POSITION PAPER
01/09/2020 – POS/20/LO/32940

ECPA comments on Pollinators Specific Protection Goals options[1]

Overview

- **ECPA is supportive of the structured and transparent process put in place by the Commission , EFSA and the Member States, to set scientifically based Specific Protection Goals.**
- Technical comments are provided on all approaches, highlighting their advantages and the challenges they present. Overall:
  - Approach 1 reliance on survival makes it more direct, but it would be better to be considered in conjunction with Option 4 (see below) and delivery of ecosystem services.
  - Approach 2 uses an acceptable range on the basis of the expected natural variability. **However, it is essential that the variability included in such approach is transparent, relevant and carefully selected**.
  - Approach 3 is based on expert idea that 7% deviation to control could be measured in the field. This is not in line with EFSA recent work. We believe the scientific basis behind this figure is not robust enough to define specific protection goals.
  - **Approach 4 gives a direct link to ecosystem services (e.g. pollination or honey production) which would be a direct measure to setup scientific based SPGs.** We believe it deserves further interest, several developments to BEEHAVE since the first publications makes this more feasible, but research needs should be outlined. For example, modelling of pollination based on parameters that are measurable in studies would need to be made a priority.
- **ECPA is concerned with the current way to consider higher tier studies and especially the use by EFSA of the Exposure Assessment Goals, which as currently written are impossible to meet in field studies which removes such studies as a higher-tier option. We believe an alternative approach to the evaluation of acceptable exposure in these studies is required.**
- On SPGs for solitary bees, we still see a critical lack of data that can be used to define SPGs and baseline scenarios. Setting up risk assessment without having the underlying data about species-specific elements will be a challenge.

Introduction

ECPA welcomes the structured and transparent process that was used to describe the different approaches to define what is an unacceptable effect to the environment for bees so that to derive corresponding specific protection goals. The scientific knowledge behind these approaches is clearly presented and allows experts to easily review the hypothesis used and possible ways to further improve them as science evolves. ECPA wishes to offer its views on each options below as well as additional comments for the expert's consideration.

Industry view on Approach 1 to 4

Out of the four options presented, option 4 gives a direct link to ecosystem services (e.g. pollination or honey production) which would be a direct measure to setup scientific based specific protection goals for

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

unacceptable effects on the environment, as per previous EFSA recommendations (EFSA, 2010 & 2016). While Approach 1 and 4 deal with different endpoints, they both use BEEHAVE (model available under General Public License) to explore the resilience of honeybee colonies to see what effects can be buffered by the colony and hence what effects can be considered negligible. On that basis, ECPA believes that this option deserves further interest, in particular with regards the actual research needs that would allow to develop it.

The advantage of option 1 is that a concrete endpoint is calculated, which makes realistic variability and uncertainty become less important. The calculated protection goal will emerge from the resilience of the simulated beehive due to the interaction of the bees. For this approach, it has already been proven to be useable for testing specific protection goals for honeybees (Thorbek et al. 2016). However, we would suggest that in this case the SPG should be based on ecosystem services delivery rather than colony survival

Within the CEFIC project CARES II, the impact of an insecticide on ecosystem services (pollination and honey production) was simulated using the BEEHAVE model, and results were presented at the CARES workshop in January 2020 (link). Honey production is directly calculated by the BEEHAVE model and pollination was calculated in relation to the number of foragers in a field per day, which could also be a measure when observing bees. With these two simple measures, the BEEHAVE model could also be used directly to simulate both ecosystem services without the need of much further research.

Option 2 assumes the magnitude of the effect on colony size following the exposure to a pesticide is acceptable when the effect remains in a range defined on the basis of the expected natural variability. This natural variability is defined as the normal operating range, and can be assessed by running the BEEHAVE model on a repeated pattern using the same input. However, as stated already by EFSA, this simulated variability needs to be checked against the control variability observed in available field studies on bees. To define the normal operating range, it is important what variability is included in the definition. Since this variability drives the definition of the protection goal, it is essential that the included variability is relevant and carefully selected. Within a field study, different variabilities are present and can be selected for this option.

- The first source of variability is the in-hive variability, which corresponds to the variability of different development trajectories of a single hive. This variability is currently implemented in BEEHAVE. The different colony trajectories a single average hive could manifest with its queen and a specific egg laying rate. In-hive variability cannot explain the variability found within semi-field or field studies (Schmolke et al. 2020). In contrast, the variability in field studies can be simulated with the BEEHAVE model if the different initial conditions of the hives are taken into account (Agatz et al. 2019).
- A second source of variability is in the egg laying rate of queens, which can also be taken into account into BEEHAVE. Since the calculated protection goal are purely based on the variability, it is key to transparently lay out which causes of variability will be included in the simulations and their effect on the protection goal. In addition, an arbitrary decision has to be made on the percentile of effect and the duration over which it is measured (i.e. is one day slightly outside of the normal operating range already an unacceptable effect to the environment?). If a non-relevant time interval is selected, then the approach does not take into account the resilience of the hive, and effects over a short time period of a single day (not detectable in field or semi-field studies) can trigger an unacceptable effect to the environment.

