Council of the
European Union

Brussels, 18 June 2021
(OR. en)

9687/21

AGRI 271
VETER 45
ENV 443

NOTE

From:	Presidency
To:	Delegations
Subject:	Setting a protection goal for honey bees in the context of the review of the 2013 Bee guidance document – *Exchange of views*

Delegations will find in Annex a background note submitted by the Presidency for the exchange of views at the Council ("Agriculture and Fisheries") meeting on 28 and 29 June 2021.

ANNEX

Setting a protection goal for honey bees in the context of the review of the 2013 Bee Guidance Document

Context and state of play

1. Pesticides can only be authorised if a comprehensive risk assessment has demonstrated that their use is not leading to harmful effects on human or animal health nor to unacceptable effects on the environment. The methodologies for conducting the required risk assessments are set out in guidance documents addressing different environmental compartments and species.

2. The status quo today, with regard to the risk assessment for honey bees, is the Guidance Document on Terrestrial Ecotoxicology of 2002[1], since the 2013 Bee Guidance Document from the European Food Safety Authority (EFSA) was not endorsed by the Member States in the Standing Committee on Plants, Animals, Food and Feed despite repeated efforts over several years.

3. In March 2019, the Commission mandated EFSA to review the 2013 Bee Guidance Document, taking into account new scientific knowledge that has emerged since 2013.

4. For completing this review, the setting of a so-called Specific Protection Goal (SPG) for bees is a crucial step. Risk managers and risk assessors from the Member States discussed the setting of this goal during the past year, based on a **document by EFSA[2] describing four possible approaches to set the protection goal for honey bees**.

5. A majority of Member States indicated a preference for an approach that takes into account the natural variability of honeybee colony sizes (also referred to as "normal operating range of honeybee colony sizes").

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[1] https://ec.europa.eu/food/system/files/2016-10/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

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

6. The selected approach was criticised by NGOs and some Members of the European Parliament (MEPs). The main reasons are related to the use of the model 'BEEHAVE'[3] (which was co-funded to 10% by industry) for simulating the natural variability in colony sizes and the expectation that the revised Bee Guidance Document would set a less protective protection goal than the non-endorsed 2013 EFSA Bee Guidance Document. NGOs and MEPS also advocated using another model, ApisRAM, for simulating the bee colony development. However, this model is still under development.

7. EFSA published on its website a detailed summary of the timelines[4] of the ApisRAM model development and calibration. The model cannot be used for simulating colony development, nor for the simulation of the effects of plant protection products (PPPs) and other stressors, before mid-2023 at the earliest.

8. In this context, the Commission asked EFSA to prepare a comprehensive supporting document, explaining all relevant issues and presenting the outcome of its simulations in great detail. EFSA published the document[5] on 15 December 2020 and presented it on 13 January 2021 in a joint information session for Member States and representatives of stakeholders (members of the group established by EFSA for this review), in order to allow for an exchange of views between all interested Parties.

Setting Specific Protection Goals

9. In a dedicated meeting on 23 February 2021 and at the meeting of the Standing Committee on Plants, Animals, Food and Feed in March 2021, all Member States confirmed their support for the method proposed by EFSA to revise the SPG for honey bees.

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[3] BEEHAVE is a publicly available model and all relevant information can be found at : https://beehave-model.net/

[4] https://www.efsa.europa.eu/sites/default/files/2021-03/timeline-ApisRAM-development-final.pdf

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

10. All Member States who expressed an opinion agreed that the simulations conducted by EFSA of the natural variability of honeybee colony size are more conservative than what is observed in nature. Therefore, those Member States agreed that choosing a protection goal, in the form of a threshold, for an acceptable reduction in honeybee colony size due to pesticides within the simulated range is sufficiently protective.

11. Regarding the numerical value for this SPG, four Member States supported 23 % (i.e. the full range of the simulated natural variability), 11 Member States supported a protection goal of 10-12.8 %, while four Member States supported 7 % (i.e. the same figure as in the 2013 EFSA Bee Guidance Document). Four Member States did not have a position.

12. The majority of Member States also agreed that the practical feasibility of field studies has to be taken into account, as otherwise it will not be possible to actually measure whether the SPG is achieved or not.

13. On 15 March 2021, the Chair of the European Parliament's ENVI Committee wrote to the Commission to recall that the Parliament objected in October 2019 to a draft Commission Regulation that would have allowed to implement a part of the 2013 EFSA Bee Guidance Document because it expected full implementation. The Chair also remained critical of the use of the BEEHAVE model in the EFSA simulations, advocating use of the ApisRAM model instead (while also being concerned about the delay in the development of that model). The Chair expressed the expectation that the revision of the 2013 EFSA Bee Guidance Document should not lead to a lower level of protection of bees and requested a debate on the SPG at political level.

14. In a letter[6] to the Minister of Agriculture of Portugal and the Chair of the ENVI Committee, the Commission proposes, as a starting point for the discussion, **a 10% colony size reduction for the SPG**. This proposal is very ambitious compared to the guidance regarding risk assessment for bees still applicable today (i.e. the Guidance Document on Terrestrial Ecotoxicology from 2002), that allows measuring only a decline in colony size in field studies bigger than 20-25% and bearing in mind that the full range of the natural variability simulated by EFSA is around 23%.

15. The Commission has also been mindful of the fact that the 2013 EFSA Bee Guidance Document, which proposed a SPG of 7% colony size reduction, has not been endorsed by a majority of the Member States because they considered it technically not feasible to conduct field studies that would allow measuring whether the goal is achieved or not. Based on the information provided by EFSA, measuring a 10% reduction in field studies is challenging, but still technically feasible[7].

16. The Commission proposes **one SPG for the whole of the EU** and not per regulatory zone as the scientific evidence in the supporting document by EFSA shows that there are only small differences between the three regulatory zones defined in the Plant Protection Products Regulation.

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6 https://ec.europa.eu/food/system/files/2021-04/pesticides_bees_letter_mep-pt-pres_en.pdf

7 See section 7.1 of the EFSA supporting document available via https://www.efsa.europa.eu/sites/default/files/topic/review-guidance-document-bees-specific-protection-goals.pdf

17. In order to enable EFSA to pursue its review of the 2013 Bee Guidance Document and the adoption of the Regulation(s) that will allow its implementation, Ministers at the Agriculture and Fisheries Council meeting on 28-29 June 2021 are invited to take part in an exchange of views on the basis of the following questions:

    a) *Do you agree that one specific protection goal for honey bees should be set for the whole of the EU?*

    b) *Do you agree with the Commission's proposal that 10 % should be the maximum permitted level of honeybee colony size reduction as a consequence of exposure to a pesticide?*