



Update on the revision of the Bee Guidance Document

European Commission
DG SANTE, Unit E4

CDG Arable Crops
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Revision of the Bee Guidance Document

- Status quo regarding the risk assessment for honeybees and other non-target arthropods is the 2002 Guidance Document on Terrestrial Ecotoxicology
- The 2013 Bee Guidance Document from EFSA was never fully endorsed by the majority of Member States in the Standing Committee on Plants, Animals, Food and Feed despite repeated efforts over several years.
- Commission mandated EFSA in March 2019 to review the 2013 Bee Guidance Document, taking into account scientific knowledge that has emerged since 2013.
- Definition of Specific Protection Goals are key for a good Environmental Risk Assessment. Discussions with Member States started in 2020. Two information sessions with stakeholders were held in January and November 2021.

Specific Protection Goal for honeybees

- Discussion was based on the EFSA technical report regarding the analysis of background variability of honeybee colony sizes.
- A majority of EU agriculture ministers supported a new specific protection goal for honeybees of 10% at the Agriculture and Fisheries Council meeting of 28 June 2021.
- This value of 10% should be understood as the maximum permitted level of honeybee colony size reduction following pesticide exposure and will be applied for the entire EU.
- This value is very ambitious compared to what is acceptable under the Guidance from 2002 and compared to the natural variability of colony size found by EFSA but verification via field studies is still technically feasible.

Specific Protection Goals for wild bees

- Discussion was based on the EFSA technical report regarding the analysis of the evidence to support the definition of SPGs for bumblebees and solitary bees.
- Absence of sufficiently robust evidence to set a specific protection goal for bumblebees and solitary bees.
- A majority of Member States indicated support for an undefined threshold approach for setting specific protection goals (SPGs) for both bumblebees and solitary bees
- The Commission concluded on 20 June 2022 on the Specific Protection Goal for bumblebees and solitary bees via email to the Member States. This conclusion was also communicated to EFSA via a letter.

Specific Protection Goals for wild bees

To proceed at this stage and in the absence of sufficiently robust evidence, with an undefined threshold approach for both bumblebees and solitary bees until further data becomes available and to require by default (in case of potential exposure of bees) field studies on bumblebees and solitary bees unless:

- the lower tier risk assessments for honeybees and non-target arthropods other than bees show no effects for the active substance, or
- semi-field (cage or tunnel studies) with bumblebees and solitary bees show absence of effects.

Furthermore, semi-field or field testing with bumblebees would also not be needed if laboratory studies according to OECD test methods No 246 and 247, show an LD50 > 100 µg active substance/bumblebee.

Next steps

- Public consultation of the revised Bee guidance Document organised by EFSA
<https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011fdP/pc0217>
- Latest news available via
https://food.ec.europa.eu/plants/pesticides/protection-bees_en

Emergency Authorisations

- Granted by Member State Authorities – may concern active substances not approved for the intended use
 - when there is a danger to plant health that cannot be controlled by other reasonable means (including non-chemical measures)
 - For a period not exceeding 120 days
- Notified in a public database: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/ppp/pppeas/screen/home>
- Commission may ask EFSA for an opinion or for scientific or technical assistance.

Emergency Authorisations for neonicotinoids

- The Commission took action in 2020 to prevent unjustified emergency authorisations (for Romania and Lithuania) after a mandate to EFSA
- EFSA was asked to assess the justifications of 11 Member States granting emergency authorisations for neonicotinoids in sugarbeet for the 2020 or 2021 growing season. EFSA published its evaluations on 18 November 2021 and concluded that all were justified.
- The Commission intends to mandate EFSA to verify the justifications for emergency authorisations for the 2022 sugar beet growing season and to develop a protocol for such verifications.
- Latest information on https://food.ec.europa.eu/plants/pesticides/approval-active-substances/renewal-approval/neonicotinoids_en#emergency_authorisations_

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