CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering the uses as seed treatments and granules

European Food Safety Authority (EFSA)

Abstract

The EFSA was asked by the European Commission to perform an updated risk assessment of neonicotinoids, including imidacloprid, as regards the risk to bees, as a follow-up of previous mandates received from the European Commission on neonicotinoids. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. In this context and in accordance with Article 31 of Regulation (EC) No 178/2002, EFSA has been previously asked by the European Commission to organise an open call for data in order to collect new scientific information as regards the risk to bees from the neonicotinoid pesticide active substances clothianidin, thiamethoxam and imidacloprid applied as seed treatments and granules in the EU. The conclusions were reached on the basis of the evaluation of the supported uses as an insecticide of imidacloprid applied as seed treatments and granules, on the new relevant data collected in the framework of the open call organised by EFSA and on the updated literature search performed by EFSA. The reliable endpoints, appropriate for use in regulatory risk assessment derived from the submitted studies and literature data as well as any other relevant data available at national level and made available to EFSA, are presented. Concerns are identified.

Keywords: imidacloprid, peer review, risk assessment, pesticide, insecticide, neonicotinoid

Requestor: European Commission

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Summary

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. A specific conclusion has been issued by European Food Safety Authority (EFSA) on the risk assessment for bees as regards the authorised uses applied as seed treatments and granules.

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013, to restrict the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these active substances have been prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering. Furthermore, the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for clothianidin, thiamethoxam and imidacloprid, taking into account all uses other than seed treatments and granules, including foliar spray uses as mentioned in recital 7 of Commission Implementing Regulation (EU) No 485/2013. EFSA finalised its conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules in July 2015.

It was a specific provision of the Commission Implementing Regulation (EU) No 485/2013 that the applicant was also required to submit to the European Commission further ecotoxicological studies by 31 December 2014. The outcomes of the peer review of the confirmatory data assessment were reported in a Technical Report and a conclusion published in 2016.

Furthermore, according to recital 16 of Regulation (EU) No 485/2013, within 2 years from the date of entry into force of that Regulation, the European Commission foresees to initiate without undue delay a review of the new scientific information available.

For this purpose, with reference to Article 31 of Regulation (EC) No 178/2002 and in accordance with Article 21 of Regulation (EC) No 1107/2009, the European Commission requested EFSA to organise an open call for data in order to collect new scientific information as regards the risk to bees from the neonicotinoid pesticide active substances clothianidin, thiamethoxam and imidacloprid applied as seed treatments and granules in the European Union (EU).

The European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for the three neonicotinoids (namely clothianidin, imidacloprid and thiamethoxam), taking into account:

- the new relevant data collected in the framework of the specific open call for data
- any other new data from studies, research and monitoring activities that are relevant to the uses under consideration
- the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees)

EFSA also considered the data available from a systematic literature review performed in June 2016, in order to collect all published scientific literature relevant for the current evaluation.

Risk assessments were performed for honeybees, bumblebees and solitary bees according to the EFSA guidance document on the risk assessment of plant protection products on bees. For exposure via residues in pollen and nectar, where a higher tier (Tier-3) risk assessment could be performed, a low risk was concluded for some crops for honeybees. However, when all the bee groups (honeybees, bumblebees and solitary bees) are considered, a high risk was concluded or it was concluded that a low risk was not demonstrated for all the uses assessed.

For the exposure via residues from dust drift, a low risk was concluded for some crops for honeybees. However, when all the bee groups (honeybees, bumblebees and solitary bees) are considered, a high risk was concluded or it was concluded that a low risk was not demonstrated for all the uses assessed.

For exposure via water consumption, a low risk to honeybees was concluded for all uses via residues in puddles or via surface water. A low risk to honeybees was concluded for residues in guttation fluid for the uses to winter cereals, sugar beet and potatoes. A high risk was concluded for all other uses.

Refer to Table 19 in the main text of the conclusion for crop-specific conclusion achieved at each assessment tier.

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Background

Imidacloprid was included in Annex I to Directive 91/414/EEC[1] on 1 August 2009 by Commission Directive 2008/116/EC[2] and has been deemed to be approved under Regulation (EC) No 1107/2009[3], in accordance with Commission Implementing Regulation (EU) No 540/2011[4], as amended by Commission Implementing Regulations (EU) No 541/2011[5]. A specific conclusion has been issued by European Food Safety Authority (EFSA) on the risk assessment for bees as regards the authorised uses applied as seed treatments and granules (EFSA, 2013a).

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013[6], to restrict the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these active substances have been prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering. Furthermore, the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for clothianidin, thiamethoxam and imidacloprid, taking into account all uses other than seed treatments and granules, including foliar spray uses as mentioned in recital 7 of Commission Implementing Regulation (EU) No 485/2013. EFSA finalised its conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules in July 2015 (EFSA, 2015).

It was a specific provision of the Commission Implementing Regulation (EU) No 485/2013 that the applicant was also required to submit to the European Commission further ecotoxicological studies by 31 December 2014. The outcomes of the peer review of the confirmatory data assessment were reported in a Technical Report (EFSA, 2016a) and a conclusion (EFSA, 2016b) finalised in 2016.

Furthermore, according to recital 16 of Regulation (EU) No 485/2013, within 2 years from the date of entry into force of that Regulation, the European Commission foresees to initiate without undue delay a review of the new scientific information available.

For this purpose, with reference to Article 31 of Regulation (EC) No 178/2002[7] and in accordance with Article 21 of Regulation (EC) No 1107/2009, in February 2015, the European Commission requested EFSA to organise an open call to collect new scientific information as regards the risk to bees from the neonicotinoid pesticide active substances clothianidin, thiamethoxam and imidacloprid applied as seed treatments and granules in the European Union (EU) (EFSA, 2014b) and then, following a second mandate received in November 2015, EFSA was requested to provide conclusions concerning an updated risk assessment for bees for the three neonicotinoids (namely clothianidin, imidacloprid and thiamethoxam).

The new relevant data collected in the framework of the open call for data and any other new data from studies, research and monitoring activities relevant for the uses under consideration were taken into account. To address the mandate, EFSA also considered the data available from a previous systematic literature review, outsourced in 2013 (Fryday et al., 2015). Furthermore, an update of this systematic review was performed in June 2016, in order to collect all published scientific literature

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[1] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32, as last amended.

[2] Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86–91.

[3] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ No L 309, 24.11.2009, p. 1–50.

[4] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

[5] Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

[6] Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p. 12–26.

[7] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–24.

relevant for the current evaluation (EFSA, 2018a). The EFSA guidance document on the risk assessment of plant protection products on bees (EFSA, 2013c) was used for the current evaluation as requested in the mandate.

A consultation on the evaluation and preliminary conclusions of EFSA on the risk assessment for bees was conducted with Member States via a written procedure in September 2017. The preliminary draft conclusion drawn by EFSA, together with the points that required further consideration in the assessment, as well as the specific issues raised by Member States following the consultation were discussed at the Pesticides Peer Review Experts' Meeting 166 on ecotoxicology in October 2017. Details of the issues discussed together with the outcome of these discussions were recorded in the meeting report. After the expert meeting, EFSA finalised the conclusions and launched a second written procedure on the final draft in December 2017–January 2018 in order to provide their comments on those parts of the conclusions and supporting documents that have been amended following the Peer Review Meeting. The compiled comments were considered by EFSA and are published as part of the background documents to the conclusions.

In addition, key supporting documents to this conclusion are the Technical Report on the evaluation of data (EFSA, 2018a) and the Peer Review Report (EFSA, 2018b).

The Technical Report provides the methodology developed by EFSA relating to the evaluation of the available data concerning their relevance for the current risk assessment and their scientific reliability. It is composed as follows:

- Technical Report on the evaluation of data (EFSA, 2018a)
- Study Evaluation Notes (Appendices D–O) to the Technical Report (EFSA, 2018a).

The Peer Review Report is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, it comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the comments received on the preliminary draft EFSA conclusion,
- the report of the scientific consultation with Member State experts,
- the comments received on the final draft EFSA conclusion.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the EU for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

The active substance and metabolites

Imidacloprid is the ISO common name for (*E*)-1-(6-Chloro-3-pyridinylmethyl)-*N*-nitroimidazolidin-2-ylideneamine (IUPAC).

Imidacloprid belongs to the group of neonicotinoid compounds which are used as insecticides. They interact with the receptor protein of nicotinic acetyl choline receptors in the nerve fibre membrane of insects.

The available earlier EU evaluations (EFSA, 2008, 2013a, 2015) have identified those metabolites of imidacloprid which require consideration in a risk assessment for bees. Many of these metabolites are several orders of magnitude less toxic to honeybees than the parent substance or had comparable acute toxicity to imidacloprid. The single additional endpoint (which was considered as relevant and reliable) submitted for this review has confirmed this (I.2020). However, their occurrence in pollen and nectar is significantly lower. In the data set considered for this conclusion, some residue data were available for metabolites imidacloprid olefin and 5-OH-imidacloprid. These new data did neither indicate higher residue levels of the metabolites in pollen and nectar than the parent imidacloprid. Therefore, it was considered that the risk from metabolites is covered by the risk assessment of the parent and no separate risk assessment for metabolites is required.

Assessment

1. Uses assessed

In accordance with the mandate received in February 2015, EFSA liaised with applicants in order to collect feedback on the uses they would like to support for the EU market. During the open call for data, the applicants were requested to submit information on the uses of imidacloprid (Good Agricultural Practices), applied as a seed treatment or granule that they wish to support. In a second step, in December 2015, Member States were requested to validate the consolidated Good Agricultural Practices (GAPs) from applicants, providing feedback on the authorised uses in their respective countries. However, the risk assessment was performed for all uses supported by the applicants. Full details of the GAPs are given in Appendix A. Tables 1 and 2 provide a brief summary of the critical GAPs relevant to the risk assessment for bees. Only the highest and lowest of the maximum application and seed treatment rates are given in Tables 1 and 2.

It has to be noted that the potato seed treatment use, as outlined by the Applicant, is an in-planter tuber treatment. This treatment is done within the planter machine via a spray application just before the tubers are dropped into the furrow.

Dummy pill use, as outlined by the applicant, is when a treated dead seed is sown together with an untreated alive seed (ratio 1:1).

Some of the vegetables are harvested before the flowering period, unless they are grown for seed production.

Table 1: Summary of the seed treatment uses considered in this conclusion

Crop	Lowest application rate (g a.s./ha)	Highest application rate (g a.s./ha)	Lowest seed treatment rate (mg a.s./seed)	Highest seed treatment rate (mg a.s./seed)	Notes
Spring cereals	112	126	0.039	0.039	–
Winter cereals	43	126	0.015	0.039	Four products, three containing other active substances[(a)]
Cotton	100	175	0.63	0.84	–
Endive	104	104	0.8	0.8	–
Lettuce	104	104	0.8	0.8	–
Endive	89	120	0.8	1.2	Applied as a dummy pill. Seeds sown in greenhouse and transplanted at BBCH 12 either in the field or in greenhouse
Lettuce	89	120	0.8	1.2	
Brassica, flowering, head, leafy (crops like broccoli, cauliflowers, brussels sprouts, head cabbages, chinese cabbage, kales)	90	90	1.5	1.5	
Maize	60	100	1	1	–
Potato	120	180	No information	No information	Two products, one also containing pencycuron
Spring rape	9	12	0.01	0.01	Single product also containing beta-cyfluthrin
Winter rape	9	12	0.01	0.01	Single product also containing beta-cyfluthrin
Sugar and fodder beet	13	117	0.1	0.9	Four products, three containing other active substances[(b)]

BBCH: growth stages of mono- and dicotyledonous plants.

(a): 'FS 373.4' contains clothianidin, prothioconazole and tebuconazole in addition to imidacloprid. 'FS 400' and 'FS 200' contains prothioconazole in addition to imidacloprid.

(b): 'FS 230' contains beta-cyfluthrin in addition to imidacloprid. 'FS 280' contains clothianidin and beta-cyfluthrin in addition to imidacloprid. 'FS 417.8' contains tefluthrin in addition to imidacloprid.

Table 2: Summary of the granular uses considered in this conclusion

Crop	BBCH at the time of application	Lowest application rate (g a.s./ha)	Highest application rate (g a.s./ha)	Notes
Managed amenity turf (golf courses, sport grounds, commercial and residential lawns)	All crop stages	150	150	Spread uniformly over the area with granular application equipment, immediately followed by sufficient irrigation to move the active ingredient through the thatch, wetting the top inch soil

BBCH: growth stages of mono- and dicotyledonous plants.

2. Summary of the data considered in this conclusion

Concerning the effect data, the present conclusion makes use of different sources.

The first source of data was the open call for data for new scientific information as regards the risk to bees from the use of the three neonicotinoid pesticide active substances clothianidin, imidacloprid and thiamethoxam applied as seed treatments and granules in the EU. EFSA launched this call from May 2015 to September 2015, as requested by the EU Commission. More details on the open call for data are available in a dedicated Technical Report (EFSA, 2014b).

Other sources of data were the systematic literature search on the neonicotinoids and the risks to bees that EFSA outsourced in 2013 (Fryday et al., 2015) and the related update performed by EFSA in June 2016 (Appendix B to EFSA, 2018a).

The first systematic literature search comprised 546 (already screened) documents, while the update of the literature search retrieved 874 documents. In addition, 376 contributions were received during the open call for data. After duplicate removal, the overall initial list included 1599 documents. A title and abstract screening step identified 680 potentially relevant documents which were then subject to full text screening. During the full text screening, all experiments within the available documents were identified and totalled 968. Of these experiments, 588 were critically appraised and the data extracted.

Finally, in accordance with the European Commission mandate, Member States were also further requested to provide any monitoring data not yet available during the open call data. The data submitted were already included in the dataset.

Full details on the collection of the available data investigating the effects and exposure of imidacloprid to bees, together with their assessment for their reliability and relevance, are given in the Technical Report on the evaluation of data and related appendices (EFSA, 2018a).

Furthermore, for what concern the exposure data, data already used in previous assessments (EFSA, 2013a) were also considered, as information on residue levels was already systematically collected and organised by EFSA during such previous assessments.

3. Principles and assessment criteria

3.1. Aim of the assessment

The current EU agreed level of protection for bees is to ensure that effects on colonies/populations are negligible. This means that the exposure of the colonies/populations at the edge of the treated fields should not exceed a level which results in an effect greater than negligible.

As requested by the European Commission mandate, to perform the risk assessment of the three active substances the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), hereafter referred to as EFSA (2013c) was followed. The basis of the risk assessment according to EFSA (2013c) is to ensure that the specific protection goals (SPG) for honeybees, bumblebees and solitary bees are met.

Namely:

- For honeybees, to ensure that there is not a greater than 7% effect on colony strength, including after overwintering, and the level of forager mortality does not breach the tolerable level, for honeybee colonies located at the edge of treated fields which are exposed to the 90th percentile predicted exposure or less.

- For bumblebees, to ensure that there is not a greater than 7% impact on the colony for bumblebee colonies located at the edge of treated fields which are exposed to the 90th percentile predicted exposure or less.
- For solitary bees, to ensure that there is not a greater than 7% effect on the population of bees located at the edge of treated fields which are exposed to the 90th percentile predicted exposure or less.

These SPGs define the problem formulation for the present assessment.

3.2. Tier-1

According to EFSA (2013c), depending on the product formulation and the application method under evaluation, different routes of exposure need to be considered to perform the risk assessment to bees. The exposure from seed treatments and granular formulations in the 'treated crop' and the 'succeeding crop' scenarios derives from residues in pollen and nectar following translocation from below ground (seeds or soil). The same route of exposure is considered relevant for the 'weeds' scenario in the case of granules application.

Concerning the surrounding area ('field margin' and 'adjacent crop' scenarios), the most relevant exposure is due to dust drift at the sowing (treated seeds)/application (granules).

Furthermore, a separate risk assessment for exposure via consumption of contaminated water should be carried out for honeybees.

Details about the entire Tier-1 risk assessment scheme can be found in EFSA (2013c).

The Tier-1 risk assessment was carried out using default exposure values in accordance with EFSA (2013c), while the selection of the toxicity endpoints is described below (Section 3.2.1). Due to the lack of suitable toxicity data for bumblebees and solitary bees, a surrogate endpoint was extrapolated from the related honeybee data (assuming the endpoint is a factor of 10 lower). In this case, throughout the present conclusion, we refer to the Tier-1 as 'screening Tier-1'.

3.2.1. Selection of the endpoints

Several endpoints from laboratory studies were obtained from the data considered in this conclusion and which had not been considered in previous EU assessments. These newer endpoints have been considered to amend the previously agreed EU endpoints (EFSA, 2015) provided that the following criteria were fulfilled:

- The endpoint was considered as relevant for a risk assessment according to EFSA (2013c) and the GAPs under consideration (e.g. the endpoint type, the test species and the test item were considered as relevant);
- The endpoint was assessed to be 'Fully reliable' or 'Reliable with minor restrictions' during the appraisal exercise (EFSA, 2018a);
- The endpoint, from a study with technical active substance, indicated higher toxicity than the previously agreed EU endpoint for the technical active substance.

Moreover, for endpoints from formulation studies, the following criteria were considered:

- the previously agreed EU endpoint originating from a formulation study was replaced only if it was less relevant (e.g. study with a spray formulation) than the newer formulation endpoint
- the previously agreed EU endpoint is a surrogate extrapolated endpoint

Where no new endpoints were available, or the criteria above were not fulfilled, the previously agreed EU endpoints were selected for risk assessment. The data available and final selection of the endpoints used for the current risk assessment are given in Section 4.

3.3. Refinement of the exposure

Within EFSA (2013c), no stepwise approach is offered for higher tier risk assessment. Nevertheless, among the options listed in the guidance, one possibility is to refine the exposure estimate, i.e. replace the default values with specific values coming from higher tier exposure studies. Within the scope of this conclusion, the risk assessment carried out with refined exposure estimates is referred to as 'Tier-2'. A further refinement option given in EFSA (2013c) is to refine the assessment by the use of higher tier effect studies performed in the field or under semifield conditions (see Section 3.4). Specific exposure assessment goals need to be determined in order to use such effect studies in a refined risk assessment, referred to as 'Tier-3'.

3.3.1. Residues in pollen and nectar

3.3.1.1. Data evaluation and selection

The newly available higher tier studies, reporting information on exposure, were evaluated in line with the validity criteria set in the literature evaluation protocol (EFSA, 2018a) and the protocols proposed in Appendix G of EFSA (2013c). The valid data on the residue levels occurring in nectar and pollen for the exposure scenarios for the treated field and the succeeding crops in line with these protocols were collated in a table. Residue determination in available field studies was assessed for their reliability both in relation to their field and laboratory phases. For the field phase, in order to refine the exposure, higher tier studies from at least five randomly selected locations in the area of use of the substance should be conducted. This minimum of five randomly selected locations in the area of use is prescribed by the guidance, to ensure that an estimate can be made of the distribution of residues that might really be encountered by the bees. This has the aim of accounting for the different temporal and spatial variability that occurs. In relation to the laboratory phase, the analytical methods were examined for their adequacy for determining residues at the low levels required. In some instances, the size of the samples collected in the field phase was lower than the sample size for which the method had been validated, in such cases appropriate correction on the method validated limit of quantification (LOQ) (for the target sample size) was applied, i.e. the LOQ was increased to account for smaller than ideal sample availability of individual sampling events.

Measured residue levels of pollen and nectar were reported for each type of sampling matrix (i.e. samples from the plant, from the bee, from the bee via pollen traps, from the comb and from soil). In general, the sampling scheme which aimed to determine residues in the same matrix (either in plant matrices or bee matrices) during the field studies was not exhaustive enough to guarantee that the time dependence of the residue over the period of interest could be captured. This prevents any analysis aimed to determine a mathematically rigorous percentile exposure value over time. Therefore, the maximum observed in the available samples was retained as representative of the exposure in each particular field experiment. This does not imply that the overall risk assessment has to be regarded as overly conservative, since the sampling frequency pattern in the studies does not guarantee that the actual maximum occurrence was picked up by the maximum measured in the samples taken. Nevertheless, it is expected that the assessment based on these principles may still be considered to represent a realistic worst-case exposure for the different substances and uses assessed.

Treated crop scenario

Regarding the field phases, the directly treated crop needed to be the same crop being assessed. Appendix R of EFSA (2013c) indicates that extrapolation between the residue values from different crops is inappropriate when substances are systemic, which is interpreted to relate to seed treatment uses or when granules are placed with seed at the time of drilling. This is because the different physiology of different crops, including the time from emergence to flowering leads to different translocation and levels of residues in different crops. When assessing the field phases of the available experiments, the most critical issues encountered were cross-contamination from fields in the vicinity and/or due to historical uses in the same field, i.e. not resulting from the treated seeds at known application rates. Only data from studies for which there was sufficient certainty that the residues observed were resulting from the application being investigated as prescribed in the study design, were retained for the exposure assessment. The presence or absence of residues measured in control plots was not part of the decision on retention.

For the exposure assessment, the measured residue values (mg analyte/kg pollen or nectar) were normalised for the seed loading (mg a.s./seed) resulting in Residue per Unit Dose (RUD) (where the unit dose is 1 mg a.s./seed) to make the residues independent from the application rate used in the studies. From one study, sometimes more than one RUD value was calculated and included in the collation table when more than one trial was conducted within the study. A standalone trial was defined when one or more of the following factors were different from other trials: type of formulation, plant species, application rate, test site, period of the trial, pretreatment of the soil and test category (i.e. field and semifield trials, where semifield means bees used to obtain samples were restricted to foraging on treated plots).

According to EFSA (2013c), in order to refine the exposure, higher tier studies from at least five randomly selected locations in the area of use of the substance should be conducted. Therefore, a minimum of five RUD values for pollen and nectar were considered necessary to perform a refined exposure assessment for each exposure scenario for each use under consideration.

Where the residue detected in a trial was reported to be lower than the LOQ (but greater than the limit of detection (LOD)), as a worst-case assumption, the residue was considered to be equal to the LOQ for the RUD calculation. In the cases that no residues were detected, the residue was considered to be equal to the LOD for the RUD calculation.

According to EFSA (2013c), in order to perform an exposure assessment, it is preferable to use measured RUD values for pollen and nectar collected from bees (specific for honeybees, bumblebees and solitary bees), e.g. using pollen traps attached to honeybee hives or sampling nectar by extracting the honey stomach from forager bees. Using the RUD values for pollen and nectar directly from the bees aims to give a better representation of the likely exposure to bees and bee colonies by accounting for dilution by non-contaminated pollen and nectar. Considering each bee taxon separately is needed to account for differences in their foraging behaviour that would be expected to mean that dilution was different between the categories. Alternatively, RUD values for pollen and nectar taken directly from the plant can be used in the exposure assessment. However, RUD values for plant pollen and nectar are considered to be an overestimation of the exposure to bees as dilution is not accounted for. Therefore, if there are a sufficient number of RUD values for bee nectar and/or pollen from field trials, only these values were used for the exposure assessment. RUD values for pollen and nectar from bees taken from semifield studies were considered to be representative of situations where there was no dilution and therefore were considered together with the RUD values for plant pollen and nectar. In the cases where RUD values were available on both bee pollen/nectar and plant pollen/nectar from the same semifield study, the values for bees only were retained. Where less than five RUD values for bee pollen/nectar were available, these were combined with the RUD values for plant pollen/nectar and bee pollen/nectar from semifield, i.e. to obtain sufficient data to perform the exposure assessment. Figure 1 summarises the process for selecting the RUD values for the refined exposure assessment for the treated crop scenario.

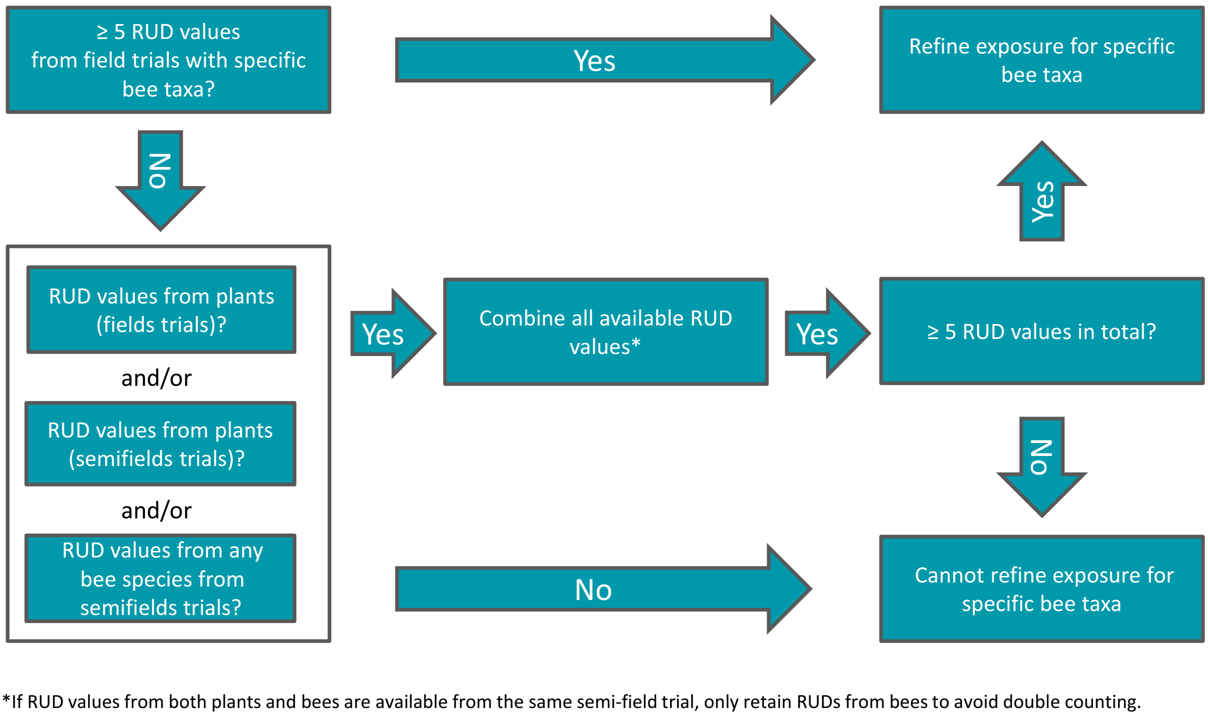

Figure 1: A summary of the selection process for RUD values for the refined exposure assessment for treated crop scenario

Succeeding crop scenario

A different approach from the treated crop scenario was used for the succeeding crop scenario. This is because the residues in the succeeding crop scenario are less dependent on the physiology of the treated crop but are instead mainly driven by the active substance concentration in soil and by the physiology of the successive crop. For this reason, in the residue trials, residues in topsoil/the following crop root zone before the planting of succeeding plant species attractive to bees had to have been measured. For trials to be retained in the assessment, the residues in soil needed to be equivalent to or higher than that estimated to occur (Predicted Environmental Concentrations (PEC)) in soil from the uses being assessed. How such PEC were calculated is outlined in Sections 5.1.1.2 and 5.2.1.2. Maximum residues in pollen and nectar from the retained trial sites were used to estimate exposure in the risk characterisation, whilst following the approach for the selection of residues directly from bees (either in open field or semi field trials) or via plant sampling as already discussed above for the treated crop scenario. As the residues trial site selection was based just on measured soil residues, it was not necessary for the agricultural practice or product formulation type that had been used at any individual trial to match the uses being assessed. As trials were retained only for sites where measured residues in soil were equivalent to or higher than the PEC soil, RUD values were not calculated.

