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

EU part

Plant protection products

Chapter 7 Ecotoxicology: terrestrial; bees

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Chapter 7 Ecotoxicology; terrestrial; bees

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GENERAL INTRODUCTION

This chapter 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].The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorization of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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 [3].

1.1 Introduction

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

Guidelines for the risk evaluation for bees are given in the Guidance Document on Terrestrial Ecotoxicology [4]. This document refers to EPPO 170.
The EPPO guideline of 2010 describes the methodology to assess the risk of systemic substances (EPPO 170, 10, [5]).
A decision tree with corresponding explanatory notes is included in Appendix II-1.
This decision tree summarises the decision scheme insofar as bees are concerned.

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

(§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 in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [6] and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 [7] 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 [8].

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.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 7.

1.2.1 Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings.
The endpoints of the study are given as well, if relevant.

The data requirements regarding the risk of the active substance for bees are described in part A of Commission Regulation (EU) No 283/2013, point 8.3 (effects on arthropods).

Introduction

1. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance shall be reported. This shall include all potentially adverse effects found during routine ecotoxicological investigations. Where required by the national competent authorities, additional studies, necessary to investigate the probable mechanisms involved and to assess the significance of these effects, shall be carried out and reported on.

2. The ecotoxicological assessment shall be based on the risk that the proposed active substance used in a plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is ‘risk quotient’ or RQ. It shall be noted that RQ can be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ). The applicant shall take into account the information from Sections 2, 5, 6, 7 and 8.

3. It may be necessary to conduct separate studies for metabolites, breakdown or reaction products derived from the active substance where non-target organisms may be exposed and where their effects cannot be evaluated by the available results relating to the active substance. Before such studies are performed, the applicant shall take into

account the information from Sections 5, 6 and 7.

Studies undertaken shall permit characterisation of metabolites, breakdown or reaction products as being significant or not, and reflect the nature and extent of the effects judged likely to arise.

4. In the case of certain study types, the use of a representative plant protection product instead of the active substance as manufactured may be more appropriate, for example testing of non-target arthropods, bees, earthworm reproduction, soil micro-flora and non-target terrestrial plants. In the case of certain plant protection product types (for example encapsulated suspension) testing with the plant protection product is more appropriate to testing with active substance when these organisms will be exposed to the plant protection product itself. For plant protection products where the active substance is always intended to be used together with a safener and/or synergist and/or in conjunction with other active substances, plant protection products containing these additional substances shall be used.

5. The potential impact of the active substance on biodiversity and the ecosystem, including potential indirect effects via alteration of the food web, shall be considered.

6. For those guidelines which allow for the study to be designed to determine an effective concentration (EC x), the study shall be conducted to determine an EC 10 , EC 20 and EC 50 , when required, along with corresponding 95 % confidence intervals. If an EC x approach is used, a no observed effect concentration (NOEC) shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

7. All of the aquatic toxicity data shall be used when developing a proposal for environmental quality standards (Annual Average EQS, AA-EQS; Maximum Acceptable Concentration EQS, MAC-EQS). The methodology for derivation of these endpoints is outlined in the 'Technical Guidance for Deriving Environmental Quality Standards([1])' for the Water Framework Directive 2000/60/EC of the European Parliament and of the Council ([2]).

8. In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species shall, where possible, be used in the various toxicity tests specified.

9. Higher tier studies shall be designed and data analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate and necessary, higher tier studies shall be supported by chemical analysis to verify exposure has occurred at an appropriate level.

10. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of relevant sub-lethal effects in the risk assessment.

Effects on arthropods
(283/2013; 8.3)

Effect on bees
(283/2013; 8.3.1)

8.3. Effect on arthropods

8.3.1. Bees

Effects on bees shall be assessed and the risk evaluated, including the risk deriving from residues of the active substance or its metabolites in nectar, pollen and water, including guttation. Reports of the tests referred to in points 8.3.1.1, 8.3.1.2 and 8.3.1.3 shall be submitted, except where plant protection products containing the active substance are for exclusive use in situations where bees are not likely to be exposed such as:
(a) food storage in enclosed spaces;
(b) non-systemic preparations for application to soil, except granules;
(c) non-systemic dipping treatments for transplanted crops and bulbs;
(d) wound sealing and healing treatments;
(e) non systemic rodenticidal baits;
(f) use in greenhouses without bees as pollinators.

