Evaluation Manual for the Authorisation of plant protection products according to Regulation (EC) No 1107/2009

EU part

Plant protection products

Chapter 6 Ecotoxicology; terrestrial; bees

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ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 6 Ecotoxicology; terrestrial; bees

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 6 Terrestrial; bees			
Version	**Date**	**Paragraph**	**Changes**
2.1	October 2016		New situation in the updated E.M.
			Text from data requirements deleted from the Manual, replaced with reference/links to Regulations (EU) No 283/2013 and 284/2013. Short list of data requirements included in the text.
			Formatting changes. Updating references to Regulation (EC) No 1107/2009
			More detailed information about the risk assessment.
2.2	January 2020		Update to discuss the new EU MRL honey guidance and give guidance on how to use chronic data in the risk assessment of products.
		1	Sentence included on the administrative EFSA guidance
2.3	July 2021	1.3	Note on active substances with a mode of action aimed at suffocation of the target organisms included.
2.4	February 2022	1.3	Note on active substances with a mode of action aimed at suffocation of the target organisms removed (until further guidance is available).
2.5	September 2023		Minor changes (text)
2.6	October 2025		Changes in the chronic risk assessment. More transparency in the conclusion of the risk assessment with regard to the different bee groups. Section 1.2 is updated with the 2023 versions of the Commission Communications. Hyperlinks are updated when necessary. Error in chapter numbering corrected (Chapter 6 is the relevant number for ecotoxicology).
2.7	May 2026	1.3.1	Update with Bullet point Ecotox from the 7th CZHW, December 2023 (adopted by the CZSC October 2025)

GENERAL INTRODUCTION

This chapter briefly describes the data requirements for estimation of the effects on bees of a plant protection product and its active substance and how reference values are derived in the EU framework (§1 - §1.5) under Regulation (EC) No 1107/2009.

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing Regulation (EU) No 540/2011.

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances.

1.1 Introduction

This chapter describes the risk assessment of plant protection products for bees. Honey bees are economically important and they are also an important indicator of negative effects on the environment. This means that, apart from a clear economic purpose, the risk assessment for bees also serves to avoid allowing products which present an unacceptable risk to the environment to reach the market. The risk to bees must be evaluated if there is a chance of exposure of these organisms.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part of the Evaluation Manual (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011.

1.2 Data requirements

In order to qualify for inclusion of an active substance in Commission Implementing Regulation (EU) No 540/2011 a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2023/C 344/02 and Commission Communication 2023/C 344 01.

Guidelines for the risk evaluation for bees are given in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final). This document refers to EPPO guidelines.Testing for bees is included under the EPPO Standards on efficacy evaluation of plant protection products (EPPO Standards on plant protection products PP 1). The most recent version of th EPPO standard for bee testing is the standard on the conduct of trials for the evaluation of side-effects of plant protection products on honeybees (PP1/170) (first published in 1991, the latest revision in 2010). However, please note the considerations for higher tier studies given in section 1.2.2.

When according to the applicant a certain study is not necessary, a relevant scientific justification can be provided for the non-submission of the particular study.

In November 2020, the Central Zone Steering Committee agreed the following with regard to

the data requirements for bees (this agreement was made because of unclarity with regard to the studies for chronic adult and larval toxicity):
'The zRMS asks for the data requirements and evaluates the data. If the MS use the submitted studies for risk assessment, the risk assessment will be done in the core.'

1.2.1 Data requirements for the active substance

The data requirements regarding the risk of the active substance for bees are described in point 8.3.1 (effects on bees) of part A (for chemical active substances) of Commission Regulation (EU) No 283/2013.

Point 8.3.1 consists of the following data requirements:
8.3.1. Effects on bees
8.3.1.1. Acute toxicity to bees
8.3.1.1.1. Acute oral toxicity
8.3.1.1.2. Acute contact toxicity
8.3.1.2. Chronic toxicity to bees
8.3.1.3. Effects on honeybee development and other honeybee life stages
8.3.1.4. Sub-lethal effects

In the last decade, several bee testing guidelines have been developed under the auspices of the OECD, e.g. on bumble bee acute contact and oral toxicity (OECD Test No. 246 and 247), chronic toxicity to adult honey bees (OECD Test no. 245) and honey bee larval toxicity. For larvae, the multiple exposure test (OECD unclassified Guidance Document No. 239) is preferred over the single exposure test (OECD Test No. 237). Acute oral test guideline development on the solitary bee *Osmia* spp. is underway.
Where final (harmonized) versions of guidelines are available, these should be used. Tests performed according to draft versions may be accepted for the risk assessment as long as the deviations from the final guideline are not expected to have severely impacted the outcome of the test (to be determined on a case-by-case basis).