In order to refine the exposure, residues from at least five trials are needed.

3.3.1.2. Calculation of refined shortcut values

The residue values selected for the refined exposure assessment for the treated crop scenario and the succeeding crop scenarios were used to calculate new shortcut values (SVs), which represent active substance intake per day (adults) or per developmental period (larvae). Such calculation was performed by means of the SHVAL tool (EFSA, 2013a, 2014a). This R-based tool fits theoretical distributions to the available data (e.g. residue levels, consumption rates, sugar concentration in nectar) and then it runs Monte Carlo simulations with 1,000 iterations (see EFSA, 2014a for details). The result of such simulation is a distribution of intake values per day (or per developmental period for larvae). Finally, the 90th percentile of this distribution is selected as the relevant crop/substance-specific SV. Separate simulations were carried out for each caste of each bee group (honeybee, bumblebee and solitary bees).

No data were available to refine consumption rates or sugar concentration in nectar. Hence, for these variables, default values as presented in Appendix J of EFSA (2013c) were used in the simulations.

3.3.1.3. Estimation of the exposure assessment goal

Treated crop scenario

To consider the higher tier effect studies in the context of the risk assessment, the exposure within those effects studies were compared to the expected exposure for the GAPs under consideration. For the treated crop scenario, specific 'exposure assessment goals' were estimated by transforming the refined shortcut values used in the Tier-2 assessment. To transform the refined shortcut values to an exposure assessment goal, the shortcut values were multiplied by the seed loading rate (in terms of mg a.s./seed) for each use.

Figure 2 presents a general overview of the stepwise approach followed for the refinement of exposure assessment described under Section 3.3.1 for the treated crop scenario.

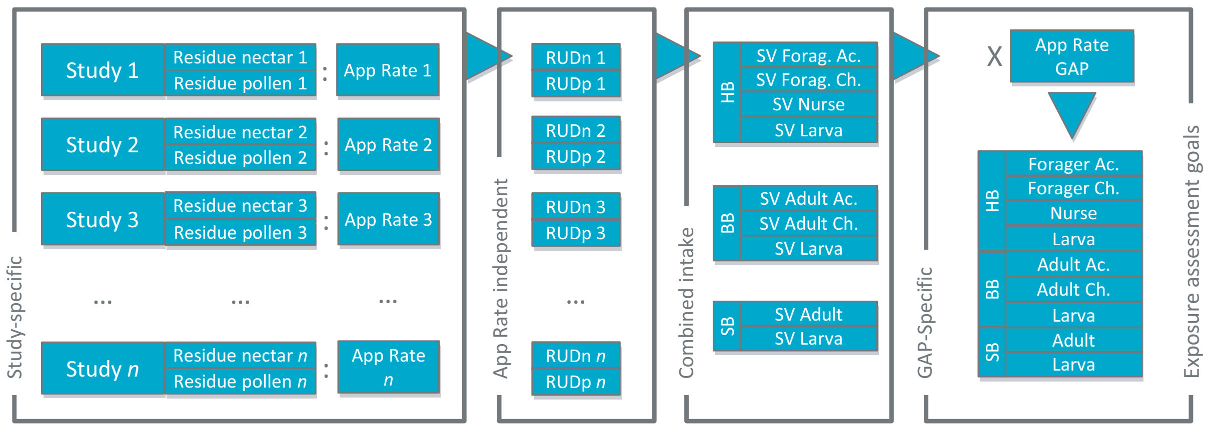

Figure 2: General overview of the refined exposure assessment for the treated crop scenario

Succeeding crop scenario

For the succeeding crop scenario, refined SVs were calculated by using actual residue values, without any further normalisation for the application rate. As such, the refined SVs obtained as described in Section 3.3.1.2 represent as well the exposure assessment goals.

Figure 3 presents a general overview of the stepwise approach followed for the refinement of exposure assessment described under Section 3.3.1 for the succeeding crop scenario.

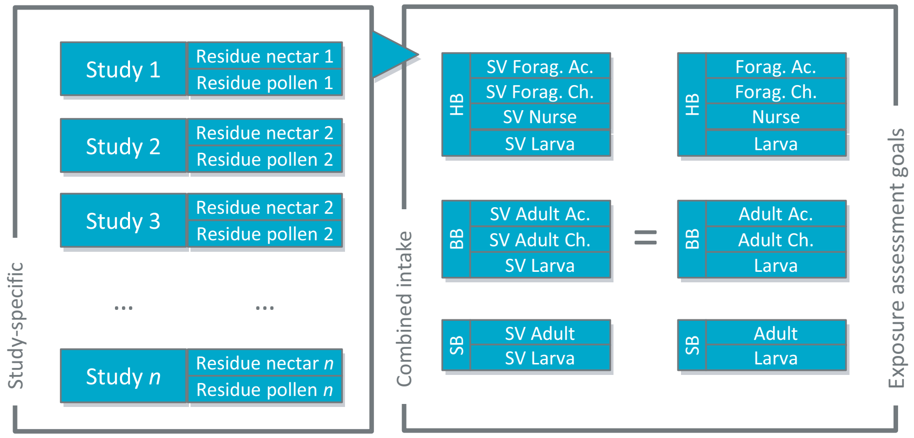

Figure 3: General overview of the refined exposure assessment for the succeeding crop scenario

3.3.2. Dust drift and deposition

According to EFSA (2013c), exposure to dust drift in the field margin or in adjacent crops is considered relevant for seed treatment uses and granular formulations. In addition, for granular uses, the exposure to dust drift is relevant for the treated crop and for the weed scenario if granules are used after emergence.

Field experiments measuring dust deposition to the horizontal ground outside the treated area at the time of drilling seeds were available. They were considered reliable when: the quality of the treated seed (in terms of dust content and active substance in the dust) had been measured, the drilling machinery used was adequately described, the application rate in terms of mass of active substance per unit treated area was adequately measured, dust deposition at different distances downwind of the treated area was adequately determined and wind speed and direction measurements were available. In many of these experiments, dust drift outside the boundary of the treated field was also measured using vertical gauze netting. These vertical gauze results were not used further, as it was not clear how the results reported as g a.s./ha were derived and what they represent. Also, agreed methodology is not available on how to use or interpret such values that may have utility in estimating exposure to field margin vegetation or adjacent crops when measured at the individual trial sites.

No studies were available for granules.

3.3.3. Weeds in the field

According to EFSA (2013c), exposure to flowering weeds within the treated field is considered relevant for uses applied as granules. Some options to refine the exposure to bees from weeds are recommended by EFSA (2013c) (e.g. considering the proportion of the treated field which is covered by flowering weeds, considering measured residues from crops exposed to dust from granular uses). However, no such data were available for the granular use on amenity turf.

3.3.4. Residues in water sources

Where the crops being assessed had experimental data where the seed loading rate was measured and residue levels were adequately determined in sampled guttation fluid exuded from the treated plants, EFSA collated the residues values.

In accordance with the recommendation of EFSA (2013c), measured residues in the guttation fluids exuded from the treated plant were considered for refining the assessment related to this route of exposure relevant for honeybees. EFSA (2013c) specifies that the guttation concentration used in the risk assessment needs to cover the 90th percentile in guttation fluid for the crop of concern (considering location, growth stage and environmental conditions). For seed treatments and granules buried with seeds, it is proposed to refine the exposure estimate by conducting (at least) five field studies and to measure the concentrations in guttation water.

Therefore, following EFSA (2013c), a refinement of the exposure can only be performed if at least five field studies are available for the same crop considering all available values added to the table of residues values. Residues from five field studies were not available for any of the crops being assessed here. However, for consistency with the confirmatory data conclusion for imidacloprid (EFSA, 2016b), Tier-2 risk assessments have been completed using the highest guttation fluid residues from the available field investigations for the crops where these were available.

No exposure refinement was necessary for assessing residues in puddles as using the Tier-1 exposure assessment indicated low risk (see Section 5.1.3.2).

3.4. Refinement with higher tier experiments

3.4.1. Building up the lines of evidence

Another approach offered by EFSA (2013c) to refine the risk assessment is to perform higher tier effect experiments. These experiments are normally carried out under field or semifields conditions, and aim at a higher environmental realism when compared to standard laboratory test.

These experiments present a wide variety of set-ups, designs and investigated endpoints. Therefore, a weight of evidence (WoE) scheme has been developed to integrate the relevant information from all available experiments. In order to perform a WoE risk assessment, it is first necessary to set the problem formulation and then identify lines of evidence which address the problem. In the case of honeybee, bumblebee and solitary bee, risk assessments performed in accordance with EFSA (2013c), the problem formulation is already defined by the SPGs.

Within the WoE, it was considered that each 'line of evidence' corresponds to the whole set of homogeneous endpoints measured in all available experiments. An endpoint in this context is defined as a parameter which could be informative of a potential effect caused by an exposure to an active substance (and its metabolites).

Within each experiment, the endpoint is identified by four dimensions:

- The **magnitude** of the observed deviation from the control. For endpoints measured as time series, the extremes of such deviation were recorded in both directions, together with a mean deviation. In case of such endpoints like forager mortality, this dimension should also account for the duration of a consistent deviation (e.g. increase of X% in forager mortality observed for Y consecutive days). Deviations in both directions were classified as: no deviation, negligible, small, medium and large deviation from the control. For this classification, the scales presented in Table 3 were used. These scales were adapted from Appendix B of EFSA (2013c) (Protection goals), except the scale for homing success, where the categories were arbitrarily chosen. An example for using these scales: if the average colony strength in a honeybee study at an observation time was 6% less in the treated group compared to the control, this was classified as a negative negligible deviation. If, at another observation day, the colony strength in the treated group was 16% more than in the control, this was classified as a positive medium deviation. It has to be noted that pending on the availability of the data on the relevant endpoints (i.e. reported details), the deviation from the control was either calculated or only estimated (e.g. when only graphical presentation was available for the endpoint).

Table 3: Scale of deviation from the control used for the weight of evidence exercise

Deviation class	All endpoints except mortality and homing success	Forager mortality and mortality in front of the hive	Homing success
No deviation	0%	0%	0%
Negligible	> 0% to < 7%	See examples in Table B1 of Appendix B of EFSA (2013c)	> 0% to < 10%
Small	7% to < 15%	See examples in Table B1 of Appendix B of EFSA (2013c)	10% to < 20%
Medium	15% to < 35%	See examples in Table B1 of Appendix B of EFSA (2013c)	20% to < 50%
Large	≥ 35%	See examples in Table B1 of Appendix B of EFSA (2013c)	≥ 50%

- The **reliability** of the endpoint: this was established on the basis of the appraisal exercise (EFSA, 2018a) and giving a score to each endpoint from 0 (not reliable) to 3 (fully reliable). The reliability was used to weigh the results obtained in different experiments, and to estimate, together with the level of consistency of the results, the level of certainty associated with the line of evidence.
- The **level of exposure:** this information is necessary to check where the level of exposure in the experiment stands compared to the exposure assessment goal(s). Furthermore, this information can be used to check whether a sort of exposure–response relationship can be identified. For oral exposure to residues in pollen and nectar, residue intake (RI) values were calculated for each caste of bee using the mean residue value on nectar and/or pollen obtained in the effects study. A sugar content of 15% was assumed for nectar for honeybees and bumblebees (EFSA, 2013c). In case of colony feeder studies, the sugar content of the sugar solution specified in the study was used. If this was not available, then a sugar content of 50% was assumed. The daily consumption values, for pollen and nectar, for each bee caste were taken from EFSA (2013c). Where a range of consumption values were available, a range of RI values was obtained.
- **The length of exposure:** this is defined as the time period in which there could have been exposure to residues of the active substance. It is noted, that the 'length of exposure' referred to in this conclusion does not account for the subsequent consumption of food stores within colonies/nests. In field and semifield studies, this corresponds to the time period the bees could be exposed to the crop during flowering. For colony-feeder studies, the length of exposure is defined by the time period during which the spiked sugar solution or pollen was given to the bees. This information is needed to check whether the length of exposure is realistic to that expected for the GAPs under consideration.

In order to visually illustrate these four dimensions of the endpoints and in order to help the interpretation of a 'line of evidence', graphical representations were prepared. A graphical representation of a 'dummy' example (invented example for illustrative purpose) is included in Figure 4 with an explanation of each element of the figure.

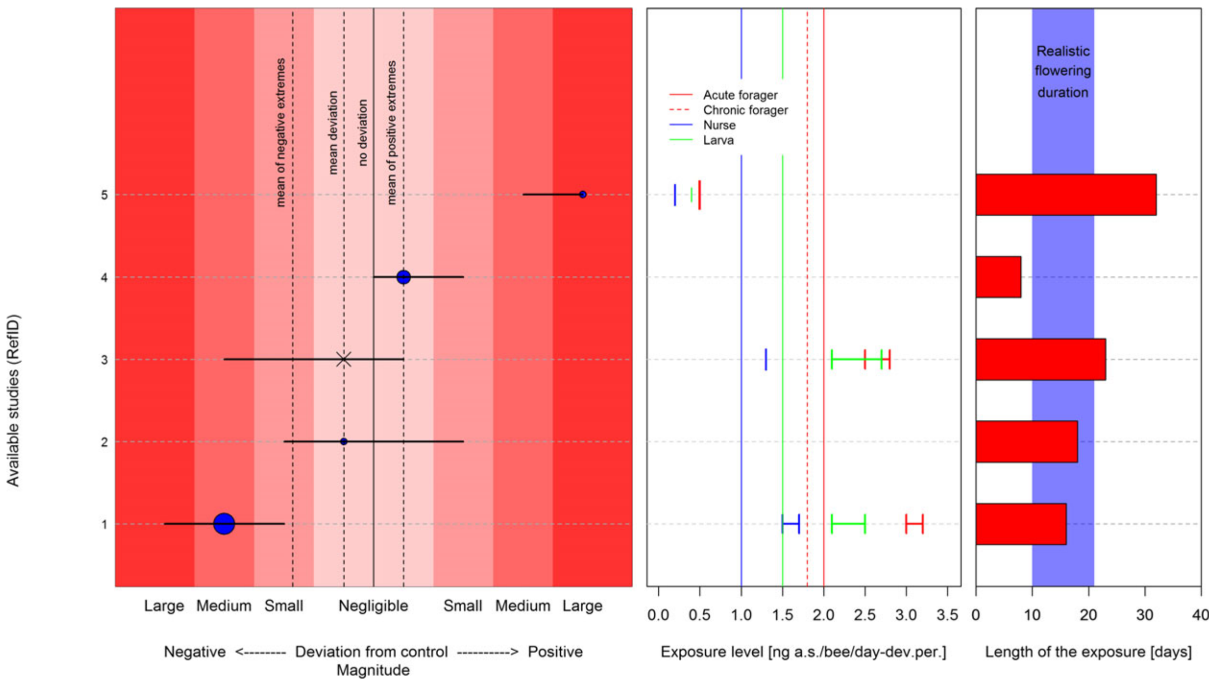

Figure 4: Lines of evidence for a 'dummy' example: colony strengths of honeybees

The figures include the following information:

- Each row in the figure represents a higher tier effects study. The numbers given on the left hand side are the reference identification codes of the individual studies which can be traced back to the reliability assessment provided in the Technical Report on evaluation of data and related Appendices from D to O (EFSA, 2018a). In Appendix G of this conclusion, an overview is given of all reference identification codes of the individual studies cited in the conclusion. A summary of the reference identification codes according to the different assessment streams identified during the evaluation of the data is summarised below. Note that several studies investigated a number of exposure levels, and therefore, these studies may be listed more than once (e.g. the highest exposure level that caused no or small deviation from the control and the lowest exposure level with apparent deviation from the control).

Assessment stream	Reference identification code
All* (with interaction)	All*
All + (no interaction)	All+
Clothianidin	C.
Imidacloprid	I.
Thiamethoxam	T.
Clothianidin * Imidacloprid (with interaction)	C*I.
Clothianidin + Imidacloprid (no interaction)	C+I.
Clothianidin * Thiamethoxam (with interaction)	C*T.
Clothianidin + Thiamethoxam (no interaction)	C+T.
Imidacloprid * Thiamethoxam (with interaction)	I*T.
Imidacloprid + Thiamethoxam (no interaction)	I+T.
Not substance-specific	NS

- The left hand panel relates to the biological observations whilst the centre and right hand panels relate to exposure.
- For each experiment, the black solid horizontal line represents the range of the observed deviations from the control (i.e. both negative and positive deviations). The magnitude of these deviations is categorised as negligible, small, medium or large. When this is not indicated, the endpoint was measured only once during the study or it was measured multiple times, but insufficient details were reported to evaluate the variability of the endpoint in time (e.g. only averages for the entire study duration were reported)
- The position of the blue circle gives an estimation of the overall deviation (mean) from the control for the entire duration of the study or during the year of use for those studies which extend over the winter.
- The size of the blue circle is an indication of the reliability score of the specific endpoint. A 'fully reliable' endpoint gives a large circle, an endpoint which was 'reliable with minor restrictions' gives a medium-sized circle and an endpoint which was 'reliable with major restrictions' gives a small circle.
- For transparency, the experiments giving endpoints which were assessed as 'not reliable' have also been included in the figure, but the overall deviation is represented by an X.
- To help interpret the figure, vertical dotted lines have been added to indicate the mean overall deviation, the mean negative deviation (if it could be calculated) and the mean positive deviation (if it could be calculated) across all of the reliable experiments (weighted for the reliability score of the endpoint).
- In the centre panel of the figure, a representation of the estimated level of exposure achieved in the experiment is given for each bee caste (i.e. ng a.s./bee per day for adult bees and ng a.s./larvae per development period for larvae). When this is not indicated, reliable information on the exposure level achieved in the study was not available.
- The vertical lines in the centre panel of the figure represent the exposure assessment goal, for each bee caste, for the GAP under consideration (see Section 3.3.1.3).

- On the right hand side of the figure, the length of exposure (in days) in the experiment is represented by the red bars. The vertical purple column is the expected range of the flowering period for the crop under consideration[8].

In order to conclude that the observed deviations are actual representations of a true effect caused by the exposure to the active substance (and its metabolites), several aspects were considered for each line of evidence.

- The presence/absence of a general trend, giving more weight to results with higher reliability.
- The level of consistency among experiments (similar results, exposure–response relationship etc.)
- The level of precision offered by the available experiments (width of the effect size ranges)

In principle, each line of evidence should provide a piece of information characterised by a certain degree of strength (consistency), precision (degree of variability) and reliability.

Furthermore, in order to use the available information to conclude on the risk assessment, it is pivotal to check the level of the exposure in the effect experiments relative to the specific exposure assessment goals and to check whether the length of potential exposure in the effect study is within the realistic flowering period for the crop (or succeeding crop) under consideration.

3.4.2. Integrating the lines of evidence

In accordance to EFSA (2013c) and the newly available EFSA guidance document on the WoE (EFSA Scientific Committee, 2017), the overall process should account for the relevance of the single lines of evidence, before performing any integration.

In the scheme, there are endpoints (lines of evidence) that are directly linked to the protection goals and have the potential to provide a straightforward response to the main issue reported in the problem formulation (see Section 3.1). For this reason, they are considered to be the higher class of endpoints in terms of relevance (Class 1). These are colony/population size (valid for all species); forager mortality (honeybees only) and all endpoints related to the reproductive output (bumblebees and solitary bees)

Other endpoints have a rather clear conceptual link with one of the previous two (e.g. brood/cocoon production can clearly influence colony/population strength), even if this link cannot be explicitly quantified. These endpoints (lines of evidence) belong to Class 2 for relevance.

Other endpoints, on the contrary, may play a role in the colony/population health, but such link is not immediate in conceptual term (e.g. average duration of foraging trips). These endpoints (lines of evidence) belong to Class 3.

Finally, there are endpoints that do not offer any explicit link with the protection goals (e.g. measurement of enzymatic levels at subindividual level). These endpoints are considered not relevant (Class 4) for addressing the protection goal according to EFSA (2013c).

A proper summary of all endpoints considered in this assessment and a detailed description of their relationship with the SPGs are available in Appendix B. A less detailed summary is reported in Table 4.

[8] A crop-specific time window for a reasonable flowering period was estimating by considering: (i) feedback from Member States; (ii) assumptions within the FOCUS scenarios; (iii) collating information reported in the present data set. For winter oilseed rape, a reasonable flowering period was estimated to last between 10 and 42 days. The selected maximum is longer than the assumptions contained in the FOCUS scenarios (maximum 28 days). During the expert meetings, some experts pointed out that 6 weeks of flowering may happen, but only in exceptional years. Nevertheless, within the present data set, flowering between 35 and 43 days was recorded in several experiments carried out in France, the UK, Germany and Hungary. Similarly, data were collected for spring oilseed rape and maize. The succeeding crop scenario is not represented by any specific crop. Therefore, on the basis of all of the available information on the flowering period of agricultural crops, it was decided that a reasonable flowering period would range from 5 to 42 days.

Table 4: A summary of the endpoint types and the related relevance class assigned within the scope of the present risk assessment

Bee group	Relevance class	Family of endpoint
Honeybees	1	Colony strength
		Forager mortality
		Overwintering assessment
	2	General mortality of individuals
		Brood production
		Homing success[(a)]
	3	Behavioural endpoints
		Comb building
		Weight of the hive
		Disease
		Food storage
		Queen
	4	Behaviour influencing exposure
		Subindividual mass
		Suborganism endpoints
		Thermoregulation capacity
Bumblebees	1	Reproductive output
		Colony strength
	2	Indirect reproduction
	3	Behaviour
		Weight of the nest (colony)
		Food storage
		General mortality
		Individual mass
		Homing success
	4	Behaviour influencing exposure
Solitary bees	1	Reproductive output[(b)]
	2	Indirect reproductive output
	3	Behaviour
		General mortality

(a): For the purposes of this conclusion, the endpoint 'homing success' is defined as the proportion of bees returning to the hive/colony after they were captured and subsequently released at a distance from the hive/colony.
(b): The number of solitary bee offspring emerging after winter was considered to represent the accumulation of several preceding endpoints related to reproductive success (e.g. number of completed nests, tubes with brood, cocoon production). Therefore, the weight of evidence focussed primarily on the number of offspring emerging after the winter.

In order to account for this hierarchical structure within the current risk assessment scheme, a stepwise procedure was followed.

As already mentioned, the first step was focussing on endpoints belonging to Class 1. If the available data are sufficient to provide a conclusive answer to the main risk assessment question, the assessment could stop. If, on the contrary, the available information is not sufficient and/or appropriate to provide a conclusive answer, the WoE will be extended to other levels of relevance, in order to get a more comprehensive picture of the available data.

If the evidence in the first two levels of relevance (Classes 1 and 2) is not sufficient/appropriate to reach a conclusion, it is considered unlikely that less relevant endpoints will help achieving a conclusive assessment.

4. Outcome of the risk assessment: toxicity endpoints

4.1. Standard endpoints

In the data set considered, there were several laboratory studies available for assessing the effects of imidacloprid, or formulated products containing imidacloprid, on honeybees, bumblebees and solitary bees. Following the selection procedure given in Section 3.2.1, it was considered whether any of the newly available data should replace the previously EU agreed endpoints (EFSA, 2016a,b) and be used for the Tier-1 and Tier-2 risk assessments.

Three acute contact toxicity endpoints for honeybees performed with the technical active substance were available and resulted in lethal dose (LD_{50}) values which were slightly lower than the previously agreed endpoint. Furthermore, there were two additional studies performed with formulated products containing imidacloprid. The lowest of the available endpoints, from study All+.1084 with the technical active substance, was selected for risk assessment (LD_{50} = 0.0251 μg/bee; 3.2 times lower than the previously agreed EU endpoint). In this experiment, the LD_{50} was only reported for an observation period of 120 h, which is longer than the time window recommended in the OECD 214. Nevertheless, both validity criteria reported in OECD 214 were considered respected: the mortality in the control was still 5.8% after 120 h, and the toxicity of other tested substances (i.e. λ-cyhalothrin, deltamethrin, esfenvalerate) was in the expected range, providing an indication that sensitivity of the system was appropriate, in lack of a formal positive control. Therefore, the LD_{50} was considered suitable for being used in the risk assessment. This issue was discussed and agreed during the expert meeting (October 2017).

There were four reliable endpoints investigating the acute oral toxicity to honeybees performed with the technical active substance and one endpoint was available from a study performed with a formulated product. The endpoints from these studies did not indicate a higher toxicity than the previously agreed acute oral honeybee endpoint, and therefore, this value was retained for risk assessment. No reliable laboratory data were available to derive a chronic oral lethal dietary dose (LDD_{50}) or a no observed effect level (NOEL) value for larval development of honeybees. Therefore, the previously EU agreed endpoints were retained for risk assessments. No NOEL value could be derived from the available data for the development of hypopharyngeal glands (HPG) in honeybees (such endpoint is neither available from previous assessments). It is noted, however, that an approximate lowest observed effect level (LOEL) of 0.243 ng/bee per 10 days was estimated from one of the studies (I.545). No data were available to assess whether the use of imidacloprid results in accumulative effects in honeybees.

