

DATA REQUIREMENTS AND RISK ASSESSMENT FOR BEES

National approach for Belgium



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Version (publication date)	Changes compared to the previous version
Version 2.4 (04/09/2020)	<i>Change of the factor used to determine whether the acute oral toxicity of a formulated product is comparable to that of the active substance from 5 to 3, in line with what was agreed at Pesticides Peer Review Meeting 185 (see EFSA Supporting publication 2019:EN-1673 for details)</i>
Version 2.3 (04/04/2019)	<i>Adaptation of e-mail address. Adaptation of instruction for mutual recognition.</i>
Version 2.2 (07/02/2018)	<i>Compared to Version 2.1, the list of acceptable test methods in Appendix A was updated, following the publication on 09-10-2017 of the final version of the following OECD Test Guidelines:</i> <ul style="list-style-type: none"> - <i>OECD Test Guideline 245: Honeybee chronic toxicity test (10-day feeding)</i> - <i>OECD Test Guideline 246: Bumblebee acute contact toxicity test</i> - <i>OECD Test Guideline 247: Bumblebee acute oral toxicity test</i> <i>The final versions of these test guidelines replace the draft versions referenced in the previous version of the current document.</i>
Version 2.1 (27/06/2017)	<i>The initial document (Version 1.0) was updated and restructured following a request from the industry for clarification on a number of points. Further, the Belgian Authorisation Committee agreed on 27/06/2017 to adapt the implementation date of the approach and to specify a number of transitional measures.</i>
Version 1.0 (25/01/2017)	<i>Initial version of the document</i>

1 Background

According to Regulation (EU) No. 284/2013, chronic toxicity studies for adult honeybees and honeybee larvae should be submitted as part of the application dossier for a plant protection product, in addition to acute toxicity studies. Further, this Regulation also implies that studies with other bee species (bumblebees and solitary bees) are required. The risk assessment scheme described in the currently agreed guidance document for the risk assessment for bees (the SANCO guidance document on terrestrial ecotoxicology – SANCO/10329/2002), however, only takes into account acute toxicity data on honeybees. In contrast, the new EFSA guidance document for bees (EFSA, 2013)¹ contains a risk assessment scheme for the chronic risk to adult honeybees and honeybee larvae, and for the risk to bumblebees and solitary bees. However, there has not yet been a take note of this guidance document in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). Consequently, it is currently not completely clear whether studies with bumblebees and solitary bees should be submitted as part of a registration dossier, and how the available data on the chronic toxicity to adult honeybees and honeybee larvae and the risk to bumblebees and solitary bees should be used in the risk assessment.

For the assessment of active substances at EU level, it was agreed by EFSA and ecotoxicology experts of different Member States to perform a Tier 1 risk assessment for chronic risk to adult honeybees and honeybee larvae according to the scheme described in the EFSA guidance document for bees (refer to the technical report of Pesticides Peer Review Expert Meeting 133²). For the authorisation of plant protection products, this issue has however not yet been discussed at the zonal level. It is thus unclear how chronic honeybee studies and studies with bumblebees and solitary bees should be used in the risk assessment for zonal authorisations.

To clarify these issues for the Belgian ecotoxicology experts and for applicants, a national approach was proposed, which was accepted by the Belgian Authorisation Committee on 08-11-2016. This document describes this national approach, and provides an overview of:

1. **The exact data requirements**, i.e. which studies with bees (honeybees, bumblebees and solitary bees) that need to be submitted as part of an application for authorisation of a plant protection product in Belgium.
2. **How the risk assessment should be performed**, i.e. which guidance documents need to be used in the risk assessment for bees in the product evaluation for Belgium

¹ EFSA (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295. doi:10.2903/j.efsa.2013.3295

² EFSA (2015). Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp.

It should be noted that this national procedure was drawn up because there has not been any recent progress in the discussion regarding the EFSA guidance document for bees at EU level. Further, from a scientific point of view, it is not acceptable to ignore available robust toxicity data on vulnerable non-target species simply because there is no generally accepted risk assessment guideline. This national procedure is considered a temporary solution, until there is agreement on a harmonized approach within the central zone or within the EU. BE will fully support any discussion to come to such a harmonized approach for bees.

2 Scope, implementation date and transitional measures

Which studies need to be present in an application dossier for a plant protection product depends on the European regulation regarding the data requirements that applies to that dossier. For dossiers to which the former data requirements (Regulation (EU) No. 545/2011) apply³, the problem for bees as outlined under Section 1 is not relevant: only acute toxicity data on honeybees are required, which can be assessed based on the SANCO guidance document on terrestrial ecotoxicology (SANCO/10329/2002). The current document consequently does not apply to this kind of dossiers. It is only relevant for dossiers to which the new data requirements (Regulation (EU) No. 284/2013) apply⁴.