The data requirements should always be addressed for honey bees. Tests on other bee species may be submitted as well.

1.2.2 Data requirements for the product

The data requirements regarding the risk of the plant production product for bees are described in point 10.3.1 (effects on bees) of part A (for plant protection products) of Commission Regulation (EU) No 284/2013.

Point 10.3.1 consists of the following data requirements:
10.3.1. Effects on bees
10.3.1.1 Acute toxicity to bees
10.3.1.1.1 Acute oral toxicity
10.3.1.1.2 Acute contact toxicity
10.3.1.2 Chronic toxicity to bees
10.3.1.3 Effects on honey bee development and other honey bee life stages
10.3.1.4 Sub-lethal effects
10.3.1.5 Cage and tunnel tests
10.3.1.6 Field tests with honeybees

These points should always be addressed for honey bees. Tests on other bee species may be submitted as well.

For laboratory tests, refer to 1.2.1.

With regard to higher tier testing, the following should be noted. As stated in section 1.2, above, the current guidance for higher tier studies with honey bees is laid down in Sanco/103229/2002 which in turn refers to EPPO guideline 1/170. However, the framework for risk assessment for bees is under development. Already in 2012 and 2013, concerns were raised by EFSA about the reliability of higher tier effect studies performed according to EPPO 1/170. In particular, the statistical robustness and proof of achieved exposure were questioned. Therefore, for active substance as well as product dossiers, higher tier effect studies will be critically evaluated and considered in light of the issues raised in EFSA PPR Panel (2012) and EFSA (2013) with regard to the methodologies used.
Please note that in the revised EFSA Bee guidance document (2023), requirements for higher tier studies and especially honey bee field studies significantly change from the former requirements.

The Ctgb does not only rely on semi-field studies to draw a conclusion on brood and longer-term colony level effects, because conditions in the tunnel are suboptimal for honey bee colonies, hampering effect detection. They are suitable to detect short-term effects on adult mortality. The results of semi-field studies for chronic effects are considered in weight-of-evidence (WoE). For product assessment, in case a particular study was included in the active substance dossier, this WoE will also include the conclusions from the peer review evaluation as laid down in the EFSA conclusion for the active substance. Please note that if *adverse* effects are seen in semi-field studies, they should be considered relevant.

As long as new guidance has not come into force, the Ctgb will evaluate field studies according to the EPPO 1/170 guidelines, but pay extra attention to the statistical power of the study and to the proof of exposure.

For specific concerns regarding brood effects, the revised Oomen bee brood feeding test may be used. Also here, specific attention should be paid to the statistical power of the study and to the proof of exposure.

1.2.3 Data requirements for metabolites
Standard laboratory tests are normally not required for metabolites. Exceptions may be cases where for example the metabolite is the pesticidal active molecule. See the general section about metabolites as described in §1.2.3 of Chapter 6 Ecotoxicology; terrestrial; Birds and mammals for general guidance. Where higher tier studies (cage/tent/tunnel or field tests) have been carried out with the pesticide under realistic exposure conditions, it may be assumed that the potential risk of metabolites has been taken into account.

1.3 Risk assessment

1.3.1 Risk assessment methodology
The risk assessment methodology for bees has in EU context been elaborated in the Sanco trrestrial guidance document. This document refers to EPPO guidelines. However, the EPPO Standards on the assessment of potential risks of environmental damage which may be caused by the use of plant protection products (EPPO Standards on plant protection products PP 3) were withdrawn by EPPO in 2018.

Active substances for which the dossier is submitted after September 2015 will be evaluated according to the first tier of the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees) (EFSA Journal 2013;11(7):3295). This was agreed in a general ecotoxicology meeting, Pesticide Peer Review

Meeting 133 which took place from 23 to 25 September 2015. The EFSA guidance document on bees has not been noted at the EU level yet. Nevertheless, as explained in the report of the meeting, the current guidance documents do not cover honey bee larvae and chronic adult honey bee toxicity, while endpoints for these are available following the current data requirements. “In the absence of alternative approaches taken note by risk managers, it was recommended that the risk assessment to honey bees should be performed (first tier) according to EFSA (2013). For higher tier, the studies should be critically evaluated and considered in light of the issues raised in EFSA PPR Panel (2012) and EFSA (2013) with regard to the methodologies used. On the basis of all the available information, a conclusion should be drawn with regard to the risk to honey bees. For bumble bees and solitary bees, it was agreed that if any data are submitted, they should be evaluated. However, currently it cannot be recommended to routinely perform a risk assessment. Where data are not available and no risk assessment can be performed, this issue will be reflected in the EFSA conclusion.”