There was an acute contact toxicity endpoint (LD_{50} value) for bumblebees performed with the technical active substance and another one performed with a formulated product. The endpoints from these studies did not indicate a higher toxicity than the previously agreed acute contact bumblebee endpoint, and therefore, this value was retained for risk assessment. There was a single study giving an acute oral LD_{50} value for bumblebees for the technical active substance. Again, this endpoint did not indicate a higher toxicity than the previously agreed acute oral bumblebee endpoint, and therefore, this value was retained for risk assessment. No reliable laboratory data were available to derive a chronic oral LDD_{50} or a NOEL value for larval development of bumblebees. These values were neither available from previous assessments.

There were no reliable and relevant toxicity data available for solitary bees nor were any data available from previous assessments.

In accordance with EFSA (EFSA, 2013c), where data are missing, surrogate endpoints can be calculated using toxicity data for honeybees divided by 10. Surrogate endpoints were therefore calculated for the acute contact and oral toxicity to solitary bees and for the chronic oral toxicity to bumblebees and solitary bees. As the available honeybee larvae endpoint had some shortcomings, it was previously concluded that this endpoint should only be considered as 'provisional' (EFSA, 2016b). Therefore, it was not considered appropriate to use this endpoint to derive surrogate endpoints for bumblebee and solitary bee larvae.

This selection procedure resulted in the change of the surrogate acute contact endpoint for solitary bees. As a consequence of no change in other honeybee endpoints, the other surrogate endpoints for solitary bees and the surrogate adult chronic endpoint for bumblebee are the same as the previously EU agreed surrogate endpoints.

On the basis of the above considerations, Table 5 summarises the toxicity endpoints selected for the Tier-1 and Tier-2 risk assessment.

Table 5: Toxicity endpoints selected for lower tier risk assessments

Risk assessment type	Endpoint	Honeybee	Bumblebee	Solitary bee
Acute contact	LD_{50} (μg a.s./bee)	0.0251 (120 h)	0.218 (96 h)	0.00251[(c)]
Acute oral	LD_{50} (μg a.s./bee)	0.0037 (48 h)	0.038 (96 h)	0.00037[(c)]
Chronic oral	10-day LDD_{50} (μg a.s./bee per day)	> 0.00282[(a)]	> 0.000282[(c)]	> 0.000282[(c)]
Larval	NOEL (μg a.s./larva per developmental period)	0.00528 as provisional[(b)]	No endpoint available or extrapolated	No endpoint available or extrapolated

LD_{50}: lethal dose, median; LDD_{50}: lethal dietary dose, median;
(a): Endpoint set at the highest concentration tested.
(b): Endpoint determined at 7 days but only 3-day exposure during the study. Endpoint is the highest dose tested. Endpoint is based on nominal amount of food offered to the larvae.
(c): Extrapolated from the endpoint for honeybee by using a factor of 10.
Note: from the previously EU agreed endpoints, only the acute contact endpoint for honeybees and the acute contact endpoint for solitary bees were changed.

4.2. Additional sublethal laboratory data

Several laboratory experiments testing sublethal effects of imidacloprid on bees were available in the data set. The endpoints investigated encompassed a wide variety of sublethal effects. The effects investigated in the available data set are listed in Table 6.

Table 6: Sublethal endpoints for honeybees, bumblebees and solitary bees investigated in laboratory studies of the available data set for imidacloprid

Organism	Effect
Apis cerana	Proboscis extension reflex (PER) – learning capacity
Apis mellifera	AChE activity Kenyon cell depolarisation Expression of genes Deformed wing virus replication Apoptosis of neurons Hemolymph collection Total haemocyte count Encapsulation response Antimicrobial activity of the haemolymph Body weight Food attractiveness (food preference) Intoxication symptoms Larvae development Locomotion activity Number of Nosema spores Parameter for flight capacity Parameters for individual immunity Parameters for social immunity Proboscis extension reflex (PER) – learning capacity Protein content of bee head Sperm viability Sucrose consumption Time spent for feeding (potential feeding) Time spent for interacting Wing length
Bombus terrestris	Accumulation in the brain Cytotoxicity of neurons Mitochondrial depolarisation Food attractiveness Locomotion activity Sucrose consumption

Organism	Effect
Melipona quadrifasciata	Locomotion activity Parameter for flight capacity Respiration
Osmia lignaria	Larvae development
Megachile rotundata	Larvae development

AChE: acetylcholinesterase.

In addition, an endpoint from a Proboscis Extension Reflex (PER) tests was available for 5-OH-Imidacloprid on honeybees.

For most of the cases, only a single endpoint was available. However, a number of the available experiments focussed on the so-called PER, which investigated how exposure to imidacloprid impairs the responsiveness to a stimulus and affect memory performances. This response was studied with different test design, such as acute contact, acute oral or chronic oral. Moreover, some of these experiments were conducted with *Apis mellifera*, while others with *Apis cerana*. In a number of those experiments, a no observed effect dose (NOED) (acute) or a no observed effect concentration (NOEC) (chronic) value could be established, while in others, no effects (i.e. statistically different response from the control) was seen at the tested doses/concentrations. The endpoints of the available acute and chronic oral tests were rather inconsistent. However, from the results of the acute contact tests, it may be concluded that the NOED would be between 0.5 and 1.25 ng/bee.

Another sublethal effect that was studied in several experiments was impairment of locomotion. Again this response was studied with different test designs, such as acute contact, acute oral, subacute oral or chronic oral. No consistent response was seen between these studies.

In several studies, it was discussed that the investigated sublethal effects at individual or subindividual level may result in a colony/population level effect. It is acknowledged that an evident linkage (direct or indirect) between certain sublethal endpoints and colony/population level effects might exist. However, no appropriate information was available to establish or further describe these links. Therefore, these endpoints could not be linked to the protection goal and they were not considered further in the risk assessments.

5. Outcome of the risk assessment

5.1. Risk assessments for seed treatment products

5.1.1. Risk via systemic translocation in plants – residues in nectar and pollen (treated crop scenario and succeeding crop scenario)

5.1.1.1. Tier-1 risk assessment

The Tier-1 risk assessment for the representative GAPs were performed using the EFSA's BeeTool (v.3.) (Appendix Y of EFSA (2013c)) for honeybees and bumblebees, where suitable toxicity data were available. A screening Tier-1 assessment was carried out for solitary bees and for the chronic adult assessment for bumblebees as only surrogate endpoints were available. Since no toxicity data was available for HPG development or for the larvae toxicity for non-*Apis* bees, no assessment was performed for these scenarios. For potato, the application rate expressed as mass/tuber was not available. The outcome of these calculations is summarised in Table 7. High risk or low risk not demonstrated is indicated for all cases since one or more combinations (categories of acute, chronic and larva combined with the treated crop scenario and following crop scenarios) indicated a high risk. The detailed results are included in Appendix C.

Table 7: Summary of the outcome of Tier-1 and screening Tier-1 risk assessment

Use	Honeybee		Bumblebee		Solitary bee	
	'Low' application rate	**'High' application rate**	**'Low' application rate**	**'High' application rate**	**'Low' application rate**	**'High' application rate**
Spring and winter cereals, cotton, endive, lettuce, brassicas (flowering, head, leafy), maize, potato, spring and winter rape, sugar and fodder beet	High risk	High risk	High risk	High risk	Low risk not demonstrated	Low risk not demonstrated

It is noted that endive, lettuce, brassicas, sugar and fodder beet may be harvested before they flower. In that case, the treated crop scenario is not relevant for those crops (low risk for that scenario). Nevertheless, the following crop scenario indicated a high risk for those crops. For the uses when crops are transplanted and grown in permanent greenhouses (but not transplanted in the field or non-permanent greenhouse), none of the scenarios are relevant (low risk for the treated crop and for the following crop scenario). It is also noted that for potato only, the following crop scenario was considered as no calculations were possible for the treated crop scenario.

As presented above, the Tier-1 dietary risk assessment for the treated crop and succeeding crop scenario for all seed treatment uses under consideration indicated a high risk to honeybees and bumblebees. By the screening assessment for solitary bees, a low risk was not demonstrated. No risk assessment could be performed for honeybee HPG development or bumblebee and solitary bee larvae.

It is noted that for endive, lettuce and brassicas, a low risk could be concluded for uses when the treated crop is grown continuously (including flowering) in permanent greenhouse.

5.1.1.2. Exposure assessment for the treated and succeeding crop scenarios

Treated crop scenario

Several reliable studies giving measured residue values in nectar and pollen originating from crops grown from seeds treated with imidacloprid were available. For the seed treatment uses under consideration, sufficient relevant data were available for oilseed rape only.

According to EFSA (2013c) in order to perform an exposure assessment, it is preferable to have measured residues in pollen and nectar collected from bees. Taking the pollen and nectar directly from the bees aims to give a better representation of the likely exposure to bees and bee colonies by accounting for dilution by non-contaminated pollen and nectar. As regards pollen, residues from pollen traps attached to the hive entrance are also considered. Alternatively, residues of pollen and nectar taken directly from the plant can be used in the exposure assessment. However, residues in plant pollen and nectar are considered to be an overestimation of the exposure to bees as dilution is not accounted for. Residue data in pollen and nectar from bees taken from semifield studies were considered to be representative of situations where there was no dilution and therefore were combined with the residues from field studies. In case of nectar, the available residue values from bees were combined with residue values taken directly from the plant, since a sufficient number of measured residue values taken from the bees was not available. As regards pollen, all the available values originated either from bees or from pollen traps. In the cases where data were available from both bee pollen and from pollen trap, the values from bees only were taken. The residue values from bees (including when pollen trap was used) were all from pollen and nectar collected from honeybees. Therefore, exposure refinements were performed only for honeybees. The available data set included two RUD values for nectar and two RUD values for pollen from studies from winter oilseed rape. As regards spring oilseed rape, four RUD values for nectar and six RUD values for pollen were available. The separate data for winter and spring oilseed rape were considered insufficient for separate risk assessments for winter and spring oilseed rape according to EFSA (2013c). Therefore, the two data sets were combined resulting in a total of six RUD values for nectar and eight RUD values for pollen. The actual residue values used for establishing the exposure assessment goals are reported in Appendix E. It is acknowledged that it is likely that RUD values for spring oilseed rape are conservative relative to those for winter oilseed rape. However, the RUD values for winter oilseed rape do not necessarily cover the residue levels for spring oilseed rape as from the available data it appeared that residues in spring oilseed rape were higher. Therefore, the refined risk assessment was performed only for winter oilseed rape. It is noted that in several cases (four of the six RUD values for nectar and six of the eight RUD values for pollen), insufficient information was available to work out the application rate used in the study in terms of seed loading (mg/seed). However, assuming a thousand grain weight (TGW), it was possible. For these cases, a TGW of 5 g was considered.

The measured residue values were normalised for the seed loading (mg a.s./seed) to give RUD values (mg a.s./kg pollen or mg a.s./kg nectar).

Such RUD values were log-transformed before being used as input for the EFSA SHVAL tool (EFSA, 2014a). A 90th percentile SV for exposure, in terms of RI, is given as output of this tool. Simulations were run for each bee species and each caste. Tier-1 data for pollen and nectar consumption and sugar content in nectar were assumed. To transform the refined shortcut values to an exposure assessment goal, the shortcut values are multiplied by the seed loading rate (in terms of mg a.s./kg seed) for each use listed in the GAP (Appendix A). The resulting refined shortcut values and exposure assessment goals for the GAP for winter oilseed rape are presented in Table 8.

Table 8: Refined shortcut values and exposure assessment goals for honeybees for winter oilseed rape applied as seed treatment

	Refined shortcut value (μg/bee per day or μg/larva per developmental period)	Exposure assessment goal for 0.01 mg a.s./seed (ng/bee per day or ng/larva per developmental period)
Acute forager	0.21	2.1
Chronic forager	0.16	1.6
Nurse	0.09	0.9
Larva	0.12	1.2

Succeeding crop scenario

As imidacloprid has the potential to accumulate in soil from use over successive years, this has to be accounted for in the succeeding crop assessment. This potential for accumulation was accounted for by calculating plateau PEC in soil following FOCUS (1997, 2006). Accordingly, the longest field dissipation study single first-order DT_{50} of 288 days (EFSA, 2008) was used to calculate an accumulated concentration in soil assuming a soil mixing (tillage) depth of 20 cm and soil bulk density of 1.5 g/cm^3. To cover the representative uses under assessment, annual soil application rates of 175, 139.6 and 34.5 g/ha were used for the calculations. The value of 175 g/ha is from continuous cropping of cotton; 139.6 g/ha ((180 + 3 × 126)/4) represents a rotation of the use on potatoes (highest dose rate 180 g/ha) followed by 3 years of use on winter cereals (highest dose rate 126 g/ha). The value of 34.5 g/ha ((9 + 3 × 43)/4) represents a rotation of the use on oilseed rape (lowest dose rate 9 g/ha) followed by 3 years of use on winter cereals (lowest dose rate 43 g/ha). Accumulated soil exposure concentrations from the other uses assessed would fall between the lower two of these three annual application rates. The accumulated PECs in soil resulting from the assumptions outlined above are 0.0415 mg/kg, 0.033 mg/kg and 0.008 mg/kg, respectively.

From the seed treatment uses under consideration, relevant data for the exposure assessment for the succeeding crop were available when the succeeding crops were phacelia, winter oilseed rape, mustard (semifield study designs) and maize (field studies, pollen collected from plants).

In these studies, the potential exposure of bees to residues in succeeding crops was investigated based on two different approaches. In a series of studies concentrations of imidacloprid, 5-OH-imidacloprid and imidacloprid olefin in nectar and pollen from these crops/plants attractive for bees were measured under conditions of 'forced' soil residues, i.e. succeeding crops grown on soils treated over their entire area with imidacloprid to obtain a theoretical plateau concentration of imidacloprid in soil. In other field studies, the untreated succeeding crops were sown in soil with a history of several years of use of imidacloprid, and thus exposed to so called 'naturally aged' residues in the soil, the residues analysed were the same as those in the forced studies. Apart from one new 'forced' study, the data set available for this conclusion was identical to the confirmatory data package evaluated in the EFSA conclusion in 2016 (EFSA, 2016b). In the previous peer review assessment, it was concluded (Pesticides Peer Review Meeting 145) that the 'forced exposure' is less representative of the exposure situation under field conditions, where the imidacloprid residues in soil had already undergone natural ageing processes, that make them potentially less available for plant uptake. Therefore, studies with 'forced' soil residues of imidacloprid in soil were not considered further and the highest residue values measured for pollen and nectar from the 'natural aged' soil residue studies were used to refine the risk assessment. This approach was also used in this conclusion.

In the 'natural aged' soil residue experiments, where the highest residue values for pollen (2.5 μg imidacloprid/kg maize, 1.5 μg imidacloprid/kg phacelia, 1.3 μg imidacloprid/kg winter oilseed rape) and nectar (3.5 μg imidacloprid/kg phacelia, 0.7 μg imidacloprid/kg winter oilseed rape) were detected, the measured soil residues were from 0.035 to 0.059 mg/kg, higher than the calculated accumulated soil PEC of 0.033 mg/kg or 0.008 mg/kg for the potato and the oilseed rape seed treatment uses, respectively. These soil residues were comparable to or higher than the calculated accumulated PEC of 0.0415 mg/kg for the cotton seed treatment use (see details of these PEC calculations above). These PECplateau values cover all the GAPs considered in this conclusion. It is noted that soil residues are independent of the GAPs for the primary crop(s) and can be used for any GAP, provided that the crop rotation and the ageing processes are leading to soil residue levels comparable to the calculated PECplateau values. In these 'natural aged' experiments, 5-OH-imidacloprid residues were always < 1 μg/kg (LOQ) in pollen (phacelia) and < 0.3 μg/kg (LOD) in nectar. Imidacloprid olefin residues were always < 0.3 μg/kg (LOD) in both pollen and nectar.

The above residue values of imidacloprid in pollen and nectar for the succeeding crop were inserted in the EFSA SHVAL tool (EFSA, 2014a). As the refined shortcut values are independent of the GAP, they also represent the exposure assessment goal for the succeeding crop scenario. The calculated values are presented in Table 9. It is noted that these values are in line with the calculated SVs for the confirmatory data for imidacloprid (EFSA, 2016b).

Table 9: Refined shortcut values and exposure assessment goals for honeybees and bumblebees for the succeeding crop scenario

	Refined Shortcut value (μg/bee per day or μg/larva per developmental period)	**Exposure assessment goal (ng/bee per day or ng/larva per developmental period)**
Honeybee forager acute	0.00244	2.44
Honeybee forager chronic	0.00189	1.89
Honeybee nurse	0.00101	1.01
Honeybee larva	0.00139	1.39
Bumblebee adult acute	0.00312	3.12
Bumblebee adult chronic	0.00269	2.69
Bumblebee larva	0.00065	6.5[(a)]

(a): The shortcut value for bumblebee larva refers only to 1 day. In order to cover the entire developmental period by the exposure assessment goal, the value was multiplied by 10, as recommended by EFSA (2013c)

5.1.1.3. Tier-2 risk assessment

Treated crop scenario

As explained above in 5.1.1.2, sufficient data on residues were available only for the representative GAP for winter oilseed rape. Tier-2 risk assessments performed by using the EFSA's BeeTool (v.3.) (Appendix Y of EFSA (2013c)) for honeybees. In these calculations, the Tier-1 shortcut values were replaced by the refined Tier-2 shortcut values. The outcomes of these calculations are summarised in Table 10. Low risk could not be demonstrated for honeybees for the winter oilseed rape use.

Table 10: Tier-2 risk assessment for honeybees for winter oilseed rape applied as seed treatments

Category	**Refined shortcut value (μg/bee per day or μg/larva per developmental period)**	**ETR for the seed treatment rate of 0.01 mg a.s./seed**	**Trigger**
Acute adult	0.21	**0.568**	0.2
Chronic adult	0.16	**0.567**	0.03
Larva	0.12	**0.227**	0.2

ETR: Exposure toxicity ratio.

Succeeding crop scenario

The Tier-2 risk assessments for the succeeding crop scenarios are reported in EFSA (2016b). Those risk assessments indicated a high risk or a high risk could not be excluded for honeybees, bumblebees and solitary bees. The PECplateau for the GAPs considered in this conclusion are lower or comparable to the measured soil residues considered in succeeding crop trials in EFSA (2016b). Therefore, the risk assessments presented in EFSA (2016b) cover the risk resulting from the GAPs of this conclusion.

5.1.1.4. Tier-3 risk assessment (weight of evidence)

As discussed in Section 3.4, a WoE approach was developed to utilise the information from the diverse range of higher tier effect experiments that were available.

The WoE risk assessment could only be performed for the GAPs for which an exposure assessment goal was calculated (Section 5.1.1.2). For the use of imidacloprid as a seed treatment, exposure assessment goals could be determined only for the treated crop scenario for winter oilseed rape foraged by honeybees. In addition, an exposure assessment goal has also been determined for the succeeding crop scenario for all uses of imidacloprid under consideration. These assessments are relevant for all bee species. Consequently, the WoE approach was applied to these combinations only. As previously discussed, the WoE exercise has two fundamental steps: firstly, the identification/ consideration of the lines of evidence and secondly, the integration of the lines of evidence.

5.1.1.4.1. Weight of evidence higher tier risk assessment for honeybees

There was a number of higher tier endpoints (dominated by colony feeder type studies) which had been assessed and integrated in a WoE exercise. First, each line of evidence (i.e. Class 1 and Class 2 endpoints) were assessed and concluded for the treated crop scenario for winter oilseed rape and for the succeeding crop scenario. The graphical representations with the interpretation of each line of evidence specific to these two situations are presented in Appendix F.

The second step of the WoE exercise is the integration of the lines of evidence. Tables 11 and 12 present the integration of the lines of evidence for the treated crop scenario for winter oilseed rape and for the succeeding crop scenario, respectively.

In addition, below Table 11, there is a brief consideration for the use on spring oilseed rape (treated crop scenario).

It is noted that no reliable data were available for forager mortality. Therefore, no consideration for this Class 1 endpoint is included in the integrations of the lines of evidence presented below.

Treated crop scenario

Table 11: The integration of the lines of evidence for honeybees for the treated crop scenario for winter oilseed rape

Class 1 endpoints	
Colony strength	Refer to Appendix F, Section 1.1.1 A relatively high number of experiments with a realistic or severe exposure regime indicated an overall negligible deviation from the control, while a fewer experiments with suitable exposure indicated a larger than negligible negative deviation from the control. Also, there was a considerable biological variability within and between the endpoints and the endpoints indicating negligible deviation were, in general, much more reliable Overall, this indicated a **moderate evidence for negligible effect**
Overwintering assessment	Refer to Appendix F, Section 1.2.1 When the deviations from the controls of the effects on honeybee populations after overwintering in combination with the exposure estimations of the relevant experiments were considered, it was concluded that the available data set was rather contradictory. Nevertheless, more weight was attributed to the available evidence indicating more than negligible negative effects However, some experiments that indicated negative effects had considerably longer exposure duration than the realistic flowering period of oilseed rape. When the severity of these endpoints was taken into consideration, the available evidences become balanced and no clear trend was apparent Overall, **this line of evidence was inconclusive**

Class 2 endpoints		
Mortality in front of the hive	Refer to Appendix F, Section 1.3.1 Relatively low number of reliable endpoints was available. All of these endpoints had low reliability, but the biological variability of them was low Only one experiment with appropriate exposure and indicating negligible effect was available, while in two experiments with mild exposure regimes temporal, larger than negligible negative deviations were indicated Overall, this indicated a **weak evidence for larger than negligible effect**	
Brood abundance	Refer to Appendix F, Section 1.4.1 There was a considerable biological variability within and between the endpoints and all the endpoints had low reliability A slightly higher number of experiments with realistic or severe exposure regime indicated an overall negligible (or even positive) deviation from the control, while slightly fewer experiments with realistic or mild exposure regime indicated more than negligible negative deviation from the control Overall, this indicated a **weak evidence for negligible effect**	
Homing success	Refer to Appendix F, Section 1.5.1 Relatively low number of endpoints was available. All were classified as reliable with major restrictions and in all but one case, the estimated exposure levels exceed the exposure assessment goal for winter oilseed rape. One of these endpoints indicated a negligible (negative) deviation from the control. The single endpoint that had an estimated exposure level slightly below, but close to the exposure assessment goal indicated no deviation from the control Overall, this indicated a **weak evidence for negligible effect**	
Integration of lines of evidence for winter oilseed rape	Class 1 endpoints, overall, suggest a moderate evidence for negligible effects. Class 2 endpoints indicated only weak evidence; overall for a negligible effect. However, data also suggested that some temporal negative effects cannot be excluded	
Uncertainty analysis in line with EFSA (2013c) (– potential to make the true risk lower + potential to make the true risk higher)	**Quantification of the effects**	
	Many of the available endpoints were assessed to be reliable with major restrictions; therefore, the overall reliability of the WoE is limited	+/–
	The reasons for the reliability assessment categorisation differed between the studies	+/–
	The consistency in case of many lines of evidence is low	+/–
	Many of the data were not presented in sufficient detail to derive accurate deviations from the control	+/–
	Within some experiments, pre-exposure measurements revealed that some endpoints did not start at comparable level. This initial difference was accounted for in the derivation of the deviation from the control, but the accuracy of the quantification in these cases is limited	+/–
	Exposure in the experiments	
	For the overwintering assessment, the food consumption of foragers and nurse bees were considered and the lower food consumption of resting winter bees was not accounted for when estimating exposure in the experiments. This might have overestimated the exposure in the experiments	+
	The exposure level of the effect field experiments on crops with nectar was calculated considering 15% sugar content of the nectar, which is the low end value of the realistic range. This may result in an overestimation of the estimated exposure of those experiments	+
	The level of the dilution of the residue concentrations of the consumed pollen and nectar in the colony-feeder experiments with free flying bees could not be estimated from the available data	++
	For some colony-feeder experiments where bees were fed with sugar solution, the actual percentage of sugar was unknown and therefore assumed to be 50%. This would have an impact on the assumed consumption and in turn on the active substance intake	+/–

	The exposure in the higher tier effect studies was estimated using mean residue measurements. In some studies, there were values reported < LOD, which were conservatively considered as 0 mg/kg. When a value was reported to be detected but < LOQ, the value was considered to be between the LOQ and LOD (average of LOQ and LOD) and the LOD was considered as half of the LOQ	–
	Exposure assessment goals	
	In several residue studies used for the exposure assessment goal, the sampling frequency and pattern did not guarantee that the actual maximum occurrence had been picked up	+
	The limited number of valid residue studies available for the exposure assessment goal, restricted the potential for the representativeness to cover 90^{th} percentile exposure situations	+
	The exposure assessment goals were calculated assuming residues equal to the LOQ every time measured concentration were < LOQ. In the cases that no residues were detected the residue was considered to be equal to the LOD	–
	The exposure assessment goals were calculated using the maximum residue levels measured within each trial	–
	Since insufficient RUD values were available from winter oilseed rape to perform an exposure assessment, the available RUD values for spring oilseed rape were also used	–
	For the determination of the exposure assessment goals, a 15% sugar content of the nectar was assumed, which is the low end value of the realistic range. This may have resulted in an overestimation of the exposure assessment goal	–
	For overwintering assessment, the exposure assessment goal was based on consumption from active bees and could therefore be overestimating the actual exposure of bees during winter	–
	Confounding factors in the experiments	
	In 4 of 23 higher tier studies, there was a confirmation of control contamination with imidacloprid or with other neonicotinoids. This could potentially mask triggering of negative effects.The presence of external substances was also seen in the treatment, creating uncertainties about detecting effects not due to the treatment	+/–
	In half of the higher tier studies where the bees were allowed to free flying, there were indications for the use of different pesticides, including insecticides (including neonicotinoids) in the landscape where the bees could forage. This may affect both control and treatment.There is also uncertainty that this practice could have been done also in experiments where this was not clearly reported	+/–
Conclusion	The weight of evidence exercise with a consideration to the uncertainties of the assessment is considered to indicate a low risk to honeybees from residues in pollen and nectar for the treated crop scenario for winter oilseed rape. It has to be noted, however, that the line of evidence for overwintering assessments was assessed as inconclusive and the indirectly relevant (Class 2) endpoint of 'mortality in front of the hive' indicated a weak evidence for more than negligible effect	

LOD: limit of detection; LOQ: limit of quantification; RUD: residue per unit dose.