Option 3 is based on expert idea that 7% deviation to control could be measured in the field as stated by EFSA. This figure is not in line with statistical analysis conducted by EFSA that announced a very high number of replicates to statistical measure this 7% deviation (EFSA Science behind). Due to the high number of colonies needed to measure this effect level in a controlled study it is highly unlikely that this effect is detectable by beekeepers in the field or relevant for hive survival or ecosystem services provided by honey bees. In addition, it was demonstrated with the BEEHAVE model that much higher level of effects up, to 20%, can be tolerated by a beehive without consequences at the colony level (Thorbek et a. 2016). In the light of current scientific and technical knowledge, the scientific basis behind the 7% effect level figure is not robust enough to define specific protection goals..

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Incorporation of forager background mortality

The EFSA (2020) document on background mortality has identified that the daily background mortality rate for foragers is significantly higher than that used in the current version of the EFSA guidance document [1]. It needs to be considered how this is implemented in BEEHAVE [2], as the model uses an hourly mortality rate based on the actual time spent outside the hive by forager bees. The hourly mortality rate currently used by BEEHAVE[2] reflects the background mortality data compiled by EFSA for forager bees [3].

BEEHAVE utilises and needs an hourly mortality rate, which is appropriate as the risk of mortality is greater the more time a forager spends outside the hive. The daily mortality rate derived in the EFSA background mortality document was derived from flight span data, but the number of days/hours spent foraging appears not to have been reported. This information is available in some publications, e.g. Thompson *et al* ([4] reference 15776 in report)) showed a maximum mean foraging time of 24.5 hours per forager (hourly mortality rate 4.1%); the reported total flight distance of foragers is 800Km and the mean flight speed of 7.5 m/s [5] would suggest a total flight span of 29.6 hours (hourly mortality rate 3.4%), and on that basis the hourly mortality rate of 3.6% (over on a 7 day foraging lifespan) used by Becher [2] is not unrealistic and could be used in BEEHAVE.

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Exposure Assessment Goal (ExAG)

According to EFSA Bee Guidance [1] residues in any field studies are required to match or exceed the 90th percentile ExAG (developed from field residue studies or the theoretical ExAG). Published data [2-9] shows for honeybee and bumble bee colonies placed directly adjacent to a highly attractive crop the proportion of pollen sourced from the crop is inherently variable and the ExAG (90th percentile residues for bees foraging on the crop) will rarely if ever be met in field studies. A goal which also cannot be reached when looking at solitary bees. This provides no certainty for the Applicant on the acceptability of studies and thus effectively removes field studies as a higher tier refinement, with no alternative identified. An alternative approach to the evaluation of higher tier studies, which takes into account the behaviour of bees in realistic cropping systems and that experimental, rather than modelled residue data are available, is required.

Comments on Appendix A: the Exposure Assessment Goal (ExAG) is used both to define the level of exposure used in lower tiers of the risk assessment and to set the validity criteria for daily residues entering the hive/nest against which higher tier studies are assessed. This use of the ExAG to assess higher-tier (field) studies is counter to a tiered-approach to risk assessment, i.e. increasing realism of exposure and effects at higher tiers.

In EFSA Bee Guidance [1], the proposed ExAG was set at the 90th percentile of the spatio-temporal exposure distribution. Appendix A of the SPG document highlights the selection of the 90th percentile modelled target exposure as commonly used in other areas of the environmental risk assessment, e.g. for the EU FOCUS surface water, groundwater scenarios and, most recently, for soil. Such an approach may be appropriate for modelling residues, but it is not used when residue data are available, for example in human dietary risk assessment. Higher tier studies are intended to determine the effects of more realistic exposure, which is based on both actual residues in pollen and nectar and behaviour of the selected species. If such an ExAG is to be developed and used, then greater clarity on how residue data should be generated (site selection, temporal sampling, sample collection, storage) and when and how these data should be used. In addition, in the current proposal the variable foraging behaviour of individual bees within the landscape defines whether the contact and oral exposure assessment goal has been reached.