For seed treatments the risk from drift of dust during drilling of the treated seed shall be taken into account. As regards granules and slug pellets the risk from drift of dust during application shall be taken into account. If an active substance is systemic and to be used on seeds, bulbs, roots, applied directly to soil, irrigation water, or applied directly to or into the plant, for example by spraying or stem injection, the risk to bees foraging those plants shall be assessed, including the risk deriving from residues of the plant protection product in nectar, pollen and water, including guttation.

Where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, shall be conducted.

Where exposure of bees to residues in nectar, pollen or water resulting from systemic properties of the active substance may occur and where the acute oral toxicity is < 100 µg/bee or a considerable toxicity for larvae occurs, residues concentrations in these matrices shall be provided and the risk assessment shall be based on a comparison of the relevant endpoint with those residue concentrations. If this comparison indicates that an exposure to toxic levels cannot be excluded, effects shall be investigated with higher tier tests.

Acute toxicity
(544/20118.3.1.1)

8.3.1.1. Acute toxicity

Where bees are likely to be exposed, testing for acute oral and contact toxicity shall be performed

Acute oral toxicity
(283/2013; 8.3.1.1.1.)

8.3.1.1.1 Acute oral toxicity

A test for acute oral toxicity shall be provided establishing the acute LD_{50} values together with the NOEC. Sub- lethal effects, if observed, shall be reported.

Test conditions
The test shall be conducted with the active substance. Results shall be presented in terms of µg active substance/bee.

Result:

LD_{50} (oral)
Acute contact toxicity
(283/213; 8.3.1.1.2.)

8.3.1.1.2 Acute contact toxicity
A test for acute contact toxicity shall be provided establishing the acute LD_{50} values together with the NOEC. Sub-lethal effects, if observed, shall be reported.

Test conditions
The test shall be conducted with the active substance. Results shall be presented in terms of µg active substance/bee.

Result:
→ LD_{50} (contact)

Chronic toxicity to bees
(283/2013; 8.3.1.2)

8.3.1.2 Chronic toxicity to bees
A test for chronic toxicity to bees shall be provided establishing the chronic oral EC_{10}, EC_{20}, EC_{50} together with the NOEC. Where the chronic oral EC_{10}, EC_{20}, EC_{50} cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.

Circumstances in which required
The test shall be carried out where bees are likely to be exposed.

Test conditions
The test shall be conducted with the active substance. Results shall be presented in terms of µg active substance/bee.

Effects on honeybee development and other honeybee life stages
(283/2013; 8.3.1.3)

8.3.1.3. Effects on honeybee development and other honeybee life stages

A bee brood study shall be conducted to determine effects on honeybee development and brood activity. The bee brood study shall provide sufficient information to evaluate possible risks from the active substance on honeybee larvae.

The test shall provide the EC_{10} , EC_{20} and EC_{50} for adult bees, where possible, and larvae together with the NOEC. Where EC_{10}, EC_{20}, EC_{50} cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.

Circumstances in which required
The test shall be carried out for active substances for which sub-lethal effects on growth or development cannot be excluded, unless the applicant shows that it is not possible that honeybee brood will be exposed to the active substance.

Result:
→ NOEL

Sub-lethal effects
(283/2013; 8.3.1.4)

8.3.1.4. Sub-lethal effects

Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees and, where applicable, on colonies may be required.

1.2.2 Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 284/2013. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings.
The endpoints of the study are given as well, if relevant.

The data requirements regarding the risk of the plant protection product to bees are described in Commission Regulation (EU) No 284/2013, point 10.4 (effects on bees).

Generally, EU and OECD guidelines for the protocol of experiments are mentioned in Commission Communication 2013/C 95/02 [9].

Introduction

1. Testing of the plant protection product shall be necessary where its toxicity cannot be predicted on the basis of data on the active substance. Where testing is necessary, the aim shall be to demonstrate whether the plant protection product, taking account of content of active substance, is more toxic than the active substance. Thus bridging studies or a limit test may be sufficient. However, where a plant protection product is more toxic than the active substance (expressed in comparable units), definitive testing shall be required. Possible effects on organisms/ecosystems shall be investigated, unless the applicant shows that exposure of the organisms or ecosystems does not occur.

Tests and studies conducted using the plant protection product as test material necessary to assess the toxicity of the active substance shall be reported in the context of the relevant data requirement concerning the active substance.

