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EDITORIAL

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EFSA is working to protect bees and shape the future of environmental risk assessment

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Europe is pursuing its ambition for a climate-neutral, sustainable future. The European Commission's Green Deal, an important step in this direction, has at its heart the protection of the European Union (EU)'s biodiversity and the resilience of its ecosystems. Reducing the use and risk of pesticides and reversing the decline of pollinators are but two of the 'calls-to-action' embedded, respectively, in the Green Deal's Farm to Fork and Biodiversity Strategies. Much of the science supporting policymakers on these highly complex bodies of work falls within the remit of the European Food Safety Authority (EFSA). EFSA scientists are working to help address these challenges, as reflected in the release in 2021 of two important scientific reports.

The first report addresses a mandate from the European Commission for a review of the 2013 bee guidance document on the risk assessment of pesticides in relation to honey bees, bumble bees and solitary bees; the second responds to the European Parliament's request for a scientific opinion on the development of an integrated and holistic approach for the environmental risk assessment (ERA) of multiple stressors in managed honey bees (*Apis mellifera*) – known as the MUST-B project.

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Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)		**Scientific Opinion** on a systems-based approach for the environmental risk assessment of multiple stressors in honey bees
European Commission	**Requested by**	European Parliament
Developed in accordance with Regulation (EC 1107/2009) on the approval of pesticides	**Legislative status**	Not constrained by or aligned to specific legislation
Guidance document, relying on the most recent methodologies and data	**Purpose**	Reflections document, presenting a risk assessment framework based on monitoring and modelling strategies
Assessment of single crop/single pesticide	**Scope**	Assessment focused on pesticides in the context of multiple stressors
For immediate implementation following approval by EU Member States	**Timeframe**	For future consideration as framework for modernisation of environmental risk assessment in the EU

Bee guidance mandate from the European Commission

The risk assessment of plant protection products (PPPs) is undertaken in line with legal requirements (for the approval of PPPs under Regulation EC 1107/2009)[1], which state that a PPP can only be approved if it 'has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honey bee larvae and honey bee behaviour'. Under this legal framework, the evaluation of risk is conducted as a single crop/single pesticide assessment, and undertaken by EFSA, the European Commission and Member States.

To support this process, the guidance document on the risk assessment of PPPs for bees (*Apis mellifera, Bombus* spp. and solitary bees) was developed in 2013. This work relies on the definition of the specific protection goals (SPGs; in brief, these goals define what to protect, to which extent, where to protect it and over what time period). The definition of the SPGs based on the methodology proposed by EFSA[2,3] requires a dialogue between risk assessors and risk managers, where risk assessors provide the scientific grounds to inform the decision-making process of risk managers.

Based on the scientific knowledge and expert judgement available at that time, risk managers agreed to protect the strength of colonies located at the edge of treated fields. This is because these colonies will be the most exposed to the PPP under evaluation, and their viability, the pollination services they provide, and their yield of hive products all depend on their strength. A colony size reduction of less than 7% was considered a negligible effect for colony strength.

Although the 2013 guidance was used in some cases such as for the assessment of neonicotinoids (thiamethoxan, clothianidin, imidacloprid)[4] and its use was recommended by risk assessors,[5] it was not fully implemented in the regulatory approval process because there was insufficient support for it among Member States.

The bee guidance document is currently being reviewed, in consultation with risk managers and stakeholders. The review is being developed in line with the existing legislative framework and will present an ambitious proposal for the protection of bees, taking into account new knowledge that has emerged.

Using systematic approaches and methodologies, the experts are examining several aspects of the guidance including, for example, the relevance of the various sources of exposure, the bee oral exposure estimation model and its parameters, the attractiveness of crops for bees due to production of pollen and nectar, the interspecies sensitivity to pesticides, and the requirements for field studies.

Systematic literature review on bee background mortality

A systematic literature review on background mortality rates in the EU has been completed, together with a survey of beekeepers from several EU countries on the impact of some beekeeping practices on honey bee mortality. An extensive analysis[6] of bee mortality rates is now available, to ensure a comprehensive understanding of this topic.