The required studies and risk assessment **protocol as described below applies in principle to all types of applications**, regardless of whether it is an application for a national or a zonal authorisation, and regardless of whether BE is zRMS or cMS. For applications for **mutual recognition** the same national data requirements and transitional measures apply but the date of submission of the application in the original member state is used as the reference date.

Initially, the Belgian Authorisation Committee decided that the data requirements and risk assessment procedure outlined in this document would apply to applications submitted after 01/02/2018. However, due to the limited duration of the honeybee testing season (march to august only) and the limited capacity of the specialized testing facilities, it will likely not be possible to submit the requested studies for all products by that time. Therefore, the Belgian Authorisation Committee decided on 27/06/2017 to delay the **implementation date**, depending on the expected level of concern for bees (i.e. a faster implementation for insecticides compared to herbicides and fungicides).

1. **Insecticides:** The data requirements specific for Belgium and procedure for risk assessment apply to new zonal applications (both for which BE is zRMS or cMS) submitted in BE after **01/01/2019**.
2. **Fungicides:** The data requirements specific for Belgium and procedure for risk assessment apply to new zonal applications (both for which BE is zRMS or cMS) submitted in BE after

³ These are dossiers for authorisation of plant protection products submitted before 31/12/2015, and for which the product for which authorisation is sought contains at least one active substance for which the dossier for (re-) authorisation at EU level was submitted before 31/12/2013. More information on the transitional measures is given in SANCO/11509/2013 rev. 5.2.

⁴ In general, these are dossiers for authorisation of plant protection products submitted after 31/12/2015, or for which the product for which authorisation is sought contains an active substance for which the dossier for (re-) authorisation at EU level was submitted after 31/12/2013. More information on the transitional measures is given in SANCO/11509/2013 rev. 5.2.

01/01/2019, unless it can be demonstrated that the active substance is of low concern to bees based on the acute toxicity, the mode of action (e.g. systemicity) and/or data available in published literature. For active substances that can be considered of low concern, the current document applies only to applications submitted in BE after **01/01/2020**.

3. **Herbicides and any other plant protection products:** The data requirements specific for Belgium and procedure for risk assessment apply to new zonal applications (both for which BE is zRMS or cMS) submitted in BE after **01/01/2020**.

Note that the implementation date above only refers to the data requirements listed in Section 3 which are specific for Belgium, and to the risk assessment procedure outlined in Section 4. For all types of plant protection products (insecticides, herbicides and fungicides) the European data requirements according to Regulation (EU) No. 284/2013 need to be fulfilled, in line with the transitional measures mentioned in article 4 of this regulation (i.e. Regulation (EU) No. 284/2013 applies to all applications submitted after 31/12/2015, with some exceptions as explained in detail in SANCO/11509/2013 rev. 5.2⁵).

Due to the discrepancy in the date of the entry into force of Regulation (EU) No. 284/2013 (01/01/2016) and the present national document (01/01/2019 or 01/01/2020), the Belgian Authorisation Committee agreed to take the following **transitional measures** into account, which **apply to dossiers that have to be in line with Regulation (EU) No. 284/2013 and are submitted in BE from 01/01/2016 to the date of entry into force of this document (see above):**

1. The data requirements for bees as listed in Section 10.3.1 of Part A of the Annex to Regulation (EU) No. 284/2013 are considered mandatory and need to be addressed. All studies available in the dossier will be summarized and evaluated in the core assessment of the draft Registration Report (dRR).
2. In case studies to address the chronic toxicity to bees (Section 10.3.1.2) or to address effects on honeybee development (i.e. larval toxicity, Section 10.3.1.3) cannot be included in the dossier, a justification needs to be provided.

Provided that all other aspects of the dossier would result in an authorisation of the plant protection product, the absence of these specific bee studies alone will not result in a refusal of the product approval. However, only a provisional product authorisation will be granted for a limited time period of 2 years for insecticides and 3 years for fungicides and herbicides. As a condition for prolongation of the authorisation, the necessary studies to

⁵ SANCO/11509/2013 rev 5.2. Guidance document on the Interpretation of the Transitional Measures for the Data Requirements for Chemical Active Substances and Plant Protection Products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013.

address these specific data requirements need to be submitted, using the preferred test methods listed in Appendix A of the current document.

3. Applicants are encouraged to already include a risk assessment for bees, in line with the procedure outlined in Section 4 of the current document, in their dossier. If such a risk assessment is not available, only a preliminary product authorisation will be granted for a limited time period of 2 years for insecticides and 3 years for fungicides and herbicides. As a condition for prolongation of the authorisation, a risk assessment in line with the procedure outlined in Section 4 of the current document and which demonstrates an acceptable risk to honeybees, needs to be submitted.

