TECHNICAL REPORT

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Theme (concept) paper – Advancing the Environmental Risk Assessment of Chemicals to Better Protect Insect Pollinators (IPol-ERA)

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Revised theme paper in light of the comments received from the European Commission (DG SANTE, DG ENVI), EU Agencies (JRC), EU Member States through the Advisory Forum, EFSA's Scientific Committee, international organisations, and risk assessment bodies in Third Countries (EPA/OPP) and stakeholders through EFSA´s list of registered stakeholders.

Disclaimer: This document does not present future project calls as part of EFSA's work programme, or any future position of EFSA. It aims to support the development of a roadmap for action and its content can be subject to change.

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1. Vision

By 2030, the methodology followed for the environmental risk assessment of chemicals across EFSA's activities will be further advanced to better protect insect pollinators (including wild and managed pollinators), their diversity, ecological functions and ecosystem services they provide, including pollination.

2. Background

In the frame of the **Farm to Fork Strategy**[1], one of the main priorities of the European Commission is to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030, especially for the most hazardous ones. This policy priority, along with those outlined in the **European Green Deal**[2] (in particular by its **EU Biodiversity Strategy**[3] **-** and **EU Pollinators Initiative**[4] **- and the EU Chemicals Strategy for Sustainability**[5] emphasising the vital role of pollinators for healthy ecosystems and food security), highlight the necessity to reverse their decline and activate all levers to protect biodiversity and particularly vulnerable ecosystems.

The EU Biodiversity Strategy also aims to bring back at least 10% of agricultural area under high-diversity landscape features to provide space for wild animals, plants, pollinators and natural pest regulators. These areas will play the role of compensatory areas in agro-ecosystems that should not be subject to any chemical application/exposure. In addition, the **EU Pollinators Initiative**[6] objectives state that **by 2030** scientific knowledge about the magnitude, causes and consequences of **insect pollinator** decline will have improved, that the main known causes of this decline will be addressed and managed, and societal awareness and collaboration amongst stakeholders strengthened.

In the first instance, EFSA will prioritise the work for pesticides, with subsequent integration of the tools and methodologies developed to other relevant chemicals. Prioritisation of other chemicals will be developed building on the experience gained in the area of pesticides.

This stepwise progress will be all the stronger due to the support and cooperation accompanying this ambition from interested partners, such as the European Commission and Parliament, Member States, stakeholders and other agencies of the European Parliament's ENVI committee.

3. Scope and objectives

EFSA's strategic goal on advancing the environmental risk assessment for insect pollinators (IPoL-ERA), with the cooperation of interested ENVI agencies and the support of the Joint Research Centre (JRC), intends to take a series of actions to support the European Commission's ambition in reducing pesticide risk/use, promoting environmentally safer alternatives to control agricultural pests and diseases, safeguarding the protection of insect pollinators and in assessing the role of landscape reservoirs (such as insect pollinator refuges) to mitigate risks to insect pollinators.

The **overarching objective** is to contribute to the further advancement of the environmental risk assessment of chemicals (such as plant protection products, biocides, veterinary drugs, fertilisers) for insect pollinators, in order to address current risk assessment challenges and ensure preparedness for future challenges.

Specific emphasis (**specific objectives**) will be put on:

1. The consolidation, update and harmonisation of risk assessment methodologies by considering their possible alignment across sectorial legislative frameworks, in close

[1] https://ec.europa.eu/food/farm2fork_en
[2] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[3] https://ec.europa.eu/environment/strategy-offline/biodiversity-strategy-2030_en
[4] https://ec.europa.eu/environment/nature/conservation/species/pollinators/policy_en.htm
[5] https://ec.europa.eu/environment/strategy/chemicals-strategy_en
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018SC0302R(01)&from=EN

coordination with the outcome of the roadmap for action on "Building a European Partnership for next generation systems based environmental risk assessment" (PERA)[7];

2. The consideration of more context-dependent (i.e. characteristics of receiving environments) and real-world scenarios;
3. The development and implementation of a systems-based approach for IPol-ERA;
4. The promotion of data/expertise sharing and multidisciplinary collaborations through partnerships.

The **initial focus** will be on **chemical pesticides**, as the further advancement of IPol-ERA for this group of chemicals is key in supporting the European Commission's mission to reduce the overall risk/use of pesticides and safeguarding the protection of insect pollinators.