Review of Specific Protection Goals

The experts have also undertaken a dialogue with risk managers for the review of the SPGs. More specifically, EFSA responded to a request to assist risk managers further by providing four different approaches[7] to guide them to reach an agreement on protection levels. A majority expressed a preference for the approach that will protect the strength of colonies located at the edge of treated

[1] Regulation (EC) 1107/2209 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32009R1107

[2] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010;8(10):1821, 55 pp. https://doi.org/10.2903/j.efsa.2010.1821

[3] EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. EFSA Journal 2016;14(6):4499, 50 pp. https://doi.org/10.2903/j.efsa.2016.4499

[4] Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid, clothianidin and thiamethoxam considering all uses other than seed treatments and granules. (EFSA, 2015); Conclusion on the peer review of the pesticide risk assessment for the active substance imidacloprid, clothianidin in light of confirmatory data submitted, (EFSA, 2016); Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid, clothianidin and thiamethoxam considering the uses as seed treatments and granules (EFSA, 2018).

[5] Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. (EFSA, 2015).

[6] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1880

[7] https://www.efsa.europa.eu/sites/default/files/topic/EFSA-Supporting-document-for-RMs-in-defining-SPGs.pdf

fields as agreed in 2013. The selected approach considers modelling of the background variability of colony sizes under different environmental conditions for the further work of defining the level of protection i.e. the acceptable level of colony size reduction.

Background variability of colony sizes

For this analysis, EFSA scientists carried out simulations in various EU environmental scenarios using the BEEHAVE colony model, which is the most suitable model currently available for simulating honey bee colony dynamics.[8] A decision on the SPG has yet to be taken.

As with most large projects that test the boundaries of scientific knowledge, data gaps have been identified. The review found limitations regarding data on wild bees – specifically, limited data on bumble bees and almost none on solitary bees. It will take years for such data to be produced, well beyond the 2021 publication for the bee guidance review. To help remedy this, EFSA has proposed setting out a multi-annual plan to address these data gaps.

MUST-B mandate from European Parliament

The second report follows a mandate from the European Parliament's Committee for the Environment, Public Health and Food Safety (ENVI) for a scientific opinion on the development of an integrated and holistic approach for the ERA of multiple stressors, such as PPPs with other types of chemicals (e.g. veterinary products, contaminants, biocides), biological agents (e.g. *Varroa*, *Nosema*) and others elements (e.g. food availability, weather conditions, beekeeping management practices), in managed honey bees. This report is known as the MUST-B scientific opinion.

In response, the MUST-B opinion proposes a systems-based approach that combines modelling and monitoring strategies, for the ERA of multiple stressors.

A framework is presented with supporting rationale that is forward-thinking, whilst acknowledging that some details will require further elaboration. The framework incorporates innovative tools and approaches, including societal perspectives (e.g. input from beekeepers, farmers and others involved in bee health and beekeeping), and will be reliant in part on new scientific developments to bring these insights into regulatory risk assessment.

Sensor-equipped sentinel bee hives

Notable elements in the MUST-B project include real-time data collection from sensor-equipped sentinel bee hives and agent-based simulation using a computer modelling system. This offers significant potential for the development of risk assessments of multiple stressors at larger spatial and temporal scales. Much of this is work in progress.

The modelling system is based on the development of an agent-based simulation, called ApisRAM, to assess either single or multiple chemicals in interaction with other stressors. It will also include other key elements from the landscape and immediate colony environment (i.e. infectious agents, viruses, pests, resource availability, foragers' decisions, weather changes, beekeeping practices) as well as specific attributes that influence the population dynamic of a honey bee colony (i.e. size, demographic structure, and behaviours) and what it produces (honey, propolis, beebread, royal jelly, and wax). Data will be collected to inform the model on the status of the honey bee colony and could be used as an early warning system.

In the medium-term (within the next 2–5 years), ApisRAM will make it possible to assess effects from more complex chemical mixtures, including synergistic and cumulative effects, moving beyond the 'single crop/single pesticide assessment' approach to reflect the complexity of the environment in which bees evolve. It will also be possible to assess chronic, sublethal and colony level effects of multiple chemicals (i.e. multiple PPPs, or PPPs with other types of chemicals present in the environment and hives), based on the EFSA guidance on chemical mixture risk assessment.[9]

[8] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honey bees at the landscape level. EFSA Journal 2015; 13:4125. https://doi.org/10.2903/j.efsa.2015.4125