3 Data requirements for bees

3.1 General considerations

The data requirements outlined in Section 3.2 below are essentially those listed in Section 10.3.1 of Part A of the Annex to Regulation (EU) No. 284/2013. For some points, small additions or clarifications have been added, specific for the situation in Belgium. These are marked with grey highlight.

The data requirements listed in this document only refer to studies with the plant protection product. For studies with the active substance, reference can be made to the studies available in the EU-dossier for the active substance. When necessary, additional studies with the active substance can be submitted as part of the plant protection product dossier.

Regulation (EU) No. 284/2013 refers to studies on the ‘effects on bees’ in general, and not specifically to honeybees, bumblebees or solitary bees. Nevertheless, the wording implies that not only honeybees but also other bee species should be considered. Therefore, when a suitable test guideline is available to address a data requirement not only for honeybees, but also for other bee species, the relevant studies with non-*Apis* bees should be submitted. Please refer to Section 3.2 and Appendix A for further details.

Commission Communication 2013/C 95/02 contains a list of test methods and guidance documents for each of the data requirements included in Regulation (EU) No. 284/2013. For bees, this list is however not up to date. For example for chronic toxicity to adult honeybees and honeybee larvae, newer and better methods than those described in 2013/95/02 are available. Further, no test guidelines for bumblebees and solitary bees are included. To test the toxicity to honeybee larvae, a final OECD test method for repeated larval exposure is available since July 2016. For chronic toxicity to adult honeybees and for acute toxicity to bumblebees, final OECD test methods have been published in October 2017. Chronic studies with bumblebees and studies with solitary bees are also being developed, but are still in a more premature stage of development. In **Appendix A**, an **overview is given of the most recent test methods and guidelines**, that are considered suitable for addressing the data requirements from Regulation (EU) 284/2013) and the specific data requirements for Belgium.

3.2 Overview of the Data Requirements

Below, an overview of the data requirements for bees is provided, using the numbering of Part A of the Annex to Regulation (EU) No. 284/2013.

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 (for a list of such situations, please refer to Part A of the Annex to Regulation (EU) No. 284/2013). In such situations, an argumentation should be submitted clearly demonstrating that no exposure is expected. When justified, such an argumentation can be used for all relevant bee species (i.e. honeybees, bumblebees and/or solitary bees).

Testing with the plant protection product is required if:

- the plant protection product contains more than one active substance, and
- the toxicity of a plant protection product cannot reliably be 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.

The two above conditions for triggering tests with a plant protection product are considered to be mainly applicable to acute toxicity studies. According to Appendix O of the EFSA guidance document for bees (2013), it is not necessary to perform studies on the chronic toxicity to adult honeybees with the formulated product when the acute oral toxicity of the formulated product is comparable to that of the active substance. Chronic studies performed with the active substance are sufficient in this case. To compare the acute oral toxicity of the active substance and formulated product, a factor of 3 is proposed⁶: if the acute oral endpoint (expressed in terms of active substance) for the formulated product is at least a factor 3 below the endpoint of the active substance, then the toxicity of the formulated product is considered higher. In that case, chronic studies with the formulated product should be submitted.

⁶ The EFSA guidance document for bees (2013) proposes a factor of 5. However, in the Pesticides Peer Review Meeting 185, on general recurring issues in ecotoxicology (9-12 October 2018), it was agreed to apply a factor of 3, as proposed in SANCO/10597/2003 rev. 10.1) and the EFSA guidance document for aquatic organisms (EFSA PPR Panel, 2013), consistently to Tier I studies for all groups of non-target organisms. Therefore, a factor 3 should also be applied for studies with bees. For more details, refer to the EFSA Technical Report on the outcome of this Peer Review Meeting 185 (EFSA Supporting publication 2019:EN-1673. Doi:10.2903/sp.efsa.2019.EN-1673).

From Appendix O it is not clear whether the above applies also to products containing more than one active substance. However, in Chapter 8 of the EFSA guidance document for bees (2013), it is explained how a surrogate endpoint for a mixture of active substances with known toxicity can be calculated, based on the concept of dose additivity. To compare the acute toxicity of the formulation with the toxicity of the active substances, the surrogate endpoint for the mixture should be calculated and be compared to the endpoint obtained from a test with the formulation. If the measured acute endpoint of the mixture is at least a factor 3 below the calculated endpoint for the mixture (both expressed in terms of active substance), it can be considered that the formulation is more toxic than predicted from the toxicity of the individual components. In that case, chronic studies with the formulated product should be submitted. If this is not the case, the toxicity of the formulation can be reliably predicted from the toxicity of the active substances it contains, and a specific chronic toxicity study with the formulation is not required. The risk assessment for chronic risk should then be performed based on the calculated mixture toxicity, based on the endpoints from chronic toxicity studies with the active substances.

