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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

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Dear Honourable Member,

Thank you for your e-mail, dated 18 September 2020, in which you sent a number of questions regarding the four approaches developed by EFSA to review the Specific Protection Goals for bees.

Please find in annex the answers to your questions, which were drafted in close cooperation with the European Food Safety Authority given their technical nature.

Yours sincerely,

Enclosure: Replies to questions on the review of the 2013 EFSA Bee Guidance Document

c.c.: (EFSA)

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Q1: EFSA in its Guidance on bees (2013) defined the protection goal as negligible exposure and decided to take 7% reduction in colony size as the threshold. Now in one of the four options presented, EFSA takes the % variability of the background mortality to derive the threshold.

a) Can you please explain why do you want to change the approach?

In the 2013 EFSA Bee Guidance Document a 7% threshold was considered by risk managers as negligible effect, based on the then available information and on expert judgement that beekeepers could only perceive an effect on honey bee colony size of 7% or higher. This threshold was thus mainly based on experts' judgement rather than scientific data .

The Commission mandated EFSA in March 2019 to review the Bee Guidance Document as requested by a large majority of Member States, taking into account all new scientific information that emerged since 2013. EFSA also considered all comments received since 2013 from Member States and stakeholders and developed 4 alternative approaches that could be used to agree – in a second step – on the specific protection goals.

Approach 1 (long-term survival of honey bee colonies) and 2 (normal operating range of honey bee colonies) make use of more scientific information, in particular population modelling with calibrated input parameters by EFSA, and as such bring more science into the risk assessment and allow for a more informed decision by risk managers.

Approach 3 is the approach followed in 2013 with a so-called 'a priori' threshold. There is currently no scientific basis available to inform decision makers for the choice of such an 'a priori' threshold. Such decision therefore depends on judgement/perception. As indicated above, the 7% threshold chosen in 2013 was based on expert judgment and not on science as scientific data were not available at the time.

Approach 4 is based on quantification of ecosystem services. However, this approach remains theoretical for the time being as currently no sufficient scientific knowledge is available.

The currently ongoing analysis of the normal operating range of honey bee colonies using approach 2 (which was supported by a majority of Member States), will thus offer to the risk manager scientific information as regards the normal variations in honey bee colony size, and therefore increase both the consideration of robust science and transparency in decision making of what impacts on colony size can be accepted due to pesticides. That decision has still to be made by the risk managers. However, from the current progress made, it is clear that basing a decision on a protection goal on the basis of approach 2 will have a better and more solid scientific basis than basing it on approach 3.

b) How does the background variability of the honeybee colony size connect to the legal provisions of Regulation 1107/2009 to define negligible exposure and negligible effects for bees?

These are two different and independent issues. Point 3.8.3 of Annex II to Regulation 1107/2009 states that an active substance can be approved if the use of that substance will result in negligible exposure of honeybees ***or*** has no unacceptable effects on colony survival and development.

Negligible exposure is a concept, which is independent from the background variability of honeybee colony sizes. In a nutshell it implies that there will be no contact among the honey bees and the active substance. An example of negligible exposure of honeybees is the use of a substance in permanent greenhouses.

If exposure is not negligible, an assessment of the risk to honeybees is necessary and should result in a conclusion that there are no unacceptable effects on colony survival and development. There is no reference to 'negligible effects' as mentioned in the question. This implies that a certain level of effects could be acceptable and this is what needs to be agreed by risk managers.

In any scientific assessment including risk assessment, natural and experimental variability need to be considered. Experimental variability compares differences between a control group that is not exposed to a given stressor (e.g. a pesticides) and a group that is exposed to the stressor. Knowledge about the natural variability within the control group is important to be able to perform a robust and sound comparison with any effects seen in the treated group. Therefore, the knowledge of the natural variability of honey bees colonies (i.e. observed even when the stressor (i.e. the pesticide) is not present) is crucial.