At higher tiers of the risk assessment EFSA Bee Guidance [1] proposes that the default 90th percentile ExAG can be refined by use of residue data from 5 suitably separated field sites in which the product is applied and residues on bees (contact exposure), in pollen collected directly from plants and in nectar collected from bees directly foraging on the plants as well as in bees returning to the hive are measured. It is assumed that a high proportion of the pollen and nectar is sourced from the treated crop and therefore residues in collected pollen and nectar and in bees reflect the variability in residues in nectar and pollen across the area of the crop and over time after application. Clearly "dilution" of pollen and nectar collected from crop plants to that entering the hive will differ significantly between studies and between sites, due to differences between landscapes, climate and the needs of the species/colony/population. EFSA Bee Guidance [1] highlights this issue: "*It is not possible to give generic guidance on an appropriate level of dilution, hence each case should be considered on a case-by-case basis and expert judgement used to determine if a study is appropriate for risk assessment purposes*." Such an approach provides no certainty for the Applicant in conducting such complex higher tier studies. In this case with up to 5 fields the 90th percentile will be defined as the maximum residue in the samples from these fields as is demonstrated by the studies identified in the EFSA evaluation of pollen and nectar [2]. If additional tunnel effect studies were conducted on these same fields (100% foraging on the crop), then by definition only one in five treated tunnels would succeed in matching or exceeding the ExAG based on residues in pollen and nectar, unless over-dosing of the active substance occurred with potential consequences on the foraging activity of the bees and the reliability of the study (compounds may reduce foraging at higher rates which would not alter the residues in pollen and nectar but may mask effects).

According to EFSA Bee Guidance [1] residues in any field studies are required to match or exceed the 90th percentile ExAG developed from the exposure studies (or if there are no acceptable residue data available the theoretical ExAG). This approach to setting an exposure goal for field studies in which honeybees forage freely in the environment is not practical even on highly attractive crops [3]. The diverse foraging strategies of honeybees, bumble bees and solitary bee species means that it is even less appropriate for non-*Apis* species. For example, for honeybees and bumble bee colonies placed directly adjacent to a highly attractive crop, such as oilseed rape, the ExAG (90th percentile residues for bees freely foraging on the crop) will rarely be met:

	Mean ± SE % oilseed rape pollen collected		
Proximity to crop	*Apis mellifera*	*Bombus terrestris*	Reference
Adjacent Site 1	40.5±2.4	40.5 ± 4.8	[4]
Adjacent Site 2	53.6±3.4	41.3±3.6	[4]
Adjacent Site 3	51.7±2.7	41.9±4.9	[4]
Adjacent Site 1	76-99	68 ± 7	[5, 6]
Adjacent Site 2	95-100	84 ± 4	[5, 6]
Adjacent Site 3	69-88	70 ± 9	[5, 6]
Adjacent Site 1	32.3±21.2- 77.5±14.1	16-51	[7, 8]
Adjacent Site 2	35.8±13.5 - 82.8±8.8	32-95	[7, 8]

To demonstrate that exposure within higher-tier studies are sufficient to reliably detect an effect, should it occur, there are a number of alternative options for consideration:

1) Set a more realistic spatio-temporal target percentile for residues collected from the treated crop based on published foraging data in realistic cropping systems (field studies are isolated from other bee-attractive crops and therefore already worst-case). An example for such an approach to setting protection goals in environmental monitoring is provided in [9].
2) Use tunnel studies to identify effects immediately following application with monitoring outside the tunnel for a suitable period to determine any effects on emerging brood with foraging assessments to confirm exposure (use of a toxic reference confirms the test system is capable of detecting an effect).

3) Use a colony feeding study in which colonies are directly fed with the agreed percentile residues and then monitored for a suitable period to determine any effects on emerging brood.

4) Use toxic reference treated fields within studies to demonstrate the ability of the study to detect an effect - this practice was halted many years ago (see EPPO 2010) due to the concerns in many countries about the impact of such an approach on the environment.

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Solitary bees – applicability of risk assessment

A risk assessment using “per bee” doses is a practical approach for honey bees but seems to be a challenge for solitary bees without having the underlying data about species-specific body sizes, consumption of food items, residue estimates, temporal and spatial variation of foraging and background mortality. In due course of the current mandate for the review on the EFSA bee guidance document, It became yet again apparent that barely any of these data are available for solitary bees [1].

The closely related honey bee is a suitable surrogate to investigate the physiological ecotoxicity [2] even with dose-based values when considering the variety of body-weights [3] whereas the different bee groups are most distinct in their life histories and ecological traits with major impact on exposure estimates. This might be one of the reasons why the current EFSA approach for exposure assessment is “not applicable to the solitary bees” [1]. The most challenging difficulty is presumably to capture the great diversity of solitary bee species compared to only one honey bee species in Europe (see e.g. [4]) even though that diversity is strongly shaped by the nature of the crops and their close environment and prioritization could be considered. Other risk assessment schemes that have been proven practical in a regulatory framework consider a species diversity of non-target organisms by either a dose-based focal species approach [5] or concentration-based estimates excluding parameters like body weights and consumption of the various species. The lack of underlying data for a dose-based approach with solitary bees brought up a number of uncertainty factors that resulted in an up to 2500 times more conservative outcome than the honey bee assessment at first tier [6] making a matching effect assessment impossible. Therefore, legitimate doubts on the applicability of the risk assessment on this bee group are raised which is partly caused by the exposure assessment that is already recognized to be not applicable to solitary bees.

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