

## EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation Pesticides and biocides

Brussels	
SANTE/E/4	(2022)2875190

Dear		and	
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## Subject: Your recent communications related to the process for setting specific protection goals for wild bees

Thank you for your letter dated 24 March 2022 to Commissioner Kyriakides and Executive Vice-President Timmermans (ref. Ares(2022)2177727), who asked me to respond on their behalf, and your emails to me dated 14 March 2022 (ref. Ares(2022)1954521) and 1 April 2022 (ref Ares(2022)2443208), respectively, regarding the definition of the level of protection of wild bees in the context of the environmental risk assessment of pesticides (Specific Protection Goals).

First of all, I would like to underline that, contrary to what you allege, in your letter and mails, at the meeting of the Committee on the Environment, Public Health and Food Safety, I never stated that control plots in field studies are always sprayed with pesticides. In my intervention, I merely concurred with the statement of MEP Bernhuber who had pointed to the fact that the design of field studies must be realistic and feasible – given in particular that one of the main reasons why the EFSA Bee Guidance Document from 2013 had never been endorsed by the majority of Member States had been the concern that the field studies required would not be feasible in practice.

I agree that field studies have to be designed such that the effect of the active substance to be tested is precisely determined. There are currently no specific recommendations regarding the fields used for control purposes in bee field studies. However, the available guidance for bee field studies<sup>1</sup> states that control and treated plots should be as homogeneous (e.g. microclimate, exposure and surrounding landscape) as reasonable practicable and that studies should be repeated where control mortality is excessively high. Risk assessors have to evaluate the acceptability of a field study and if deviations are observed, the reliability of the study must be questioned and the study might be rejected.

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See <a href="https://pp1.eppo.int/standards/PP1-170-4">https://pp1.eppo.int/standards/PP1-170-4</a>

EFSA is aware of the need to provide more detailed recommendations for field studies and we expect that recommendations as to the design of field studies and suitability of control plots will be included in the revised Bee Guidance Document. As you know, EFSA will launch a public consultation on the draft revised Guidance and you are very welcome to provide any comments at that time. This public consultation will be held later this year via the website of the EFSA<sup>2</sup>.

Please note also that the setting of a Specific Protection Goal for honeybees relied on simulations with the model Beehave and not on control data from field studies. Also, the proposal made by Commission for the Specific Protection Goal for bumble bees and solitary bees during the Standing Committee Plants, Animals, Food and Feed of 30-31 March 2022 does not rely on control data of field studies.

In fact, during that meeting, the Commission proposed to work, at this moment and considering the current absence of sufficiently robust evidence, on the basis of an undefined threshold for both solitary bees and bumblebees. The Commission also proposed to require, as part of the data requirements, by default field studies on bumblebees and solitary bees unless the lower tier risk assessments for honeybees, bumblebees and non-target arthropods other than bees show no effects for the active substance under investigation. Member States were invited to send in their position on this proposal by 25 April 2022.

Yours sincerely,

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https://www.efsa.europa.eu/en/calls/consultations