2. All potentially adverse effects found during routine ecotoxicological investigations shall be reported and such additional studies, which may be necessary to investigate the mechanisms involved and assess the significance of these effects, shall be undertaken and reported.

3. Whenever a study implies the use of different doses, the relationship between dose and adverse effect shall be reported.

4. Where exposure data are necessary to decide whether a study has to be performed, the data obtained in accordance with Section 9 shall be used.

For the estimation of exposure of organisms, all information on the plant protection product and on the active substance shall be taken into account. A tiered approach shall start with default worst-case parameters for exposure and be followed by a parameter refinement based on the identification of representative organisms. Where relevant, the parameters set out in this Section shall be used. Where it appears from available data that the plant protection product is more toxic than the active substance, the toxicity data for the plant protection product shall be used for the calculation of appropriate risk quotients (see point 8 of this introduction).

5. The requirements laid down in this Section shall include certain study types that are set out in Section 8 of Part A of the Annex to Regulation (EU) No 283/2013 (such as standard laboratory tests with birds, aquatic organisms, bees, arthropods, earthworms, soil micro-organisms, soil meso-fauna and non-target plants). While each point shall be addressed, experimental data with a plant protection product shall be generated only if its toxicity cannot be predicted on the basis of data on the active substance. It may be sufficient to test the plant protection product with that species of a group that was most sensitive with the active substance.

6. A detailed description (specification) of the material used as provided for in accordance with point 1.4 shall be provided.

7. In order to facilitate the assessment of the significance of test results obtained, the same strain of each species shall, where possible, be used in the various toxicity tests specified.

8. The ecotoxicological assessment shall be based on the risk that the proposed plant protection product poses to non-target organisms. In carrying out a risk assessment, toxicity shall be compared with exposure. The general term for the output from such a comparison is ‘risk quotient’ (RQ). RQ may be expressed in several ways, for example, toxicity:exposure ratio (TER) and as a hazard quotient (HQ).

9. For those guidelines which allow for study to be designed to determine an effective concentration (EC x), the study shall be conducted to determine an EC 10 and EC 20 along with corresponding 95 % confidence intervals. If an EC x approach is used, a NOEC shall still be determined.

Existing acceptable studies that have been designed to generate a NOEC shall not be repeated. An assessment of the statistical power of the NOEC derived from those studies shall be carried out.

10. For solid formulations an assessment of the risk from dust drift on to non-target arthropods and plants shall be required. Details on the likely exposure levels shall be presented in accordance with Section 9 of this Annex. For aquatic life, the risk of movement of the whole particle as well as dust particles shall be considered. Until agreed dust dissipation rate assessments are available likely exposure levels shall be used in the risk assessment.

11. Higher tier studies using a plant protection product shall be designed and data analysed using suitable statistical methods. Full details of the statistical methods shall be reported. Where appropriate, higher tier studies shall be supported by chemical analysis to

verify exposure has occurred at an appropriate level.

12. Pending the validation and adoption of new studies and of a new risk assessment scheme, existing protocols shall be used to address the acute and chronic risk to bees, including those on colony survival and development, and the identification and measurement of sub-lethal effects in the risk assessment.

Effects on arthropods
(284/2013; 10.3)

Effects on bees
(284/2013; 10.3.1.)

10.3.1. Effects on bees

The possible effects on bees shall be investigated except where the plant protection product is for exclusive use in situations where bees are not likely to be exposed such as:
(a) food storage in enclosed spaces;
(b) non-systemic plant protection products for application to soil, except granules;
(c) non-systemic dipping treatments for transplanted crops and bulbs;
(d) wound sealing and healing treatments;
(e) non-systemic rodenticidal baits;
(f) use in greenhouses without bees as pollinators.

Testing shall be required if:
— the plant protection product contains more than one active substance,
— the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance tested, in accordance with the requirements set out in points 8.3.1 and 8.3.2 of Part A of the Annex to Regulation (EU) No 283/2013.

For seed treatments the risk from drift of dust during drilling of the treated seed shall be taken into account. As regards granules and slug pellets the risk from drift of dust during application shall be taken into account. If the plant protection product is systemic and to be used on seeds, bulbs, roots, applied directly to soil, for example sprayed on to soil, granules/pellets applied to soil, irrigation water, or applied directly to or into the plant, for example by spraying or stem injection, then the risk to bees foraging those plants shall be assessed, including the risk deriving from residues of the plant protection product in nectar, pollen and water, including guttation.