Honeybee larvae in a hive are never actually exposed to the formulated product. Therefore, studies on the toxicity of the formulated product to honeybee larvae are not considered required, provided that a study with the active substance is available, which can be used instead.

10.3.1.1 *Acute toxicity to bees*

Where bee acute testing with the plant protection product is required, both the acute oral and contact toxicity tests shall be conducted. A test shall be provided establishing the acute (oral or contact) LD₅₀ values together with the NOEC. Sub-lethal effects, if observed, shall be reported.

Note that the test guideline to test the acute oral and contact toxicity to bumblebees is almost finalized (i.e. has been ring-tested) and is considered suitable for use in practice. Therefore, in addition to acute toxicity studies with **honeybees**, acute studies with **bumblebees** should also be submitted.

10.3.1.2 *Chronic toxicity to bees*

A test for chronic toxicity to bees shall be provided establishing the chronic oral EC₁₀, EC₂₀, EC₅₀ together with the NOEC. Where the chronic oral EC₁₀, EC₂₀, EC₅₀ cannot be estimated, an explanation should be provided. Sub-lethal effects, if observed, shall be reported.

In case a study according to the draft OECD guideline on the chronic toxicity to honeybees (10-day feeding) is available, the LDD₅₀ should be determined as endpoint for this study.

As no agreed or finalised test guideline is available to test the chronic toxicity to bumblebees or solitary bees, chronic toxicity studies with these bee species are not mandatory. Chronic toxicity studies with **honeybees** should however always be submitted.

10.3.1.3 *Effects on honeybee development and other honey bee life stages (= larval toxicity)*

A bee brood study shall be conducted to determine effects on honeybee development and brood activity. The bee brood test shall provide sufficient information to evaluate possible risks from the plant protection product to honeybee larvae. The test shall provide the EC₁₀, EC₂₀, EC₅₀ for adult bees/larvae (or an explanation if they cannot be estimated) together with the NOEC. Sub-lethal effects, if observed, shall be reported.

As no agreed or finalized test guideline is available to test the chronic toxicity to bumblebee or solitary bee larvae, larval toxicity studies with these bee species are not mandatory. Larval toxicity studies with **honeybees** should however always be submitted.

10.3.1.4 *Sub-lethal effects*

Tests investigating sub-lethal effects, such as behavioural and reproductive effects, on bees or colonies may be required according to Regulation (EU) No. 284/2013. However, as there are currently no agreed or finalized test guidelines available to test sub-lethal effects, these studies are not mandatory for the time being.

10.3.1.5 *Cage and tunnel tests*

When acute or chronic effects on honeybee colony survival and development cannot be ruled out based on the available laboratory toxicity tests and the performed Tier 1 risk assessment, cage and tunnel tests shall be carried out.

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

As no agreed or finalized test guideline is available to perform cage and tunnel tests with bumblebees or solitary bees, such studies with these bee species are

not mandatory, even if the Tier 1 risk assessment as described in Section 4 does not demonstrate an acceptable risk. For **honeybees**, cage and tunnel studies shall be submitted when the Tier 1 risk assessment fails.

10.3.1.6 *Field tests with honeybees*

When acute or chronic effects on honeybee colony survival and development cannot be ruled out based on the available laboratory toxicity tests and/or cage and tunnel tests, field tests shall be carried out.

As no agreed or finalized test guideline is available to perform field tests with bumblebees or solitary bees, such studies with these bee species are not mandatory, even if the Tier 1 risk assessment as described in Section 4 does not demonstrate an acceptable risk. For **honeybees**, field studies shall be submitted when the Tier 1 risk assessment fails.

4 Guidance documents to be used for the risk assessment

The currently accepted guidance document for the risk assessment for bees (the SANCO guidance document on terrestrial ecotoxicology - SANCO/10329/2002) does not include a risk assessment scheme to assess the chronic risk to honeybees and the acute and chronic risk to bumblebees and solitary bees. Therefore, it is outlined below how these assessments should be performed.

4.1 Honeybees – Acute risk assessment for adults

A risk assessment scheme for acute toxicity to adult honeybees is included in the SANCO guidance document for terrestrial ecotoxicology (SANCO/10329/2002). As the SANCO guidance document is the currently accepted guidance document, the acute risk assessment (both for oral and contact toxicity) will be performed according to this guidance document. The risk assessment scheme is described in Section 4.2 and 4.3 of SANCO/10329/2002.

