European Food Safety Authority

# EFSA Guidance Document on the Risk Assessment of Plant Protection Products on bees (Apis mellifera, Bombus spp. and solitary bees)
# Protection goals and trigger values

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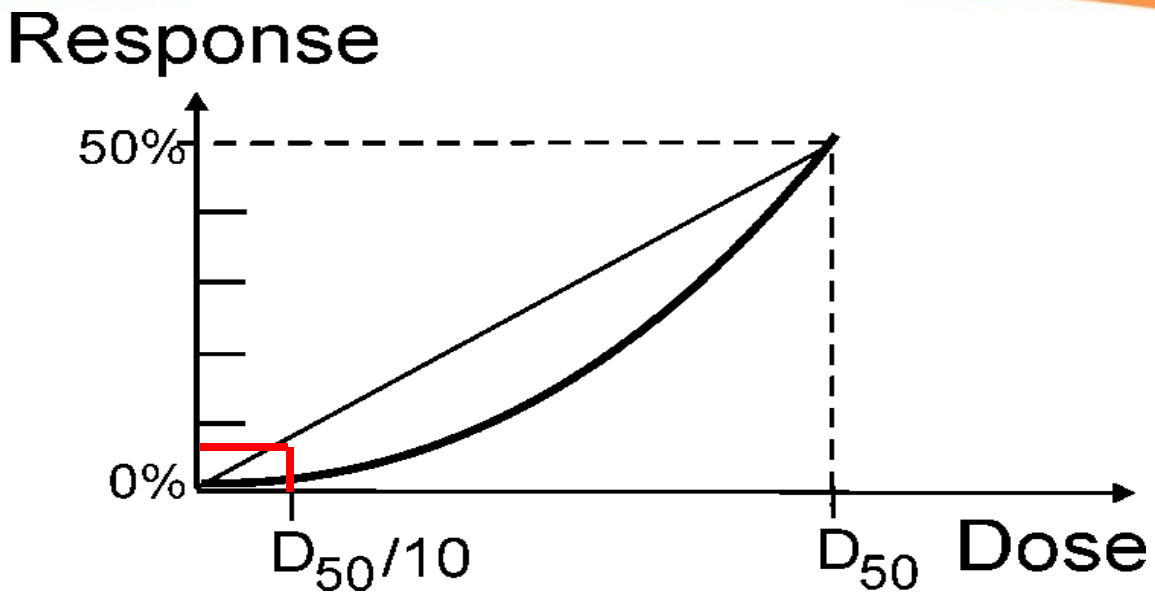
# Trigger values

The risk assessment scheme and associated trigger values enable an assessment that, if met, would ensure that exposure does not exceed a value that could lead to effects which are more than negligible in 90 % of sites (i.e. treated fields) where honey bee colonies are situated on the edge of treated fields

# Trigger values




For the case where the acceptable mortality is 5% we obtain the exposure value of D50/10. The trigger value is 10.

Macc% = Dx50%/D50
D = Macc% x D50/50% = 5% x D50/50 = D50/10
T = D50/D = 10

# Trigger values

The model of Khoury et al. (2011) was used to translate effects on colony size into forager mortality.

| Multiple of background mortality of forager bees | Negligible effect Reduction of colony size by ≤7% |
|---|---|
| × 1.5 (*m* = 0.231) | 6 days |
| × 2 (*m* = 0.308) | 3 days |
| × 3 (*m* = 0.462) | 2 days |

# Trigger values

The model of Khoury et al. (2011) was used to translate effects on colony size into forager mortality.

The background mortality in the modelling is 15.3% (m = 0.153).

**This background mortality was not used to derive the trigger values.**

Instead, **the relative increase in mortality** (= factor of increase of background mortality) **was used to derive trigger values** as outlined below (this factor of increase in background mortality is also called increment (I)).

Hence the actual trigger values are independent of the background mortality which was chosen for the Khoury model.

# Trigger values

The **increase of mortality over the duration of the acute and chronic toxicity tests** is relevant for deriving the trigger values.

Acute: 2 days = factor 3

Chronic: 10 days = factor 1.27

The mortality in the laboratory studies is already corrected for background mortality observed in the controls. Therefore it is **necessary to reduce the factor of increase of mortality by 1** to derive the addional acceptable mortality (= maximum increment above background level)

# Trigger values

**Example:**

The acceptable mortality (maximum increment above background level) is $max.increment = (I - 1) \times m_E$

**Test =** acute mortality over 2 days

**Protection goal =** increase of mortality of not more than by a factor of 3 over 2 days (as the LD50 is a 48h study), increment ($I$) = 3

**Background mortality** (= $m_E$) = 5.3%

**Acceptable addional mortality** (= *max.increment*) = $(I - 1) \times m_E$ = (3-1) x 5.3% = 10.6%

**Trigger value** = 50/10.6 = $T$ = 4.7

# Trigger values

| Endpoint | Honey bees | Bumble bees | Solitary bees |
|---|---|---|---|
| Acute contact LD50<br>downward spray<br>upward/sideward spray | <br>HQ <42<br>HQ <85 | <br>HQ <7<br>HQ <14 | <br>HQ <8<br>HQ <16 |
| Acute oral LD50 | ETR <0.2 | ETR <0.036 | ETR <0.04 |
| Chronic oral LC50 | ETR <0.03 | ETR <0.0048 | ETR <0.0054 |
| Larval toxicity NOEC | ETR <0.2 | ETR <0.2 | ETR <0.2 |
| Development hypopharyngeal glands | ETR <1 | Not assessed | Not assessed |

# Trigger values

Larval toxicity and effects on hypopharyngeal glands could not be quantitatively linked to the protection goals.

Therefore it was decided to use NOECs as endpoints assuming that no effects are to be expected at colony level.

In order to account for potential differences in subspecies of bees and for extrapolation from lab to field an assessment factor of 5 was added for the assessment of larvae mortality.

# Trigger values

Larvae effect is based on mortality and hence of direct relevance for the colony.

For effects on the development of hypopharyngeal glands it is more difficult to make a quantitative link to effects on brood care and larvae survival in the field.

Therefore no additional assessment factor was proposed for the time being.

# Trigger values

To make **use of honey bee endpoints** it is proposed to add an **assessment factor of 10**.

This is based on a **comparison of sensitivity** of honey bees and bumble bees and solitary bees (Arena and Sgolastra 2013).

The analysis included data for **45 substances** and **18 species**.

In **95%** of the cases the difference in sensitivity was **less than a factor of 10**.

# Trigger values

**Future refinements** of first tier trigger values will be possible once more information becomes available on:

-**Background mortality** rates of foragers
-**Larvae mortality** and effects on colony size
-**Effects** on development of **hpg** and colony size
-**Calibration** of trigger values with **field studies**

# Trigger values

## Questions

triggered?