In approach 2, the natural variability of honeybee colony size is considered when deciding what would be regarded as unacceptable effects of pesticides on honey bee colony size.

c) Is the background mortality the best option for deriving threshold for the protection of pollinators considering that natural background mortality comes from multiple sources and is very context dependent?

Approach 2 to review the specific protection goal for bees, which is supported by a majority of Member States, does actually not concern the percentage variability of the background mortality The modelling of the normal operating range, considers how honey bee colonies develop under different climate and environmental conditions. For further explanations see next question.

d) What is the evidence that this natural variability does not come from background pesticides pollution, diseases and/or reduced biodiversity? Also considering that the data that EFSA uses are not derived from pristine areas.

The vast majority of honey-bee colonies in Europe are managed colonies and therefore not living in natural "pristine" conditions. The interventions of beekeepers to optimise honey production or pollination, or to manage the genetics of the colonies, is enough to make the living conditions of bees "not pristine". The analysis by EFSA focuses on the variability in colony size (normal operating range), i.e. what is the difference in the number of adult bees in colonies in different scenarios and how this changes during a year.

The methodology used for assessing background variability of colony size makes use of scientific population modelling which is based on experimental data (published literature data and geographical data from the JRC GIS platform[1]). There are many potential drivers of variability in colony size, with intrinsic biological variability being one of the main ones. In agricultural environments, it is possible that the presence of stressors (e.g. background pesticides and bee diseases like Varroa) may affect variability between colonies. Nevertheless, in the model simulations, EFSA has purposefully avoided to include any kind of pesticide exposure, in order to mimic perfect control conditions (something to be considered a gold standard also for any experimental work).

e) Last but not least, does it mean that other indicators for colony resilience such as pollination, honey production and swarming are or will not be considered?

[1] https://ec.europa.eu/jrc/en/pvgis

Focusing on the natural variability of honey bees colonies and aiming at maintaining honey bee colonies within the natural variability, implies that it is expected that ecosystem services provided by honey bees such as pollination and honey production will not be impacted.

A quantification of the delivered ecosystem service (e.g. pollination, honey production, etc.) and its quantitative link on the strength of bee colonies, would have been possible approach 4 mentioned above. However, for the moment relevant scientific information is not yet available and therefore this approach cannot be implemented within a short timeframe.

Q2. In the Appendix C - Illustrative example of model simulation A.4. Results of the preliminary simulations of the Supporting document EFSA observed "40% decrease compared to the mean in the simple scenarios, and up to 80% in the most complex one".

a) Are more outcomes with BEEHAVE already available at EFSA? Does it confirm either the 20%, 40% or 80% OR 100%?

As clearly stated in the EFSA supporting document, figure 2 was only meant to provide an illustrative example of the possible outcome of using approach 2, in order to make it clearly understandable from a conceptual point of view. It is thus not derived by actual simulations and any concrete value reported there should not be given any further consideration.

During the summer, EFSA performed the actual simulations according to approach 2, which will be presented in a next supportive document for risk managers. This document is currently being finalised. Once finalised, it will be made publically available via the EFSA website. The ad -hoc stakeholder group which EFSA set up for the review of the Bee Guidance Document will be notified prior to its publication on the EFSA website.

b) What percentile is EFSA recommending to use and what is the science underpinning the choice of the percentile?

EFSA is not recommending any percentage but is giving all possible scientific information to risk managers. It should be kept in mind that with approach 2 the normal operating range (natural variability) of honeybee colony size is the basis for deciding – in a 2nd step -what would be unacceptable effects on colony size caused by pesticides.

c) Could you please indicate what % variability gives what quantitative level of protection? What is the quantitative level of protection of bees in case of 20 % variability and 30 % variability?

It is not possible to answer this question at this stage. As explained in the answer to the preceding question, it can only be answered once the further information that EFSA is working on will be available.

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d) Could the effect of pesticides in case of 80% variability be hidden behind this variation (risk of false negative)? And if yes, how will EFSA take account of false negatives?

