



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Deputy Director General for Food Sustainability responsible for Directorates D, E, F and G

Brussels
SANTE.E4/ (2022)4730620

Dear [REDACTED],

Subject: Specific protection goals for bumble bees and solitary bees in the context of the mandate to EFSA to revise the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

On 11 March 2019, the Commission sent a mandate (Ref. Ares(2019)1608315) to EFSA with the request to review the Guidance Document on the Risk Assessment of Plant Protection Products on Bees¹ by March 2021.

On 9 August 2021, the Commission informed you by letter (Ref. Ares(2021)5019682) of the confirmation by the AGRIFISH Council of 28 June 2021² of a specific protection goal (SPG) for honeybees corresponding to a value of 10% for the entire EU as the maximum permitted level of honey bee colony size reduction following pesticide exposure. With that letter, the Commission asked EFSA to take this value into account for honeybees (*Apis mellifera*) during the review of the Bee Guidance Document and for your continued support for the setting of SPG for bumblebees and solitary bees.

I hereby would like to thank EFSA for the technical report regarding the analysis of the evidence to support the definition of an SPG for bumblebees and solitary bees. This analysis and the possible approaches for setting SPGs set out in the report was the basis for the discussions with Member States at the Standing Committee on Plants, Animals, Food and Feed.

As a result of these discussions, a majority of Member States supported the Commission's proposal to proceed at this stage and in the absence of sufficiently robust evidence with an undefined threshold approach for both solitary bees and bumblebees.

¹ EFSA (European Food Safety Authority), 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268pp., doi:10.2903/j.efsa.2013.3295

² https://www.consilium.europa.eu/media/50983/st10238_edited-en21.pdf

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This implies in practice that in cases of potential exposure of bees for the representative use, field studies on bumblebees and solitary bees would always be needed.

In addition, following discussions with Member States, it is important to consider:

- that in case the lower tier risk assessments for honeybees and non-target arthropods other than bees show no effects for the active substance, such field tests would not be needed.
- that semi-field (cage or tunnel studies) with bumble bees and solitary bees might be an alternative to field studies, and that field studies would not be needed if semi-field studies show absence of effects.
- that semi-field or field testing with bumble bees would also not be needed if laboratory studies according to OECD test methods No 246 and 247, show an LD₅₀ higher than the maximum dose requested in these tests (100 µg active substance/bumblebee).

This approach is expected to increase the scientific evidence for setting - at a later stage - specific protection goals based on evidence.

I would like to request EFSA to finalise the review of the guidance document on the basis of this approach. Recommendations for the experimental design of field and semi-field studies, keeping consistency of approaches with other ecotoxicological areas under Regulation (EC) No 1107/2009, need to be included in the guidance document.

My services remain at your disposal for further information.

Yours sincerely,

Claire Bury

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