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Brussels,

Dear [redacted], [redacted], [redacted] and [redacted],

Thank you for your letter of 8 February 2021 to Executive Vice-President Timmermans and myself about your concerns regarding the scientific and technical approach of the European Food Safety Authority (EFSA) for setting specific protection goals for bees and its regulatory consequences. This response is also on behalf of the Executive Vice-President.

I note your concerns regarding the BEEHAVE model and would like to mention that the model was developed with 90% public funding from the UK Biotechnology and Biological Sciences Research Council and 10% private funding from Syngenta. It is common in scientific research for universities to seek co-financing with a share of private funding, and this is also frequently the case for research-funding initiatives under Horizon 2020 and Horizon Europe. The model was subjected to the standard scientific scrutiny as it was published in scientific journals (Becher *et al.* (2014). It was also peer-reviewed by the EFSA's Panel on Plant Protection Products and their Residues (PPR) in 2015. It is an open-source model, which means that full transparency is guaranteed. For the time being, BEEHAVE is the best modelling option available to simulate honey-bee colony dynamics.

EFSA has indeed invested considerable budget and resources in the development of the new ApisRAM model. However, EFSA confirmed, after consultation with its ApisRAM contractors, that ApisRAM cannot be considered for the evaluation of the effect of plant protection products (PPPs) or any other stressors on honey bees before mid-2023. ApisRAM can therefore not be applied immediately. However, once ready and accepted, its use could be implemented in the guidance in a further update.

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I note your opposition regarding the setting of a value for the specific protection goal for honeybees based on BEEHAVE. However, I would like to emphasise that EFSA has used BEEHAVE for the sole purpose of simulating natural variability in colony size i.e. the development of colonies over time without exposure to pesticides. When comparing the results of the simulations to the variability measured in the control colonies in field studies (i.e. those not exposed to the pesticide under investigation), it is clear that the simulated variability is narrower than what is occurring in reality. Therefore, a threshold for an acceptable reduction in honey-bee colony size due to pesticides chosen within this simulated range is sufficiently protective.

Let me also underline that no value for a specific protection goal has been agreed yet by Member States and that BEEHAVE cannot and will not inform the choice of the actual protection goal. For this purpose, the feasibility of field studies will need to be considered. In fact, all Member States are of the opinion that the reference for setting the goal should be field studies. I agree that it must be ensured that, in line with the precautionary principle, the most ambitious protection goal must be pursued, while making it possible that field studies can still be performed in practice. If this is not the case, it will not be possible to actually measure whether the intended protection goal is achieved for a given substance.

I would also like to reassure you that the mandate of the Commission to EFSA to review the Bee Guidance Document also covers bumble bees and solitary bees. The Commission trusts that EFSA will fully take into account any new scientific knowledge on solitary bees and bumblebees that has emerged since 2013. Currently, the discussion focusses on the setting of a specific protection goal for honeybees. Once the specific protection goal for honeybees is endorsed, EFSA can continue the work to finalise the review of the guidance document, including supporting the setting of specific protection goals for bumble bees and solitary bees.

You will find detailed responses – prepared in consultation with EFSA – to the technical points raised in your letter in the Annex. Please note that these answers will be made available on the website of the European Commission, as they are also of interest to the wider public.

To conclude, let me recall the commitment I made during my hearing in front of the European Parliament to present an ambitious and protective proposal for the protection of bees following the completion of the update of the guidance by EFSA. In my view, the current situation is not satisfactory as the guidance in place dates back to 2002. Defining the protection goals based on significantly more data than those available in 2013 will allow to set ambitious protection goals on a stronger basis, which will not be possible if action is further delayed by awaiting ApisRAM, as you call for.

Yours sincerely,

[redacted]

Enclosure: Responses to technical points

Annex

1. ***BEEHAVE relies on a very simple model that does not mimic reality, nor the different factors that affect bee colony dynamics. On 13 January 2021, EFSA staff several times mentioned that the model was an important simplification of reality.***

   It is normal practice to base predictive models on a simplified reality as it is not possible to mathematically reproduce all biological processes and environmental conditions. Such models aim at being a proxy of the reality with different level of complexity.

   BEEHAVE considers in its predictions: the colony processes, the foraging behaviour, some diseases, and beekeeping practices. Therefore, BEEHAVE is not a 'very simple model', but rather among the most complex models to predict behaviour of bee colonies currently available. In fact, it is the model that accounts for the largest number of biological and ecological processes.

   This is underpinned in the statement of the EFSA PPR Panel[1], concluding that "BEEHAVE simulates well colony dynamics".

   Please note that the general principle of parsimonious data modelling states that if two models in some way adequately model a given set of data, the one that is described by a fewer number of parameters will have better predictive ability given new data. Or in other words, simpler is not necessarily a bad thing in modelling as it will lead to better predictions.

2. ***The environment/weather module of the model is very simple and does not mimic the reality of what bees are exposed to. EFSA considered that the egg-laying rate was the same in all colonies, they did not make differences between the different EU honey bee subspecies, landscapes, etc. Everything is over-simplified.***

   EFSA used actual climatic data to simulate different processes: the daily foraging period, the temporal pattern of food availability in the landscape, and the temporal pattern of egg-laying rate. It is inaccurate to state that the egg-laying rate was the same in all colonies as the egg-laying rate was adjusted for each scenario. All details on the input parameters are described in the EFSA supporting document and its annexes of December 2020[2].

