



Outline of

the revision of the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013)

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1. Introduction

In March 2019, the European Commission mandated EFSA to revise the guidance document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013). Although the EFSA 2013 guidance has been used for the assessment of neonicotinoids and its use was recommended by risk assessors in a general ecotoxicology expert meeting (EFSA, 2015), the guidance has not been fully implemented in the process for the approval of the active substances.

The mandate included the following terms of references:

1. *Take account of the feedback from Member States and stakeholders on the EFSA (2013) guidance document;*
2. *Provide a review and summary of the evidence as regards bee background mortality, in particular considering realistic bee keeping management for *Apis mellifera* and natural background mortality. EFSA is requested to provide this summary in a separate document from the guidance document;*
3. *Review the list of bee-attractive crops in particular considering presence of bees, guttation and agricultural practices (harvesting time before or after flowering). This reviewed list shall also mention at which growing phases (e.g. BBCH codes) a crop is considered bee-attractive;*
4. *Review the current risk assessment methodologies in light of recent scientific research and developments e.g. exposure estimation, relevance of the exposure scenarios (e.g. weed scenario) and relevance of some risk assessment schemes. Available relevant guidance developed by Member States should be considered (e.g. draft Guidance Document on seed treatments and/or its follow up work) (ToR4);*
5. *Review the requirements for higher tier testing, in particular by reconsidering the magnitude of detectable effects vs the statistical power and validated population modelling in light of realistic agro-environmental conditions (ToR5);*
6. *Take into account planned and on-going discussions initiated by the Commission on defining specific environmental protection goals and review the risk assessment guidance based on the specific protection goals agreed during this process (ToR6).*

2. State of the art

For the revision of the guidance EFSA established a scientific working group¹ (WG) according to the EFSA rules and standards. EFSA staff and external experts from academia and national regulatory MS bodies are members of the WG. The external experts have been selected for their specific experience and expertise relevant to the mandate.

The European Chemicals Agency (ECHA) and EFSA are cooperating to harmonise approaches for assessing risks to bees under the biocides and pesticides regulations. This cooperation includes the possibility for ECHA to comment on documents and be involved in the WG as an observer. This would allow ECHA to follow the work in progress for pesticides and to reflect on commonalities in its activity on the same topic for biocides². Reciprocally, to ensure consistency, EFSA will be consulted on the preparation of the biocides guidance on this topic and may involve the WG.

EFSA has created an *ad hoc* Stakeholder Consultation Group³ to support the revision of the guidance document together with experts from Member States nominated through the Pesticides Steering Network⁴ (PSN).

¹ <https://www.efsa.europa.eu/it/science/scientific-committee-and-panels/ppr#working-groups>

² <https://echa.europa.eu/support/guidance/consultation-procedure/ongoing-bpr>

³ https://www.efsa.europa.eu/sites/default/files/Minutes_Selection_Board_SH_24_May_2019.pdf

⁴ <https://www.efsa.europa.eu/it/science/scientific-committee-and-panels/ppr>



2.1. Work completed

The Working Group has worked on different fronts: 1) plan and execute the revision of the guidance document; 2) collect feedback from stakeholders and MSs for framing its revision and 3) develop scientific ground to support the risk managers defining the SPGs.

2.1.1. Regarding the review of the GD

In 2020, a technical report was published on data collection and analysis regarding the bee background mortality⁵. The task was carried out with a systematic review approach for gathering and evaluating the evidence on bee mortality rates. In total 11000 papers were considered, and 5000 measurements have been included for the 3 groups of bees. The draft protocol for the systematic review was commented by the stakeholders and MS experts (see point below).

As a starting point of the revision, the WG prepared a protocol to tailor the review of the tier 1 risk assessment, describing the plan and the methodologies for addressing various aspects of the guidance document.

From July 2019 to September 2020 the WG ran several consultations of the *ad hoc* Stakeholder Group and MS experts organised by EFSA:

- First consultation was launched in July 2019 to collect feedback on the guidance (EFSA,2013) and use the comments to frame its revision.
- Second consultation was run to collect feedback on the protocol for the systematic review on background mortality, mentioned in the paragraph above.
- Third consultation was run to collect feedback on the draft protocol proposed to tailor the review of the tier 1 risk assessment. Comments were also discussed in a workshop held on the April 2020. Based on the feedback received, EFSA has finalised the protocol⁶ and initiated its implementation.
- Info session with stakeholders held in September 2020 to inform on the approach developed for supporting the risk managers on the decision for the SPG.

2.1.2. Regarding the review of the SPG

Development of four approaches for defining SPG⁷. To support the risk managers, the WG has developed different approaches. These approaches represented a combination of possible scientific and pragmatic processes for risk managers to determine specific protection goals (SPGs). These approaches were developed by considering the request of the European Commission mandate to *take into account planned and ongoing discussions initiated by the Commission on defining specific environmental protection goals and review the risk assessment guidance based on the specific protection goals agreed during this process*

Analysis of the background variability of honey bee colony sizes⁸. EFSA implemented the approach selected by MSs by carrying out 10000 in-silico hives simulations in 19 European environmental scenarios identified for covering various EU conditions. The work supported the decision to establish a specific protection goal for honey bees (*Apis mellifera*).