It must be considered that background variability in colony size exists in real life - irrespectively of the present analysis by EFSA - hence its explicit consideration is needed in the overall process. It is not possible to carry out a scientific assessment, which does not consider real data or real situation.

As explained before, the analysis of the background variability does not include any pesticide exposure, i.e. the model simulations are performed without exposure to any stressor, i.e. the colonies modelled are assumed to be in perfect health and well managed. For instance, input model parameters were excluded if it was reported that they have been investigated under any insecticide exposure.

Variability, confidence level and statistical power all concur in determining the risk of both false positives and false negatives in the risk assessment, and this needs to be considered when developing for instance requirements of higher tier studies (i.e. replication).

Q3: Next to the BEEHAVE, other models to assess risks to honeybees have been considered or are under development, including Khoury and ApisRAM. The model BEEHAVE might be better than the Khoury model, but it is likely inferior to the ApisRAM, which is EFSA developing and which integrates multiple stressors.

a) Why is EFSA working with the BEEHAVE model, which is not validated with field tests and which does not seem to be appropriate in a regulatory context of pesticides (see European Food Safety Authority, 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 honeybees at the landscape level. EFSA J13:4125.), instead of waiting until the ApisRAM model is ready?

It has to be noted that BEEHAVE is not proposed as a tool for pesticides risk assessment, but for simulating the background colony size variability across the EU. The model was developed for this purpose.

EFSA is using BEEHAVE as it represents, for the time being, the best model available to simulate honey bee colony dynamics. The choice of this model is underpinned by the EFSA PPR Panel statement in 2015[2], which concluded that "BEEHAVE performs well in modelling honeybee colony dynamics". Within this statement, limitations were also found, and those that are relevant for the present activity will be transparently mentioned in the supporting document for managers under development and, when possible, the related uncertainty will be quantified.

ApisRAM will only be available in July 2021 and the results from the B-Good research project only in 2023 so after the deadline for EFSA to finalise the review of the Bee Guidance document. Furthermore, the use of ApisRAM in a regulatory context or in the context of investigating the natural variability, currently performed during the review, would require even more time (e.g. 12 months). This is because the parametrisation of the model across the different scenarios selected within approach #2 may be more complex due to the higher complexity of ApisRAM.

Therefore, neither ApisRAM nor B-Good could be considered by EFSA during the current review of the Bee Guidance Document as this would lead to an unacceptable delay of the review of this guidance document. The Commission considers it of utmost importance to reinforce the protection

[2] http://www.efsa.europa.eu/en/efsajournal/pub/4125

of bees and other pollinators in the context of the Plant Protection Products Regulation as soon as possible.

However, when available and considered to be an improvement, other models and data could be considered for a further update of the guidance document at a later point in time.

b) Is the combined BEEHAVE output variability compared to real world variability under sufficient range of conditions?

EFSA is running simulations with BEEHAVE for a number of scenarios in the EU, with different environmental and climatic conditions. In addition, EFSA will check the plausibility of the BEEHAVE simulations against the control colonies of field studies, although this cannot be considered as a validation of the model.

Further detailed explanations will be included in the next supportive document for risk managers which is currently being finalised (see response to question 2 a)).

c) What is the source of the variation for stochastic parameters in BEEHAVE?

Stochasticity is defined as an event determined by random processes. In this specific case, the parameters mortality and forager activity of the model are not fixed, but assume different values at every run, under equal conditions, on the basis of probability distributions. The variation in the value(s) of these parameters determines the variability in the model output.

So in BEEHAVE, stochasticity concerns two main processes, i.e. mortality and forager activity:

- Mortality of single bees is random in BEEHAVE. However, this occurs with different pre-defined probabilities. In hive-bees die with different daily probabilities for each life stage (eggs, larvae, pupae, adult, all different for drones and workers). Scarcity of nurse bees or lack of pollen may influence brood mortality as well, but these aspects do not have a random nature and they are added on the top of the stochastic mortality. Foragers have a certain probability of dying for every second spent foraging, so that longer foraging times entails higher mortality probability.

