

EN
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Answer given by Mr Várhelyi
on behalf of the European Commission
(24.9.2025)

In 2023, the European Food Safety Authority (EFSA) adopted an updated guidance on the risk assessment methodology for bees¹, which includes extrapolation factors for toxicity from honeybees to wild bees. However, EFSA underlines that a lower tier risk assessment scheme requires defined numerical specific protection goals (SPGs) for wild bees.

In 2022, when risk managers discussed the setting of SPGs for bees, most Member States supported an undefined threshold approach for wild bees in the absence of robust scientific evidence.

To endorse and implement the updated bee guidance document, amendments are needed to the Commission Regulations on data requirements and uniform principles for evaluation and authorisation of plant protection products². The Commission initiated discussions with the Member States on this in May 2023.

The resulting draft Regulations were published for public feedback on 4 September 2025³. The Commission proposes that field studies with bumble and solitary bees are required if screening or first tier risk assessments for honeybees and/or other non-target arthropods show unacceptable effects, or, if available, laboratory studies show median lethal dose values lower than the limit dose, or, if available, semi-field studies show adverse effects. The studies should account for differences in toxicity and exposure for wild bees.

Data from these field studies should enable setting a defined SPG for wild bees in the future. The adoption of the Regulations first requires support from Member States⁴, followed by scrutiny of the Parliament and the Council. The updated Bee Guidance document can be endorsed by Member States thereafter (expected in the beginning of 2026).

¹ Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), available online via <https://www.efsa.europa.eu/en/efsajournal/pub/7989>.

² Regulation (EU) No 283/2013, Regulation (EU) No 284/2013, and Regulation (EU) No 546/2011.

³ The three draft regulations are available on the 'Have your say' portal via:
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14841-Amendment-of-data-requirements-for-applications-for-the-approval-of-active-substances_en;
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14840-Amendment-of-data-requirements-for-applications-for-the-authorisation-of-plant-protection-products_en;
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14839-Uniform-principles-for-evaluation-and-authorisation-of-plant-protection-products_en.

⁴ I.e.: favourable opinion of the Standing Committee on Plants, Animals, Food and Feed – section phytopharmaceuticals legislation.