



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

## Terms of reference:

- The Guidance Document should address the risk to ***Apis mellifera*, *Bombus spp* and to solitary bees.**
- The assessment of the **acute and chronic effects** of Plant Protection Products on bees, including the colony survival and development.
- The estimation of the **long term effects** due to exposure to **low concentrations.**
- The development of a methodology to take into account **cumulative and synergistic effects.**
- The **evaluation of the existing validated test protocols** and the possible **need to develop new protocols**, especially to take into account the exposure of bees to pesticides through **nectar and pollen.**

- **EFSA-Q-2011-00417:** Scientific Opinion on the science behind the development of a Risk Assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees).
- **EFSA-Q-2011-00418:** Guidance Document on the Risk Assessment of Plant Protection Products on bees (including *Apis mellifera*, *Bombus spp.* and solitary bees).
- **EFSA-Q-2011-00794:** Public consultation on the draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (including *Apis mellifera*, *Bombus spp.* and solitary bees).

**Scientific Opinion** on the science behind the development of a GD was issued in **May 2012**

<http://www.efsa.europa.eu/en/efsajournal/doc/2668.pdf>

**Public consultation** on draft GD:  
October-November 2012 and February-March  
2013

<http://www.efsa.europa.eu/en/efsajournal/doc/451e.pdf>

<http://www.efsa.europa.eu/en/efsajournal/doc/452e.pdf>

**Guidance Document** was issued in **July 2013**

<http://www.efsa.europa.eu/en/efsajournal/pub/3295.htm>

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## 2. Protection goals as agreed with risk managers from Member States

### Ecosystem services to protect:

1. Pollination
2. Food production (hive products)
3. Genetic resources and cultural services (education, aesthetic, recreation)

### Attributes to protect:

EU regulation (EC) No 1107/2009 lists **acute and chronic effects** on the **survival and development** of **colonies** and effects on **larvae** and **honey bee behaviour** as attributes to protect. It is suggested to include also abundance/biomass and reproduction because they are important for long-term survival of the colony.

## 2. Protection goals as agreed with risk managers from Member States

The viability of each colony, the pollination services it provides, and its yield of hive products all depend on the colony's strength.

Therefore special focus on impacts on colony strength.



Effect	Magnitude (reduction in colony size)
Large	>35%
Medium	15 % to 35%
Small	7% to 15%
Negligible	3.5 % to 7%

## 2. Protection goals as agreed with risk managers from Member States

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

<b>Multiple of background mortality of forager bees</b>	<b>Negligible effect Reduction of colony size by <math>\leq 7\%</math></b>	<b>Small effect Reduction of colony size by <math>\leq 15\%</math></b>	<b>Medium effect Reduction of colony size by <math>\leq 35\%</math></b>	<b>Viable after 50 days?</b>
$\times 1.5$ ( $m = 0.231$ )	6 days	13 days	40 days	Yes
$\times 2$ ( $m = 0.308$ )	3 days	7 days	18 days	Yes
$\times 3$ ( $m = 0.462$ )	2 days	4 days	10 days	No

## 2. Protection goals as agreed with risk managers from Member States

The exposure assessment goal was defined as 90<sup>th</sup> percentile worst-case considering colonies at edges of treated fields in area of use of the substance.

**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**

## Routes of exposure considered:

- **exposure via contact** – either from spray deposits (i.e. overspray or spray drift) or from dust particles when bees are either foraging the treated crop, weeds in the field, plants in field margin and the adjacent crop;
- **consumption of pollen** – from the treated crop, weeds in the field, plants in field margin, the adjacent crop or succeeding crop/permanent crop the following year;
- **consumption of nectar** – from the treated crop, weeds in the field, plants in field margin, the adjacent crop or succeeding crop/permanent crop the following year;
- **consumption of water** – guttation fluid, surface water and puddles
- **risk from metabolites present in pollen and nectar**

The standard first tier (screening + first tier) assessment covers the following effects:

- acute effects on adults (contact and oral)
- chronic effects on adults (oral)
- sublethal effects related to brood care (effects on the hypopharyngeal glands)
- toxicity to larvae
- accumulative effects

## Higher tier approaches:

- Refinement of exposure – see Chapter 7
- Refinement of effects – see Chapter 8
- Risk mitigation – see Chapter 11

## 6. Uncertainty analysis

- Every refined risk assessment should be accompanied by at least a qualitative evaluation of the uncertainties affecting it, using a systematic tabular approach. In assessments with multiple lines of evidence, the uncertainties affecting each line of evidence should be evaluated separately.
- The overall characterisation of risk should be derived by a qualitative weight-of-evidence assessment considering all relevant lines of evidence and their uncertainties using a systematic tabular approach. If the overall characterisation is expressed qualitatively (in words) rather than quantitatively, great care should be taken to describe the outcome and its uncertainty as clearly as possible.
- Examples are provided in Appendix V on how to assess uncertainties in higher tier studies.

