



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides"

1. Background

- (1) Bees and other pollinators are critically important in the environment, sustaining biodiversity by providing essential pollination for a wide range of crops and wild plants.
- (2) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions “EU Pollinators Initiative”¹ [COM (2018) 395 final] sets long-term objectives and short-term actions under three priorities, the first being: Improving knowledge on pollinator decline, its causes and consequences.
- (3) Moreover, by the end of 2020, the Commission will review the progress on the implementation of the “EU Pollinators Initiative” and, if necessary, propose recommendations for further action.
- (4) The Commission has recently requested EFSA to review the Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera*, *Bombus* spp. and solitary bees) adopted in 2013².
- (5) EFSA was requested to closely cooperate with ECHA in this review, as some active substances have a dual use both in plant protection products and in biocidal products and consistency on the implementation of the regulatory frameworks for plant protection and biocidal products is necessary.
- (6) Article 19(1)(b)(iv) of the Biocidal Products Regulation establishes that a biocidal product, when used as authorised, shall not generate unacceptable effects on the environment, having particular regard to the impact of the biocidal product on non-target organisms, which include bees and other pollinators.
- (7) The Guidance on the Biocidal Products Regulation (e.g. Volume IV: Environment) specifies that, at the moment, no method is available for

¹ <https://eur-lex.europa.eu/legal-content/GA/ALL/?uri=CELEX:52018DC0395>

² 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

biocides on how to perform the risk assessment for bees and other non-target arthropods and considers that the methods applied under the EU framework for plant protection products are not directly applicable. However, if tests on bees or other non-target arthropods are available under the EU legal framework for plant protection products, the guidance states that a qualitative risk assessment should take place if the exposure pattern is comparable. The Guidance states that for neonicotinoid substances or other insecticides with high toxicity to bees, exposure should be quantified, however, if no data is available, a qualitative assessment should be performed.

- (8) A report of UNAF³ (Union Nationale de L'Apiculture Française), published on 15 November 2018, pointed out that a better integration of the adverse effects on bees and other non-target arthropods is required in the evaluation of biocides. In addition, the report states that applicants should provide analytical methods for the determination of active substances in matrices associated with bees and other non-target arthropods (for example honey, pollen, etc.)

2. The questions referred to ECHA

- (9) Pursuant to Article 75(1)(g) of Regulation (EU) No 528/2012, ECHA is requested:

-To develop a guidance for assessing the risks to arthropod pollinators (including bees) from biocides exposure in order to ensure a high and harmonised level of protection of the environment, taking into account EFSA's Guidance Document on the Risk Assessment of Plant Protection Products on Bees – currently under review.

-To specify the information required to enable a conclusion by the evaluating authority on whether the product complies with the criteria under Article 19(1)(b)(iv) concerning bees and other arthropod pollinators .

1) Elements to be considered by ECHA when addressing this question

- (10) In order to develop a specific guidance to assess the risk to arthropod pollinators (including bees) from the use of biocides, ECHA shall use any information already available, and in particular the past and current work of EFSA in this field.
- (11) To ensure that all available information can be considered in the opinion a targeted consultation of stakeholders should occur. For this consultation, if ECHA considers it appropriate, an overview of biocidal active substances and biocidal products to which arthropod pollinators could be exposed and may trigger directly or indirectly the occurrence of adverse effects in them could be prepared.

³ <https://www.unaf-apiculture.info/actualites/comment-les-pesticides-utilises-dans-les-elevages-menacent-les-abeilles-un.html>

- (12) The current references to the assessment of risk to arthropod pollinators included in the ECHA Guidance on the Biocidal Products Regulation shall also be considered, along with the work in this field already carried out by the competent authorities and scientific bodies from the EU Member States.

2) Deadline for the ECHA opinions

- (13) ECHA shall inform DG SANTE on the outcome of this evaluation no later than 31 December 2021.