⁵<https://doi.org/10.2903/sp.efsa.2020.EN-1880>

⁶The protocol finalised after the consultation of stakeholders and MSs will be published with the publication of the guidance document

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

⁸ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6518>



Consultation with MS (risk managers/risk assessors) and stakeholders organised by the European Commission in form of workshops⁹ or an info-session, where EFSA provided technical support:

- First workshop took place in March 2020 with Member States. EFSA explained how the specific protection goals had been set in guidance 2013; MSs were given the opportunity to comment and provide their feedback. This was used by EFSA to frame the scientific work needed for supporting the decision-making process on the SPG.
- Second workshop took place in June 2020 with Member States. EFSA presented the four approaches. In this event MSs expressed a preference for the approach based on the analysis of normal operating range of the colony sizes for honey bees, which was confirmed by the Standing Committee on Plants, Animals, Food and Feed in July 2020
- Info-session held in January 2021 for Member States and the stakeholder group established by EFSA for allowing an exchange of views between all interested parties on the analysis of the background variability of honey bee colony sizes.
- Third workshop took place in February 2021 with Member States to further discuss the outcome of the simulations of the background variability of honey bee colony size and the possible setting-up of field studies to measure a given percentage of reduction in colony size.

Upon the proposal of the European Commission, a discussion took place on the 29 June 2021 at the meeting of the Council for Agriculture and Fisheries.

Agreed Specific Protection Goal for honey bees

The work completed so far supported the decision to establish **a specific protection goal for honey bees (*Apis mellifera*) for the entire EU corresponding to a value of 10% as the maximum permitted level of honey bee colony size reduction following pesticide exposure.**

2.2. Work in progress

The review of the 2013 GD is driven by an evidence-based approach and most of the work is completed. As presented in the protocol to tailor the review of the tier 1 risk assessment, for the most critical parameters systematic literature reviews were performed. In a nutshell, the main areas tackled are:

- Systematic review for a better estimate of food consumption of bees (11000 papers considered more than 150 fully appraised)
- Systematic review for sugar content of nectar (2000 papers considered; 3000 measurements covering 60 crops).
- Analysis of more than 150 residue trials and 70 dissipation studies for a better estimation of pesticide residues and their behaviour in pollen and nectar.

These above are the most important components for estimating the residue intake via dietary exposure.

- Reconsideration of the applied models describing the dietary and the contact exposure with introduction of new parameters in order to make them more realistic. In parallel, parametrisation of the new parameters.
- Experts knowledge elicitation (EKE) for the crop attractiveness for pollen and nectar. This area lacks literature data therefore the EKE process allowed to draw on the expertise from a panel of experts and to

⁹ https://ec.europa.eu/food/plants/pesticides/protection-bees_en



report existing but previously unreported knowledge, together with a quantitative description of the related uncertainty.

- A re-assessment of the relevance of the weed scenario, based on 7000 efficacy trials (>10000 considered).
- Re-assessment of the relevance of the water consumption scenarios based on 25 field trials and relevant literature
- Use of the dose-response relationships (> 600 ecotoxicity studies considered).
- Analysis of interspecies sensitivity based on 500 studies on 15 species to identify proper factors to extrapolate the toxicity from one species to another.
- Update of the risk assessment for the metabolites and for the mixture that undergo authorisation under the Regulation 1107/2009.
- Update of the risk assessment methodology for low doses and for sublethal effects.
- Implementation of the agreed SPG for honey bees in the assessment.
- Revision of the requirements for exposure and effect field studies.

3. Next steps

Following the discussion and conclusion on honey bees, the European Commission asked EFSA to support risk managers in their decision-making regarding the SPGs for bumble bees and solitary bees to be implemented for the regulatory risk assessment of pesticides under the Regulation 1107/2009.

Upon a request from the EC, EFSA is preparing a third supporting document to provide the existing body of evidence that can be used by risk managers to pragmatically define the SPG for wild bees. In this document EFSA will report an overview of the available data, will consider existing approaches for SPGs in the area of ecotoxicology and specifically highlight the knowledge gaps.

On November 15, EFSA will hold an information session to share with the ad hoc stakeholder group and experts from MSs the methodology for implementing the agreed SPG for honey bees (i.e. $\leq 10\%$ colony size reduction) in the lower tier risk assessment and the recommendations for higher tier studies.

The European Commission will hold on 23 November 2021 an information session separately for the ad hoc stakeholder group and experts for Member States for a preliminary presentation of the content of the supporting document on wild bees.

EFSA is preparing a new Topic Page on its website specifically devoted to the review of the bee guidance document, in which all relevant reports and documents will be uploaded.

3.1. Timeline

EFSA can finalise the guidance document revision once the agreed SPGs for wild bees have been communicated. A tentative time plan is illustrated in **figure 1**, including the timeline for the public consultation and the finalisation/publication of the guidance. The public consultation can be launched by the end of March 2022. The finalisation of the guidance to include, where relevant, the changes triggered by the comments and its publication can be scheduled by the end of September 2022.

In the **figure 1** the events that will engage the ad hoc stakeholder group and experts from Member States are also reported. Beside the information sessions mentioned above, a workshop will be organised at the end of the public consultation to collect and discuss the comments from the stakeholders of the ad hoc group and Member States.



It should be noted that the tentative time plan as illustrated in **figure 1** assumes that risk managers have agreed SPGs for wild bees by January 2022. Any delay in that milestone may cause delay in the following steps of the tentative time plan.



Figure 1: Indicative time plan for the finalisation of the GD