# 10. Mixture toxicity

- The method to assess mixture toxicity is based on concentration addition.
- If measured toxicity (e.g. for formulations) is greater than the calculated toxicity then the measured toxicity should be used in the risk assessment.
- Dismissing the endpoints of the formulation in higher tiers would only be acceptable if the observed greater toxicity could be clearly ascribed to a factor that would not be relevant under environmental exposure conditions.

# 11. Risk mitigation options

Currently the only harmonized **risk mitigation phrase aimed at reducing the exposure** and hence risk to bees is the following **SPE8** from **Annex V of 1999/45/EC**.

*“Dangerous to bees./To protect bees and other pollinating insects do not apply on flowering crops./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./ Do not apply when flowering weeds are present./ Remove weeds before flowering./Do not apply before (state time).”*

This phrase is still relevant under 1107/2009/EC (see Article 65.1)

# 11. Risk mitigation options

The **following points** were considered **important** when developing risk mitigation measures:

- Ensure that all risk mitigation phrases are workable and enforceable.
- Always ensure that the risk mitigation phrase is seen by the relevant person. This is usually straightforward for spray formulations, where the risk mitigation can be stated on the product label. However it is more complicated for treated seeds.

# 11. Risk mitigation options

## Issues identified:

1. The practicality of the phrase **'Remove or cover beehives during application and for [state time] after treatment'**, as it may result in an impact on honey bee colonies, for example from overheating. There are also practical difficulties as beekeeper may not live or be in the vicinity of their hives at the time of application. This risk mitigation measure is not relevant for bumble bees and solitary bees.
2. **"Do not apply before (state time)"**, is potentially unclear, and hence clarification on the label would be required

# 11. Risk mitigation options

## Issues identified:

3. The recommendation “**remove weeds before flowering**” is likely to have undesired side effects such as removing a source of nectar and pollen, which in turn may impact on honey bees, solitary bees and bumble bees.

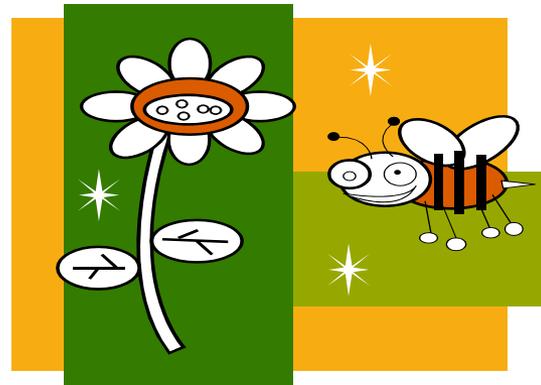
It is therefore, recommended that MS consider the wider implications of this risk mitigation measure before implementation on product labels.

# 12. Sublethal effects

The proposed standard risk assessment takes into account **effects on brood care** (effects on hypopharyngeal glands).

Other sublethal effects are not taken into account in the first tier standard risk assessment because it was not possible at this stage to develop a risk assessment scheme for other sublethal effects such as behavioural effects.

An illustrative scheme for assessment of sublethal effects was included in Appendix W.



# 12. Sublethal effects

The following issues need to be solved before sublethal effects can be fully integrated in a risk assessment scheme:

1. Protection goals and trigger values in first tier
2. Interpretation of sub-lethal effects in terms of effects on the colony
3. Exposure assessment goals for homing flight study
4. Interpretation of effects observed in the homing flight study

## Elements in the risk assessment which contribute to conservatism of the assessment

Trigger values are based on the lowest background mortality rates which were found in literature

The lowest sugar content is used in the initial steps of the risk assessment

The risk assessment for consumption of nectar and pollen in the hive is based on the maximum in time of the concentration of the residues entering the hive.

The risk assessment considers colonies which are placed next to the treated field

## Elements in the risk assessment which make the assessment less conservative

No account is taken of exposure to multiple products.

Sublethal effects (e.g. effects on behaviour) are not included in the screening which could underestimate the risk in the lower tiers.

Exposure from residues in wax is not currently considered in the risk assessment scheme.

Exposure via honey dew was not included in the risk assessment scheme because of high uncertainty around this exposure route.

Exposure to residues in soil is not included in the risk assessment scheme.



Thank you  
for your  
attention!