EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

Brussels,
SANTE.E.4/ (2020)4522759

Dear ,

Subject: your e-mail of 16 July 2020 concerning the review of the EFSA Bee Guidance Document

Thank you for your above mentioned email and your letter to the members of the Standing Committee on Plants, Animals, Food and Feed of 7 July 2020 (registered respectively under our references Ares(2020)3781596 and Ares(2020)3599575) regarding the ongoing review of the 2013 EFSA Bee Guidance Document (Bee GD).

I regret that you perceive the process for the review of the Bee GD as secretive. In the mandate for the review of the Bee GD, the Commission has asked EFSA to keep stakeholders closely informed throughout the review. You and Noa Simon Delso from Beelife were selected by EFSA as members of the dedicated stakeholder consultation group for the review of the Bee GD. This enables you to provide directly input to the EFSA scientific working group charged with reviewing the document. As far as we are aware, EFSA has consulted the stakeholder group so far on three occasions: in July 2019, in September 2019, and in March 2020.

Likewise, the mandate to EFSA explicitly asks for consultation of risk managers and this is clearly set out in the outline of the process for the review of the Bee GD, which is publically available on EFSA's website[1]. In fact, the review of the Bee GD is a standing point on the agenda of the meetings of the Standing Committee on Plants, Animals, Food and Feed. In the meeting on 16/17 July 2020 of this Committee, the Commission consulted Member States on four scientific approaches presented by EFSA, as a basis to discuss the specific protection goals at a later stage.

These four approaches were developed by EFSA for honey bees and are explained in a discussion paper (which will soon be made available online on its website):

- **Approach 1** considers the survival of the colony until next season or longer. It uses scientific population modelling and the concept of maximum tolerable effects on the colony, which would need to be defined in a second step as protection goal.
- **Approach 2** considers the natural variability in colony size. It assumes that if the natural variability does not change, there will be no impact. The approach is based on scientific population modelling on the basis of which the natural variability of colony

[1] http://www.efsa.europa.eu/sites/default/files/event/Bee_Guidance_review.pdf

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size is predicted in the form of a Normal Operating Range (NOR). EFSA plans to work with different environmental scenarios (e.g. temperatures,) and healthy colonies are the basis of these modelling following normal practice in regulatory risk assessment. Again, the maximum tolerable effects on the NOR, to be used as a threshold for defining the magnitude of acceptable effect on colony size, needs to be defined in a second step as protection goal.

- **Approach 3** is the approach at the basis of the 2013 Bee GD and is based on acceptable levels on colony/population size. The acceptable impacts were set at 7% in the 2013 Bee GD based on the perception of beekeepers of what is a negligible (i.e. undetectable) effect and was thus not underpinned by a scientific model.
- **Approach 4** focusses on the provision of the ecosystem services by bees. This approach requires scientific research on the possible link between the impact on the provision of the ecosystem services and the possible effects on bees (the service providing units) and is therefore not feasible within the timeline of the current mandate as the data is not available.

EFSA has developed these four approaches in order to address the explicit request in the mandate from the Commission to consider natural variation and also to consider the comments of some Member States that colonies can survive even when split following normal beekeeping practice.

Let me emphasise, that at this point is not possible to say whether any of the approaches will be more or less conservative than the 2013 Bee GD, as within each approach, the actual level of protection (the Specific Protection Goal - SPG) will still need to be defined in a next step.

I also would like to point out that the SPG of 7% in the 2013 Bee GD never concerned the number of foragers by colony as indicated in your letter of 7 July 2020. The EFSA Opinion (2012) indeed included a tentative exercise to set an SPG focussing on forager mortality but this did not result in a workable proposal (e.g. no clear definition for time scale for effects on foragers). A practical SPG proposal was only made in 2013 and included in the Bee GD after a limited risk manager consultation.

Although both the Opinion (EFSA, 2012) and the Bee GD mention a value of 7%, these values have different origins and are only incidentally the same figure. In particular, the 7% value from the Opinion (EFSA, 2012) was derived from an increase of 100% (i.e. doubling) of the daily natural background mortality of foragers, which was estimated to be around 3-3.5%. However, at that time, the 7% forager mortality was only included as a general indication[2]. The proposal in the Bee GD, i.e. the magnitude of acceptable effects (<7%), clearly relates to the whole colony size.

Both approaches 1 and 2 above make use of scientific population models. The EFSA Working Group for the review of the Bee GD[3] considers the BEEHAVE model (Becher et al. 2014) suitable with regard to honeybees because the PPR Panel of EFSA evaluated the model in 2015 (EFSA, 2015[4]) and found that it performs well in modelling honeybee colony dynamics. Because it has a number of shortcomings for its use in risk assessment,

[2] See Opinion (EFSA, 2012): "It was decided not to use absolute numbers or percentages of mortality to define the magnitude of effects because of the variability of mortality rates depending on the season, health status, climatic conditions etc. Instead, it is suggested to use factors of increase in mortality compared to controls."

[3] Names and declarations of interest of the members of this working group are available at: https://ess.efsa.europa.eu/doi/doiweb/wg/685752

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

simulating colony dynamics is therefore the only use that is currently envisaged for the model. In addition, it must be underlined that EFSA is not suggesting using this model for defining natural background mortality. EFSA has carried out a separate systematic literature review on bee background mortality. EFSA will use the results of this analysis[5] as an input parameter in the BEEHAVE model. To note also that BEEHAVE was developed within a project co-funded by the Biotechnology and Biological Sciences Research Council of the UK[6] (90% of total funding) and Syngenta (10%). The main author works for the Environment & Sustainability Institute of the University of Exeter and the non-profit research centre Rothamsted Research.

As regards the ApisRAM model as an alternative for honey bees, EFSA invested significant resources on its development and is confident it will be used as the reference model in future. However, it is still under development and will not be available within the timeframe of the review of the Bee GD.

As regards bumble bees and solitary bees, EFSA indicated that a further model is probably suitable to be used for bumblebees (BumbleBEEHAVE) while for solitary bees scientific data are scarce in general. Therefore, extrapolation will be needed for solitary bees in any of the 4 approaches.

Please be informed that during the meeting of the Standing Committee on 16-17 July Member States were indeed consulted on the preferred approach, but no vote was held. 14 Member States indicated a preference for approach 2, while three Member States supported approach 2 for honeybees (and possibly bumblebees) while preferring approach 3 for solitary bees. Four Member States preferred approach 3 (with some openness to consider approach 2) and two Member States preferred approach 1. The remaining four Member States still need to indicate their preference. Based on this feedback from Member States, approach 2 emerged as the preferred way forward by Member States for honeybees and, if possible, for bumblebees. The approach to review the SPG for solitary bees is still open.

As already indicated above, the actual level of protection (dimensions of Specific Protection Goal) will only be defined in a next step, on the basis of scientific information to be prepared by EFSA on the basis of approach 2, in particular the necessary population modelling. Further consultations, including a public consultation, are planned later on.

I hope that I have responded to your questions and I would like to emphasise again that the protection of bees and pollinators is of high importance to the Commission. We remain of course available for further discussion.

Yours sincerely,

[redacted]

[5] Expected to be published on the EFSA website on 28 July 2020
[6] https://bbsrc.ukri.org/about/