In lack of exposure assessment goals, a similar weight of evidence exercise as for winter oilseed rape (integration of lines of evidences obtained from realistic exposure estimations) could not be performed for the other crops. For the same reason, it is not possible to extrapolate the risk assessment of winter oilseed rape to the other crops except for spring oilseed rape.

It is expected, and confirmed by the available (rather limited) data for residues in pollen and nectar (see Appendix D), that the residue levels in spring oilseed rape tend to be higher than in winter oilseed rape. However, the application rate and the attractiveness of the two crops are the same. The residue levels from spring oilseed rape studies had been considered in the assessments for winter oilseed rape. Therefore, overall, the risk to spring oilseed rape is expected to be similar than the risk to winter oilseed rape (i.e. low risk), noting that this includes some uncertainties due to the expected higher residue levels.

Succeeding crop scenario

The exposure assessment goal for the succeeding crop scenario is only marginally different from the exposure assessment goal for winter oilseed rape (see Section 5.1.1.2). Also, the difference between the length of realistic flowering period of winter oilseed rape and any possible succeeding crop, as considered in this conclusion (10–42 days for winter oilseed rape and 5–42 days for the succeeding crop scenario), was not important, since all the reliable higher tier studies had more than 10 days exposure period. Therefore, the integration of the lines of evidence and the conclusion for winter oilseed rape is equally applicable for the succeeding crop scenario. For the sake of simplification, only the uncertainty analysis and the conclusions that are different from the assessment for winter oilseed rape are detailed in Table 12. All the other parts of the integration of the lines of evidence for winter oilseed rape as presented in Table 11 are applicable for the succeeding crop scenario.

Table 12: The integration of the lines of evidence for honeybees for the succeeding crop scenario

Class 1 endpoints		
Colony strength	Refer to Appendix F, Section 1.1.2 For narrative description, see Table 11 for winter oilseed rape	
Overwintering assessment	Refer to Appendix F, Section 1.2.2 For narrative description, see Table 11 for winter oilseed rape	
Class 2 endpoints		
Mortality in front of the hive	Refer to Appendix F, Section 1.3.2 For narrative description, see Table 11 for winter oilseed rape	
Brood abundance	Refer to Appendix F, Section 1.4.2 For narrative description, see Table 11 for winter oilseed rape	
Homing success	Appendix F, section 1.5.2 For narrative description, see Table 11 for winter oilseed rape	
Integration of lines of evidence for the succeeding crop scenario	For narrative description, see Table 11 for winter oilseed rape	
Uncertainty analysis in line with EFSA (2013c) (– potential to make the true risk lower + potential to make the true risk higher)	**Quantification of the effects**	
	Most of the available endpoints were assessed to be reliable with major restrictions; therefore, the overall reliability of the WoE is limited	+/–
	The reasons for the reliability assessment categorisation differed between the studies	+/–
	The consistency in case of many lines of evidence is extremely low	+/–
	Many of the data were not presented in sufficient detail to derive accurate deviations from the control. Therefore, only crude estimates could be used in the lines of evidence	+/–
	Within some experiments, pre-exposure measurements revealed that some endpoints did not start at comparable level. This initial difference was accounted for in the derivation of the deviation from the control, but the accuracy of the quantification in these cases is limited	+/–
	Exposure in the experiments	
	For the overwintering assessment, the food consumption of foragers and nurse bees was considered and the lower food consumption of resting winter bees was not accounted for when estimating exposure in the experiments. This might have overestimated the exposure in the experiments	+
	The exposure level of the effect field experiments on crops with nectar was calculated considering 15% sugar content of the nectar, which is the low end value of the realistic range. This may result in an overestimation of the estimated exposure of those experiments	+

	The level of the dilution of the residue concentrations of the consumed pollen and nectar in the colony-feeder experiments with free flying bees could not be estimated from the available data	++
	For some colony-feeder experiments where bees were fed with sugar solution, the actual percentage of sugar was unknown and therefore assumed to be 50%. This would have an impact on the assumed consumption and in turn on the active substance intake	+/−
	The exposure in the higher tier effect studies was estimated using mean residue measurements. In some studies, there were values reported < LOD, which were conservatively considered as 0 mg/kg. When a value was reported to be detected but < LOQ, the value was considered to be between the LOQ and LOD (average of LOQ and LOD), and the LOD was considered as half of the LOQ	−
	Exposure assessment goals	
	For the determination of the exposure assessment goals, a 15% sugar content of the nectar was assumed, which is the low end value of the realistic range. This may have resulted in an overestimation of the exposure assessment goal	−
	For overwintering assessment, the exposure assessment goal was based on consumption from active bees and could therefore be overestimating the actual exposure of bees during winter	−
	The PECplateau for the GAPs under consideration are lower than the soil residue levels of the available residue trials. Therefore, the exposure assessment goals are conservative for the GAPs under consideration. The only exception was the use on cotton where the PECplateau was comparable with the residue levels of the test soils	−
	The exposure assessment goal was based on residue values from semifield studies or samples taken directly from the crop, i.e. landscape dilution was not taken into consideration	−
	Confounding factors in the experiments	
	In 4 of 22 higher tier studies, there was a confirmation of control contamination with imidacloprid or with other neonicotinoids. This could potentially mask triggering of negative effects The presence of external substances was also seen in the treatment, creating uncertainties about detecting effects not due to the treatment	+/−
	In half of the higher tier studies where the bees were allowed to free flying, there were indications for the use of different pesticides, including insecticides (including neonicotinoids) in the landscape where the bees could forage. This may affect both control and treatment. There is also uncertainty that this practice could have been done also in experiments where this was not clearly reported	+/−
Conclusion	The weight of evidence exercise with a consideration to the uncertainties of the assessment is considered to indicate a low risk to honeybees from residues in pollen and nectar for the succeeding crop scenario It has to be noted however that the line of evidence for overwintering assessment was assessed as inconclusive and the indirectly relevant (Class 2) endpoint of 'mortality in front of the hive' indicated a weak evidence for more than negligible effect	

WoE: weight of evidence; LOD: limit of detection; LOQ: limit of quantification; PEC: predicted environmental concentration; GAP: good agricultural practices.

5.1.1.4.2. Weight of evidence higher tier risk assessment for bumblebees

A number of higher tier endpoints (dominated by colony feeder type studies) has been assessed and integrated in a weight of evidence exercise. First, each line of evidence (i.e. class 1 and class 2 endpoints) were assessed and concluded for the succeeding crop scenario. The graphical representations with the interpretation of each line of evidence, which had multiple endpoints, are presented in Appendix F. One of the Class 1 and the available Class 2 endpoints had only one or two data points; therefore, no graphical representations were performed. These endpoints however are briefly summarised in Appendix F.

The second step of the WoE exercise is the integration of the lines of evidence. Table 13 present the integration of the lines of evidence for the succeeding crop scenario.

Table 13: The integration of the lines of evidence for bumblebees for the succeeding crop scenario

Class 1 endpoints	
Queen production	Refer to Appendix F, Section 2.1 Only one experiment with appropriate exposure indicated negligible effect and only one experiment with rather mild exposure regime resulted in a large-negative deviation from the control. However, another endpoint with low exposure level but long exposure duration also indicated negative deviation from the control Overall, this indicated a **weak evidence for larger than negligible effect**
Worker production	Refer to Appendix F, Section 2.2 Two experiments with appropriate exposure indicated a clear negative deviation from the control. One of them had higher reliability than all the other endpoints, while the other one had some uncertainties. On the other hand, three experiments could be considered as evidence indicating no negative deviation from the controls. However, none of them had a clearly representative or severe exposure regime. No clear trend could be seen when all these positive and negative elements were balanced Overall, this **line of evidence was inconclusive**
Drone production	Refer to Appendix F, Section 2.3 Two experiments with low exposure level indicated a clear negative deviation from the control. One of them had too long exposure length, while the other one had some uncertainties. On the other hand, two experiments could be considered bearing some evidences that indicate no negative deviations from the controls. However, none of them had a clearly representative or severe exposure regime. No clear trend could be seen when all these positive and negative elements were balanced Overall, this **line of evidence was inconclusive**
Reproductive output of queenless microcolonies	Refer to Appendix F, Section 2.4 A number of endpoints with relatively low exposure levels (and one of them with a realistic exposure length) indicated clear negative deviations from the control. No endpoint was available indicating negligible or positive deviation from the control Overall, this indicated a **moderate evidence for larger than negligible effect**
Brood production	Refer to Appendix F, Section 2.5 A number of experiments indicated clearly negative deviations from the control. Five of these experiments had a mild exposure regime. On the other hand, only two endpoints could be considered as evidence indicating no negative deviation from the controls. However, none of them had a clearly representative or severe exposure regime Overall, this indicated a **moderate evidence for larger than negligible effect**
Colony strength	Refer to Appendix F, Section 2.6 Only two endpoints were available. The estimated exposure levels associated to these endpoints were in the range of or lower than the exposure assessment goals for succeeding crops. The length of the exposure was in the realistic range or only marginally longer than the flowering period of succeeding crops. One of the endpoints was considered as fully reliable. The deviation from the control was between negligible to large negative and the mean deviation was assessed as medium negative. The other endpoint was considered as reliable with major restrictions. The deviation from the control was large negative in this experiment This indicated a **strong evidence for larger than negligible effect**

Class 2 endpoints		
Emergence rate (workers)	Refer to Appendix F, Section 2.7 Only one endpoint was available and the estimated exposure level associated to this endpoint was in the range of the exposure assessment goals for succeeding crops. The length of the exposure was in the realistic range of the flowering period of succeeding crops. The deviation from the control bridged from large positive to large negative, and the mean deviation was assessed as medium negative. The endpoint was considered as fully reliable This indicated a **moderate evidence for more than negligible effect**	
Mating ability of the new queens	Refer to Appendix F, Section 2.8 Only one endpoint was available originating from a field study on sunflower with a 9-day exposure period. No exposure estimation was available for this endpoint. This **line of evidence was inconclusive**	
Integration of lines of evidence for the succeeding crop scenario	Class 1 endpoints, overall, suggest a moderate evidence for larger than negligible effects. This was also indicated by the single Class 2 endpoint, which was conclusive	
Uncertainty analysis in line with EFSA (2013c) (– potential to make the true risk lower + potential to make the true risk higher)	**Quantification of the effects**	
	Many of the available endpoints were assessed to be reliable with major restrictions; therefore, the overall reliability of the WoE is limited	+/–
	The reasons for the reliability assessment categorisation differed between the studies	+/–
	For some colony-feeder experiments where bees were fed with sugar solution, the actual percentage of sugar was unknown and therefore assumed to be 50%. This would have an impact on the assumed consumption and in turn on the active substance intake	+/–
	The level of the dilution of the residue concentrations of the consumed pollen and nectar in the colony-feeder experiments with free flying bees could not be estimated from the available data	++
	In some colony-feeder studies, the amount of the offered food (i.e. the spiked sugar solution) was not ad libitum. In one field study, non-spiked food was offered to the colonies after the exposure phase. These may lead to excessive dilution of the residue concentrations	+
	In a few colony-feeder studies, some avoidance to the feeding solution had been reported	+/–
	Exposure in the experiments	
	The exposure in the higher tier effect studies was estimated using mean residue measurements. In two field experiments, which were on potato (i.e. relevant only for pollen), there were values reported < LOD, which were conservatively considered as 0 mg/kg. When a value was reported to be detected but < LOQ, the value was considered to be between the LOQ and LOD	–
	Exposure assessment goals	
	The exposure assessment goal was based on residue values from semifield studies or samples taken directly from the crop, i.e. landscape dilution was not taken into consideration	–
	The PECplateau for the GAPs under consideration are lower than the soil residue levels of the available residue trials. Therefore, the exposure assessment goals are conservative for the GAPs under consideration. The only exception was the use on cotton where the PECplateau was comparable with the residue levels of the test soils	–

	Confounding factors in the experiments	
	In a few cases of the higher tier studies, there was a confirmation of control contamination with imidacloprid or with other neonicotinoids. This could potentially mask triggering of negative effects In some experiments, pollen collected by honeybees without sufficient information on potential residue contamination was offered to the colonies. Potential presence of external substances creates also uncertainties about detecting effects not due to the treatment	+/–
	In many of the higher tier studies where the bees were allowed to free flying, there were indications for the use of different pesticides, including insecticides (including neonicotinoids) in the landscape where the bees could forage. This may affect both control and treatment. There is also uncertainty that this practice could have happened also in experiments where this was not clearly reported	+/–
Conclusion	The weight of evidence exercise with a consideration to the uncertainties of the assessment is considered to indicate a high risk to bumblebees from residues in pollen and nectar for the succeeding crop scenario	

WoE: weight of evidence; LOD: limit of detection; LOQ: limit of quantification; PEC: predicted environmental concentration; GAP: good agricultural practices.

5.1.1.4.3. Solitary bees

No higher tier studies were available for solitary bees.

5.1.2. Risk from contamination of adjacent vegetation via dust drift (field margin and adjacent crop scenario)

5.1.2.1 Tier-1 risk assessment

The Tier-1 risk assessment for the representative GAPs were performed by using the EFSA's BeeTool (v.3.) (Appendix Y of EFSA, 2013c) for honeybees and bumblebees, where suitable toxicity data were available. A screening Tier-1 assessment was carried out for solitary bees and for the chronic adult assessment for bumblebees as only surrogate endpoints were available. Since no toxicity data were available for HPG development nor for the larvae toxicity for non-*Apis* bees, no assessment was performed for these scenarios.

It was assumed that a deflector was used during the seed drilling. The potato seed treatment use is an in-planter tuber treatment via a spray application. Therefore, no dust formation was considered for this use.

The outcome of these calculations is summarised in Tables 14 and 15. A low risk is indicated only if all categories (acute, chronic and larva) for all the relevant scenarios resulted in low risk. When one or more combinations (categories of acute, chronic and larva combined with the relevant scenarios) indicated a high risk than high risk or low risk not demonstrated (for Tier-1 screening assessments) is indicated in the table below. The detailed results are included in Appendix C.

Table 14: Summary of the outcome of Tier-1 and screening Tier-1 risk assessment for the contact route of exposure

Use	Honeybee		Bumblebee		Solitary bee	
	'Low' application rate	**'High' application rate**	**'Low' application rate**	**'High' application rate**	**'Low' application rate**	**'High' application rate**
Spring cereals, cotton, endive, lettuce, brassicas (flowering, head, leafy) and maize	High risk	High risk	High risk	High risk	Low risk not demonstrated	Low risk not demonstrated

Use	Honeybee		Bumblebee		Solitary bee	
	'Low' application rate	**'High' application rate**	**'Low' application rate**	**'High' application rate**	**'Low' application rate**	**'High' application rate**
Winter cereal	High risk	High risk	Low risk with deflector	High risk	Low risk not demonstrated	Low risk not demonstrated
Spring and winter rape	Low risk with deflector	Low risk with deflector	Low risk with deflector	Low risk with deflector	Low risk not demonstrated	Low risk not demonstrated
Sugar and fodder beet	Low risk with and without deflector	Low risk with and without deflector	Low risk with and without deflector	Low risk with and without deflector	Low risk with and without deflector	Low risk with deflector
Potato	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)

Table 15: Summary of the outcome of Tier-1 and screening Tier-1 risk assessment for the dietary route of exposure

Use	Honeybee		Bumblebee		Solitary bee	
	'Low' application rate	**'High' application rate**	**'Low' application rate**	**'High' application rate**	**'Low' application rate**	**'High' application rate**
Spring and winter cereals, cotton, endive, lettuce, brassicas (flowering, head, leafy), maize	High risk	High risk	High risk	High risk	Low risk not demonstrated	Low risk not demonstrated
Spring and winter rape	High risk	High risk	Low risk not demonstrated	Low risk not demonstrated	Low risk not demonstrated	Low risk not demonstrated
Sugar and fodder beet	Low risk with and without deflector	Low risk with deflector	Low risk not demonstrated	Low risk not demonstrated	Low risk with deflector	Low risk not demonstrated
Potato	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)	Not relevant (Low risk)

Since no dust formation is expected from the use on potato, a low risk was concluded for the field margin and adjacent crop scenario for this use. Accounting for both contact and oral exposure, a low risk to honeybees for the field margin and adjacent crop scenario was indicated to sugar beet and fodder beet. It is noted that the endpoint for larvae was only considered to be provisional, a reliable endpoint for HPG is not available and there was no assessment of the potential for accumulative effects available. Nevertheless, the provisional risk assessment is considered sufficient to conclude a low risk for this particular crop and scenario, but it would be prudent to update the risk assessment when further data are available. The screening level assessment performed for bumblebees and for the high application rate for solitary bees was not sufficient to demonstrate a low risk. A low risk was indicated for solitary bees for the low application rate of sugar beet and fodder beet. For spring and winter rape, a high risk to honeybees was indicated and a low risk to bumblebees and solitary bees was not demonstrated with a screening assessment. For all other seed treatment uses under consideration, a high risk to honeybees and bumblebees was indicated and a low risk to solitary bees was not demonstrated with a screening assessment. No risk assessment could be performed for bumblebee and solitary bee larvae.

It is noted that for endive, lettuce and brassicas, a low risk could be concluded for uses when the treated crop is sown in permanent greenhouse.

5.1.2.2. Exposure assessment for the field margin and adjacent crop scenario

In addition to the data set al.ready used in a previous EFSA conclusion (EFSA, 2016b), results from dust drift trials measuring imidacloprid in dust deposition outside the drilled field originating from treated seed at the time of drilling were available for winter barley (two experimental sites), winter wheat (two experimental sites) and winter oilseed rape (one experimental site). All these experiments were carried out with the same type of pneumatic seed driller (Accord DL No. 009190). Information on the presence or absence of a deflector and the deflector type was not provided.

In the two winter barley trials, seed dustiness was characterised with mean measured Heubach values of 0.093 g/10^5 seeds and 0.076 g/10^5 seeds. For seeds treated at 0.031 mg/seed with drilling rate 3,312,699–3,317,593 treated winter barley seeds/ha, residues in petri dishes placed on the ground were 12.63–12.81 mg/ha at 3 m and 17.04–22.00 mg/ha at 1 m from the edge of the drilled area. For seeds treated at 0.024829 mg/seed with drilling rate 3,535,405 treated winter barley seeds/ha, residues in petri dishes were 10.584 mg/ha at 3 m and 16.589 mg/ha at 1 m.

In the two winter wheat trials, seed dustiness was characterised with mean measured Heubach values of 0.062 g/10^5 seeds and 0.064 g/10^5 seeds. For seeds treated at 0.03096 mg/seed with drilling rate 4,588,640–4,603,114 treated winter wheat seeds/ha, residues in petri dishes were 8.53–13.976 mg/ha at 3 m and 13.424–16.047 mg/ha at 1 m. For seeds treated at 0.025619 mg/seed with drilling rate 4,314,833 treated winter wheat seeds/ha, residues in petri dishes were 8.953 mg/ha at 3 m and 11.202 mg/ha at 1 m.

In a winter oilseed rape trial, seed dustiness was characterised with mean measured Heubach values of 0.0006 g/10^5 seeds. For seeds treated at 0.01136–0.01137 mg/seed with drilling rate 649,877–672,332 treated oilseed rape seeds/ha, residues in petri dishes were 3.214 mg/ha at 3 m and 2.934 mg/ha at 1 m at one trial plot. At the second plot, concentrations were $<$ 2.934 mg/ha (LOQ).

As these trials only represent one seed drill type and two experiments for each crop, with these seed batch quality measured dustiness (Heubach determinations), it was considered not credible to use them to replace the Tier-1 values of the guidance. Therefore, no credible refined exposure assessment for contamination in field margins and adjacent crops could be performed.

In addition to the dust deposition field trials, information on dustiness of neonicotinoid treated seeds was available.

In the open call for data information was provided on the measurement of the dust content of oilseed rape and maize seeds (Heubach values); and in most cases for oilseed rape, also information on active ingredient content in the dust (Heubach a.i. values) was provided from seed samples from seed merchants. Dust was quantifiable/present in all seed batches tested. In maize seed, measured dust was just reported to be significantly below the industry standard of below 3 g dust/100 kg seed. Oilseed rape seeds treated in 2013 from 326 seed treatment sites had a 90th percentile total dust Heubach value of 0.192 g/700,000 seeds. These values for Heubach a.i. were 6 mg/700,000 seeds for clothianidin (156 sites), 1.4 mg/700,000 seeds for imidacloprid (52 sites) and 7.8 mg/700,000 seeds for thiamethoxam (104 sites).

Heubach a.i. values in seed samples from an additional 10 different seed treatment facilities also where seed was treated in 2013 were 0.21, 0.27, 0.33, 0.46, 0.6, 0.96, 1.29, 1.3, 8.9 and 16.6 mg/700,000 seeds for clothianidin.

As all these results are from the same year, so they did not provide any information on dustiness of the seed being supplied to farmers in different years and whether dust levels have reduced in recent years. It is clear that the Heubach a.i. values can be variable. It is clear that reducing the dust content of seed to be treated as well as any dust produced during the treatment process as well as any that might be generated during storage and transport of seed is a good target for improved risk management. However, with the information available in this review, it was not possible to account for this in any refined exposure and/or risk characterisation.

5.1.2.3. Tier-2 risk assessment

Since the available higher tier data for the exposure characterisation was not considered to be sufficient for a refinement, no Tier-2 risk assessment could be performed.

5.1.2.4. Tier-3 risk assessment

Only two higher tier effect studies were available. In the study I.848, winter barley seeds treated with imidacloprid were drilled in fields, which were surrounded by flowering *Phacelia tanacetifolia* where honeybee colonies were located. Class 1 and Class 2 endpoints (colony strength, brood abundance, mortality in front of the hive) were investigated. The brood abundance and the colony strength were very similar in the control and treatment group (with only a few percent deviation on average) with no statistical difference. The data on mortality in front of the hive indicated a constant higher mortality rate in the treated field than in the control (although this was the case in the pre-exposure period, as well). There were some periods when the mortality in the treated group was notably higher (up to a factor of 2, and in two cases, the available statistical analysis indicated a significant difference). However, the average number of dead bees was generally low, generally < 10 bee/day.

In the study C*I.1324, sugar beet pills treated with clothianidin (0.60 mg/pill), imidacloprid (0.30 mg/pill) and beta-cyfluthrin (0.08 mg/pill) were drilled in the field. The sugar beet pills were also treated with the fungicides thiram and hymexazol. Class 1 and Class 2 endpoints (colony strength, colony strength after overwintering, brood abundance, mortality in front of the hive) were investigated.

Overall, the colony strength during the season (i.e. until before the winter) and the mortality in front of the hive had similar trends to the control, although the maximum negative deviation from the control for the colony strength was marginally above the 7% (7.3%). No negative deviation was observed on the colony strength after the winter. The data on brood abundance indicated some fluctuations, it varied between small-positive to medium-negative deviation from the control.

All the endpoints from both studies were assessed as reliable with major restrictions. Moreover, in the study on sugar beet, other insecticides, including clothianidin, were used. Overall, the information available for the Tier-3 assessment was not considered to be sufficient for a robust conclusion on the risk via dust drift.

5.1.3. Risk via water consumption

5.1.3.1. Guttation water

The risk assessment based on water solubility indicated a high risk. The detailed results are included in Appendix D.

It should be highlighted that the EFSA evaluation of the confirmatory data for imidacloprid and clothianidin (EFSA, 2016b,c) concluded that the exposure of honeybees from contaminated guttation fluids in the crops considered therein (winter cereals, sugar beet and potatoes) was of low relevance. Such conclusion was confirmed during the expert meeting related to this assessment (Pesticide Peer Review Meeting 166), despite the experts acknowledged that such an assessment was based on studies presenting major limitations. On the basis of this, no risk assessment from exposure to contaminated guttation fluids was carried out, and a low risk was concluded for winter cereals, sugar beet and potatoes. In addition, considering this, a low risk was concluded for fodder beets.

In addition, it is noted that for endive, lettuce and brassicas, a low risk could be concluded for uses when the treated crop is grown continuously in permanent greenhouse.

Higher tier assessment for crops other than winter cereals, sugar beet and potatoes

Valid reliable field studies (two trials in Italy) investigating imidacloprid, 5-OH imidacloprid and imidacloprid olefin residues in guttation water collected from maize were available. As would be expected, highest residues occurred when plants were small (interval from drilling to guttation fluid sampling was short). The highest residues determined were up to 222 mg imidacloprid/L from an application rate of 1.25 mg/seed and 47 mg imidacloprid/L from an application rate of 0.5 mg/seed.

This small data set was considered not sufficient for selecting a 90th percentile exposure value as suggested by EFSA (2013c). Therefore, in line with the consideration of the experts at the meeting for the confirmatory data for imidacloprid (EFSA, 2016b), the maximum measured concentrations were considered to perform a refined risk assessment for maize. The refined calculations are presented in Table 16.

Table 16: Tier-2 risk assessment to honeybees exposed via consumption of contaminated guttation fluids

Bee type	Category	Water consumption (µL/bee or µL/larva)	Measured concentration in guttation fluid (µg/µL)	ETR	Trigger
Maize					
Honeybee forager	Acute	11.4	0.222	**684**	> 0.2
Honeybee forager	Chronic	11.4		**897**	> 0.03
Honeybee larva	Larva	111		**4,667**	> 0.2

ETR: Exposure toxicity ratio.

On the basis of this Tier-2 assessment, a low risk could not be concluded for maize.

No higher tier effect studies were available for crops other than winter cereals, potato or sugar beet; therefore, no further assessments were performed.

5.1.3.2. Puddle water

It was not necessary to perform exposure modelling to predict residues of imidacloprid in puddles as the concentrations in surface runoff calculated by any version of the PRZMsw tool are always negligible when seeds are drilled below the soil surface. Consequently, a low risk to honeybees from residues in puddles for the seed treatment uses under consideration is concluded following EFSA (2013c) that indicates that concentrations in runoff water as calculated by PRZMsw are an appropriate estimate of puddle water concentrations. Experts from member states noted that the EFSA (2013c) approach might represent a best case as cultivation following harvesting of the treated crop redistributes soil residues, such that concentrations at the soil surface will be present to desorb into puddles. PRZM calculations as prescribed by FOCUS surface water do not account for this as the FOCUS PRZM tool and FOCUS surface water runoff scenarios do not account for soil cultivation.