As long as no further decisions have been taken at the risk management level on the relevant guidance for bees, Ctgb will follow this agreement for active substance evaluation (both for first evaluation and renewal) and will present two first tier risk assessments based on the two different guidance documents. Please note that a risk assessment according to the new Guidance for larval toxicity in instances when only a single dose test is available, is not considered appropriate, as the trigger value for larval toxicity in the new guidance is based upon an assumption of multiple exposures.

Similar as for active substances, for products there is unclarity how to do the chronic risk assessment for bees. The current EU-agreed guidance to evaluate risks to bees (Terrestrial guidance, SANCO/10329/2002) only provides a methodology to assess acute risks to honey bees. The Regulations (EU) 283/2013 and 284/2013 require studies evaluating the chronic oral effects of the active substance / product on adult honey bees and on honey bee larvae. However, there is currently no EU-agreed methodology to use these chronic data in the risk evaluation of honey bees. Indeed, the EFSA Journal 2013;11(7):3295 was never noted and the revised guidance (EFSA Journal 2023;21(5):7989) has not yet been noted either.

The risk assessment for bees in product assessment has been discussed in the 7th and 8th central zone harmonization workshops (CZHW) for ecotoxicology. Several agreements were reached.

The agreements from the 7th CZHW have been noted by the central zone steering committee (CZSC).

How to deal with the intermediate period between guidances (7th CZHW (Warsaw, Poland; December 2023; CZSC October 2025)

The majority of experts agreed to the following:

In reference to bee guidances:

- The chronic and larvae RA based on EFSA (2013) will be presented in the Core;
- In case an unacceptable risk is demonstrated at Tier 1 with EFSA (2013), the exposure parameters such as e.g. DT50, RUD in nectar and pollen, etc., may be refined using EFSA (2023);
- When refinement of the exposure parameters in line with EFSA (2023) is proposed by the Applicant, this should be done for all crops indicated in the Central Zone GAP, even when acceptable risk was concluded for some crops in RA based on EFSA (2013);
- Refinement based on EFSA (2023) should be suggested by the Applicant and not performed by the zRMS;

- Information on the harvesting of the crop before flowering from the new EFSA (2023) may be considered in the Core since this issue is not covered in EFSA (2013);
- The risk assessment for seed treatments will be performed in line with indications of EFSA (2013).

The agreements of the 8th CZHW have not been fully formalized at the central zone level and are therefore not yet included in the central zone evaluation manual. However, they reflect the Ctgb viewpoint and current way of working in product risk assessment.

In addition to the points listed above, the Ctgb requires the following:

- The EFSA Beetool is used for the calculations of the risk according to EFSA (2013).
- In case data (acute and/or chronic) for non-*Apis* bees are available, the assessment should be performed in the core dossier (based on EFSA GD 2013 and the Beetool).

Details with regard to refinement in case the Tier 1 assessment according to EFSA GD 2013 fails and the exposure needs to be refined:

- In case unacceptable risk is demonstrated in Tier 1 for only one category (categories are chronic adult, larval), the refinements based on default exposure values from the EFSA Bee GD 2023 should only be applied to this category.
- The SV should be refined with the SHVAL tool in case new default values from EFSA GD 2023 are relied upon; the calculations have to be made by the applicant and checked by the zRMS.
- The revised interception factors for deposition on weeds (Appendix B of EFSA GD 2023) can be used to refine the weed scenario.
- The information regarding the lack of relevance of the flowering weed scenario for sugar beet in EFSA GD 2023 can be extrapolated to fodder beet.

The risk assessment for bees has historically been focused on the honey bee (*Apis mellifera*). It has become clear that this is not necessarily protective of other bees. Scientific developments in this area are ongoing. Acute study protocols with Bombus and Osmia species have recently become available but are not formally required. Chronic study protocols are not available yet for non-Apis bees.

As described above, for other bees than honey bees, a risk assessment will be performed according to the EFSA (2013) Bee guidance document (using the BeeTool) when studies are available for these non-Apis species. Extrapolated endpoints from tests with *A. mellifera* will not be used. A conclusion will only be drawn based on available studies with the respective bee group. It is expected that in most dossiers, a conclusion can only be drawn for honey bees. In some dossiers, an additional conclusion may be drawn for the acute risk to bumble bees and/or solitary bees. When there are no studies available, no conclusion can be drawn on the risks to other bees than the honey bee.