4.2 Honeybees – Chronic risk assessment for adults and larvae

A risk assessment scheme to assess the chronic risk to adult honeybees and honeybee larvae is not included in the SANCO/10329/2002 guidance document. However, such a risk assessment scheme is described in the EFSA guidance document for bees (EFSA, 2013; revised July 2014)⁷. Therefore, the chronic risk assessment should in general be performed as described in the EFSA guidance document for bees (revision of 4 July 2014).

In the risk assessment scheme described in the EFSA guidance document for bees, the following routes of exposure are considered:

1. **Contact exposure** from spray deposits or dust particles
2. **Oral exposure** through the consumption of pollen and nectar from:
 - The treated crop,
 - Weeds in the field,
 - Plants in the field margin
 - The adjacent crop
 - Succeeding crop / permanent crop the following year
3. Assessment of **accumulative toxicity**
4. Oral exposure through the consumption of **contaminated water** through:
 - Guttation water
 - Surface water
 - Water in puddles

Contact exposure is only of short duration, and is therefore only relevant for the acute risk assessment. Regarding the accumulative toxicity, no methods/guidelines are currently available for testing potential accumulative effects. Therefore, this will not be considered in the risk assessment for the time being.

According to the EFSA guidance document for bees, the initial tiers of the risk assessment scheme for the risk following exposure through guttation water are very conservative and precautionary, due to uncertainty in the degree to which guttation occurs, the degree to which honey bees forage guttation fluid and the use of guttation fluid in royal jelly and other brood food. As a consequence, it is likely that this will result in many failures at the lower tiers and the need for higher tier studies. Further, in the confirmatory data package for bees for the neonicotinoid active substances clothianidin and imidacloprid, higher tier studies on the effect of contaminated

⁷ EFSA (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295. doi:10.2903/j.efsa.2013.3295

guttation fluid on honeybees are available (see EFSA 2016a⁸ and b⁹). Beside some temporal slight tendency of higher mortality compared to the control in some studies, no apparent effects on the honeybee colonies were observed. Further, bees using guttation were only rarely observed. Therefore, the experts at Pesticides Peer Review Meeting 145 agreed that the risk from exposure to residues in guttation fluids can be considered of low concern for the uses and crops under concern in the available studies. Since some questions were raised regarding the robustness of these studies to assess the effects, it was however not considered appropriate to extrapolate this conclusion to other uses and active substances. Nevertheless, taking into account all of the above, it is not required to perform a risk assessment for exposure through guttation water for product authorisation for the time being.

For the risk from exposure through the consumption of surface water and puddle water, experience from the assessment of active substance with a high toxicity to bees shows that the exposure and risk for these scenarios can also be considered of relatively low relevance. Therefore, a risk assessment for these exposure scenarios does not need to be performed for the authorisation of plant protection products for the time being.

Overall, **only oral exposure through the consumption of pollen and nectar currently have to be considered in the chronic risk assessment**. It should be noted that the EFSA guidance document for bees also states that a risk assessment for effects on the development of the hypopharyngeal glands (HPG) should be performed. However, as there is currently no validated methodology for the assessment of sublethal effects, this will not be considered in the risk assessment for the time being.

The assessment scheme described in the EFSA guidance document for bees starts with a screening step, which is based on the worst-case scenario (which for honeybees is the treated crop). If the screening step scenario fails then all other scenarios have to be assessed in the first tier unless it is justified that a specific scenario is not relevant because exposure is expected to be negligible.

If the **treated crop** is not attractive to bees, then the treated crop scenario does not need to be assessed. A list of bee attractive crops is provided in Appendix D of the EFSA guidance document for bees. Further, the growth stage of the treated crop needs to be considered. If the application occurs after flowering (from BBCH 70 onwards) then the crop is not attractive for bees. Similarly, if a crop is harvested before flowering, it can also be considered not attractive to bees. In both

⁸ EFSA (2016a). Peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted. EFSA Journal 2016;14(11):4606. Doi:10.2903/j.efsa.2016.4606

⁹ EFSA (2016b). Peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted. EFSA Journal 2016;14(11):4607. Doi:10.2903/j.efsa.2016.4607

cases, the exposure from foraging on the treated crop is negligible. A standard risk assessment is then however still needed for all other relevant scenarios (e.g. weeds in the treated crop).

In the first tier, it is assumed that bees may fly on flowering **weeds in the field**. The EFSA guidance document states that if less than 10% of the area of use of a substance is covered by weeds at the application time, no weeds will occur in the 90th percentile case and thus their exposure can be ignored (see Appendix N of the EFSA Guidance Document). In the Netherlands, it is assumed that when more than two flowering weeds per square meter are present, the flowering weed cover is sufficient to attract foraging honeybees. If the number of flowering weeds is lower, exposure can be considered negligible (refer to the ctgb Evaluation manual for the authorisation of plant protection products, version 2.1, October 2016¹⁰). In the higher tier, information can thus be used about the likelihood of a large amount of flowering weeds in a crop under normal agricultural practice, to address the relevance of this scenario. For example, a large dataset from efficacy trials (Maynard *et al.*, 2015¹¹) suggests that the presence of a large number of flowering weeds is not expected for many crops under normal agricultural practices. For perennial crops (e.g. grassland, orchards, vineyards), the data from the herbicide efficacy trials however show that flowering weeds are more abundant in these crops.