5.1.3.3. Surface water

PEC in surface water were calculated at Step 3 following FOCUS surface water (2001) guidance and the FOCUS tools SWASH 5.3, SPIN 2.2, MACRO 5.5.4, PRZMsw 3.3.2 and TOXSWA 4.4.3. for the active substance imidacloprid. The PECs were calculated for the GAPs on potatoes and winter cereals. Substance input values were selected in accordance with generic guidance for FOCUS surface water scenarios from the list of endpoints of EFSA (2008). The laboratory geomean single first-order DT_{50} for soil used was 117.7 days and that for water was 67 days with a value of 1,000 days (default) used for sediment. The geomean KFoc of 209.5 mL/g (KFom 121.5 mL/g) arithmetic mean 1/n 0.8 were used as input in the simulations. The option soil incorporation was selected and the application window was set in line with the planting dates specified at each scenario for winter cereals and potatoes. For PRZM CAM 8 was selected, i.e. that the incorporation was at a specific depth with 4 cm which is applicable for cereals and represents a conservative approach regarding surface runoff for potatoes. The highest PEC surface water calculated with this approach was 0.075 µg/L for the D6 ditch scenario from the use on winter cereals. From the simulations for potatoes, the highest PEC surface water was 0.042 µg/L for the D4 stream scenario. For these uses where seeds are drilled and granules are incorporated below the soil surface, concentrations in surface runoff as calculated by PRZMsw are always negligible. Therefore, as for puddle water (see 5.1.3.2), concentrations in the FOCUS surface water bodies are also always characterised as negligible for the FOCUS surface water runoff scenarios, when the option soil incorporation is selected.

Exposure toxicity ratio (ETR) calculations with the above-mentioned water concentrations resulted in a low risk to all honeybee castes (for details of the calculations see Appendix D). As no toxicity endpoint was available for the HPG development, a risk assessment could not be performed for this scenario. However, considering the notable margin of safety (two orders of magnitude in the chronic risk assessment) obtained in these assessments, a low risk was concluded for this scenario, as well.

5.2. Risk assessments for granule

5.2.1. Risk via systemic translocation in plants – residues in nectar and pollen

This route of exposure is relevant for the treated crop scenario, for the weed and for the succeeding crop scenario.

5.2.1.1. Tier-1 risk assessment for treated crop scenario, weed scenario and succeeding crop scenario

The Tier-1 risk assessments for the representative GAPs were performed by using the EFSA's BeeTool (v.3.) (Appendix Y of EFSA, 2013c) for honeybees and bumblebees, where suitable toxicity data were available. A screening Tier-1 assessment was carried out for solitary bees and for the chronic adult assessment for bumblebees as only surrogate endpoints were available. Since no toxicity data was available for HPG development or for the larvae toxicity for non-*Apis* bees, no assessment was performed for these scenarios.

The outcome of the calculations is summarised in Table 17. A high risk or low risk not demonstrated (for Tier-1 screening assessments) is indicated in the Table 17 since all combinations (categories of acute, chronic and larva combined with the relevant scenarios) indicated a high risk. The only exception is for the treated crop scenario, but only when the application is done after the flowering period of the crop. The detailed results are included in Appendix C. It is however to be noted that turf is typically a mix of different plant species that may flower in different periods. Moreover, turf may be mowed during the vegetative season and shortly after mowing, turf may flower again. Therefore, this scenario (application is done after the flowering of the crop) has a limited applicability for this use. During the experts meeting (October 2017), some Member States highlighted that country-specific authorisations of some products are limited to some specific categories that are generally considered as 'highly managed amenity turf'. That includes generally low abundance of weeds and regular mowing of the field, which makes the field, in general, unattractive to bee species. Therefore, in the Member States where granular uses on amenity vegetation are authorised, this issue should be further considered. Moreover, it is noted that typically amenity vegetation is grown for several years on the same field. Therefore, the succeeding crop is typically a real vegetation growing from the same root system. The Tier-1 calculations for succeeding crop refer to the situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

Table 17: Summary of the outcome of Tier-1 and screening Tier-1 risk assessment for the dietary route of exposure

Use	Honeybee		Bumblebee		Solitary bee	
	'Low' application rate	'High' application rate	'Low' application rate	'High' application rate	'Low' application rate	'High' application rate
Managed amenity turf	High risk				Low risk not demonstrated	

5.2.1.2. Exposure assessment for the treated crop, succeeding crop scenarios and for flowering weeds

No new data that could be used for an exposure refinement for the treated crop scenario and for the weed scenario were available for the evaluation of the GAPs for granular formulations.

As the concentrations in pollen and nectar in succeeding crops are considered to be independent of the GAP and formulation type, the available information as assessed in Section 5.1.1.2 (for the seed treatment uses) are also applicable to the granular uses under consideration.

5.2.1.3. Tier-2 risk assessment

As no refined exposure assessment for residues in pollen and nectar for the treated crops scenario or flowering weeds scenario or information on weed coverage was available, no Tier-2 risk assessment could be performed for these scenarios.

The risk assessments performed under Section 5.1.1.3 (for the seed treatment uses) are also applicable to the granular use under consideration. A low risk for the succeeding crop scenario could not be demonstrated with the available exposure refinements. It is noted, however, that the succeeding crop scenario is relevant only for situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

5.2.1.4. Tier-3 risk assessment

Treated crop scenario

Only one higher tier study was available (I.462) for granular uses. In this study, the effects on bumblebee colonies (*Bombus impatiens*) were investigated in semifield conditions in the USA. The cages were set up in grassland with flowering white clovers. A granular formulation (Merit 0.5 G) was applied by hand, and shortly after the treatment, the plots were irrigated. From the most relevant endpoints (Class 1 and Class 2), only colony strength and brood production were studied. At the end of the study, on average, 26% less workers were counted in the treated group. Contrary, the number of brood chambers was 43% higher than in the control group. The endpoints were considered as reliable with major restrictions.

Therefore, the information available for the Tier-3 assessment was not considered to change the conclusion of the Tier-1 risk assessment.

Weed scenario

No higher tier data were available for the weed scenario. However, the assessments and conclusions for the treated crop scenario are considered also applicable for the weed scenario.

Succeeding crop scenario

As the concentration in pollen and nectar in succeeding crops is considered to be independent of the GAP and formulation type, the weight of evidence risk assessment performed under Section 5.1.1.4 (for the seed treatment uses) is also applicable to the granular uses of imidacloprid under consideration. It is noted that the succeeding crop scenario is relevant only for situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

5.2.2. Risk from contamination via dust drift

This route of exposure is relevant for the field margin and adjacent crop scenarios. In addition, this route of exposure is relevant for the treated crop scenario and for the weed scenario after emergence for the use in managed amenity turf.

5.2.2.1. Tier-1 risk assessment

The Tier-1 risk assessments for the representative GAPs were performed by using the EFSA's BeeTool (v.3.) (Appendix Y of EFSA, 2013c) for honeybees and bumblebees, where suitable toxicity data were available. A screening Tier-1 assessment was carried out for solitary bees and for the chronic adult assessment for bumblebees as only surrogate endpoints were available. Since no toxicity data was available for HPG development or for the larvae toxicity for non-*Apis* bees, no assessment was performed for these scenarios.

The outcome of the calculations is summarised in Table 18. A high risk or low risk not demonstrated (for Tier-1 screening assessments) is indicated in Table 18, since all combinations (categories of acute, chronic and larva combined with the relevant scenarios) indicated a high risk (for both the contact route of exposure and the dietary route of exposure). The detailed results are included in Appendix C.

Table 18: Summary of the outcome of Tier-1 and screening Tier-1 risk assessment for the contact route of exposure and the dietary route of exposure

Use	**Honeybee**		**Bumblebee**		**Solitary bee**	
	'Low' application rate	**'High' application rate**	**'Low' application rate**	**'High' application rate**	**'Low' application rate**	**'High' application rate**
Managed amenity turf	High risk				Low risk not demonstrated	

5.2.2.2. Exposure assessment for the field margin and adjacent crop scenario

No new data on dust drift deposits of granular formulations containing imidacloprid were available for this evaluation. Therefore, no refined exposure assessment for contamination in field margins and adjacent crops could be performed.

5.2.2.3. Tier-2 risk assessment

As no refined exposure assessment for dust drift was available, no Tier-2 risk assessment could be performed.

5.2.2.4. Tier-3 risk assessment

No new higher tier data investigating the effects to bees from dust drift generated during the application of granules in accordance with the use on amenity turf were available. Therefore, no Tier-3 risk assessment was performed.

5.2.3. Risk via water consumption

5.2.3.1. Guttation water

The risk assessment based on water solubility indicated a high risk. The detailed results are included in Appendix C.

Higher tier assessment

No new valid data were submitted for refining the risk to bees from exposure to guttation fluid from the granular uses.

5.2.3.2. Puddle water

It was not necessary to perform exposure modelling to predict residues of imidacloprid in puddles as the concentrations in surface runoff calculated by any version of the PRZMsw tool are always negligible when granules are buried or otherwise incorporated (i.e. by watering) below the soil surface. Consequently, a low risk to honeybees from residues in puddles for the granular uses under consideration is concluded following EFSA (2013c) that indicates that concentrations in runoff water as calculated by PRZMsw are an appropriate estimate of puddle water concentrations.

5.2.3.3. Surface water

The assessments and the conclusion as presented in Section 5.1.3.3 (for the seed treatment uses) are applicable for the granular uses, as well. Therefore, a low risk to honeybees from residues in surface water for the granular uses under consideration was concluded.

6. Overall conclusion

The conclusion of the risk assessment to bees for the uses of imidacloprid as seed treatment is summarised below, considering the different scenarios. It should be highlighted that for the seed treatment uses, the weed scenario was not considered relevant, in agreement with EFSA (2013c).

For the crop-specific conclusion achieved at each assessment tier, please refer to Table 19. The assessments included in this conclusion considered the risk to bees from imidacloprid as active substance only. It should be noted that formulation products containing imidacloprid may also contain other insecticides including clothianidin, as shown in the GAP table in Appendix A.

6.1. Seed treatment uses

Risk via systemic translocation in plants – residues in nectar and pollen

Treated crop scenario

A risk assessment was carried out for all the uses with the exception of the use on potato. For potato, no information was available on the amount of imidacloprid sprayed to the individual tubers. Therefore, the assessment could not be finalised for the treated crop scenario for potato. A high risk at the Tier-1 was concluded for all the other crops and for all bee groups. It should be noted that, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. It should also be noted that vegetable crops and sugar and fodder beets may be harvested before they flower. In that case, the treated crop scenario is not relevant for those crops (low risk for the treated crop scenario). Vegetable crops may be grown continuously in permanent greenhouse. A low risk could be concluded for those situations.

The availability of residue data for winter oilseed rape allowed carrying out a Tier-2 risk assessment for honeybees. The Tier-2 risk assessment resulted in a high risk.

A Tier-3 risk assessment was also carried out for the use on winter oilseed rape, using data from colony-feeder, semifield and field experiments. The Tier-3 risk assessments resulted in a low risk. This was extrapolated to spring oilseed rape; therefore, a low risk was concluded for both winter and spring oilseed rape for the treated crop scenario.

Succeeding crop scenario

A high risk at Tier-1 was concluded for all crops and all bee groups. It should be noted once again that, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. Vegetable crops may be grown continuously in permanent greenhouse. A low risk could be concluded for those situations.

The availability of residue data allowed carrying out a Tier-2 risk assessment for the succeeding crop scenario. The Tier-2 risk assessment resulted in a high risk for all the uses. As for the Tier-1 assessments, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data.

A Tier-3 risk assessment was also carried out for honeybees and bumblebees, using data from colony-feeder, semifield and field experiments that were available for honeybees and bumblebees. The Tier-3 risk assessments resulted in a low risk for honeybees. For bumblebees, a high risk was indicated by the risk assessments.

Risk from contamination of adjacent vegetation via dust drift

Field margin and adjacent crop scenarios

A risk assessment was carried out for all the uses with the exception of the use on potato. The use on potato was an in-planter tuber spraying; therefore, it was considered that there is no dust emission from this use. A high risk at the Tier-1 was concluded for all the other crops and for all bee groups with the exception of the uses on sugar and fodder beets. For the use with the lowest application rate on sugar and fodder beets, a low risk was indicated by the Tier-1 risk assessment for solitary bees considering that a deflector was used. The use with the highest application rate resulted in a high risk. A low risk was indicated for both the lowest and the highest application rates for honeybees. In case of the highest application rate, the use of a deflector was taken into consideration. It should be noted, however, that toxicity data for the HPG development and data on accumulative toxicity were not available.

It is noted that for endive, lettuce and brassicas, a low risk could be concluded for uses when the treated crop is sown in permanent greenhouse.

As already mentioned above, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. The high risk identified for bumblebees for the uses on spring and winter oilseed rape and on sugar and fodder beets was based on surrogate toxicity data.

The available data did not allow performing any refined risk assessment for exposure via dust drift.

Risk via consumption of contaminated water

Guttation fluids

A low risk to honeybees was concluded for the uses on winter cereals, potato and sugar beet in agreement with the evaluation of the confirmatory data for imidacloprid (EFSA, 2016b) and clothianidin (EFSA, 2016c) and confirmed during the expert meeting related to this assessment. The conclusion on sugar beet was extrapolated to fodder beet; therefore, a low risk was also concluded for fodder beet.

For all other crops, a low risk to honeybees could not be demonstrated using the screening assessment based on the solubility of imidacloprid.

However, it is noted that for endive, lettuce and brassicas, a low risk could be concluded for uses when the treated crop is grown continuously in permanent greenhouse.

An exposure refinement could be considered for maize. The refined risk assessments indicated a high risk to honeybees.

Puddle water

A low risk is concluded to honeybees from residues in puddles for the seed treatment uses under consideration.

Surface water

PECs in surface water considering FOCUS surface water modelling at Step 3 were calculated for the uses under evaluation. The risk assessments considering these PECs resulted in a low risk to honeybees. It is noted that no toxicity endpoint was available for the HPG development and data on accumulative toxicity were not available.

6.2. Granular uses

Only one use on granular formulation was considered in this assessment: the use on amenity turf.

Risk via systemic translocation in plants – residues in nectar and pollen

Treated crop scenario

A high risk at the Tier-1 was concluded. It should be noted that, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. It should also be noted that a low risk could be concluded for highly managed amenity turf where regular mowing of the crop takes place.

The available data did not allow performing any refined risk assessment.

Weed scenario

A high risk at the Tier-1 was concluded. It should be noted that, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. It should also be noted that a low risk could be concluded for highly managed amenity turf, which, in general, has a low abundance of attractive weeds and where regular mowing takes place.

The available data did not allow performing any refined risk assessment.

Succeeding crop scenario

A high risk at the Tier-1 was concluded. It should be noted that, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimation based on honeybee data. Moreover, it is noted that typically amenity vegetation is grown for several years on the same field. Therefore, the succeeding crop is typically areal vegetation growing from the same root system. The Tier-1 calculations for succeeding crop refer to the situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

The availability of residue data allowed carrying out a Tier-2 risk assessment for the succeeding crop scenario. The Tier-2 risk assessment resulted in a high risk. As for the Tier-1 assessments, in lack of specific toxicity data, a high risk for solitary bees was identified using only surrogate toxicity estimations based on honeybee data.

A Tier-3 risk assessment was also carried out for honeybees and bumblebees, using data from colony-feeder, semifield and field experiments that were available for honeybees and bumblebees. The Tier-3 risk assessments resulted in a low risk for honeybees. For bumblebees, a high risk was indicated by the risk assessments.

Risk from contamination of adjacent vegetation via dust drift

Field margin and adjacent crop scenarios

A high risk at the Tier-1 was concluded.

The available data did not allow performing any refined risk assessment for exposure via dust drift.

Risk via consumption of contaminated water

Guttation fluids

A low risk to honeybees could not be demonstrated using the screening assessment based on the solubility of imidacloprid.

The available data did not allow performing any refined risk assessment.

Puddle water

A low risk is concluded to honeybees from residues in puddles for the seed treatment uses under consideration.

Surface water

The risk assessment considering FOCUS surface water PECs resulted in a low risk to honeybees. It is noted that no toxicity endpoint was available for the HPG development and data on accumulative toxicity were not available.

Table 19: A summary of the conclusions for the tiered risk assessment

		Honeybee								Bumblebee					Solitary bee				
Use	**Tier**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Guttation fluid**	**Surface water**	**Puddle water**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**
Spring cereals (112–126 g a.s./ha, 0.039 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Winter cereals (43–126 g a.s./ha, 0.015–0.039 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	L	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Cotton (100–175 g a.s./ha, 0.63–0.84 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive and lettuce – field use (104 g a.s./ha, 0.8 mg a.s./seed) Harvested after flowering	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive and lettuce – field use (104 g a.s./ha, 0.8 mg a.s./seed) Harvested before flowering	Tier 1	L	N/R	R1	R1	R1	R2	L	L	L	N/R	R1	R1	R1	L	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					

Use	Tier	Honeybee								Bumblebee					Solitary bee				
		Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Guttation fluid	Surface water	Puddle water	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop
Endive, lettuce and Brassica[(a)], transplanted from non-permanent greenhouse to field or to non-permanent greenhouse, harvested after flowering	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive, lettuce and Brassica[(a)], transplanted from non-permanent greenhouse to field or to non-permanent greenhouse, harvested before flowering	Tier 1	L	N/R	R1	R1	R1	R2	L	L	L	N/R	R1	R1	R1	L	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive, lettuce and Brassica[(a)], transplanted from non-permanent greenhouse to permanent greenhouse, harvested before or after flowering	Tier 1	L	N/R	R1	R1	L	L	L	L	L	N/R	R1	R1	L	L	N/R	R2	R2	L
	Tier 2																		
	Tier 3																		

Use	Tier	Honeybee								Bumblebee					Solitary bee				
		Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Guttation fluid	Surface water	Puddle water	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop
Endive, lettuce and Brassica[(a)], transplanted from permanent greenhouse to field or to non-permanent greenhouse, harvested after flowering	Tier 1	R1	N/R	L	L	R1	R2	L	L	R1	N/R	L	L	R1	R2	N/R	L	L	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive, lettuce and Brassica[(a)], transplanted from permanent greenhouse to field or to non-permanent greenhouse, harvested before flowering	Tier 1	L	N/R	L	L	R1	R2	L	L	L	N/R	L	L	R1	L	N/R	L	L	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Endive, lettuce and Brassica[(a)], transplanted from permanent greenhouse to permanent greenhouse, harvested before or after flowering	Tier 1	L	N/R	L	L	L	L	L	L	L	N/R	L	L	L	L	N/R	L	L	L
	Tier 2																		
	Tier 3																		
Maize (60–100 g a.s./ha, 1 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R1	R1	R1	R2	N/R	R2	R2	R2
	Tier 2					R1	R1							R1					R2
	Tier 3					L								R1					

Use	Tier	Honeybee								Bumblebee					Solitary bee				
		Treated crop scenario	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Guttation fluid**	**Surface water**	**Puddle water**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**
Potato (120–180 g a.s./ha)	Tier 1	X	N/R			R1	L	L	L	X	N/R			R1	X	N/R			R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Spring rape (9–12 g a.s./ha, 0.01 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R2	R2	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3	L				L								R1					
Winter rape (9–12 g a.s./ha, 0.01 mg a.s./seed)	Tier 1	R1	N/R	R1	R1	R1	R2	L	L	R1	N/R	R2	R2	R1	R2	N/R	R2	R2	R2
	Tier 2	R1				R1								R1					R2
	Tier 3	L				L								R1					
Sugar and fodder beet (13 g a.s./ha, 0.1 mg a.s./seed) Harvested after flowering	Tier 1	R1	N/R	L	L	R1	L	L	L	R1	N/R	R2	R2	R1	R2	N/R	L	L	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Sugar and fodder beet (13 g a.s./ha, 0.1 mg a.s./seed) Harvested before flowering	Tier 1	L	N/R	L	L	R1	L	L	L	L	N/R	R2	R2	R1	L	N/R	L	L	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Sugar and fodder beet (117 g a.s./ha, 0.9 mg a.s./seed), harvested after flowering	Tier 1	R1	N/R	L	L	R1	L	L	L	R1	N/R	R2	R2	R1	R2	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					

Use	Tier	Honeybee								Bumblebee					Solitary bee				
		Treated crop scenario	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Guttation fluid**	**Surface water**	**Puddle water**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**	**Treated crop scenario**	**Weed scenario**	**Field margin**	**Adjacent crop**	**Succeeding crop**
Sugar and fodder beet (117 g a.s./ha, 0.9 mg a.s./seed), harvested before flowering	Tier 1	L	N/R	L	L	R1	L	L	L	L	N/R	R2	R2	R1	L	N/R	R2	R2	R2
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
Managed amenity turf (golf courses, sport grounds, commercial and residential lawns) (150 g a.s./ha)	Tier 1	R1	R1	R1	R1	R1[(c)]	R2	L	L	R1	R1	R1	R1	R1[(c)]	R2	R2	R2	R2	R2[(c)]
	Tier 2					R1								R1					R2
	Tier 3					L								R1					
'Highly' managed amenity turf (golf courses, sport grounds, commercial and residential lawns)[(b)] (150 g a.s./ha)	Tier 1	L	L	R1	R1	R1[(c)]	R2	L	L	L	L	R1	R1	R1[(c)]	L	L	R2	R2	R2[(c)]
	Tier 2					R1								R1					R2
	Tier 3					L								R1					

L: A low risk is concluded for the risk assessment (for the field margin and adjacent crop scenario for the seed dressing uses, the use of a deflector was considered).
R1: A high risk is concluded on the basis of the assessment.
R2: A low risk cannot be demonstrated as a result of the assessment (screening-type risk assessment or incomplete conclusion at Tier-3).
X: Assessment not finalised (lack of exposure or endpoint for effects).
Empty grey box: no assessment.
N/R: scenario not relevant.
(a): The application rates for endive and lettuce are 89–120 g a.s./ha, 0.8–1.2 mg a.s./seed and for brassicas (flowering, head, leafy) 90 g a.s./ha, 1.5 mg a.s./seed). Brassicas (flowering, head, leafy) includes crops like broccoli, cauliflowers, Brussels sprouts, head cabbages, Chinese cabbage and kales.
(b): Member States highlighted during the peer review that country-specific authorisations of some products are limited to some specific categories that are generally considered as 'highly managed amenity turf'. That includes generally low abundance of weeds and regular mowing of the field, which makes the field, in general, unattractive to bee species.
(c): Amenity vegetation is typically grown for several years on the same field. Therefore, the succeeding crop is typically areal vegetation growing from the same root system. The risk assessment for succeeding crop refers to the situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

Overall appraisal of the uncertainty related to the risk assessment

In order to reach the aforementioned conclusions on the risk assessment of imidacloprid, clothianidin, and thiamethoxam, EFSA has considered a large number of documents, reporting very diverse experiments, where many heterogeneous endpoints were measured under different conditions and using different methodologies.

One of the most relevant outputs of this complex exercise is to account for the uncertainty related to the overall assessment. At the lower tier (e.g. Tier-1 and screening), this is accounted for by the use of conservative estimates which is particularly important when standard Tier-1 parameters have been extrapolated from more worse-case situations (e.g. in cases where data were lacking for a particular crop). On the contrary, as acknowledged in EFSA (2013c), there are several routes of exposures which are not covered by the risk assessment scheme (e.g. insect honeydew, exposure via soil).

At higher tiers (Tier-2 and Tier-3), the uncertainty starts to act in two opposite ways, and it is worth breaking it up in different factors, whose relative importance can be investigated more in detail.

Several factors were identified as source of uncertainty when establishing the revised shortcut values and exposure assessment goals. Some of them indicated that the estimated exposure assessment goals might be overestimated with respect to the actual exposure to bees (e.g. calculation of the exposure assessment goals using the maximum value from each trial, assuming residues equal to the LOQ every time they were > LOQ), consequently have the potential to decrease the actual risk in comparison with the present assessment. On the contrary, other factors may act in the opposite way (e.g. the sampling frequency was insufficient to ensure that the peak residue was captured, limited number of residue trials resulting in a lower capacity to ensure that the 90th percentile determination was captured).

Similar factors were identified as source of uncertainty for the estimates of exposure within the effect experiments. For some sources of uncertainty which were applicable to both the calculation of the exposure assessment goals and the estimated exposure within the experiments, it was ensured that the same assumption was equally applied to both. In this way, the uncertainty is balanced, e.g. the same percentage of sugar content in nectar was assumed for both the exposure assessment goal and the estimated exposure in the experiments.

Other sources of uncertainty are related to the quantification of the effects. In this case, the direction of the uncertainty is rarely identifiable, as the uncertainty itself is linked to low reliability of the experimental design/methodology and to the lack of precision in reporting the results.

Finally one of the most important sources of uncertainty is related to the presence of ‘confounding factors’ in most of the higher tier experiments, particularly those performed under field conditions. As an example, other chemicals (i.e. herbicides, fungicides, acaricides or other classes of insecticides) were often applied to both the treatments and the control plots in line with standard field practises. Nevertheless, the relative influence that exposure to these substances might have on the bees in the control and in the treatment is unknown.

Furthermore, putting together the information from all field experiments considered for the present risk assessment review (encompassing imidacloprid, clothianidin, and thiamethoxam), EFSA noted that in more than 40% of the cases (15 experiments of 35), some matrices collected from the controls (e.g. from hives, plants, or soils) were contaminated with at least one neonicotinoid substance. Contamination of controls was sometimes even indicated in experiments where bee colonies were exposed via contaminated sugar solutions.

It is worth noting that, in the large majority of the cases, the residue analysis only focused on the substance used in the treatment and on its metabolites. There were only six studies where residues for a wider range of neonicotinoid substances were investigated. Five of these experiments reported residues of substances not included in the study design at quantifiable concentrations. Cross-contamination from substances other than the test item resulted in some cases in residue levels comparable to those due to the applied treatment.

Similar issues had been already pointed out by EFSA in relation to other studies not included in the present review (EFSA, 2013a,b).

