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

EU part

Plant protection products

Chapter 7 Ecotoxicology; terrestrial; bees

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ctgb

Board for the Authorisation of plant protection products and biocides

Chapter 7 Ecotoxicology; terrestrial; bees

Category: Plant Protection Products

Important changes with the last version of the E.M.

Evaluation manual PPP EU part Chapter 7 Terrestrial; bees Version 2.0; January 2014		**Evaluation manual PPP EU part Chapter 7 Terrestrial; bees Version 2.1; October 2016**	
Paragraph and page number	Short explanation of old EM situation	Paragraph and page number	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.

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.

1.1 Introduction

This chapter describes the risk assessment of plant protection products for bees. Honeybees 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 2013/C 95/01.

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. The most recent version of this concerning tests on bees 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).

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.

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

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

Several bee testing guidelines are currently being developed under the auspices of the OECD, e.g. on bumblebee acute toxicity, chronic toxicity to adult honeybees and honeybee larval toxicity. Until final versions are available, the most recent drafts should be followed. Where final (harmonized) versions are available, these should be used, with the exception of larval toxicity testing, where the multiple exposure test (currently available only in draft) is preferred over the already finalized single exposure test (OECD Test No. 237).

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 honeybees. Tests on other bee species may be submitted as well.

Several bee testing guidelines are currently being developed under the auspices of the OECD, e.g. on bumblebee acute toxicity, chronic toxicity to adult honeybees and honeybee larval toxicity. Until final versions are available, the most recent drafts should be followed. Where final (harmonized) versions are available, these should be used, with the exception of larval toxicity testing, where the multiple exposure test (currently available only in draft) is preferred over the already finalized single exposure test (OECD Test No. 237).

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 7 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

The risk assessment methodology for bees has in EU context been elaborated in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final). This document refers to EPPO guidelines. The most recent version of this concerning the risk

assessment for bees is EPPO Series PP 3 Environmental Risk Assessment Scheme for Plant Protection products – Chapter 10: Honeybees (first published in 1993, the latest revision in 2010). This is used by Ctgb for the risk assessment of active substances and plant protection products.

In addition, 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 honeybee larvae and chronic adult honeybee 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 honeybees 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 honeybees. For bumblebees 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. However, we will not perform a risk assessment according to the new Guidance for larval toxicity in instances when only a one dose test is available, as the trigger value for larval toxicity in the new guidance is based upon an assumption of multiple exposures, and we therefore do not consider it appropriate to compare the single dose toxicity value with the multiple dose trigger.

Each study is summarized and analyzed 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.

Combination toxicity
Combination toxicity must be determined when plant protection products contain several active substances, and for tankmixes that are specified on the label. The issue of combined toxicity is further described in Appendix A.

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 and these are highlighted below.

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.

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 7 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.

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 only 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. To date, this guidance document has not been noted by the Standing Committee on Plants, Animals, Food and Feed (SCOPaFF) and it is thus not part of the official list from the European Commission of guidelines to be used for active substance and plant protection product approval.

Ctgb notes that EFSA is currently working on the ‘Preparation of Background document for the re-evaluation of shortcut values for bees and development of dilution factors based on residue trials’ (see EFSA-Q-2015-00628 of Mandate 2015-0078 in the EFSA Register of Questions).

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 honeybees 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.

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 honeybees (MUST-B).