The scenario '**succeeding crop / permanent crop in the following year**' is in general considered only relevant for substances which are both systemic and persistent, as only such substances are likely to be present in the nectar and/or pollen of succeeding flowering crops. According to the EFSA guidance document, there is no need to perform an assessment for this scenario for substances with a DegT50 of less than 2 days for applications within the same year, and less than 5 days for applications in different years (for details see Appendix N of the EFSA guidance document for bees). Regarding systemicity, it is stated in the EFSA guidance document for bees that no clear definition exists which could be used as a trigger for the assessment of the risk from foraging the following year on a permanent crop or on the succeeding crop. Therefore, this will be evaluated on a case-by-case basis.

¹⁰ Evaluation manual for the authorisation of plant protection products and biocides according to Regulation (EC) No 1107/2009 – NL Part. Chapter 7 Ecotoxicology: terrestrial; bees. Version 2.1; October 2016. Available for download from <http://ctgb.nl/docs/default-source/gewas.-toetsingskader/evaluation-manual-v2.1/nl-part-v2.1/g-7-ecotox-terrestrial-bees-nl-em2-1-alg.pdf?sfvrsn=2>

¹¹ Maynard *et al.* (2015). Weeds in the treated field – a realistic scenario for pollinator risk assessment? Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, Ghent (Belgium), September 15-17, 2014, 56 Julius-Kühn-Archiv, 450.

Table 1. Overview of the different sections of the EFSA guidance document for bees that have to be taken into account in the chronic risk assessment for adult honeybees and honeybee larvae.

Exposure route	Risk assessment step	Reference to the EFSA Guidance Document (revision of 4 July 2014)	
		Spray applications	Solid applications
Oral exposure from pollen and nectar	Screening step	Chapter 3.2.2 Table 3	Chapter 3.3.2 Table 7
	Tier 1 ^{a,b}	Chapter 3.2.2 Table 5 - Ef-values from tables X1a and X2a as appropriate for the relevant scenario - SV-values from Tables Jx and Jy as appropriate for the relevant scenario	Chapter 3.3.2 Table 9 - Ef values from Table X1b, X1c and X2 as appropriate for the relevant scenario - SV-values from Tables Jxx and Jyy as appropriate for the relevant scenario
	Higher tier	- Consider risk mitigation measures - Consider refinement of exposure estimate - Risk assessment based on (semi-)field studies (expert judgement)	- Consider risk mitigation measures - Consider refinement of exposure estimate - Risk assessment based on (semi-)field studies (expert judgement)
Exposure from guttation water		Chapter 3.5.1	Chapter 3.5.1
Exposure from surface water		Chapter 3.5.2	Chapter 3.5.2
Exposure from puddle water		Chapter 3.5.3	Chapter 3.5.3

^a should be performed for all relevant exposure scenarios; ^b can only be performed based on endpoints derived from the newly developed OECD laboratory studies. In case only other acceptable studies are available, a higher tier assessment is directly performed based on the outcome of these studies.

In Table 1, an overview is given of the different sections in the EFSA guidance document that have to be used in the chronic risk assessment for adult honeybees and honeybee larvae. As stated above, the risk assessment starts with a screening step. If the screening step fails, a Tier 1 assessment has to be performed. If no acceptable risk is demonstrated at Tier 1, a higher tier assessment needs to be performed. For this higher tier assessment, additional studies may not always be necessary, as risk mitigation measures may be sufficient to reduce the risk to an acceptable level and still maintain the usefulness of the product (refer to Chapter 9 of the EFSA guidance document). Further, it may be sufficient to replace one of the default exposure values

with a 'real' figure that is relevant to the product, use and exposure scenario before running a higher tier study (e.g. a field study). Finally, when higher tier effect studies are performed, it may not be necessary to carry out a higher tier study for every use or crop combination as it may be possible to read across from existing studies. If this approach is used, then it is necessary to ensure that the exposure in terms of both concentrations (in nectar and/or pollen) and duration is appropriate.

4.3 Bumblebees – acute risk assessment for adults

A risk assessment scheme to assess the acute risk to bumblebees is not included in the SANCO/10329/2002 guidance document. However, such a risk assessment scheme is described in the EFSA guidance document for bees (EFSA, 2013; revised July 2014)¹². Therefore, the acute risk assessment for bumblebees should in general be performed as described in the EFSA guidance document for bees (revision of 4 July 2014).