This finding can be explained considering that neonicotinoids substances have been largely used in Europe for several years and on a wide range of crops. Furthermore, neonicotinoids insecticides are persistent in the environment, particularly in soil. EFSA (2008) reported field DT_{50} value ranging from 104 to 228 days for imidacloprid. For the other two substances, some DT_{50} values are reported in the respective EU review reports (European Commission, 2006a,b). The mean/median DT_{50} values reported therein are 156 days for clothianidin and 174 days for thiamethoxam. It might be worth noting that the main soil metabolite of thiamethoxam is clothianidin, so the DT_{50} of the active substance alone is not fully representative of the whole exposure time-variable profile.

It is important to note that this finding has implications on different aspects of the present Tier-3 risk assessment for the treated crop and succeeding crops scenarios. Firstly, it impaired the reliability of some experiments where contamination of controls was recorded. Furthermore, it creates high uncertainty around the reliability of the results for those studies where either residue measurements were not available or, as in the vast majority of the studies, where substances other than the test item were not properly investigated. In general, this finding highlights a general disadvantage about the use of field studies for addressing the risk assessment. It exposed a source of uncertainty related to the biological observations from field studies, particularly for their interpretation and their reliability when used in the risk assessment.

It is very likely that one cause of the control contamination/cross-contamination recorded in the available studies was due to applications performed during previous years on the control plots.

Other sources may be from other treated crops or contaminated plants in the landscape. It is acknowledged that the same mechanism had the potential to artificially increase the exposure in the 'treated' groups of the experiments, thus potentially amplifying effects expected from the treatment alone. Nevertheless, widespread use of these substances makes this situation likely to occur in the environment, and the data should not necessarily be disregarded as uninformative for the present risk assessment.

7. Overview of the concerns identified for each representative use considered

Table 20: Summary of concerns for each scenario according to the risk assessment scheme in EFSA (2013c)

Use	Honeybee	Bumblebee	Solitary bee
Spring cereals	X	X	X
Winter cereals	X	X	X
Cotton	X	X	X
Endive and lettuce, field use, Harvested before or after flowering	X	X	X
Endive, lettuce, Brassica, sown in or transplanted to non-permanent greenhouse, Harvested before or after flowering	X	X	X
Endive, lettuce, Brassica, sown and grown in permanent greenhouse, Harvested before or after flowering			
Maize	X	X	X
Potato	X	X	X
Spring rape	X	X	X
Winter rape	X	X	X
Sugar and fodder beet Harvested after flowering	X	X	X
Sugar and fodder beet Harvested before flowering		X	X
Managed amenity turf, 'highly' managed amenity turf	X	X	X

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Abbreviations

1/*n*	slope of Freundlich isotherm
λ	wavelength
a.s.	active substance
AChE	acetylcholinesterase
BBCH	growth stages of mono- and dicotyledonous plants

BW	body weight
DT_{50}	period required for 50% dissipation (define method of estimation)
EC_{50}	effective concentration
EEC	European Economic Community
ETR	exposure toxicity ratio
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	Good Agricultural Practice
HPG	hypopharyngeal glands
HQ	hazard quotient
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
K_{Foc}	Freundlich organic carbon adsorption coefficient
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
LOD	limit of detection
LOEL	lowest observed effect level
LOQ	limit of quantification
mm	millimetre (also used for mean measured concentrations)
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
OECD	Organisation for Economic Co-operation and Development
PEC	predicted environmental concentration
PEC_{soil}	predicted environmental concentration in soil
PER	Proboscis Extension Reflex
ppm	parts per million (10^{-6})
RI	residue intake
RUD	residue per unit dose
SMILES	simplified molecular-input line-entry system
SPG	specific protection goal
SVs	shortcut values
TGW	thousand grain weight
WoE	weight of evidence

Appendix A – List of supported uses

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5178

Appendix B – Overview of endpoint types and related relevance class assigned within the scope of the present risk assessment

Specie	Endpoint as defined in the study/study evaluations	Family of endpoint	Relevance to the protection goal	Relevance Class
Honeybee	• Colony strength • Number of frames with bees present	Colony strength	Directly relevant. These endpoints have a direct link to the protection goal as the correct entity was studied	1
	• Forager mortality (far from the hive)	Forager mortality		
	• Overwinter success • Overwintering • Overwintering (colony strength) • Overwintering survival	Overwintering assessments		
	• Mortality (in front of the hives) • Worker longevity • Foraging lifespan • Queen survival	General mortality of individuals	Indirectly relevant. These endpoints have an obvious, but not quantified conceptual link to the protection goal (e.g. mortality measured in front of the hives consist of forager mortality, but also includes an unknown proportion of mortality of in-hive bees and do not include forager mortality occurred in the field)	2
	• Brood development (time) • Brood production (comb area with eggs, larvae, pupae) • Brood termination rate • Capped brood • Drone cells • Larvae mortality • Worker production (yes/no)	Brood production		
	• Homing failure • Homing success • Number of bees returning to the hive • Number of returning foragers	Homing success		
	• Activity index • Behaviour • Queen flight activity • Duration of foraging trip • Duration of the foraging bouts • Flight activity (bees exiting the hive) • Flight behaviour • Foraging/flight intensity • Learning ability/capacity • Mean time between flights • Number of flights per bee per day • Number of foraging bouts	Behavioural endpoint	Indirectly relevant. These endpoints likely have a link to the protection goal, but this link is not clear and not quantified (e.g. a detrimental effect on the foraging behaviour may contribute to the weakening of the colony, but the link between the two entities is unknown)	3

Specie	Endpoint as defined in the study/study evaluations	Family of endpoint	Relevance to the protection goal	Relevance Class
	• Number of visits to the feeder • Time to first foraging • Time to first foraging trip • Total flight time per bee • Swarming events • Pollination efficiency			
	• Comb cell production • Comb construction	Comb building		
	• Hive weight (including hive, combs, food etc.) • Hive weight (including hive, wax, food stores etc.) • Weight gain of the hives	Weight of the hive		
	• Varroa mite count (prevalence) • Viral load of Black queen cell virus (BQCV) • Viral load of Deformed wing virus (DWV) • Viral load of Israeli acute paralysis virus (IAPV)	Disease		
	• Food storage • Honey storage (area/ weight) • Pollen storage	Food storage		
	• Queen rearing success • Queen supersedure • Queen survival • Queen flight activity	Queen		
	• Food consumption • Guttation fluid use • Quantity of taken syrup	Behaviour influencing exposure	Not relevant. These endpoints have no explicit link to the protection goals	4
	• Expression of AChE gene • Expression of genes • Apoptosis of neurons • Assessment of HPG • Lipid content of royal jelly • Total haemocyte count • Encapsulation response	Suborganism endpoint		
	• Ovary weight of queens • Queen subindividual reproductive system	Subindividual mass		
	• Thermoregulation capacity	Thermoregulation capacity		

Specie	Endpoint as defined in the study/study evaluations	Family of endpoint	Relevance to the protection goal	Relevance Class
Bumblebee	• Colony strength • Number of foragers	Colony strength	Directly relevant. These endpoints have a direct link to the protection goal as the correct entity was studied	1
	• Brood production (comb area with eggs, larvae, pupae) • Male vs. queen production • Number of brood • Drone production • Egg production • No. of drones • No. of young queens and queen brood cells • Produced queens (BB) • Produced workers (BB) • Queen production • Queens produced • Worker production • Worker/males produced • Reproductive output [queenless microcolonies]	Reproductive output		
	• Emergence rates • Mating ability • Total cast biomass • Queen mortality	Indirect reproduction	Indirectly relevant. These endpoints have an obvious, but not quantified conceptual link to the protection goal (e.g. emergence contributes to the reproductive success, but alone does not determine the reproductive output)	2
	• Foraging/flight intensity • Learning ability • Duration of flower visit (mean) • Duration of the foraging bouts • Duration of the foraging bouts for pollen only • Flower visitation rate (flowers/bee per minute) • Foraging time • Nectar load size • Number of forager carrying pollen • Number of foraging bouts • Number of foraging days • Number of switches between flower varieties • Pollen load size	Behaviour	Indirectly relevant. These endpoints likely have a link to the protection goal, but this link is not clear and not quantified (e.g. a detrimental effect on the foraging behaviour may contribute to the weakening of the colony, but the link between the two entities is unknown)	3

Specie	Endpoint as defined in the study/study evaluations	Family of endpoint	Relevance to the protection goal	Relevance Class
	• Proportion of visit to a certain flower variety • Time between flower visits • Visited flowers • Learning ability (PER)			
	• Hive weight (including hive, wax, food stores etc.) • Weight gain of the hives	Weight of the nest (colony)		
	• Honey storage (area/ weight) • Pollen storage • Food collection	Food storage		
	• Worker longevity • Dead bees (in the nest) • Death rate • Forager age • Forager mortality (far from the hives) • Mortality (in front of the hives) • Worker mortality • Queen mortality (old queens) • Queen longevity • Mortality • Dead larvae	General mortality		
	• Homing success • Number of returning foragers	Homing success		
	• BW (of individuals) • Weight of newly emerged bees • Average bee weight • Cocoon weight • Worker size	Individual mass		
	• Quantity of taken syrup • Sugar water collection	Behaviour influencing exposure	Not relevant. This endpoint has no explicit link to the protection goals	4
Solitary bee	• Emergence after winter • Hatching success • Offspring failure • Overwinter success • Overwintering (hatching) • Cell production • Completed nests • Nest occupation • Number of tubes with brood cells	Reproductive output	Directly relevant. These endpoints have a direct link to the protection goal as the correct entity was studied	1

Specie	Endpoint as defined in the study/study evaluations	Family of endpoint	Relevance to the protection goal	Relevance Class
	• Offspring (cocoon) production • Reproduction rate • Undeveloped eggs and larvae			
	• Cocoon weight • Offspring weight • Sex ratio after emergence • Cocoon sex	Indirect reproductive output	Indirectly relevant. These endpoints have an obvious, but not quantified conceptual link to the protection goal	2
	• Foraging/flight intensity	Behaviour	Indirectly relevant. These endpoints likely have a link to the protection goal, but this link is not clear and not quantified (e.g. a detrimental effect on the foraging intensity may have an indirect effect on the reproductive success, but the link between the two entities is unknown)	3
	• Forager mortality	General mortality		

AChE: acetylcholinesterase; BW: body weight.
Notes: Colony survival length was assessed in a single experiment C.1290. As it is a Class 1 endpoint, in principle it should have been considered further in the assessment. However, as the endpoint was assessed to be unreliable, no further consideration was given to this endpoint type.
Non-*Apis* bee monitoring was assessed in a single experiment C.1184. As it is a Class 1 endpoint, in principle it should have been considered further in the assessment. However, as the endpoint was assessed to be unreliable, no further consideration was given to this endpoint type.

Appendix C – Tier-1 risk assessment based on EFSA (2013c)

Contact exposure and exposure to consumption of contaminated pollen and nectar

1) Seed treatment

Spring cereals 112 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**44.2**	14	**5.1**	2.3	**441.8**	2.6

HQ: hazard quotient.

Spring cereals 112 g a.s./ha, 0.039 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.13	0.2	0.03	0.036	**1.05**	0.04
	Field margin	**1.11**	0.2	**0.19**	0.036	**6.89**	0.04
	Adjacent crop	**1.10**	0.2	**0.16**	0.036	**8.28**	0.04
	Succeeding crop	**21.19**	0.2	**2.65**	0.036	**148.32**	0.04
Chronic	Treated crop	**0.17**	0.03	**4.15**	0.0048	**1.38**	0.0054
	Field margin	**1.14**	0.03	**23.20**	0.0048	**9.04**	0.0054
	Adjacent crop	**1.11**	0.03	**18.87**	0.0048	**10.87**	0.0054
	Succeeding crop	**21.45**	0.03	**309.79**	0.0048	**194.61**	0.0054
Larva	Treated crop	0.01	0.2	–	0.2	–	0.2
	Field margin	**0.46**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.45**	0.2	–	0.2	–	0.2
	Succeeding crop	**8.48**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.

Winter cereals 43 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**17.0**	14	2.0–**19.5***	2.3	**169.6**	2.6

HQ: hazard quotient.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c.

Winter cereals 43 g a.s./ha, 0.015 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.05	0.2	0.01	0.036	**0.41**	0.04
	Field margin	**0.43**	0.2	**0.07**	0.036	**2.65**	0.04
	Adjacent crop	**0.42**	0.2	**0.06**	0.036	**3.18**	0.04
	Succeeding crop	**8.14**	0.2	**1.02**	0.036	**56.95**	0.04
Chronic	Treated crop	**0.06**	0.03	**1.60**	0.0048	**0.53**	0.0054
	Field margin	**0.44**	0.03	**8.91**	0.0048	**3.47**	0.0054

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
	Adjacent crop	**0.42**	0.03	**7.25**	0.0048	**4.17**	0.0054
	Succeeding crop	**8.23**	0.03	**118.94**	0.0048	**74.72**	0.0054
Larva	Treated crop	0.01	0.2	–	0.2	–	0.2
	Field margin	0.18–**1.77****	0.2	–	0.2	–	0.2
	Adjacent crop	0.17–**1.72****	0.2	–	0.2	–	0.2
	Succeeding crop	**3.26**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013c).

Spring and Winter cereals 126 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**49.7**	14	**5.7**	2.3	**497.0**	2.6

HQ: hazard quotient.

Spring and Winter cereals 126 g a.s./ha, 0.039 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.13	0.2	0.03	0.036	**1.05**	0.04
	Field margin	**1.25**	0.2	**0.21**	0.036	**7.75**	0.04
	Adjacent crop	**1.24**	0.2	**0.18**	0.036	**9.32**	0.04
	Succeeding crop	**23.84**	0.2	**2.98**	0.036	**166.86**	0.04
Chronic	Treated crop	**0.17**	0.03	**4.15**	0.0048	**1.38**	0.0054
	Field margin	**1.28**	0.03	**26.10**	0.0048	**10.17**	0.0054
	Adjacent crop	**1.24**	0.03	**21.23**	0.0048	**12.22**	0.0054
	Succeeding crop	**24.13**	0.03	**348.51**	0.0048	**218.94**	0.0054
Larva	Treated crop	0.01	0.2	–	0.2	–	0.2
	Field margin	**0.52**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.50**	0.2	–	0.2	–	0.2
	Succeeding crop	**9.55**	0.2	–	0.2	–	0.2

Cotton 100 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
field margin	**67.7**	14	**7.8**	2.3	**677.3**	2.6

HQ: hazard quotient.

Cotton 100 g a.s./ha, 0.63 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**119.19**	0.2	**14.92**	0.036	**834.32**	0.04
	Field margin	**1.68**	0.2	**0.29**	0.036	**10.44**	0.04
	Adjacent crop	**1.66**	0.2	**0.24**	0.036	**12.48**	0.04
	Succeeding crop	**18.92**	0.2	**2.37**	0.036	**132.43**	0.04
Chronic	Treated crop	**120.64**	0.03	**1742.55**	0.0048	**1094.68**	0.0054
	Field margin	**1.73**	0.03	**35.15**	0.0048	**13.70**	0.0054
	Adjacent crop	**1.67**	0.03	**28.44**	0.0048	**16.37**	0.0054
	Succeeding crop	**19.15**	0.03	**276.60**	0.0048	**173.76**	0.0054
Larva	Treated crop	**47.73**	0.2	–	0.2	–	0.2
	Field margin	**0.70**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.68**	0.2	–	0.2	–	0.2
	Succeeding crop	**7.58**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.

Cotton 175 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**118.5**	14	**13.6**	2.3	**1185.3**	2.6

HQ: hazard quotient.

Cotton 175 g a.s./ha, 0.84 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**158.92**	0.2	**19.89**	0.036	**1112.43**	0.04
	Field margin	**2.94**	0.2	**0.50**	0.036	**18.28**	0.04
	Adjacent crop	**2.91**	0.2	**0.42**	0.036	**21.84**	0.04
	Succeeding crop	**33.11**	0.2	**4.14**	0.036	**231.76**	0.04
Chronic	Treated crop	**160.85**	0.03	**2323.40**	0.0048	**1459.57**	0.0054
	Field margin	**3.02**	0.03	**61.51**	0.0048	**23.98**	0.0054
	Adjacent crop	**2.92**	0.03	**49.76**	0.0048	**28.65**	0.0054
	Succeeding crop	**33.51**	0.03	**484.04**	0.0048	**304.08**	0.0054
Larva	Treated crop	**63.64**	0.2	–	0.2	–	0.2
	Field margin	**1.23**	0.2	–	0.2	–	0.2
	Adjacent crop	**1.18**	0.2	–	0.2	–	0.2
	Succeeding crop	**13.26**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.

Endive 104 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**70.4**	14	**8.1**	2.3	**704.4**	2.6

HQ: hazard quotient.

Endive 104 g a.s./ha, 0.8 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**151.35**	0.2	**18.95**	0.036	**1059.46**	0.04
	Field margin	**1.75**	0.2	**0.30**	0.036	**10.86**	0.04
	Adjacent crop	**1.73**	0.2	**0.25**	0.036	**12.98**	0.04
	Succeeding crop	**19.68**	0.2	**2.46**	0.036	**137.73**	0.04
Chronic	Treated crop*	**153.19**	0.03	**2212.77**	0.0048	**1390.07**	0.0054
	Field margin	**1.80**	0.03	**36.55**	0.0048	**14.25**	0.0054
	Adjacent crop	**1.73**	0.03	**29.57**	0.0048	**17.03**	0.0054
	Succeeding crop	**19.91**	0.03	**287.66**	0.0048	**180.71**	0.0054
Larva	Treated crop*	**60.61**	0.2	–	0.2	–	0.2
	Field margin	**0.73**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.70**	0.2	–	0.2	–	0.2
	Succeeding crop	**7.88**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: Not relevant when the crop is harvested before it flowers.
Note: The 'Leafy vegetable' scenario was considered in these calculations above.

Lettuce 104 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**70.4**	14	**8.1**	2.3	**704.4**	2.6

HQ: hazard quotient.

Lettuce 104 g a.s./ha, 0.8 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**2.59**	0.2	**18.95**	0.036	**1059.46**	0.04
	Field margin	**1.75**	0.2	**0.30**	0.036	**10.86**	0.04
	Adjacent crop	**1.73**	0.2	**0.25**	0.036	**12.98**	0.04
	Succeeding crop	**19.68**	0.2	**2.46**	0.036	**137.73**	0.04
Chronic	Treated crop*	**3.40**	0.03	**85.11**	0.0048	**28.37**	0.0054
	Field margin	**1.80**	0.03	**36.55**	0.0048	**14.25**	0.0054
	Adjacent crop	**1.73**	0.03	**29.57**	0.0048	**17.03**	0.0054
	Succeeding crop	**19.91**	0.03	**287.66**	0.0048	**180.71**	0.0054
Larva	Treated crop*	**0.30**	0.2	–	0.2	–	0.2
	Field margin	**0.73**	0.2	–	0.2	–	0.2

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
	Adjacent crop	**0.70**	0.2	–	0.2	–	0.2
	Succeeding crop	**7.88**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: Not relevant when the crop is harvested before it flowers.

Maize 60 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
field margin	**40.6**	14	**4.7**	2.3	**406.4**	2.6

HQ: hazard quotient.

Maize 60 g a.s./ha, 1.0 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**3.24**	0.2	**0.79**	0.036	**27.03**	0.04
	Field margin	**1.01**	0.2	**0.17**	0.036	**6.27**	0.04
	Adjacent crop	**1.00**	0.2	**0.14**	0.036	**7.49**	0.04
	Succeeding crop	**11.35**	0.2	**1.42**	0.036	**79.46**	0.04
Chronic	Treated crop	**4.26**	0.03	**106.38**	0.0048	**35.46**	0.0054
	Field margin	**1.04**	0.03	**21.09**	0.0048	**8.22**	0.0054
	Adjacent crop	**1.00**	0.03	**17.06**	0.0048	**9.82**	0.0054
	Succeeding crop	**11.49**	0.03	**165.96**	0.0048	**104.26**	0.0054
Larva	Treated crop	**0.38**	0.2	–	0.2	–	0.2
	Field margin	**0.42**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.41**	0.2	–	0.2	–	0.2
	Succeeding crop	**4.55**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.

Maize 100 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**97.7**	14	**7.8**	2.3	**677.3**	2.6

HQ: hazard quotient.

Maize 100 g a.s./ha, 1.0 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**3.24**	0.2	**0.79**	0.036	**27.03**	0.04
	Field margin	**1.68**	0.2	**0.29**	0.036	**10.44**	0.04
	Adjacent crop	**1.66**	0.2	**0.24**	0.036	**12.48**	0.04
	succeeding crop	**18.92**	0.2	**2.37**	0.036	**132.43**	0.04

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Chronic	Treated crop	**4.26**	0.03	**106.38**	0.0048	**35.46**	0.0054
	Field margin	**1.73**	0.03	**35.15**	0.0048	**13.70**	0.0054
	Adjacent crop	**1.67**	0.03	**28.44**	0.0048	**16.37**	0.0054
	Succeeding crop	**19.15**	0.03	**276.60**	0.0048	**173.76**	0.0054
Larva	Treated crop	**0.38**	0.2	–	0.2	–	0.2
	Field margin	**0.70**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.68**	0.2	–	0.2	–	0.2
	Succeeding crop	**7.58**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.

Potato 120 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	N/R	14	N/R	2.3	N/R	2.6

N/R: not relevant; HQ: hazard quotient.

Potato 120 g a.s./ha (application rate expressed as mg a.s./tuber was not available)

Acute, chronic and larvae oral exposure – **ETRs**

Category	scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	–	0.2	–	0.036	–	0.04
	Field margin	N/R	0.2	N/R	0.036	N/R	0.04
	Adjacent crop	N/R	0.2	N/R	0.036	N/R	0.04
	Succeeding crop	**22.70**	0.2	**2.84**	0.036	**158.92**	0.04
Chronic	Treated crop	–	0.03	–	0.0048	–	0.0054
	Field margin	N/R	0.03	N/R	0.0048	N/R	0.0054
	Adjacent crop	N/R	0.03	N/R	0.0048	N/R	0.0054
	Succeeding crop	**22.98**	0.03	**331.91**	0.0048	**208.51**	0.0054
Larva	Treated crop	–	0.2	–	0.2	–	0.2
	Field margin	N/R	0.2	–	0.2	–	0.2
	Adjacent crop	N/R	0.2	–	0.2	–	0.2
	Succeeding crop	**9.09**	0.2	–	0.2	–	0.2

N/R: not relevant; ETR: exposure toxicity ratio.

Potato 180 g a.s./ha

Acute contact exposure – **HQ**

scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	N/R	14	N/R	2.3	N/R	2.6

N/R: not relevant; HQ: hazard quotient.

Potato 180 g a.s./ha (application rate expressed as mg a.s./tuber was not available)

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	–	0.2	–	0.036	–	0.04
	Feld margin	N/R	0.2	N/R	0.036	N/R	0.04
	Adjacent crop	N/R	0.2	N/R	0.036	N/R	0.04
	Succeeding crop	**34.05**	0.2	**4.26**	0.036	**238.38**	0.04
Chronic	Treated crop	–	0.03	–	0.0048	–	0.0054
	Field margin	N/R	0.03	N/R	0.0048	N/R	0.0054
	Adjacent crop	N/R	0.03	N/R	0.0048	N/R	0.0054
	Succeeding crop	**34.47**	0.03	**497.87**	0.0048	**312.77**	0.0054
Larva	Treated crop	–	0.2	–	0.2	–	0.2
	Field margin	N/R	0.2	–	0.2	–	0.2
	Adjacent crop	N/R	0.2	–	0.2	–	0.2
	Succeeding crop	**13.64**	0.2	–	0.2	–	0.2

N/R: not relevant; ETR: exposure toxicity ratio.

Spring and winter rape 9 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	2.4–**23.7***	14	0.3–**2.7***	2.3	**23.7**	2.6

HQ: hazard quotient.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c.

Spring and winter rape 9 g a.s./ha, 0.01 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**1.89**	0.2	**0.24**	0.036	**13.24**	0.04
	Field margin	0.06–**0.59***	0.2	0.01–**0.1***	0.036	**0.37**	0.04
	Adjacent crop	0.06–**0.61***	0.2	0.01–**0.09***	0.036	**0.46**	0.04
	Succeeding crop	**1.70**	0.2	**0.21**	0.036	**11.92**	0.04
Chronic	Treated crop	**1.91**	0.03	**27.66**	0.0048	**17.38**	0.0054
	Field margin	**0.06**	0.03	**1.24**	0.0048	**0.48**	0.0054
	Adjacent crop	**0.06**	0.03	**1.04**	0.0048	**0.60**	0.0054
	Succeeding crop	**1.72**	0.03	**24.89**	0.0048	**15.64**	0.0054
Larva	Treated crop	**0.76**	0.2	–	0.2	–	0.2
	Field margin	0.02	0.2	–	0.2	–	0.2
	Adjacent crop	0.02	0.2	–	0.2	–	0.2
	Succeeding crop	**0.68**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c.

Spring and winter rape 12 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	3.2–**31.6***	14	0.4–**3.6***	2.3	**31.6**	2.6

HQ: hazard quotient.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013a.

Spring and winter rape 12 g a.s./ha, 0.01 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**1.89**	0.2	**0.24**	0.036	**13.24**	0.04
	Field margin	0.08–**0.79***	0.2	0.01–**0.14***	0.036	**0.49**	0.04
	Adjacent crop	0.08–**0.81***	0.2	0.01–**0.12***	0.036	**0.61**	0.04
	Succeeding crop	**2.27**	0.2	**0.28**	0.036	**15.89**	0.04
Chronic	Treated crop	**1.91**	0.03	**27.66**	0.0048	**17.38**	0.0054
	Field margin	**0.08**	0.03	**1.66**	0.0048	**0.65**	0.0054
	Adjacent crop	**0.08**	0.03	**1.39**	0.0048	**0.80**	0.0054
	Succeeding crop	**2.30**	0.03	**33.19**	0.0048	**20.85**	0.0054
Larva	Treated crop	**0.76**	0.2	–	0.2	–	0.2
	Field margin	0.03–**0.33***	0.2	–	0.2	–	0.2
	Adjacent crop	0.03–**0.33***	0.2	–	0.2	–	0.2
	Succeeding crop	**0.91**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c.

Sugar and fodder beet 13 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	0.0–0.2*	14	0.00–0.002*	2.3	0.2–1.6*	2.6

HQ: hazard quotient.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c.
Note: The 'Sugar beet' scenario was considered for both the sugar beet and the fodder beet crops.