Where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, shall be conducted.

Where exposure of bees to residues in nectar, pollen or water resulting from systemic properties of the active substance may occur and where the acute oral toxicity is < 100 µg/bee or a considerable toxicity for larvae occurs, residues concentrations in these matrices shall be provided and the risk assessment shall be based on a comparison of the relevant endpoint with those residue concentrations. If this comparison indicates that an exposure to toxic levels cannot be excluded, effects shall be investigated with higher tier tests.

Acute toxicity to bees
(284/2013; 10.3.1.1)

10.3.1.1. Acute toxicity to bees
Where bee acute testing with the plant protection product is required, both acute oral and contact toxicity tests shall be conducted.

Acute oral toxicity
(284/2013; 10.3.1.1.1)

10.3.1.1.1. Acute oral toxicity

A test for acute oral toxicity shall be provided establishing the acute LD_{50} values together with the NOEC. Sub-lethal effects, if observed, shall be reported.

Test conditions
Results shall be presented in terms of µg plant protection product/bee.

Result:
→ LD_{50} (oral)

Acute contact toxicity
(284/2013; 10.3.1.1.2.)

10.3.1.1.2. Acute contact toxicity

A test for acute contact toxicity shall be provided establishing the acute LD_{50} values together with the NOEC. Sub-lethal effects, if observed, shall be reported.

Test conditions
Results shall be presented in terms of µg plant protection product/bee.

Result:
→ LD_{50} (contact)

Chronic toxicity to bees
(284/2013; 10.3.1.2.)

10.3.1.2. Chronic toxicity to bees

A test for chronic toxicity to bees shall be provided establishing the chronic oral EC_{10}, EC_{20}, EC_{50} together with the NOEC. Where the chronic oral EC_{10}, EC_{20}, EC_{50} cannot be estimated, an explanation shall be provided. Sub-lethal effects, if observed, shall be reported.

Circumstances in which required
The test shall be carried out where bees are likely to be exposed.

Test conditions
Results shall be presented in terms of µg plant protection product/bee.

Effects on honey bee development and other honey bee life stages
(284/2013; 10.3.1.3)

10.3.1.3. Effects on honey bee development and other honey bee life stages

A bee brood study shall be conducted to determine effects on honey bee development and brood activity.

The bee brood test shall provide sufficient information to evaluate possible risks from the plant protection product on honey bee larvae.

The test shall provide the EC_{10}, EC_{20} and EC_{50} for adult bees/larvae (or an explanation if they cannot be estimated) together with the NOEC. Sub-lethal effects, if observed, shall be reported.

Sub-lethal effects
(284/2013; 10.3.1.4)

10.3.1.4. Sub-lethal effects

Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees and, where applicable, on colonies may be required.

Cage and tunnel tests
(284/2013; 10.3.1.5.)

10.3.1.5. Cage and tunnel tests

The test shall provide sufficient information to evaluate:
— possible risks from the plant protection product for bee survival and behaviour, and
— impact on bees resulting from feeding on contaminated honey dew or flowers.

Sub-lethal effects shall be addressed, if necessary, by carrying out specific tests (for example foraging behaviour).

Circumstances in which required
When acute or chronic effects on colony survival and development cannot be ruled out, further testing shall be required especially if effects are observed in the honeybee brood feeding test (see point 8.3.1.3 of Part A of the Annex to Regulation (EU) No 283/2013) or if there are indications for indirect effects such as delayed action, effects on juvenile stages, or modification of bee behaviour; or other effects such as prolonged residual effects; in those cases cage/tunnel tests shall be carried out and reported.

Test conditions
The test shall be carried out using healthy queen-right honey bee colonies in which pathogens are low and regularly monitored.

Field tests with honeybees
(284/2013; 10.3.1.6)

10.3.1.6. Field tests with honeybees

The test shall have an adequate statistical power and shall provide sufficient information to evaluate possible risks from the plant protection product on bee behaviour, colony survival and development.

Sub-lethal effects shall be addressed, if necessary by carrying out specific tests (for example homing flight).
Circumstances in which required
When acute or chronic effects on colony survival and development cannot be ruled out, further testing shall be required if:
— effects are observed in the honeybee brood feeding test (see point 8.3.1.3 of Part A of the Annex to Regulation (EU) No 283/2013), or
— there are indications for indirect effects such as delayed action, effects on juvenile stages, or modification of bee behaviour or other effects such as prolonged residual effects.