Each study is summarized and analysed separately. The final conclusion and the endpoint per aspect (such as LD_{50}(oral)) are presented in a list of endpoints. The risk assessment is based on a comparison of exposure and toxicity, using a relevant trigger value.

1.3.2 Combination toxicity

Combination toxicity must be determined when plant protection products contain several active substances, and for tank mixtures that are specified on the label. The issue of combined toxicity is further described in Chapter 6 General introduction.

1.3.3 Specific considerations for applications where the Ctgb is not the zRMS

As explained in Chapter 1.3.1, the risk assessment methodology is not fully harmonised at the moment, and as a result, the data requirements have not always been completely fulfilled in core dossiers, especially with regard to the presence and/or evaluation of chronic laboratory studies. Therefore, in applications for Mutual Recognition (MR) and where the Ctgb is a concerned Member State (cMS), the risk assessment in the core dossier may not fully comply with sections 1.2 and 1.3.1 above.
General instructions for MR and cMS dossiers are described in the 'Realignment of policy on mutual recognition and CMS applications'.
The implementation date of this policy is:

- For Mutual Recognition: submission date of dossier per 01/01/2026
- For applications where the Ctgb is a cMS: start commenting round per 01/01/2026

From the policy, specific instructions for bees are derived which are described here (before the implementation dates, expert judgement will be applied).

For MR and cMS dossiers, the Ctgb will act as follows:

a) Chronic laboratory studies should be present and evaluated in the core dossier.

a.1) The Ctgb is a concerned Member State:

If chronic adult and larval studies are not present ánd evaluated in the core dossier:

- The Ctgb will comment in the commenting round;
- Applicant and/or zRMS to repair;
- If the studies are not present and evaluated in the final core, the application is rejected.

a.2) The Ctgb receives an application for Mutual Recognition:

If chronic adult and larval studies are not present in the core dossier:

- In the intake, Ctgb will ask the applicant to provide the studies in the National Addendum.
- If the studies are provided and summaries are included in the National Addendum, the Ctgb will evaluate them. Costs will be charged to the applicant.
- If the studies are not provided, the application is rejected.

If chronic adult and larval studies are present, but not evaluated in the core dossier:

- In the intake, the Ctgb will ask applicant to provide the summaries in the National Addendum;
- The Ctgb will evaluate the studies in the National Addendum. Costs will be charged to the applicant.
- If the summaries are not provided, the application is rejected.

b) The chronic risk assessment should be done according to the EFSA 2013 Bee GD in the core dosser.

If there is no chronic risk assessment according to the EFSA 2013 Bee GD in the core dossier:

- cMS: In the commenting round, the Ctgb will ask the zRMS to repair this.
- For Mutual Recognition, there is no commenting round.
- If there is no risk assessment according to EFSA 2013 Bee GD in the final core, the Ctgb will ask the applicant to include this in the National Addendum, during the intake.
- The Ctgb will then evaluate the risk assessment in the National Addendum. Costs will be charged to the applicant.

- If the requested risk assessment is not provided, the application is rejected.

1.3.4 Exposure routes

The risk assessment considers the potential risk to bees from exposure resulting from the use of the plant protection product according to the GAP. This clearly concerns exposure via the crop itself (from direct overspray and systemic uptake), but other exposure routes may also be relevant. The main exposure routes are highlighted below.

Exposure via flowering crops

On national level, an overview is given of the attractiveness of agricultural crops for honey bees for the collection of nectar and/or pollen (hereafter named the NL Bee List; see the NL part of Evaluation Manual for bees, appendix II-1). This document is used for identification of relevant crops for honey bee risk assessment. Moreover, this document is valuable for the understanding of risk mitigation sentences in which the phrase 'bee-attractive crops' is mentioned.

It is noted that per January 1st 2020, the guidance for determining the magnitude of pesticide residue levels in honey and setting Maximum Residue Levels in honey (SANTE/11956/2016 Rev. 9) is in force. While this guidance document is aimed at protecting humans from exposure to pesticides in honey, it has a link with the risk assessment for bees, in that it contains a list of melliferous crops (Appendix II of the honey MRL guidance, hereafter named MRL honey list).