Sugar and fodder beet 13 g a.s./ha, 0.1 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop**	**18.92**	0.2	**2.37**	0.036	**132.43**	0.04
	Field margin	0.00–0.00*	0.2	0.00–0.00*	0.036	0.00–0.02*	0.04
	Adjacent crop	0.00–0.00*	0.2	0.00-0.00*	0.036	0.00–0.03*	0.04
	Succeeding crop	**2.46**	0.2	**0.31**	0.036	**17.22**	0.04
Chronic	Treated crop**	**19.15**	0.03	**276.60**	0.0048	**173.76**	0.0054
	Field margin	0.00–0.00*	0.03	**0.01**	0.0048	0.00–**0.03***	0.0054
	Adjacent crop	0.00–0.00*	0.03	**0.01**	0.0048	0.00–**0.04***	0.0054
	Succeeding crop	**2.49**	0.03	**35.96**	0.0048	**22.59**	0.0054

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Larva	Treated crop**	**7.58**	0.2	–	0.2	–	0.2
	Field margin	0.00–0.00*	0.2	–	0.2	–	0.2
	Adjacent crop	0.00–0.00*	0.2	–	0.2	–	0.2
	Succeeding crop	**0.98**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c
**: Not relevant when the crop is harvested before it flowers
Note: The 'Sugar beet' scenario was considered for both the sugar beet and the fodder beet crops.

Sugar and fodder beet 117 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	0.1–1.4*	14	0.0–0.2*	2.3	1.4–**14.0***	2.6

HQ: hazard quotient.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c
Note: The 'Sugar beet' scenario was considered for both the sugar beet and the fodder beet crops.

Sugar and fodder beet 117 g a.s./ha, 0.9 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop**	**170.3**	0.2	**21.3**	0.036	**1191.9**	0.04
	Field margin	0.00–0.04*	0.2	0.00–0.01*	0.036	0.02–**0.22***	0.04
	Adjacent crop	0.00–0.04*	0.2	0.00–0.01*	0.036	0.03–**0.27***	0.04
	Succeeding crop	**22.14**	0.2	**2.77**	0.036	**154.95**	0.04
Chronic	Treated crop**	**172.3**	0.03	**2489.3**	0.0048	**1563.8**	0.0054
	Field margin	0.00–**0.04***	0.03	**0.07**	0.0048	**0.03**	0.0054
	Adjacent crop	0.00–**0.04***	0.03	**0.06**	0.0048	**0.04**	0.0054
	Succeeding crop	**22.40**	0.03	**323.62**	0.0048	**203.30**	0.0054
Larva	Treated crop**	**68.2**	0.2	–	0.2	–	0.2
	Field margin	0.00–0.01*	0.2	–	0.2	–	0.2
	Adjacent crop	0.00–0.01*	0.2	–	0.2	–	0.2
	Succeeding crop	**8.86**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio;
*: The higher value reflects a scenario sowing without deflector as considered in EFSA, 2013c
**: Not relevant when the crop is harvested before it flowers
Note: The 'Sugar beet' scenario was considered for both the sugar beet and the fodder beet crops.

2) Seed treatment as dummy pill uses

Brassica, flowering, head, leafy, Endive, Lettuce, 90 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin*	**61.0**	14	**7.0**	2.3	**609.6**	2.6

HQ: hazard quotient.
*: Not relevant when the application is done in permanent greenhouse.

Brassica, flowering, head, leafy, 90 g a.s./ha, 1.5 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[(a),(b)]	**283.78**	0.2	**35.53**	0.036	**1986.49**	0.04
	Field margin[(c)]	**1.51**	0.2	**0.26**	0.036	**9.40**	0.04
	Adjacent crop[(c)]	**1.50**	0.2	**0.21**	0.036	**11.23**	0.04
	Succeeding crop[(b)]	**17.03**	0.2	**2.13**	0.036	**119.19**	0.04
Chronic	Treated crop[(a),(b)]	**287.23**	0.03	**4148.94**	0.0048	**2606.38**	0.0054
	Field margin[(c)]	**1.55**	0.03	**31.63**	0.0048	**12.33**	0.0054
	Adjacent crop[(c)]	**1.50**	0.03	**25.59**	0.0048	**14.74**	0.0054
	Succeeding crop[(b)]	**17.23**	0.03	**248.94**	0.0048	**156.38**	0.0054
Larva	Treated crop[(a,b)]	**113.64**	0.2	–	0.2	–	0.2
	Field margin[(c)]	**0.63**	0.2	–	0.2	–	0.2
	Adjacent crop[(c)]	**0.61**	0.2	–	0.2	–	0.2
	Succeeding crop[(b)]	**6.82**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
(a): Not relevant when the crop is harvested before it flowers.
(b): Not relevant when the crop is grown in permanent structure greenhouse.
(c): Not relevant when the application is done in permanent greenhouse.

Endive, Lettuce 89 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
field margin*	**60.3**	14	**6.9**	2.3	**602.8**	2.6

HQ: hazard quotient.
*: Not relevant when the application is done in permanent greenhouse.

Endive, 89 g a.s./ha, 0.8 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[(a),(b)]	**151.35**	0.2	**18.95**	0.036	**1059.46**	0.04
	Field margin[(c)]	**1.50**	0.2	**0.26**	0.036	**9.29**	0.04
	Adjacent crop[(c)]	**1.48**	0.2	**0.21**	0.036	**11.11**	0.04
	Succeeding crop[(b)]	**16.84**	0.2	**2.11**	0.036	**117.86**	0.04
Chronic	Treated crop[(a),(b)]	**153.19**	0.03	**2212.77**	0.0048	**1390.07**	0.0054
	Field margin[(c)]	**1.54**	0.03	**31.28**	0.0048	**12.19**	0.0054
	Adjacent crop[(c)]	**1.48**	0.03	**25.31**	0.0048	**14.57**	0.0054
	Succeeding crop[(b)]	**17.04**	0.03	**246.17**	0.0048	**154.65**	0.0054
Larva	Treated crop[(a),(b)]	**60.61**	0.2	–	0.2	–	0.2
	Field margin[(c)]	**0.62**	0.2	–	0.2	–	0.2
	Adjacent crop[(c)]	**0.60**	0.2	–	0.2	–	0.2
	Succeeding crop[(b)]	**6.74**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
(a): Not relevant when the crop is harvested before it flowers.
(b): Not relevant when the crop is grown in permanent structure greenhouse.
(c): Not relevant when the application is done in permanent greenhouse.
Note: The 'Leafy vegetable' scenario was considered in the calculations above.

Lettuce, 89 g a.s./ha, 0.8 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[(a),(b)]	**2.59**	0.2	**18.95**	0.036	**1059.46**	0.04
	Field margin[(c)]	**1.50**	0.2	**0.26**	0.036	**9.29**	0.04
	Adjacent crop[(c)]	**1.48**	0.2	**0.21**	0.036	**11.11**	0.04
	Succeeding crop[(b)]	**16.84**	0.2	**2.11**	0.036	**117.86**	0.04
Chronic	Treated crop[(a),(b)]	**3.40**	0.03	**85.11**	0.0048	**28.37**	0.0054
	Field margin[(c)]	**1.54**	0.03	**31.28**	0.0048	**12.19**	0.0054
	Adjacent crop[(c)]	**1.48**	0.03	**25.31**	0.0048	**14.57**	0.0054
	Aucceeding crop[(b)]	**17.04**	0.03	**246.17**	0.0048	**154.65**	0.0054
Larva	Treated crop[(a),(b)]	**0.30**	0.2	–	0.2	–	0.2
	Field margin[(c)]	**0.62**	0.2	–	0.2	–	0.2
	Adjacent crop[(c)]	**0.60**	0.2	–	0.2	–	0.2
	Succeeding crop[(b)]	**6.74**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
(a): Not relevant when the crop is harvested before it flowers.
(b): Not relevant when the crop is grown in permanent structure greenhouse.
(c): Not relevant when the application is done in permanent greenhouse.

Endive, Lettuce, 120 g a.s./ha

Acute contact exposure – **HQ**

scenario	Honeybee		Bumblebee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
field margin*	**81.3**	14	**9.4**	2.3	**812.7**	2.6

HQ: hazard quotient.
*: Not relevant when the application is done in permanent greenhouse.

Endive, 120 g a.s./ha, 1.2 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[(a),(b)]	**227.03**	0.2	**28.42**	0.036	**1589.19**	0.04
	Field margin[(c)]	**2.02**	0.2	**0.34**	0.036	**12.53**	0.04
	Adjacent crop[(c)]	**2.00**	0.2	**0.29**	0.036	**14.97**	0.04
	Succeeding crop[(b)]	**22.70**	0.2	**2.84**	0.036	**158.92**	0.04
Chronic	Treated crop[(a),(b)]	**229.79**	0.03	**3319.15**	0.0048	**2085.11**	0.0054
	Field margin[(c)]	**2.07**	0.03	**42.18**	0.0048	**16.44**	0.0054
	Adjacent crop[(c)]	**2.00**	0.03	**34.12**	0.0048	**19.65**	0.0054
	Succeeding crop[(b)]	**22.98**	0.03	**331.91**	0.0048	**208.51**	0.0054
Larva	Treated crop[(a),(b)]	**90.91**	0.2	–	0.2	–	0.2
	Field margin[(c)]	**0.84**	0.2	–	0.2	–	0.2
	Adjacent crop[(c)]	**0.81**	0.2	–	0.2	–	0.2
	Succeeding crop[(b)]	**9.09**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
(a): Not relevant when the crop is harvested before it flowers.
(b): Not relevant when the crop is grown in permanent structure greenhouse.
(c): Not relevant when the application is done in permanent greenhouse.
Note: The 'Leafy vegetable' scenario was considered in these calculations above.

Lettuce, 120 g a.s./ha, 1.2 mg a.s./seed

Acute, chronic and larvae oral exposure – **ETRs**

category	scenario	Honeybee		Bumblebee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop(a),(b)	**3.89**	0.2	**28.42**	0.036	**1589.19**	0.04
	Field margin(c)	**2.02**	0.2	**0.34**	0.036	**12.53**	0.04
	Adjacent crop(c)	**2.00**	0.2	**0.29**	0.036	**14.97**	0.04
	Succeeding crop(b)	**22.70**	0.2	**2.84**	0.036	**158.92**	0.04
Chronic	Treated crop(a),(b)	**5.11**	0.03	**127.66**	0.0048	**42.55**	0.0054
	Field margin(c)	**2.07**	0.03	**42.18**	0.0048	**16.44**	0.0054
	Adjacent crop(c)	**2.00**	0.03	**34.12**	0.0048	**19.65**	0.0054
	Succeeding crop(b)	**22.98**	0.03	**331.91**	0.0048	**208.51**	0.0054
Larva	Treated crop(a),(b)	**0.45**	0.2	–	0.2	–	0.2
	Field margin(c)	**0.84**	0.2	–	0.2	–	0.2
	Adjacent crop(c)	**0.81**	0.2	–	0.2	–	0.2
	Succeeding crop(b)	**9.09**	0.2	–	0.2	–	0.2

ETR: exposure toxicity ratio.
(a): Not relevant when the crop is harvested before it flowers.
(b): Not relevant when the crop is grown in permanent structure greenhouse.
(c): Not relevant when the application is done in permanent greenhouse.

3) Granular uses

Managed amenity turf, 150 g a.s./ha

Acute contact exposure – **HQ**

scenario	BBCH	Honeybee		Bumblebee		Solitary bee	
		HQ	Trigger	HQ	Trigger	HQ	Trigger
treated crop	≥ 10	**597.6**	14	**68.8**	2.3	**5976.1**	2.6
weeds	≥ 10	**597.6**	14	**68.8**	2.3	**5976.1**	2.6
field margin	All stages	**573.7**	14	**66.1**	2.3	**5737.1**	2.6

BBCH: growth stages of mono- and dicotyledonous plants; HQ: hazard quotient.

Acute, chronic and larvae oral exposure – **ETRs**

Category	Scenario	BBCH	Honeybee		Bumblebee		Solitary bee	
			ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	< 10	**28.38**	0.2	**3.55**	0.036	**198.65**	0.04
		≥ 70	0.00	0.2	0.00	0.036	0.00	0.04
		10–69	**92.43**	0.2	**13.26**	0.036	**693.24**	0.04
	Weeds	All stages	**45.00**	0.2	**7.70**	0.036	**279.73**	0.04
	Field margin	All stages	**14.40**	0.2	**2.46**	0.036	**89.51**	0.04
	Adjacent crop	All stages	**13.86**	0.2	**1.99**	0.036	**103.99**	0.04
	Succeeding crop(a)	All stages	**28.38**	0.2	**3.55**	0.036	**198.65**	0.04
Chronic	Treated crop	< 10	**28.72**	0.03	**414.89**	0.0048	**260.64**	0.0054
		≥ 70	0.00	0.03	0.00	0.0048	0.00	0.0054
		10–69	**92.55**	0.03	**1579.79**	0.0048	**909.57**	0.0054
	Weeds	All stages	**46.28**	0.03	**941.49**	0.0048	**367.02**	0.0054
	Field margin	All stages	**14.81**	0.03	**301.28**	0.0048	**117.45**	0.0054
	Adjacent crop	All stages	**13.88**	0.03	**236.97**	0.0048	**136.44**	0.0054
	Succeeding crop(a)	All stages	**28.72**	0.03	**414.89**	0.0048	**260.64**	0.0054

Category	Scenario	BBCH	Honeybee		Bumblebee		Solitary bee	
			ETR	Trigger	ETR	Trigger	ETR	Trigger
Larva	Treated crop	< 10	**11.36**	0.2	–	0.2	–	0.2
		≥ 70	0.00	0.2	–	0.2	–	0.2
		10–69	**37.50**	0.2	–	0.2	–	0.2
	Weeds	All stages	**18.75**	0.2	–	0.2	–	0.2
	Field margin	All stages	**6.00**	0.2	–	0.2	–	0.2
	Adjacent crop	All stages	**5.63**	0.2	–	0.2	–	0.2
	Succeeding crop[(a)]	All stages	**11.36**	0.2	–	0.2	–	0.2

BBCH: growth stages of mono- and dicotyledonous plants; ETR: exposure toxicity ratio.
(a): This scenario refers to the situations when the amenity vegetation is removed as a result of the preparation of a seed bed to plant an attractive following crop.

Tier-1 Screening – Risk from residues in guttation fluid

All outdoor field uses

Category	Water uptake	Honeybee	
		ETR	Trigger
Acute	11.4 μL/bee per day	1,889	0.2
Chronic	11.4 μL/bee per day	1,338	0.03
Larva	111 μL/larva per 5 days	9,279	0.2

ETR: exposure toxicity ratio.
Note: calculations based on the water solubility of 613 mg/L (demineralised water, pH 5.5, 20°C), EFSA, 2008.

Tier-1 – Risk from residues in surface water

All outdoor field uses (represented by winter cereals)*

Category	Water uptake	Honeybee	
		ETR	Trigger
Acute	11.4 μL/bee per day	0.0002	0.2
Chronic	11.4 μL/bee per day	0.0003	0.03
Larva	111 μL/larva per 5 days	0.0016	0.2

ETR: exposure toxicity ratio.
*: Represented by the highest PEC surface water of 0.075 μg/L, which was calculated for the D6 ditch scenario from the use on winter cereals.

Appendix D – Measured residue values and RUD values used for calculation of exposure assessment goals

Exposure assessment goal	Crop	Matrix	Study type	Site	Seed loading mg/seed	Maximum measured residue value mg/kg	RUD mg/kg	Reference
Honeybee pollen for winter oilseed rape	Winter oilseed rape	Sorted oilseed rape pollen from foragers	Field	Germany	0.0191	< 0.0003	0.015707	I.1094
		Pollen from pollen trap	Field	Poland	0.0105[(a)]	< 0.0008	0.07619	All+.1080
	Spring oilseed rape	Pollen from foragers	Semifield	Germany	0.0398	< 0.0015	0.037688	E 370 1548-8
		Pollen from foragers	Semifield	Germany	0.0398	< 0.005	0.125628	E 370 1553-4
		Sorted oilseed rape pollen from foragers	Field	Germany	0.0211[(a)]	0.009	0.42654	I.1095
		Pollen from pollen trap	Field	Poland	0.01[(a)]	< 0.0008	0.08	All+.1080
		Pollen from pollen trap	Field	Canada	0.0488[(a)]	< 0.001	0.02049	110403 CAN/US
		Sorted canola pollen from pollen trap	Field	USA	0.0488[(a)]	0.0076	0.155738	110403 CAN/US
Honeybee nectar for winter oilseed rape	Winter oilseed rape	Nectar from foragers	Field	Germany	0.0191[(a)]	< 0.0003	0.015707	I.1094
		Nectar from flowers	Field	Poland	0.0105[(a)]	< 0.0002	0.019048	All+.1080
	Spring oilseed rape	Nectar from flowers	Semifield	Germany	0.0398	< 0.005	0.125628	E 370 1548-8
		Nectar from flowers	Semifield	Germany	0.0398	< 0.005	0.125628	E 370 1553-4
		Nectar from foragers	Field	Germany	0.0211[(a)]	0.01	0.473934	I.1095
		Nectar from flowers	Field	Poland	0.01[(a)]	< 0.0002	0.02	All+.1080

RUD: residue per unit dose.
(a): Seed loading in terms of mg a.s./seed not provided in the study and could not be calculated from the available information. The RUD was therefore calculated assuming thousand grain weight (TGW) of 5 g/1,000 seeds.

Reference	Exposure assessment goal	Crop	Matrix	No of sampling events during flowering	Tot No samples	LOQ µg/kg	Range µg/kg	No samples ≤ LOQ	No samples > LOQ – 10 µg/kg	No samples > 10 µg/kg
I.1094	Honeybee pollen for winter oilseed rape	Winter oilseed rape	Sorted oilseed rape pollen from foragers	3	4	0.3	< 0.3	4	0	0
All+.1080			Pollen from pollen trap	4, from 3 to 4 day duration	20	0.8	< 0.8	20	0	0
E 370 1548-8			Pollen from foragers	2	2	5	< 1.5	2	0	0
E 370 1553-4			Pollen from foragers	2	2	5	< 5	2	0	0

Reference	Exposure assessment goal	Crop	Matrix	No of sampling events during flowering	Tot No samples	LOQ µg/kg	Range µg/kg	No samples ≤ LOQ	No samples > LOQ – 10 µg/kg	No samples > 10 µg/kg
I.1095		Spring oilseed rape	Sorted oilseed rape pollen from foragers	3	4	0.3	< 0.3–9	1	3	0
All+.1080			Pollen from pollen trap	4, from 3 to 4 day duration	20	0.8	< 0.8	20	0	0
110403 CAN/US			Pollen from pollen trap	2	2	1	< 1	2	0	0
110403 CAN/US			Sorted canola pollen from pollen trap	2	2	1	< 1–7.6	1	1	0
I.1094	Honeybee nectar for winter oilseed rape	Winter oilseed rape	Nectar from foragers	3	3	0.3	< 0.3	3	0	0
All+.1080			Nectar from flowers	'Several times'	6	0.2	< 0.2	All	0	0
E 370 1548-8		Spring oilseed rape	Nectar from flowers	Not reported	Not reported	5	< 5	All	0	0
E 370 1553-4			Nectar from flowers	Not reported	Not reported	5	< 5	All	0	0
I.1095			Nectar from foragers	3	5	0.3	< 0.3–10	0	5	0
All+.1080			Nectar from flowers	'Several times'	6	0.2	< 0.2	All	0	0

LOQ: limit of quantification.

Appendix E – Residue intake in higher tier studies providing reliable Class 1 and Class 2 endpoints

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
Honeybee	I.1498	Field	Pollen/nectar from sunflower field	Pollen: 2.7 µg/kg; nectar 0.75 µg/kg	0.16	0.64	0.188	0.282	0.301	0.302	The exposure length was 11 days. Mean residue for pollen was calculated from five samples (includes positive findings, but also values < LOD). Mean residue for nectar was derived from LOQ and LOD
	I.2043	Field	Pollen from maize field	1.51 µg/kg	0	0	0.01	0.018	0.002	0.003	The exposure length was 18 days. Mean residue was calculated from five samples (includes positive findings, but also values < LOQ)
	I.2044	Field	Pollen/nectar from sunflower field	Pollen: 2.18 µg/kg; nectar: 1.05 µg/kg	0.224	0.896	0.252	0.376	0.419	0.42	The exposure length was 15 days. Mean residues for pollen and nectar were derived from LOQ and LOD
	I.2045	Field	Pollen/nectar from winter oilseed rape field	Pollen: 0.13 µg/kg; nectar: 0.0 µg/kg	0	0	0.0008	0.0016	0.0002	0.0003	The exposure length was 11 days. Mean residue for pollen was calculated from five samples that consisted of values < LOD and < LOQ). All values for nectar was < LOD
	I.2046	Field	Pollen/nectar from spring oilseed rape field	Pollen: 2.2 µg/kg; nectar: 5.0 µg/kg	1.067	4.267	1.148	1.693	1.983	1.984	The exposure length was 11 days. Mean residue for pollen was calculated from five samples (includes positive findings, but also values < LOD). Mean residue for nectar was derived from a positive sample and from a value < LOD

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
	I.163	Colony feeder	Sugar syrup	12.5 ppb	0.8	3.2	0.85	1.25	1.485	1.485	The exposure period was 42 days. Intake obtained with default consumption values and 50% sugar content
	I.163	Colony feeder	Sugar syrup	25 ppb	1.6	6.4	1.7	2.5	2.97	2.97	The exposure period was 42 days. Intake obtained with default consumption values and 50% sugar content
	I.163	Colony feeder	Sugar syrup	50 ppb	3.2	12.8	3.4	5	5.94	5.94	The exposure period was 42 days. Intake obtained with default consumption values and 50% sugar content
	I.362	Colony feeder	Pollen patties	5 µg/kg	0.24	0.96	0.29	0.43	0.45	0.45	Exposure period was 84 days. Intake obtained with default consumption values and 67% sugar content (pollen patties consisted pollen and sugar syrup)
	I.2017	Colony feeder	Pollen patties	5 µg/kg	0.24	0.96	0.29	0.43	0.45	0.45	Exposure period was 84 days. Intake obtained with default consumption values and 67% sugar content (pollen patties consisted pollen and sugar syrup)
	I.2017	Colony feeder	Pollen patties	100 µg/kg	4.78	19.10	5.73	8.66	9.02	9.07	Exposure period was 84 days. Intake obtained with default consumption values and 67% sugar content (pollen patties consisted pollen and sugar syrup)

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
	I.411	Colony feeder	Sugar syrup	0.5 µg/kg	0.032	0.128	0.034	0.05	0.059	0.059	The exposure period was 33 days. Intake obtained with default consumption values and 50% sugar content
	I.411	Colony feeder	Sugar syrup	5 µg/kg	0.32	1.28	0.34	0.5	0.594	0.594	The exposure period was 33 days. Intake obtained with default consumption values and 50% sugar content
	I.843	Colony feeder	Sugar syrup	400 µg/kg	25.6	102.4	27.2	40.0	47.52	47.52	The exposure period was 63 days. Intake obtained with default consumption values and 50% sugar content was assumed
	I.843	Colony feeder	Sugar syrup	20 µg/kg	1.28	5.12	1.36	2	2.376	2.376	The exposure period was 63 days. Intake obtained with default consumption values and 50% sugar content was assumed
	C+I.844	Colony feeder	Sugar syrup	136 µg/L	8.704	34.816	9.248	13.6	16.157	16.157	
	I.178	Colony feeder	Sugar syrup	100 ppb	6.4	25.6					Acute exposure regime. Intake obtained with default consumption values and 50% sugar content
	I.178	Colony feeder	Sugar syrup	500 ppb	32	128					Acute exposure regime. Intake obtained with default consumption values and 50% sugar content
	C+I.423	Colony feeder	Sugar syrup	7.5 ng/bee	7.5	7.5					Acute exposure regime. Test dose provided by the study authors

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
	C+I.423	Colony feeder	Sugar syrup	11.25 ng/bee	11.25	11.25					Acute exposure regime. Test dose provided by the study authors
	C+I.1244	Colony feeder	Sugar syrup	1.5 ng/bee	1.5	1.5					Acute exposure regime. Test dose provided by the study authors
	C+I.1244	Colony feeder	Sugar syrup	6 ng/bee	6	6					Acute exposure regime. Test dose provided by the study authors
	I.2025	Colony feeder	Sugar syrup	20 ppb	0.889	3.556	0.944	1.389	1.65	1.65	The exposure length was 39 days feeding. Intake obtained with default consumption values and 72% sugar content was assumed (honey was used)
	I.1455-II	Colony feeder	Sugar syrup	6.1 ppb	0.390	1.562	0.415	0.610	0.725	0.725	The exposure length was 84 days feeding. Intake obtained with default consumption values and 50% sugar content. Study authors estimated an adult consumption of 0.12 ng/bee per day
Bumblebee	C+I.1248	Colony feeder	Sugar syrup	10 ppb	1.46	2.98			4.76	4.76	The exposure period was 11 weeks (77 days). Intake obtained with default consumption values and 50% sugar content
	I.475	Colony feeder	Sugar syrup	10 ppb	1.46	2.98			4.76	4.76	The exposure period was 28 days. Intake obtained with default consumption values and 50% sugar content was assumed

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
	I.2019	Colony feeder	Pollen/sugar syrup	19.2 ppm (0.0192 mg/g)	3314	6303			11117	16723	The exposure period was 30 days. Intake obtained with default consumption values and with 72% sugar content of the syrup assumed (honey)
	I.2004	Colony feeder	Sugar syrup	10 ppb	1.825	3.725			5.95	5.95	The exposure period was 42 days. Intake obtained with default consumption values and 40% sugar content
	I.787	Colony feeder	Sugar syrup	0.15 ppb	0.0219	0.0447			0.0714	0.0714	The exposure period was 14 days. Intake obtained with default consumption values and 50% sugar content was assumed. The 0.15 ppb is a calculated EC_{10} values from the series of test concentrations
	I.787	Colony feeder	Sugar syrup	1.44 ppb	0.21024	0.42912			0.68544	0.68544	The exposure period was 14 days. Intake obtained with default consumption values and 50% sugar content was assumed. The 1.44 ppb is a calculated EC_{50} values from the series of test concentrations
	I.788	Colony feeder	Sugar syrup	1.27 ppb	0.18542	0.37846			0.60452	0.60452	The exposure period was 13 days. Intake obtained with default consumption values and 50% sugar content was assumed
	I.2051	Colony feeder	Sugar syrup	98.4 ppb	14.3664	29.3232			46.8384	46.8384	The exposure period was 14 days. Intake obtained with default consumption values and 50% sugar content was assumed

Organism	Reference	Type	Exposure	Mean residue values/test concentration/ test dose	Forager		Nurse		Larva		Notes
					ng/bee per day		ng/bee per day		ng/bee per developmental period		
					Min	max	Min	max	Min	max	
	I.937	Colony feeder	Pollen	7 ppb	0.1862	0.2121			0.721	2.765	The exposure period was 84 days. Intake obtained with default consumption values
	I.2052	Colony feeder	Pollen	7 ppb	0.1862	0.2121			0.721	2.765	The exposure period was 84 days. Intake obtained with default consumption values
	I.2052	Colony feeder	Pollen	30 ppb	0.798	0.909			3.09	11.85	The exposure period was 84 days. Intake obtained with default consumption values.
	I.1386	Colony feeder	Pollen/sugar syrup	Pollen: 6 ppb; syrup: 10 ppb	1.1329	2.1685			3.7913	5.5433	The exposure period was 85 days. Intake obtained with default consumption values and with 75% sugar content of the syrup. Study authors calculated a residue consumption of 2.15 ng/bee per day for adults
	I.1386	Colony feeder	Pollen/sugar syrup	Pollen: 16 ppb; syrup: 25 ppb	2.8589	5.4515			9.5813	14.2533	The exposure period was 85 days. Intake obtained with default consumption values and with 75% sugar content of the syrup. Study authors calculated a residue consumption of 4.81 ng/bee/day for adults
	I.1505	Colony feeder	Pollen/sugar syrup	Pollen: 6 ppb; syrup: 0.7 ppb	0.2618	0.3904			0.9512	2.7032	The exposure period was 14 days. Intake obtained with default consumption values and 50% sugar content was assumed
	I.1505	Colony feeder	Pollen/sugar syrup	Pollen: 12 ppb; syrup: 1.4 ppb	0.5236	0.7808			1.9024	5.4064	The exposure period was 14 days. Intake obtained with default consumption values and 50% sugar content was assumed

Organism	Reference	Type	Exposure	Mean residue values/test concentration/test dose	Forager ng/bee per day		Nurse ng/bee per day		Larva ng/bee per developmental period		Notes
					Min	max	Min	max	Min	max	
	I+T.931	Colony feeder	Sugar syrup	10 ppb	1.46	2.98			4.76	4.76	The exposure period was 77 days. Intake obtained with default consumption values and 50% sugar content was assumed
	I+T.2015	Colony feeder	Sugar syrup	10 ppb	1.46	2.98			4.76	4.76	The exposure period was 77 days. Intake obtained with default consumption values and 50% sugar content was assumed
	C+I.2017	Colony feeder	Sugar syrup	2.1 ppb	0.3066	0.6258			0.9996	0.9996	The exposure period was 43 days. Intake obtained with default consumption values and 50% sugar content was assumed
	I.724	Field	Pollen from potato field	0.37 μg/kg	0.0098	0.0112			0.0381	0.1462	The exposure length was 17 days. Mean residue for pollen was calculated from three samples (includes positive findings, but also values < LOD). Mean residue for nectar was derived from a positive sample and from a value < LOD
	I.725	Field	Pollen from potato field	0.77 μg/kg	0.0204	0.0232			0.0790	0.3028	The exposure length was 15 days. Mean residue for pollen was calculated from five samples (includes positive findings, but also values < LOQ). Mean residue for nectar was derived from a positive sample and from values < LOQ

LOD: limit of detection; LOQ: limit of quantification.