According to the EFSA guidance document for bees, the same exposure routes as listed in Section 4.2 for honeybees are relevant for bumblebees. Regarding the accumulative toxicity, no methods/guidelines are currently available for testing potential accumulative effects. Therefore, this will not be considered in the risk assessment for the time being. As for bees, an assessment for exposure to contaminated water does not need to be performed for bumblebees for the time being. Overall, **only contact exposure and oral exposure through the consumption of pollen and nectar have to be considered in the acute risk assessment for bumblebees.**

The assessment scheme described in the EFSA guidance document for bees starts with a screening step, which is based on the worst-case scenario (which for bumblebees is the risk from weeds in the treated field). If the screening step scenario fails then all other scenarios have to be assessed in the first tier unless it is justified that a specific scenario is not relevant because exposure is expected to be negligible. In Section 4.2, some guidance is given regarding on how the relevance of specific scenarios can be addressed.

In Table 2, an overview is given of the different sections in the EFSA guidance document that have to be used in the acute risk assessment for bumblebees. It should be noted that if an acceptable risk could not be demonstrated at the screening step and Tier 1, the assessment scheme in the

¹² EFSA (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295. doi:10.2903/j.efsa.2013.3295

EFSA guidance document provides the option to perform a higher tier assessment based on e.g. (semi-)field effect studies. For bumblebees, it is currently however not possible to perform such a higher tier assessment, as there are currently no agreed test methods for (semi-)field studies with bumblebees. Therefore, failure of the acute Tier 1 assessment for bumblebees will not result in a non-approval of the product. Although there are important differences in biology between bumblebees and honeybees, for the time being, reference can be made to the risk assessment for honeybees. If the product passes the conservative honeybee risk assessment, it can be considered to be protective for the acute risk to bumblebees¹³. In case there is still a concern, risk mitigation measures can also be proposed.

Table 2. Overview of the different sections of the EFSA guidance document for bees that have to be taken into account in the acute risk assessment for bumblebees.

Exposure route	Risk assessment step	Reference to the EFSA Guidance Document (revision of 4 July 2014)	
		Spray applications	Solid applications
Contact exposure	Screening step	Chapter 3.2.1 Table 2	Chapter 3.3.1 Table 6
	Tier 1 ^a	Chapter 3.2.1 Table 2 <i>f_{dep}</i> from Table H1a	Chapter 3.3.1 Table 6 <i>f_{dep}</i> from Table H1b
Oral exposure from pollen and nectar	Screening step	Chapter 3.2.2 Table 3	Chapter 3.3.2 Table 7
	Tier 1 ^a	Chapter 3.2.2 Table 5 - Ef-values from tables X1a and X2a as appropriate for the relevant scenario - SV-values from Tables Jx and Jy as appropriate for the relevant scenario	Chapter 3.3.2 Table 9 - Ef values from Table X1b, X1c and X2 as appropriate for the relevant scenario - SV-values from Tables Jxx and Jyy as appropriate for the relevant scenario

^a should be performed for all relevant exposure scenarios

¹³ This does however not mean that a risk assessment for bumblebees is not necessary if an acceptable risk to honeybees is demonstrated. The studies as specified in section 3.2 need to be submitted, and a Tier I risk assessment as described in the present section is to be performed.

4.4 Bumblebees – chronic risk assessment / Solitary bees – acute and chronic risk assessment

Currently, no agreed test guidelines are available to address the chronic toxicity to bumblebees and the acute and chronic toxicity to solitary bees. Consequently, such toxicity studies are not required for the time being (see Section 3), and a risk assessment is not performed.

Note that the EFSA guidance document for bees (2013) suggests that, in case no endpoint is available for bumblebees or solitary bees, a risk assessment can still be performed using an estimated endpoint. This estimated endpoint is determined by dividing the respective endpoint for honeybees by a factor of 10. However, the applied safety factor of 10 is still under discussion. Therefore, it is currently not considered expedient to perform a risk assessment based on such an estimated endpoint.