In those cases field tests shall be carried out.
Test conditions
The test shall be carried out using healthy queen-right honey bee colonies in which pathogens are low and regularly monitored.

Test guideline
The design of higher tier studies to be used shall be discussed with the relevant competent authorities.

1.2.3 Data requirements for metabolites

Standard laboratory tests are normally not required for metabolites. Metabolites that are the actual active molecule may be exceptions. See the general part 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 Ecology [4].

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as LD_{50}(oral)) are presented in a list of endpoints (see Appendix B to Chapter 7). Risk assessment is based on testing against endpoints.

1.4 Approval

1.4.1 Approval of the active substance

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

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

an active substance. The texts specifically applicable to the aspect bees are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites
Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

3.8. Ecotoxicology

3.8.1. An active substance, safener or synergist shall only be approved if the risk assessment demonstrates risks to be acceptable in accordance with the criteria laid down in the uniform principles for evaluation and authorisation of plant protection products referred to in Article 29(6) under realistic proposed conditions of use of a plant protection product containing the active substance, safener or synergist. The assessment must take into account the severity of effects, the uncertainty of the data, and the number of organism groups which the active substance, safener or synergist is expected to affect adversely by the intended use.

3.8.3. An active substance, safener or synergist shall be approved only if it is established following an appropriate risk assessment on the basis of Community or internationally agreed test guidelines, that the use under the proposed conditions of use of plant protection products containing this active substance, safener or synergist:
- will result in a negligible exposure of honeybees, or
- has no unacceptable acute or chronic effects on colony survival and development, taking into account effects on honeybee larvae and honeybee behaviour.

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 [10]. These are the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.
The specific principles Environmental effects, part Effect on species that are no target species are as regards honeybees in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.3. Member States shall evaluate the possibility of exposure of honeybees to the plant protection product under the proposed conditions of use; if this possibility exists they shall evaluate the short-term and long-term risk to be expected for honeybees after use of the plant protection product according to the proposed conditions of use.
(a) This evaluation will take into consideration the following information:
(i) the specific information on toxicity to honeybees as provided for in the Annex to Regulation (EU) No 544/2011 and the results of the evaluation thereof;
(ii) other relevant information on the active substance such as:

- solubility in water,
- octanol/water partition coefficient,
- vapour pressure,
- photodegradation rate and identity of breakdown products,
- mode of action (e. g. insect growth regulating activity);

(iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011, including the toxicity to honeybees;

(iv) where relevant, other authorized uses of plant protection products in the area of envisaged use, containing the same active substance or which give rise to the same residues;

(b) This evaluation will include:

(i) the ratio between the maximum application rate expressed in grammes of active substance per hectare and the contact and oral LD50 expressed in ìg of active substance per bee (hazard quotients) and where necessary the persistence of residues on or, where relevant, in the treated plants;

(ii) where relevant, the effects on honeybee larvae, honeybee behaviour, colony survival and development after use of the plant protection product according to the proposed conditions of use.

1.4.3 Decision making for plant protection products

The principles for decision making as regards the effects on the environment are presented in Commission Regulation (EU) No 546/2011. These are the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.
The specific principles Environmental effects, part Effect on species that are no target species are as regards honeybees in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011.

2.5.2.3. Where there is a possibility of honeybees being exposed, no authorization shall be granted if the hazard quotients for oral or contact exposure of honeybees are greater than 50, unless it is clearly established through an appropriate risk assessment that under field conditions there are no unacceptable effects on honeybee larvae, honeybee behaviour, or colony survival and development after use of the plant protection product according to the proposed conditions of use.

1.5 Developments

In May 2012, 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) [11]. A Guidance document for bees based on this scientific opinion is currently being developed. A first draft has already been open for public consultation. In its current state, the guidance document is not suitable to use for risk assessment.

When the final guidance document is available (expected spring 2013) this manual will be updated.

While waiting for harmonised EU guidance, NL has collated information to aid the risk assessment for bees in the Netherlands:
A list indicating for all crops whether they are attractive to honeybees was developed in 2011 (published on www.ctgb.nl at 30/03/2012) 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 (published on www.ctgb.nl at 15/10/2010) and is attached to the NL

part of this Evaluation Manual.

2 APPENDICES

None

3 REFERENCES

1 Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte

2 Directive 91/414/EEC, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte

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