The Ctgb has compared the two lists and found that, generally, the lists are in line: they either deem a crop attractive or not attractive to honey bees. Differences between the lists can usually be explained by one or more of the following:

a) The MRL honey list covers all crops for which an MRL is needed (according to Annex I Reg (EC) No 396/2005)), including imported crops (such as citrus and almond). The NL Bee List only contains crops which are grown in the Netherlands.
b) Crops grown for seed production are flowering per definition. The MRL honey list mentions per crop if it is considered attractive only when grown for seed production, while the bee list contains a specific category for seed production ('Plant breeding crops and basic seed production for arable, vegetable and fruit crops, herbs and ornamental crops').
c) Certain crops do not produce nectar, and are thus not relevant for honey production, but are still attractive to honey bees for their pollen.

Two differences cannot be easily explained: In the NL Bee List, rose is considered attractive to honey bees both for nectar and pollen, but it is not considered to be a melliferous crop in the MRL honey list. Conifer is not considered attractive to honey bees in the NL Bee List, but is considered to have melliforous capacity in the MRL honey list. These differences will be investigated. Until further notice, Ctgb will use the NL Bee List as published in the NL part of this Evaluation Manual as a basis for the risk assessment for bees.

Exposure via honey dew

The Ctgb considers exposure to honey dew relevant for honey bees and will perform a risk assessment. Please refer to the NL part of this evaluation manual.

Exposure via flowering weeds

In the first tier, it is assumed that bees may fly on flowering weeds in the field. In higher tier, information can be used about the likelihood of a large amount of flowering weeds in a crop under normal agricultural practice. If relevant, applicants should address this for all countries relevant for their application. Note that if such a refinement is proposed, the Ctgb will refer to the exposure factors given in Appendix B to EFSA (2023); we consider this to be the most up-to-date scientific assessment of available data.

Off-field risk
Spray applications: In cases where in-field risk to bees has been determined, an off-field risk should be calculated using the drift values as used for the off-field risk assessment for non-target arthropods (see §1.3 of the EU part of Chapter 6 Ecotoxicology: terrestrial; non target arthropods).
Seed treatments: A list indicating whether there is potential risk to bees from dust drift during sowing of treated seeds was developed in 2010 and is attached to the NL part of this Evaluation Manual.

Succeeding crops
Persistent and systemic substances may be present in nectar and/or pollen of succeeding flowering crops (including replacement crops). See §2.3.

1.3.5 Risk mitigation measures
If a potential risk is indicated, this may be addressed with additional data. Alternatively, it is often possible to address a potential risk with a restriction sentence on the instructions for use. As these sentences are member state specific, the Ctgb will mention the generic intention of the sentences in the EU evaluation or the core dossier.

1.4 Approval
This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1 Approval of the active substance
Annex II of Regulation (EC) No 1107/2009 provides the procedure and criteria for the approval of an active substances, safeners and synergists.

Point 3 of Annex II of Regulation (EC) No 1107/2009 gives the criteria for the approval of an active substance.

1.4.2 Evaluation of plant protection products
The principles for the evaluation regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for evaluation for bees are included in Part B Evaluation, point 2.5.2.3.

1.4.3 Decision making for plant protection products
The principles for the decision-making regarding the effects on the environment are presented in Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles). The specific principles for decision making for bees are included in Part C Decision making, point 2.5.2.3.

1.5 Developments
In May 2012, the EFSA published their 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). A Guidance document for bees based on this scientific opinion was published by EFSA in 2013 and updated in 2014. A revised version of this Guidance document was published in 2023. To date, this guidance document has not been noted by the Standing Committee on Plants, Animals, Food and Feed (SCOPaFF).

While waiting for harmonized EU guidance, the NL has collated information to aid in the risk assessment for bees in the Netherlands, including:

- A list for all crops indicating whether they are attractive to honey bees was developed in 2011 and revised in 2015, and is attached to the NL part of this Evaluation Manual.

- A list indicating whether there is potential risk from dust drift during sowing of treated seeds was developed in 2010 and is attached to the NL part of this Evaluation Manual.

- A list indicating for which crops exposure via honeydew should be considered in the risk assessment was developed in 1997 and revised in 2018, and is attached to the NL part of this Evaluation Manual.

In early 2015 EFSA launched a major project with the aim of developing a holistic approach to the risk assessment of multiple stressors (including pesticides) in honey bees (MUST-B).

Also, several EU research projects are ongoing which may impact the bee risk assessment in future:

- https://www.syberac.eu/
- https://pollinera-horizon.eu/ -
- https://www.eu-parc.eu/ -