5 Disclaimer for Registration Report

In the (draft) Registration Report for the plant protection product the following text will be included, to briefly explain the rationale for the national procedure used in the risk assessment for bees:

*The risk assessment for acute effects on bees is conducted in accordance with the Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002). Following the data requirement according to Regulation (EU) No. 284/2013, data on the chronic risk to adult honeybees and honeybee larvae are available. Further, data on the acute risk to bumblebees have been submitted. However, in the currently notified SANCO Guidance Document, these data are not considered in the risk assessment scheme. A new guidance document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) has been published in 2013 by EFSA, in which risk assessment schemes for the chronic risk to adult honeybees and honeybee larvae, and for the risk to bumblebees are described. Although this Guidance Document is not yet noted by the Standing Committee on Plants, Animals, Food and Feed, a risk assessment for the chronic risk to honeybees and for the acute risk bumblebees according to the new EFSA Guidance Document is included below. That way, all available data on bees is taken into account in a risk assessment.*

Appendix A – Acceptable test methods/ guidelines to address the data requirements for bees

Below, an overview is given of the test methods/guidelines that are considered suitable for addressing the data requirements from point 10.3.1 of Part A of the Annex to Regulation (EU) No. 284/2013, and the additional data requirements for Belgium outlined in Section 3. This list can be considered an update of Commission Communication 2013/C 95/02, and includes newly developed laboratory test guidelines for honeybees and bumblebees.

Note that for the acute risk test guidelines for honeybees and bumblebees are included, while for the chronic risk and the risk to larvae only test methods for honeybees are mentioned. For bumblebees, currently no agreed test method for addressing the chronic risk is available. Similarly, agreed test methods for solitary bees (both for the acute and chronic risk) are not yet available.

All methods/guidelines included in the table below are considered acceptable for addressing the data requirements. However, for some points more than one test methods for the same bee species is mentioned (i.e. the method/guideline included in Commission Communication 2013/C 95/02 and a newly developed OECD guideline). When this is the case, studies according to the more recent laboratory methods are preferred, as these are the only studies from which an endpoint for use in a Tier 1 risk assessment according to EFSA (2013)¹⁴ can be derived. **In case new studies have to be generated, they should be performed according to the new OECD guidelines.** When more than one test method is available, the preferred method/guideline is highlighted by means of grey shading.

¹⁴ European Food Safety Authority (2013). Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013; 11(7):3295. doi:10.2903/j.efsa.2013.3295

Reference to Part A of the Annex to regulation (EU) No. 284/2013	Test methods
10.3.1.1 Acute toxicity to bees	-
10.3.1.1.1 Acute oral toxicity	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - OECD Test Guideline 213: Honeybees, acute oral toxicity test - EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees <p><i>Bumblebees:</i></p> <ul style="list-style-type: none"> - OECD Test Guideline 247: Bumblebee, acute oral toxicity test (October 2017)¹⁵
10.3.1.1.2 Acute contact toxicity	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - OECD Test Guideline 214: Honeybees, acute contact toxicity test - EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees <p><i>Bumblebees:</i></p> <ul style="list-style-type: none"> - OECD Test Guideline 246: Bumblebee, acute contact toxicity test (October 2017)¹⁶
10.3.1.2 Chronic toxicity to bees	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - OECD Test Guideline 245: Honeybee chronic toxicity test (10-day feeding) (October 2017)¹⁷ - Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. Redia XC: 87-90 - Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.

¹⁵ To download from:

<http://www.oecd-ilibrary.org/docserver/download/9717511e.pdf?expires=1518002057&id=id&accname=guest&checksum=F670DA4924672DA152769230E86A0C4E>

¹⁶ To download from:

<http://www.oecd-ilibrary.org/docserver/download/9717501e.pdf?expires=1518002005&id=id&accname=guest&checksum=A87D2B0C33AB33EB5E3FEEB8B4B8BDE1>

¹⁷ To download from:

<http://www.oecd-ilibrary.org/docserver/download/9717481e.pdf?expires=1518002087&id=id&accname=guest&checksum=34E1D63F82D4EE0DC39828C541D494BD>

Reference to Part A of the Annex to regulation (EU) No. 284/2013	Test methods
<p>10.3.1.3 Effect on honeybee development and other honeybee life stages</p>	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - OECD Guidance Document 239 on Honey Bee Larval Toxicity Test following Repeated Exposure¹⁸ - OECD Guidance Document 75 on the honeybee (<i>Apis mellifera</i> L.) brood test under semi-field conditions - Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honey bee brood. Redia XC: 87-90 - Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.
<p>10.3.1.4 Sub-lethal effects ¹</p>	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - Oomen PA, de Ruijter A and van der Steen J, 1992. Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616. - OECD Guidance Document 75 on the honeybee (<i>Apis mellifera</i> L.) brood test under semi-field conditions
<p>10.3.1.5 Cage and tunnel tests</p>	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees
<p>10.3.1.6 Field tests with honeybees</p>	<p><i>Honeybees:</i></p> <ul style="list-style-type: none"> - EPPO Standard PP1/170 (4) Test methods for evaluating the side-effects of plant protection products on honeybees

¹ Data requirement according to Regulation (EU) No. 284/2013, but it is currently not considered mandatory to address this specific point for plant protection products

¹⁸ To download from:

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2016\)34&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2016)34&doclanguage=en)
www.fytoweb.be