[9] EFSA Scientific Committee, More SJ, Bampidis V, Benford D, Bennekou SH, Bragard C, Halldorsson TI, Hern_andez-Jerez AF, Koutsoumanis K, Naegeli H, Schlatter JR, Silano V, Nielsen SS, Schrenk D, Turck D, Younes M, Benfenati E, Castle L, Cedergreen N, Hardy A, Laskowski R, Leblanc JC, Kortenkamp A, Ragas A, Posthuma L, Svendsen C, Solecki R, Testai E, Dujardin B, Kass GEN, Manini P, Jeddi MZ , Dorne J-LCM and Hogstrand C, 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal 2019;17 (3):5634, 77 pp. https://doi.org/10.2903/j.efsa.2019.5634

In the longer term (beyond 5 years), additional ApisRAM features could include invasive species (e.g. the Asian hornet and small hive beetle which impact bees).

EU Bee Partnership prototype to launch 2021

Stakeholders will play a pivotal role in the collection and sharing of accessible, reliable and harmonised data. One example is the EU Bee Partnership (EUBP)[10] established by EFSA and stakeholders following a request from MEPs, and which includes EU beekeeping, veterinary and farming associations, academia, NGOs and industry. After 3 years of collaboration, the Partnership is set to launch its data platform prototype in early 2021 based on the Horizon 2020-funded 'IoBee, the internet of bees'[11] project and 'bee hub'[12] concept.

Beekeeping and honey bee colony losses are embedded into a complex socioecological system.[13,14] Stakeholders are willing to help in producing a more fit-for-purpose bee risk assessment of multiple stressors, to inform the provision of concrete benefits and practical solutions. Additionally, EUBP members were interviewed to gather their views and to discuss expectations for the future following a 'partnership synergy framework' methodology,[15] which explores collaboration relationships. These interviews were carried out to fulfil the request that MEPs made in their mandate for EFSA to provide guidance to the EUBP for harmonised data collection and evidence-based risk assessments.

The systems-based approach would have applications in, and potential benefits for, beekeeping, farming, research, risk assessment, risk management, policymaking and broader society.

This body of work presents ideas and concepts for consideration, and the future development of practical solutions to the critical areas of ERA, including the integration of landscape-level effects from exposure to multiple stressors. The potential for the future is significant.

Outlook

With the Green Deal goals in mind, EFSA is proactively positioning itself by setting out new priorities for ERA, not only to address current and new challenges, but also as a response to growing societal concerns and aspirations towards a risk reduction and a more sustainable use of PPPs. These reports reflect this ambition.

The two reports exemplify EFSA's approach to continuous improvement of ERA. The bee guidance document will enable immediate regulatory implementation of ERA of PPPs while the MUST-B scientific opinion highlights EFSA's vision for next generation ERA, which is demanding a holistic and integrated systems-based approach.

It will be a long journey. The regulatory guidance documents will be updated and renewed in the coming years, as new knowledge emerges.

The MUST-B systems-based approach has been developed for honey bees, but could become a model for ERA of multiple stressors for other organisms.

The reports set the stage of an integrated system of ERA of PPPs and multiple stressors to protect bees and more broadly Europe's biodiversity and ecosystems, upon which all citizens ultimately rely.

Abbreviations

ENVI	Committee for the Environment, Public Health and Food Safety
ERA	environmental risk assessment
EUBP	EU Bee Partnership
MEP	Member of the European Parliament
PPPs	plant protection products
PREV	Pesticides Peer Review
SCER	Scientific Committee and Emerging Risks
SPG	specific protection goal

[10] Terms of Reference for EU Bee Partnership: http://www.efsa.europa.eu/en/supporting/pub/en-1423
[11] https://io-bee.eu/
[12] https://www.bee-life.eu/post/the-bee-hub-developing-an-integrative-platform-for-pollinator-health-data
[13] Cilia, 2019. The plight of the honeybee: a socioecological analysis of large-scale beekeeping in the United States. Journal of the European Society for rural sociology. https://doi.org/10.1111/soru.12253
[14] Marshman et al., 2019. Anthropocene crisis: climate change, pollinators and food security. Environments, 6, 22. https://doi.org/10.3390/environments6020022
[15] Weiss et al., 2002. Making the most of collaboration: exploring the relationship between partnership synergy and partnership functioning. Health Education & Behavior, 29. https://doi.org/10.1177/109019802237938