



POLLINIS



Commissioner S. Kyriakides
Vice-President F. Timmermans
European Commission
Rue de la Loi 200
1049 Brussels
Belgium

Brussels, 8 February 2021

Dear Commissioner Kyriakides, Dear Vice-president Timmermans,

On 13 January 2021, the European Commission held, jointly with the European Food Safety Authority (EFSA), a workshop where the EFSA exposed its methodology to fix the Specific Protection Goals (SPGs) for honey bees. We are writing to you because we have several concerns related to the scientific and technical approach that EFSA has applied and the regulatory consequences of this recent work from EFSA.

About the scientific and technical approach of the EFSA for defining SPGs:

This approach relies on the use of a model (Beehave) that has not been endorsed by the scientific or beekeeping community, that has been co-funded by Syngenta, and, to our knowledge, is currently being disregarded by non-industry researchers, while at the same time EFSA has been and still is investing in the preparation of another model, the ApisRAM model.

During the meeting, we have been convinced that the proposed approach and its use are not appropriate and that this approach will not allow for a high-level of protection of bees against pesticides.

In our view, the approach from EFSA is inappropriate as:

1. It relies on a very simple model (Beehave) that does not mimic reality, nor the different factors that affect bee colony dynamics. During the meeting, EFSA staff several times mentioned that the model was an important simplification of reality.

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.

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.

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 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.

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.

During the meeting, it was explained that the current model that EFSA is developing (ApisRAM) will be finalised in June 2021, and then it could take several months of work to validate it. Last week, the EFSA communicated around this development in the press[1]. This ApisRAM model is much more sophisticated, much closer to the reality of the biology of honey bees, it is mechanistic and includes a more developed landscape approach. We are well aware that looking for a better and more scientific alternative might lead to additional delays but we consider that it is the price to pay for a more appropriate risk assessment. Moving forward with the current approach is in our view, certainly not an improvement compared to the current situation.

For the reasons mentioned previously, we respectfully ask you to send a mandate to EFSA to stop the current process of defining specific protection goals using the Beehave model. We also ask to mandate EFSA to assess the possibility of using the model ApisRAM to carry out the task of defining the variability of a honey bee colony and defining SPGs accordingly. We also request that the work includes honey bee modellers, honey bee biologists, and beekeepers that would use data from the beekeeping field, rather than data from artificial regulatory tests.

About the potential future regulatory implications of the work developed by EFSA:

We wished to express our extreme concern about some calculations made by EFSA and published in the document provided for the preparation of the January 13th meeting. Indeed, EFSA has shown (Table 4, p.28 of the supporting document) that to determine a reduction of a honey bee colony size of 7% - as fixed by the risk manager in the Bee Guidance Document of 2013 - the experiment would need to be carried out with more than 120 hives located at the edge of the field. This has been criticized by the pesticide industry as biologically irrelevant, unfeasible, and extremely expensive. EFSA has also shown that based on the power analyses of the field test set up according to the current praxis in terms of field trials for regulatory purposes, it would not be possible to demonstrate an effect that is, in the best-case scenario, lower than 25%. This means that beekeepers' colonies could lose up to one-fourth (most likely more as the current approach considers bees are exposed to a single pesticide at the time) of their strength and it would still be considered acceptable in the eyes of risk managers. However, such a reduction is unacceptable from a beekeeping or environmental point of view. Table 4 of the supporting document contributes to new technical and scientific knowledge showing that for a large number of authorised pesticides for which a field trial has been requested, the risk to bees could not be detected unless the effects on the colony strength were larger than 25%. We expect that your services will take into consideration this new scientific knowledge produced by EFSA and mandate a study to verify the number of field trials in DARs and RARs for which this is the case. Following the results of this analysis, we request you to consider their potential withdrawal.

Furthermore, it arose several times during the meeting the importance of setting SPGs at a level that allows industry to practically run field trials. All in all, field tests are the reference decision-making tier for honey bees. We strongly believe this approach is unacceptable and illegal. It should be obvious for the scientific EFSA staff, as well as for risk managers, that the current approach having field tests as the reference tier for decision-making does not work, neither from a biological nor from a statistical point of view. As a result, the reference tier should be changed at once and be replaced, for instance, by semi-field tests or laboratory tests. Decision-making could be then supported by post-registration Phyto-pharmacovigilance and bee health monitoring, and completed with modelisation with ApisRAM as soon as it is available. The SPGs should never exceed the level of 7%, as it was accepted in the 2013 GD no matter what it requires in terms of field trials. If the decision-making tool is not fit for purpose, we should not reduce the protection levels to make it workable. We need to set good protection levels first and then find ways to evaluate their fulfillment. Our goal is above all to ensure that we protect the bees and respect regulation 1107/2009.

Finally, we also wished to draw your attention to bumblebees and solitary bees. Those have not been discussed during the workshop, but we consider that they must be protected as well, for many of their species are facing a dramatic decline. Together with honey bees, they play a major role to ensure pollination of wild plants and crops. Only pollination by a diversity of pollinator species can ensure resilient and productive agroecosystems. Therefore, we ask you to adopt the approach proposed by the EFSA in the 2013 Bee Guidance Document and define Uniform Principles for these species based on the existing amount of scientific knowledge.

Today, in a meeting with stakeholders and Member States, the European Commission recalled, regarding the ongoing work on Specific Protection Goals for honey bees, the importance to work little step by little step, based on science and on the precautionary principle. We feel this is clearly missing here.

To conclude, the very worrying evolution of the discussions around the Bee Guidance Document and SPGs is in complete opposition with the objectives of the Biodiversity Strategy. Only a strong risk assessment methodology and an efficient control of pesticide use will allow for the effective protection of bees and recovery of biodiversity in rural areas. An attempt by the Commission and Member States to implement the Bee Guidance Document “in a weak way” has already been opposed by the European Parliament. For the sake of coherence and good governance, we respectfully request you to align the revision of the Bee Guidance Document with the Biodiversity Strategy objectives and to swiftly put in place the implementation of a bumblebee and solitary bee risk assessment.

From beforehand, we thank you for your consideration and your reaction.

Best regards,

Francesco Panella, President of BeeLife

Nicolas Laarman, Director of POLLINIS

Jeff Pettis, President of Apimondia

Martin Dermine, Policy officer, PAN Europe

[1] <https://www.euractiv.com/section/agriculture-food/news/eu-food-safety-agency-presents-plan-for-integrated-risk-assessments-for-pollinators/>