *Apis mellifera*) in international journals and has edited a few books. He will be assisted by a team of experienced researchers to develop *in silico* toxicology and fate models for SO3.

The Bologna University (UNIBO) team is led by Fabio Sgolastra, Associate Professor in General and Applied Entomology at the University of Bologna. He has 20 years of experience in bee research, which mainly focuses on ecotoxicology and conservation of managed and wild pollinators in the agroecosystems and the valorisation of the pollination service. He is/was actively involved in several European projects (e.g., FP7 AMIGA, LIFE4POLLINATORS, PRIMA DREAM) and innovative and policy-oriented initiatives linked with bee health (e.g., EFSA working groups for the preparation of Scientific Opinions and Guidance Documents, EIP-AGRI Focus Group on Bee health and Sustainable beekeeping). Members of UNIBO team are also Professors Giovanni Burgio and Maria Luisa Dindo. Their expertise in insect rearing and management will contribute to developing protocols for the new model species.

University of Osnabrück (UOS), is represented by Professor Andreas Focks with more than 15 years of experience in development and regulatory application of TKTD models. He was member of the EFSA working group on TKTD models and of the EFSA working group on the bee guidance revision, where he is responsible for integration of dynamic effect modelling. His experience includes the development, usage, and evaluation of population models for environmental risk assessment of chemicals, amongst others he is chairing the SETAC working group on Model acceptability criteria and scenario development.

Swedish University of Agricultural Sciences (SLU) main contribution is the pesticide analysis for all samples collected in PollinERA as part of the source and route characterization of pesticide exposure in the key pollinator groups (wild bees, butterflies, hoverflies, moths). SLU has long experience with monitoring pesticides in environmental samples, including expertise in development of analytical methods to detect pesticides residues in complex environmental matrices. SLU was involved in a number of research project about pesticide residues in pollinators, such as BiNeo, MixToxBee, and AirBeeSafe, and currently in PARC 6.4.4.

Združba IP, d.o.o., under brand name **ZIP Solutions** is a web development SME. ZIP is experienced in the field of digital marketing and website development, with project including the development of the Pollinator Hub from TRL1 up to TRL8. Other noticeable projects include Austrian Varroa Alert System (bienengesundheit.at) as well as Beehive wandering exchange for Niederösterreich and Oberösterreich in Austria. On all these projects Gregor Sušanj, full-stack software engineer, owner and CEO of the company was the lead architecture designer and developer. As well as main contributions to the SO4 framework development, ZIP will also support technical development in WP3, WP5 & WP6.

3.2.3 Overview of expertise fit to the call

The partner group as a whole matches the Part-A specific aspects of the call matching each aspect with key experts in the field, covering pollinator ecology and pesticide exposure (ULUND, UNIBO), toxicological testing including mixtures and development of sensitivity distributions (UJAG, INC-PAS), predictive *in silico* modelling (effects, classification, mixture effects and fate) (IRFMN), TKTD modelling (UOS), pollinator monitoring and risk indicators (ULUND), pesticide monitoring (SLU), pesticide risk assessment (AU, ULUND), landscape simulation modelling (UJAG, AU), and agent-based pollinator population models (AU), policy (BEBC, ULUND) and open databases/hubs (ZIP), stakeholder engagement (AU, BEBC) and communications (PEN).

4. Ethics self-assessment

4.1 Ethical dimension of the objectives, methodology and likely impact

PollinERA will carry out laboratory effect tests with model organisms (species of wild bees, hoverfly, butterfly, and moth). Tests will follow the highest experimental and safety protocols, as well as complying with all international, EU and national health and safety laws and guidelines to ensure human and environmental safety. Laboratory work and testing will be conducted in Sweden, Italy, and Poland using the specialised facilities and resources of partners (ULUND, SLU, UNIBO, UJAG, and INC-PAS). No animals will be imported or exported between partner countries, except the transfer of experimental data. No vertebrates will be included in any of these experiments.

PollinERA, as part of its multi-actor and co-development approach (WP5 and 6), will engage with target audience to ensure regulatory relevance of risk assessment methods, models and acceptance of the integrative risk assessment approach developed as part of the project. These interactions will be facilitated with selected key European stakeholders, the External Advisory Board and related networks and communities, using a variety of engagement activities, for example: participatory workshops. The involvement of the relevant target audience as part of these activities is not foreseen as having any adverse consequences for participants. No physical injury, financial, social, or legal harm will be posed to the participants, and potential psychological risks will not exceed the daily life standard. However, engagement with target audience will entail the collection and processing of personal data. Personal data will be collected from participants as (data subjects), and the ethical considerations related to the protection of personal data are raised and addressed in the following section. *PollinERA* will also use machine learning (artificial intelligence - AI) for deep learning and artificial neural networks data analysis for in silico toxicity models towards pollinators. However, these methodologies are considered as posing ‘minimal or no’ risk to public safety or rights, since only toxicity data sets will be used. Furthermore, the specific purpose and modalities of AI use within *PollinERA* will not relate to important aspects of personal interest, such as recruitment, education, and healthcare or law enforcement, as defined by proposed EU harmonised rules on artificial intelligence (Artificial Intelligence Act) but are restricted to identifying physiological linkage between pesticides and physiological responses in model organisms.

4.2 Compliance with ethical principles and relevant legislations

PollinERA will only collect personal data from the human participants that take part in the project's co-development activities and social science studies carried out to facilitate the development and acceptance of the integrative *PollinERA* One System approach.

The personal data collected will be limited to what is strictly necessary to achieve the objectives of the research and input needed. Individuals contacted will be adult healthy volunteers. Sensitive personal information relating e.g., to health, ethnicity, sexual lifestyle, political opinions, religious or philosophical conviction fall beyond the scope of the project and will not be probed for. Ethical protocols and guidelines will be produced as part of the project's Ethics and Security Plan (D7.2). This document will ensure the collection, processing, and storage of personal data follows EU GDPR rules and research activities adhere to international guidelines for medical (e.g., Declaration of Helsinki) and social research (e.g., EC Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research, 2010), as well as Horizon Europe ethical standards. These include the implementation of principles and protocols seeking, where necessary ethical approval from relevant ethics review boards (ERB), gaining informed consent (e.g., provision of participant information leaflets and informed consent forms) and the secure storage of personal data (e.g., anonymised, stored in a non-identifiable format, kept securely, and shared for study purpose only in aggregated forms). The host institution of the project coordinator, Aarhus University (AU), will appoint a Data Protection Officer (DPO) and the contact details of the DPO will be made available to all data subjects involved in the research as part of the informed consent literature.

Conflicts of interest

The authors have declared that no competing interests exist.

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