- Forager activities have several random aspects: the choice of a bee to start or stop its foraging activity, the choice to forage pollen and/or nectar are all determined by probabilities, which are in turn driven by the hive needs. The event of a flower patch to be detected is linked to a certain probability (driven by its size and distance from the hive).

Other stochastic parameters exist for the Varroa module of BEEHAVE which was not used in the present exercise.

d) How will the European Parliament´s mandate on multiple stressors (MUST-B SO) for bees be integrated in EFSA's approach?

The MUST-B Scientific Opinion is aimed at developing an integrated approach to the environmental risk assessment of multiple (regulated and non-regulated) stressors in honey bees (i.e. including multiple lines of evidence). The ApisRAM agent-based simulation that is part of the MUST-B project

may be used as a higher tier risk assessment tool, but also beyond risk assessment, i.e. as a tool to inform beekeepers and researchers, subject to the final validation of the model.

ApisRAM will only be available in July 2021 and can therefore not be considered by EFSA during the current review of the Bee Guidance Document, however it may be considered in further updates. See also answer to Q3.a above.

Q4. Within the approach 2 EFSA runs BEEHAVE control model stimulation. The exercise will be, as it states, repeated in selected scenarios, covering different EU environmental conditions. Can you please explain:

a) How will EFSA select its "scenarios", considering the huge variability of landscapes in Europe? How many different EU´s environmental conditions will be covered? Will the threshold (i.e. percentile of % background variability of the honey bee colony size) be applied for zones, countries, regions or fields?

In order to cover a realistic range of the different conditions throughout the EU, EFSA superimposed a grid over the map of the EU leading to 25 cells of equal size. For the 20 cells, which were not oceans, EFSA randomly selected one location per cell and attempted the construction of related environmental scenarios for running model simulations in each of them.

Further detailed explanations will be included in the next supportive document for risk managers which is currently being finalised (see response to question 2a).

How these different scenarios will be considered in the decision on the protection goals will be discussed by risk managers in the next workshop, depending on the results of the simulations provided by EFSA.

b) Colony is much more vulnerable at the start for stressors and consequences of loos of workers for the hive are different in different seasons. Will the threshold (% variability of background mortality) be an average for every year, or a specific moment (e.g. 220 days)?

The colony size background variability will be presented in terms of average over the entire year, as well as average over each active season (spring, summer, autumn). How these scenarios for the different seasons will be considered will be discussed by risk managers in the next workshop, depending on the results of the simulations to be provided by EFSA.

c) Would an EU-wide threshold be possible?

This will be discussed by risk managers in the next workshop, depending on the results of the simulations to be provided by EFSA.

Q5. The second approach on honey bees has almost no relation to the risk assessment of wild bees such as bumble bees and solitary bees. Nevertheless, the Commission has recognized in its EU Pollinators Initiative that the protection of wild bees needs to get more priority given the biodiversity collapse, including by full implementation of EFSA Guidance document of 2013. How does the Commission and EFSA plan to ensure protection of these wild bees from pesticides?

As regards bumble-bees, it needs to be seen to which extent extrapolation or adaptation is possible. The BumbleBEEHAVE model may be considered for bumble bees but it has not been fully evaluated by EFSA, and more time would be needed to do this than is available within the timeline for delivery of the review. There are currently no suitable models or data available on solitary bees.

This was made clear in the approaches that have been proposed by EFSA to risk managers for their decision-making process and will be further discussed with risk managers in a next workshop.

As stated in the summary report of the Standing Committee of July 2020[3], a considerable number of Member States, therefore consider approach 3, i.e. a choice of a so-called 'a priori' threshold, as a way forward to set a protection goal for solitary bees.

[3] https://ec.europa.eu/food/sites/food/files/plant/docs/sc_phyto_20200716_ppl_sum.pdf