EFSA's IPoL-ERA will be informed by and complement other relevant EFSA theme papers and associated activities/projects:

- Building of a European partnership for next generation, systems-based ERA (PERA);
- New approach methodologies (NAMs) in risk assessment;
- Risk assessment of combined exposure to multiple chemicals (RACEMiC).

4. Risk assessment development areas

The further advancement of insect pollinator environmental risk assessments will require the implementation of a portfolio of activities clustered in **development areas**. Currently, the six following interrelated risk assessment development areas are proposed for further consideration and action:

1. Engaging towards a joint IPol-ERA partnership

This development area aims to:

- Broaden the scope of the EU Bee Partnership (EUBP) currently focused on honey bees to insect pollinators, and involve new relevant partners to build an IPol-ERA partnership at EU level for data and expertise sharing on insect pollinators;
- Build linkages with relevant and complementary partnerships (e.g. One Health platform, EU Partnership for the Assessment of Risk from Chemicals [PARC], EU Partnership for Biodiversity [BiodivERsA] and PERA);
- Support the setting of research priorities for developing environmental risk assessment methodologies in line with IPol-ERA objectives (e.g. through the establishment of an EU steering network composed of Member States, stakeholders, EFSA, EU ENVI agencies and scientists from ongoing relevant research projects);
- Address risk assessment issues (e.g. through the establishment of a scientific expert Working Group with expertise in the environmental risk assessment of chemicals for insect pollinators, as well as other required technical expertise in biology and ecology, as needed).

Note that the IPol-ERA partnership will feed the risk assessment development areas for insect pollinators listed below, where relevant, and will be integrated in PERA.

2. Assessing ecological consequences of chemical effects on insect pollinators

This development area will increase the knowledge about chemical effects on insect pollinators and their impacts on ecosystems (including ecological traits of species and ecosystem structure and functions). The improved knowledge will provide the scientific basis to support the definition of specific protection goals.

[7] The roadmap for action on the project 'Building a European Partnership for next generation systems based environmental risk assessment' (PERA) will be completed in March 2022

- Determine the impact of chemical effects on insect pollinators and the ecosystems (i.e. pollination function, genetic resources, food chain structure) they contribute to, both in relation to the normal operating range of insect pollinator populations in EU ecosystems and to the effects caused by the chemicals they are exposed to;
- Describe the options for specific protection goals in line with the EFSA method for supporting risk managers in their decision making processes[8,9]
- Define quantitative links between effect levels of chemicals and their impacts, at population and community levels, in EU ecosystems for the various options for specific protection goals.
- Explore the possibility to develop qualitative and quantitative Adverse Outcome Pathways (AOPs) to extrapolate across multiple levels of biological organisation.

3. Advancing hazard and exposure characterisation

This development area has the objective of increasing knowledge about exposure scenarios in terms of where insect pollinators are exposed in ecosystems, the type of exposure (e.g. contact, dietary, sources of exposure), as well as about the types of adverse effects (e.g. acute, chronic, sub-lethal).

- Generate and collect data on chemical effects on insect pollinators (acute, chronic and sub-lethal toxicity, toxicokinetics and toxicodynamics (TK/TD), field effect data including potential for recovery);
- Determine interspecies sensitivity by e.g. analysing literature data, performing experimental work, considering models;
- Explore new and alternative approaches/methods for hazard assessment (e.g. *in silico* tools to predict chemical toxicity: read-across methods, [quantitative] structure-activity relationship [Q]SAR models, biologically-based models [such as kinetic-dynamic and dynamic energy budget models], ecological structure activity relationships (ECOSAR) predictive models and OMICs) and assess their relevance and reliability for regulatory purposes; test them against current approaches using relevant test case studies; promote their regulatory uptake and use; and make these approaches/methods available to all through existing relevant open-source databases (such as EFSA's chemicals hazard database, the OpenFoodTox[10]);
- Generate and collect data on routes and sources of chemical exposure to insect pollinators (by reviewing relevant information reported in databases, dossiers and scientific literature, and liaising with relevant scientific expert groups, when needed) and develop/refine methods for exposure estimation;
- Investigate the role of the different sources and routes of exposure (contact and dietary); in particular, investigate the relevance of the exposure via contaminated soil for insect pollinators (e.g. most solitary bees are ground nesting).

4. Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators

This development area will target the development and implementation of risk assessment approaches to address combined hazard/exposure to multiple chemicals with the following high-level activities:

- Prioritise, develop and implement methodologies for hazard characterisation of multiple chemicals in insect pollinators considering combined toxicity for acute, chronic and sublethal effects (concentration-addition, response-addition and interactions);
- Prioritise, develop and implement methodologies for exposure assessment (environmental fate, occurrence of multiple chemicals);

[8] https://www.efsa.europa.eu/en/efsajournal/pub/1821
[9] https://www.efsa.europa.eu/en/efsajournal/pub/4499
[10] https://zenodo.org/record/4740174#.YO_25OgzbD4

- Support the development and implementation of fit-for-purpose monitoring programmes/activities. This would include the improvement of analytical methods by expanding the number of pesticide residues analysed and by improving their analytical limits (detection and quantification limits) in various relevant matrices;
- Prioritise, develop and implement harmonised methodologies for risk characterisation that enable consideration of combined exposure to multiple chemicals.

5. Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors

This development area aims to advance the development of spatially and temporally explicit tools in support of landscape scale population level based IPol-ERA that also account for environmental stressors. The following high-level activities are proposed:

- Develop spatially- and temporally-explicit tools (e.g. population models) to consider adverse effects associated with chemical exposure at higher levels of biological organisation (population, community, ecosystem) and the relevant spatio-temporal scales;
- Assess the importance of landscape features/heterogeneity/connectivity, type of management of local fields, spatial and temporal population dynamics, and recovery potential of insect pollinators at a landscape scale;
- Develop methodologies to assess indirect effects on insect pollinators (e.g. reduced beneficial weeds/host plants, shelter, food sources) due to herbicide usage at a landscape scale;
- Ensure the calibration, testing and validation (e.g. plausibility check of model predictions) of new tools;
- Consider the complex of environmental stressors (such as competition between managed and wild bees, biological agents, resources and abiotic factors such as climate/weather land structure, invasive alien species) that can potentially impact insect pollinators and assess their relevance for insect pollinator risk assessment.

6. Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context

This development area will build on previous development areas and integrate their outcomes to contribute to the development of a more holistic environmental risk assessment framework for insect pollinators that follows systems-based approaches. Hence, the objective is the implementation of holistic and integrated risk assessment tools and methodologies and make them operational for use in a regulatory context.

The following high-level activities are proposed:

- Develop approaches to facilitate the integration of empirical data (e.g. landscape features), risk assessment tools and methodologies (including fit-for-purpose modelling, risk assessment of combined exposure to multiple chemicals) and monitoring/surveillance[11];
- Develop tools for the integration of environmental monitoring, surveillance and pesticide data in prospective insect pollinator risk assessments;
- Integrate in the ERA risk indicators to monitor the health of insect pollinators in agro-ecosystems;
- Develop user-friendly tools (e.g. IT integrated support systems) for use by risk assessors, risk managers, applicants and other stakeholders for addressing their respective needs (e.g. regulatory assessment, consideration of risk mitigation measures, alternative options for pest management, best agricultural practices, etc.);

[11] https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-scientific-committee-opinion-1

- Build capacity in the use of the new tools/approaches and their future implementation.

5. Opportunities

- Develop an EU-level approach/network for environmental monitoring for insect pollinators;
- Identify emerging insect pollinator risk assessment needs, and bridge risk assessment gaps;
- Co-develop and implement innovative/complementary tools and methods for insect pollinator risk assessments;
- Advance and harmonise insect pollinator risk assessments, across regulatory silos;
- Adapt existing models/simulations or build new ones to understand colony effects on honeybees (and bumblebees) and population effects of solitary species and other insect pollinators;
- Move beyond honey bees as a model species, not only including bumblebees but also solitary bees and other taxa of insect pollinators in regulatory risk assessments;
- Identify, prioritise and promote research and innovation needs for insect pollinator risk assessments, and align research and innovation in insect pollinator risk assessments with EU/national Research & Innovation investments to improve coherence and reduce overlap between national and EU funding in ERA research;
- Address new policy targets, the 'one substance – one assessment' concept[12], and societal needs;
- Identify elements to improve best management practices to reduce impact on biodiversity and pollinators.
- Strengthen cooperation opportunities with other EU institutions working on pollinator activities and with relevant Horizon 2020 research projects.