   EFSA opted in its simulations for the use of a simplified landscape, but simultaneously performed a separate analysis concerning the effect of an increased landscape complexity. The outcome of that analysis revealed that an increase in landscape complexity would result in a wider variability among colonies. It should be kept in mind that a wider variability leads to less conservatism and hence a lower level of protection.

3. ***EFSA has been using data from honey bee colonies that are located in agricultural environments where pesticides are used, to define the possible variability in the size of a honey bee colony. This is not scientific: if we want to protect bees, we need to define what the normal variability of a colony is based on colonies placed in pristine environments.***

[1] https://www.efsa.europa.eu/en/efsajournal/pub/4125

[2] Available online at https://www.efsa.europa.eu/sites/default/files/topic/review-guidance-document-bees-specific-protection-goals.pdf

The objective of the work carried out by EFSA in its latest supporting document[3] was to investigate and analyse the background variability of colony strength. This entails two main aspects:

- the conditions surrounding the simulated colonies should resemble the typical habitat for honey bees in agricultural areas;
- exposure to pesticides must not be accounted for.

In the real world, agricultural areas are unlikely to be completely pesticide-free, while this could be the case for some non-agricultural areas (e.g. mountains, forests). However, habitats in these (pristine) areas are completely different in terms of structure, food availability, competition and predation compared to agricultural areas.

BEEHAVE makes use of input values, i.e. not calculated by the model but imposed by the user, describing the biology of bees. These encompass aspects related to reproduction and development, foraging, food consumption, mortality and brood care.

In principle, each one of the biology-related input values mentioned above can be influenced by both the habitat type and by the environmental stressors like exposure to pesticides or to any other hazardous chemical. Hence, the conditions of the experimental studies used to derive these input values are relevant.

For the most important biological parameters, EFSA checked these conditions and overall origin of the data. For example:

- The developmental time for brood is similar in agricultural areas and in controlled laboratory conditions (where any kind of exposure can be excluded).
- For mortality of adult bees, the input values were calibrated on the basis of the data included in the recent review of the evidence of bee background mortality (EFSA et al, 2020a). For that review, data from both agricultural and non-agricultural areas were considered, but studies presenting evidence that bees were exposed to insecticides were excluded.
- The maximum egg-laying rate over time was adjusted for each scenario considering daily temperature and sunlight hours. However, the starting point was the egg-laying rate used by Becher et al. (2014), which was based on a previous model (Schmickl and Crailsheim, 2007). This model made use of observations from Ebert (1922). While it was not possible to ascertain whether these observations were performed in agricultural areas, considering the time of publication it is safe to assume that bees were not exposed to synthetic pesticides in the original study.

4. ***EFSA used data from regulatory tests to validate the model. Honey bee colonies from regulatory tests are not real colonies: they are artificial small colonies created just before the test in a standardised way, all of them having the same approximate initial number of bees, brood frame, honey frames, etc. Furthermore, these are very small and non-productive colonies. This has nothing to do with the reality of a healthy and productive honey bee colony. The pollination services of these small "regulatory test colonies" are expected to be***

[3] Available online at https://www.efsa.europa.eu/sites/default/files/topic/review-guidance-document-bees-specific-protection-goals.pdf

significantly lower than those of real productive colonies. EFSA thus bases its work on artificial data, not on real-life colonies that regulators are supposed to protect.

The claim that the colony size EFSA used in its simulation is inappropriate or even 'artificial' is unsubstantiated. In the simulations performed by EFSA, colonies would start the year with 10.000 (±1000) bees, which is a rather standard number for new colonies.

The claim that colonies of this size are non-productive is unsubstantiated. Harbo (1985) tested the performance of colonies of different sizes (from 2.300 to 35.000 bees) and concluded that a starting population size of 9.000 bees - i.e. very close to EFSA's starting number - was optimal for balancing brood and honey production efficiency.

Furthermore, the calibration of the model made explicit use of average honey production in different Member States, so that the actual honey production in the simulated colonies would match the typical production of hives managed for production, rather than hives for effect field studies.

It must be underlined that the uncertainty analysis performed by EFSA indicated that variability is likely to be underestimated in the performed simulations. It should be kept in mind that a smaller variability leads to more conservatism in the risk assessment and hence a higher level of protection.

5. ***During the meeting, EFSA has not been able to explain how this approach would lead to an efficient protection of honey bees. Furthermore, we consider that there is an excessive amount of uncertainties linked to this approach. We hence consider that the approach followed by EFSA is not in line at all with the high level of protection of bees as required by pesticide regulation 1107/2009.***

   EFSA explained during the information session of 13 January 2021 that the magnitude of the effect on colony size (=percentage of colony size reduction) is acceptable when it remains within the range of the expected background variability. This was referred to as 'threshold of acceptable effect' on colony size reduction and it represents a mean effect that can be tolerated by exposed colonies in an apiary.

   EFSA clarified in its first supporting document[4] that with this approach an explicit link between the effect on the service providing units (honey bees) and the ecosystem service provision (pollination) is not established. Nevertheless, it is assumed that ecosystem services are likely not impacted, so within the range of their natural variability, if effects on honeybee colonies are within the background variability.

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