EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Director

11. 03. 2019

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SANTE/E4/SH/gb(2019)1623216

Dear Dr Url,

Subject: **Mandate to EFSA to revise the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)**

EFSA adopted in 2013 a Guidance Document on the Risk Assessment of Plant Protection Products on Bees[1], which so far has not been fully implemented because of insufficient support by Member States represented in the Standing Committee on Plants, Animals, Food and Feed. Many Member States have requested a review of the guidance document before considering full implementation.

Since 2013, new evidence is expected to be available. Therefore, the Commission asks EFSA to review the Guidance on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees) considering, in particular:

- A review and summary of the evidence as regards bee background mortality, in particular considering realistic bee keeping management and natural background mortality.

- Review the different exposure routes in particular considering spray application and seed treatment or granular application.

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[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

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- Review the list of bee-attractive crops in particular considering presence of bees, guttation and agricultural practices.

- Review the methodology with regard to higher tier testing.

The Commission also intends to mandate ECHA to develop a methodology to assess the risk to bees from the use of biocides. As some active substances have a dual use in biocidal products and plant protection products there is a need to achieve consistency of the implementation of the regulatory frameworks for plant protection and biocidal products. In order to ensure this consistency and in the context of the Memorandum of Understanding between the European Chemicals Agency and EFSA, EFSA is kindly requested to closely cooperate with ECHA in the implementation of this mandate.

Given the sensitivity of the subject matter, we would recommend you consider consulting all relevant stakeholder groups and risk managers during the process, if needed in a reiterate way, and to take into account the contributions received when finalising the review of the guidance.

Procedural aspects including an outline of the timelines will be agreed between EFSA and the Commission within 3 months after the start of this mandate.

I would like to ask EFSA to complete this mandate within 24 months of receipt.

My services remain at your disposal for further information.

Yours sincerely,

Sabine Jülicher

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Background

The potential risk to bees from active substances used in plant protection products has to be assessed under Regulation (EC) No 1107/2009. Applicants have to provide studies and information on exposure, effects and potential risks to bees in accordance with specific data requirements[2]. Member States and EFSA assess these data according to existing guidance documents and the Uniform Principles laid down in Regulation (EU) No 546/2011.

The EFSA Guidance document on the Risk Assessment of Plant Protection Products on Bees (in short the "Bee GD") published in 2013, did not receive sufficient support from Member States for its endorsement until the date of submission of this mandate. The main issues where Member States do not agree are first the proposed chronic risk assessment and secondly the feasibility of the proposed higher tier tests for both the acute and the chronic risk.

Therefore, it is appropriate to review the risk assessment methodology proposed by EFSA in the Bee GD (2013) taking account of the most recent relevant scientific evidence. The outcome of the review should also be consistent with the Scientific Opinion to be delivered following the mandate of the European Parliament to develop a holistic approach for the risk assessment of multiple stressors in managed honeybees (*Apis mellifera*) (Ref.: D 311791 / 12.07.2018).

The Commission also intends to mandate ECHA to develop a methodology to assess the risk to bees from the use of biocides. As some active substances have a dual use in biocidal products and plant protection products, EFSA and ECHA collaboration on this mandate will be important as to ensure consistency in the implementation of the regulatory frameworks for plant protection and biocidal products.

Terms of reference

The review of the Bee GD should, in particular:

- take account of the feedback from Member States and stakeholders on the EFSA (2013) guidance document.
- provide a review and summary of the evidence as regards bee background mortality, in particular considering realistic bee keeping management for *Apis mellifera* and natural background mortality. EFSA is requested to provide this summary in a separate document from the guidance document.
- review the list of bee-attractive crops in particular considering presence of bees, guttation and agricultural practices (harvesting time before or after flowering). This reviewed list shall also mention at which growing phases (e.g. BBCH codes) a crop is considered bee-attractive.

[2] Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013

- review the current risk assessment methodologies in light of recent scientific research and developments e.g. exposure estimation, relevance of the exposure scenarios (e.g. weed scenario) and relevance of some risk assessment schemes. Available relevant guidance developed by Member States should be considered (e.g. draft Guidance Document on seed treatments and/or its follow up work).
- review the requirements for higher tier testing, in particular by reconsidering the magnitude of detectable effects *vs* the statistical power and validated population modelling in light of realistic agro-environmental conditions.
- take into account planned and on-going discussions initiated by the Commission on defining specific environmental protection goals and review the risk assessment guidance based on the specific protection goals agreed during this process.