6. Cooperation

Developing IPoL-ERA will help strengthen the cooperation to share and promote knowledge, expertise, methods and data (to minimise redundancies in data generation, collection, analysis and technology transfer) with interested and relevant national institutions, EU Agencies and EU institutions (e.g. ECHA, EEA, EMA, JRC) and international partners (e.g. the US EPA, and other non-EU regulatory partners).

A stronger interagency and international cooperation will also strengthen the reliability and transparency of insect pollinator risk assessments, prevent duplication of efforts and enhance effective dialogue between risk assessors and managers, and other relevant partners at European, national and regional level, while building public trust.

With the incorporation of research findings from research projects developed in support of IPoL-ERA into regulatory guidance, EFSA will support decision and policy makers in identifying and implementing key elements of the EU Green Deal. To achieve this goal, a close cooperation with key European players is needed, such as with DG JRC, ECHA, EEA and EU Member States to ensure key research areas are identified and EU Biodiversity Strategy targets are adequately addressed and can be successfully delivered (such as reducing harmful pesticides by 50%, increasing biodiversity-rich landscape features on agricultural land and halting and reversing the decline of insect pollinators).

In addition, close follow up of the work and planned deliveries for the Horizon 2020-funded European Green Deal Calls, in particular those covering area 6: Farm to fork, area 7: Biodiversity and ecosystems and area 8: Zero-pollution, toxic-free environments, will be needed to ensure synergies and avoid duplication of efforts. Close cooperation with partners and stakeholders (e.g., beekeepers and their networks, nature conservation sector and civil society organisations) is also needed to

[12] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/EFSA-ECHA-position-paper-OSOA.pdf

identify additional priorities and complementarity of research work, e.g. with the EU Bee Partnership[13], EU Partnership for the Assessment of Risks from Chemicals [PARC][14] and the European co-funded Partnership on Biodiversity [BiodivERsA][15]and other future Horizon Europe Cluster 6 research projects.

7. Impact for EFSA and partners

- Increases preparedness for more comprehensive environmental risk assessments; using new tools and methodologies to better characterise the impact of chemicals to non-target insect pollinators;
- Enhances future networking and cooperation opportunities with partners in the Commission (JRC) and EU agencies (such as EEA, ECHA and EMA);
- Promotes the development of an updated risk assessment paradigm, with further interagency cooperation on the development and implementation of a systems-based environmental risk assessment for regulated substances/compounds or products;
- Strengthens the position of EFSA as an important partner for the development of methodologies to characterise the impact of chemicals present in agro-ecosystems to insect pollinators, at EU level and also internationally;
- Demonstrates EFSA's awareness to societal interests, increasing and reinforcing its visibility and commitment to environmental protection and preventing biodiversity loss;
- Facilitates contributions from national competent authorities, EU Member States international partners, stakeholders and the scientific community for transparent and informed discussions and developments in the area of advancing the environmental risk assessment for insect pollinators.

[13] https://www.efsa.europa.eu/en/supporting/pub/en-1423

[14] https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf

[15] https://www.biodiversa.org/1759

Abbreviations

AOPs	Adverse Outcome Pathways
BiodivERsA	EU Partnership for Biodiversity
DG	Directorate General
ECHA	European Chemicals Agency
ECOSAR	Ecological Structure Activity Relationships
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENVI	Environmental Committee in the European Parliament
ERA	Regulatory Environmental Risk Assessment
EU	European Union
EUBP	EU Bee Partnership
IPoL-ERA	Advancing the Environmental Risk Assessment for Insect Pollinators
IT	Information Technology
JRC	Joint Research Centre
NAMs	New approach methodologies
PARC	EU Partnership for the Assessment of Risk from Chemicals
PERA	Building of a European partnership for next generation, systems-based ERA
RACEMiC	Risk assessment of combined exposure to multiple chemicals
TD	Toxicodynamics
TK	Toxicokinetics
[Q]SAR	[Quantitative] structure-activity relationship
US EPA	United States Environmental Protection Agency