Appendix F – Tier-3 lines of evidence

The graphical representation of the lines of evidence for the treated crop scenario for winter oilseed rape for honeybees and the succeeding crop scenario for honeybees and bumblebees.

F.1 Honeybees

F.1.1. Colony strength (Class 1 endpoint)

Three figures are presented for the treated crop scenario (winter oilseed rape) and one for the succeeding crop scenario. All of them are based on the same data set (colony strength for honeybee colonies), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for all figures for honeybee colony strength.

General interpretation

- Altogether 20 endpoints were available, but eight of them were considered as non-reliable.
- The biological variability of many of the reliable endpoints was considerably high and in many cases fluctuated both negatively and positively relative to the control
- There is also variability between the experiments. The mean deviation from the control ranged from negligible to medium negative
- Exposure estimation and information on the exposure lengths was available for all reliable experiments.
- No dose–response pattern could be seen when all reliable endpoints are considered
- Two experiments had more than one test concentrations. In one of them, a dose–response trend could be observed, while this was not that clear in the other experiment (I.2017)

F.1.1.1. Winter oilseed rape

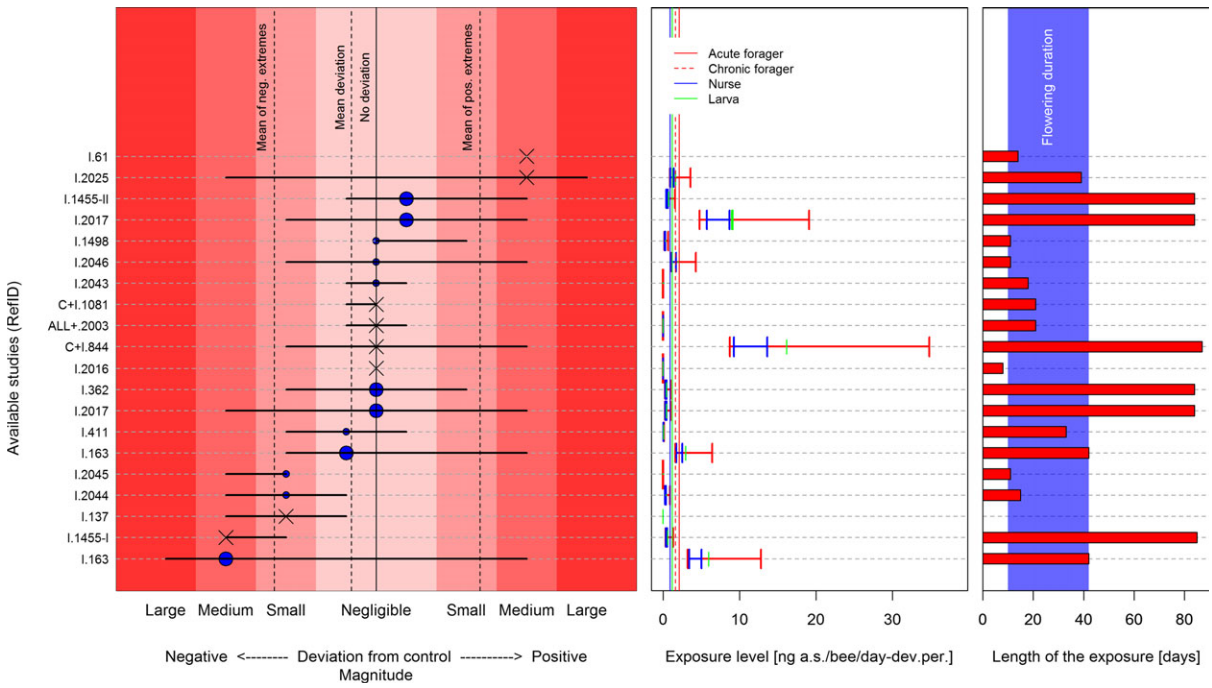

Figure F.1: Summary of the observed deviations for honeybee colony strength for seed treatment use to winter oilseed rape – all available endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the available data

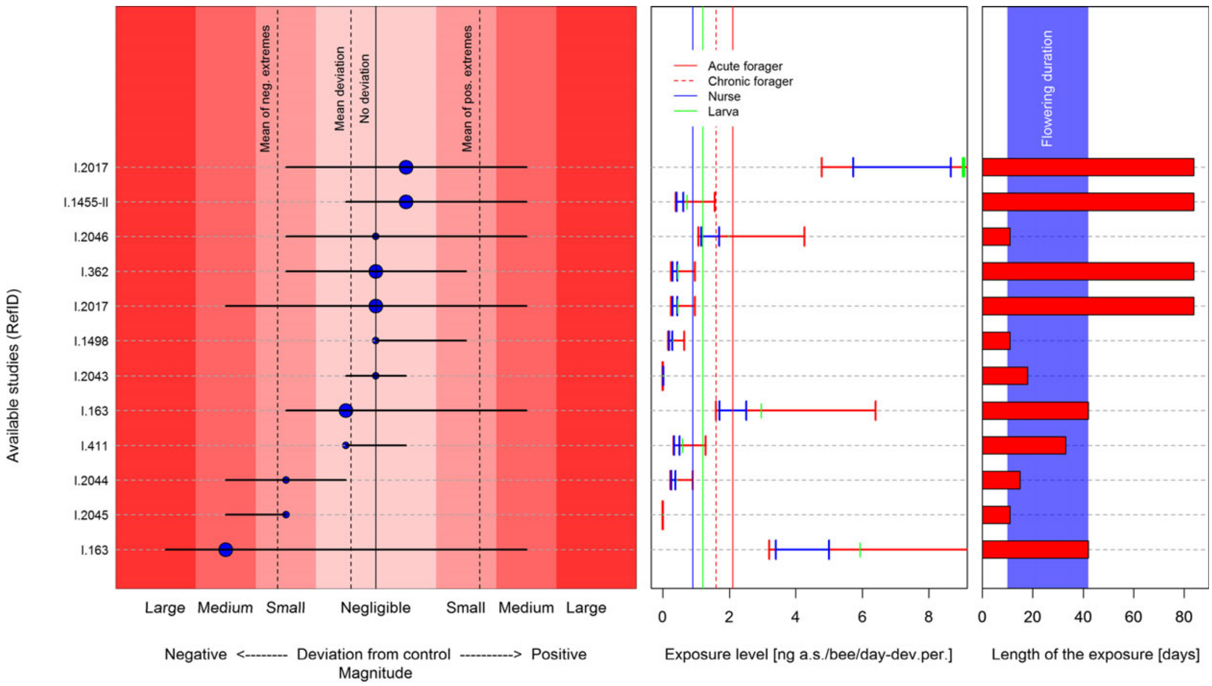

Figure F.2: Summary of the observed deviations for honeybee colony strength for seed treatment use to winter oilseed rape – only the reliable endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

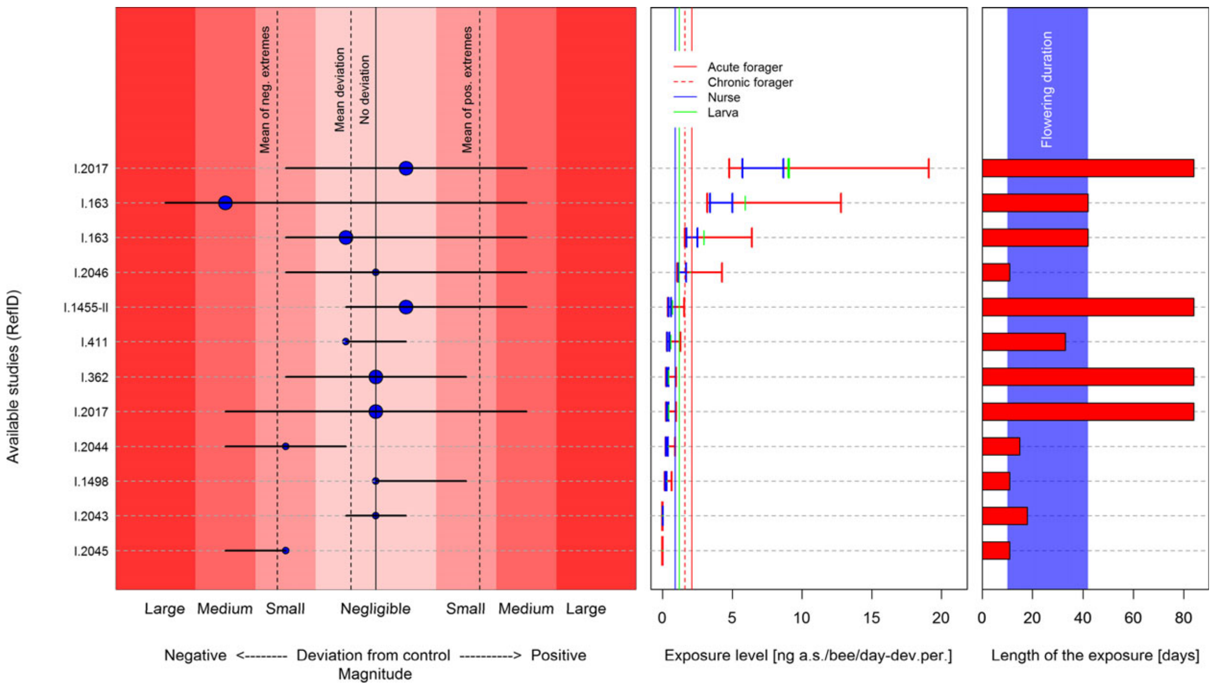

Figure F.3: Summary of the observed deviations for honeybee colony strength for seed treatment use to winter oilseed rape – only the reliable endpoints are indicated in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the available data

Interpretation for the treated crop scenario for the winter oilseed rape use	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The maximum negative deviation from the controls was larger than negligible in eight experiments. Although in four of these cases, the exposure was too long or the estimated exposure was somewhat higher than the exposure assessment goal, the exposure regime of four experiments was not unrealistically severe (I.2046, low dose of I.163, I.2044, I.2045)	The maximum negative deviation from the controls was not larger than negligible in four experiments. Although two of them represented a rather low exposure regime, in the other two cases (I.1455-II, I.411), the exposure regime, in general, was not too mild (and one of the studies had an unrealistically long exposure)
Considering the mean deviations from the control, it was more than negligible in the negative direction in case of three experiments (I.2044, I.2045, high dose of I.163). Although in one of these cases, the estimated exposure was somewhat higher than the exposure assessment goal, the exposure regimes of the other two experiments represented the lower end of the realistic exposure situations (or even below for I.2045)	Nine endpoints indicated negligible mean deviation from the control. Although, two of them (I.2043, I.1498) represented a rather low exposure regime, seven of them had a realistic or severe exposure regime; five of these seven were considered as reliable with minor deviations
The available evidence indicating not more than negligible deviation from the control has more weight than has the evidence indicating more than negligible negative deviation from the control.This is because a relatively high number of experiments with a realistic or severe exposure regime indicated an overall negligible deviation from the control, while a fewer experiments with suitable exposure indicated a negative deviation from the control. Also, there was a considerable biological variability and the endpoints indicating negligible deviation were, in general, much more reliable.Overall, this indicates a **moderate evidence for negligible effect**	

F.1.1.2 Succeeding crop

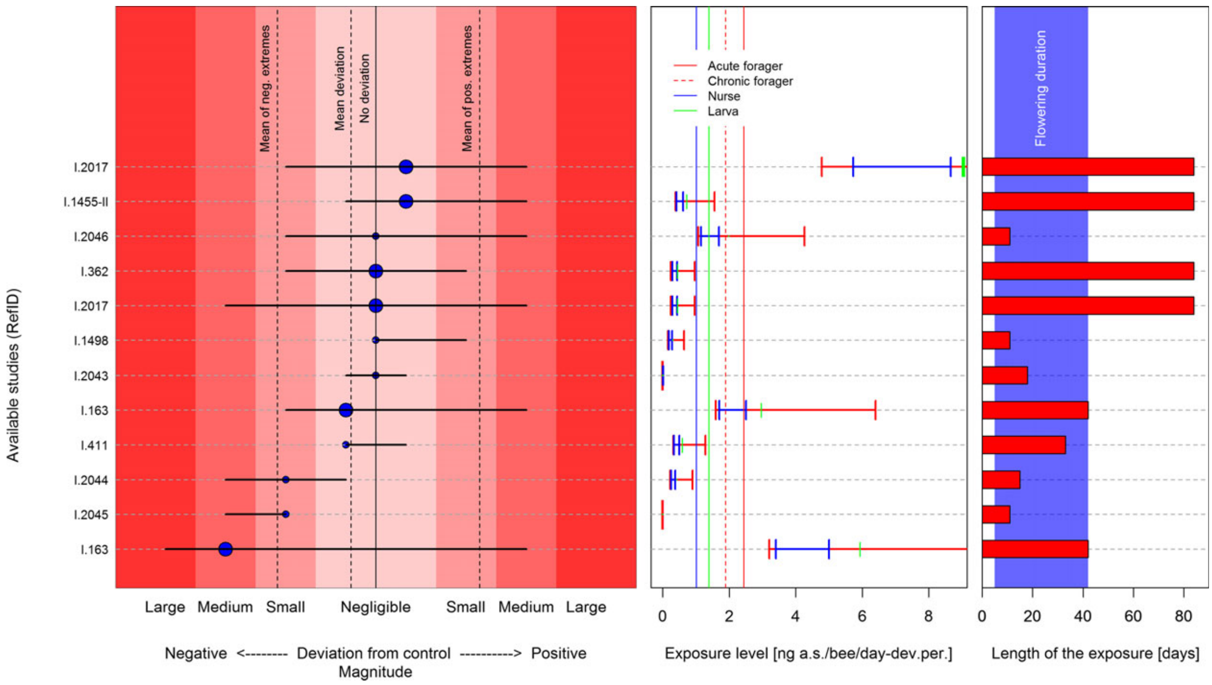

Figure F.4: Summary of the observed deviations for honeybee colony strength for seed treatment use to the succeeding crop scenario – only the reliable endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

Interpretation for the succeeding crop scenario
The exposure assessment goals for the succeeding crop scenario are only marginally different from the exposure assessment goals for winter oilseed rape (see Section 5.1.1.2). Also, when the exposure length of the experiments is compared to the range of expected flowering period, only marginal differences could be identified between the figures for the succeeding crop scenario and for the winter oilseed rape. Therefore, the indications for effects and for lack of effects with the overall balancing as presented for winter oilseed rape above is equally applicable for the succeeding crop scenario

F.1.2. Overwintering assessment (Class 1 endpoint)

Two figures are presented below for the treated crop scenario (winter oilseed rape) and one for the succeeding crop scenario. All of them are based on the same data set (colony strengths of honeybee colonies after overwintering), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for all figures for overwintering assessment.

It is noted that the colony strength after overwintering was calculated by considering the colony strength of the dead colonies as 0. This was however done only for those studies where detailed data on the individual colonies were available (i.e. it was possible to identify which and how many hives were lost during the winter and what was the colony strength of the colonies that survived the winter).

In addition, there were some experiments where the overwintering survival was studied, but not by measuring the colony strength after overwintering. These experiments are briefly summarized further below and an integration of all the information on overwintering is provided.

General interpretation
• Altogether nine endpoints were available, but four of them were considered as non-reliable • The variability between the reliable endpoints was very high; ranged from large positive to large negative deviation from the controls • Exposure estimation and information on the exposure lengths was available for all the reliable experiments • No dose–response pattern could be seen when all reliable experiments are considered • Within the experiments with more than one test concentration, a dose response trend could be observed (considering the mean effects)

F.1.2.1. Winter oilseed rape

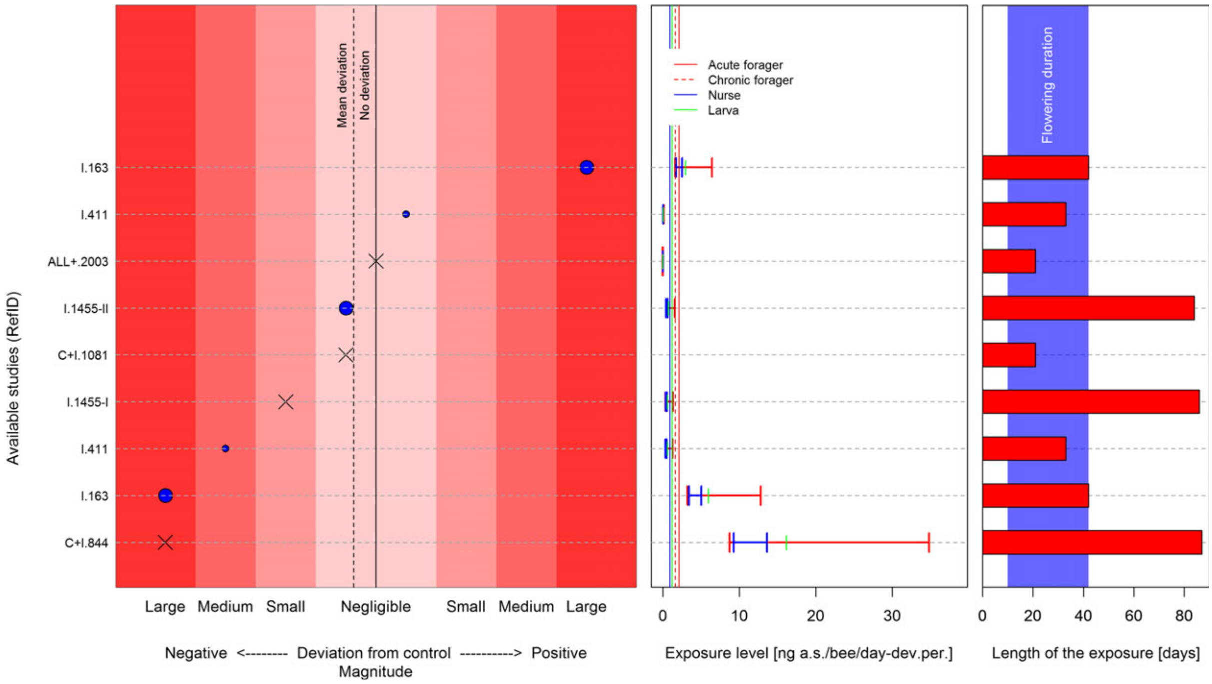

Figure F.5: Summary of the observed deviations for honeybee colony strength after overwintering for seed treatment use to winter oilseed rape – all available endpoints are indicated in the order of the magnitude of the deviation from the control, scale for exposure level aligned to the available data

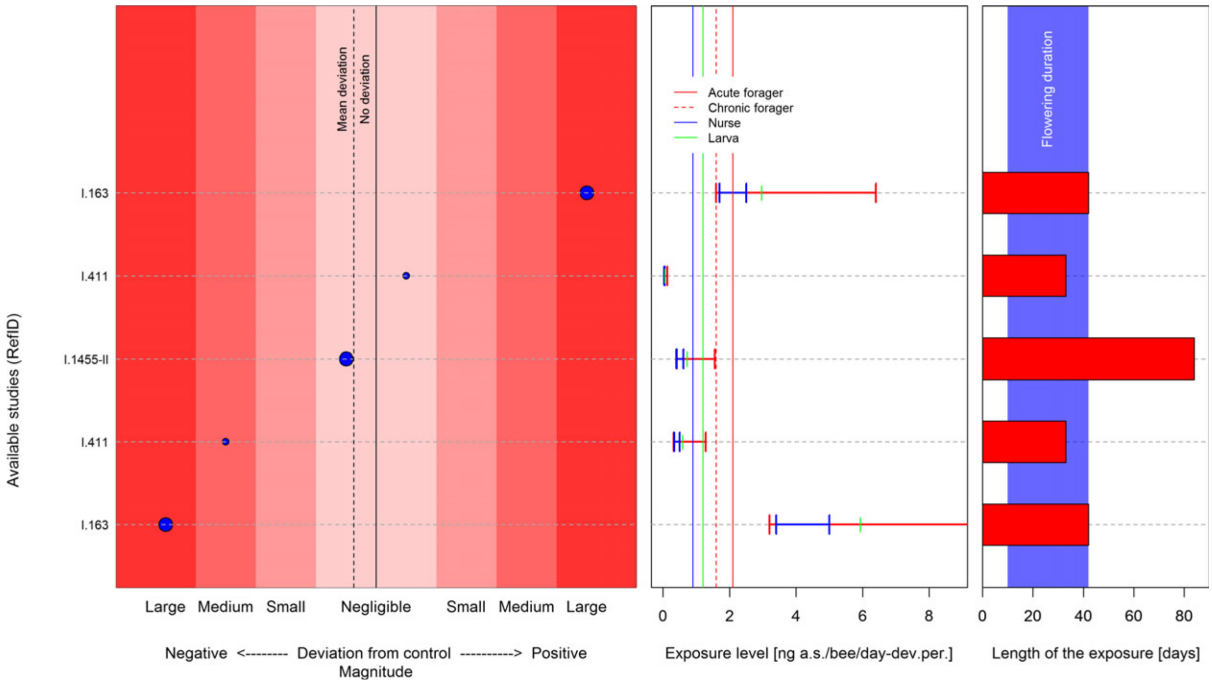

Figure F.6: Summary of the observed deviations for honeybee colony strength after overwintering for seed treatment use to winter oilseed rape – only the reliable endpoints are indicated in the order of the magnitude of deviation from the control, scale for exposure level aligned to the exposure assessment goals (zoom into the relevant part)

Interpretation for the treated crop scenario for the winter oilseed rape use	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
Two endpoints indicated more than negligible negative deviation from the control. Although one of them had high exposure level, the high dose of the experiment I.411 had comparable but somewhat lower estimated exposure than the exposure assessment goal and the length of the exposure was in the realistic range of the flowering period. This endpoint was considered as reliable with major restrictions	Three experiments indicated not more than negligible negative deviation from the control. Although one of them had too low exposure level, in the other two cases the exposure regime, in general, was not mild. These two endpoints were considered as reliable with minor restrictions
The available evidence indicating not more than negligible deviation from the control has more weight than has the evidence indicating more than negligible negative deviation from the control This is because only one experiment with a realistic exposure regime indicated more than negligible negative deviation from the control, while two experiments with suitable exposure indicated not more than negligible negative deviation from the control. In addition, both of these two endpoints were more reliable than the one with the more than negligible negative deviation Overall, this indicates a moderate evidence for negligible effect	

In addition, as reported above, there were three colony-feeder experiments (I.2017, I.843 and I.362) where the overwintering success was studied, but not by measuring the colony strength after overwintering. In these studies, the proportion of the successfully overwintered test colonies were reported.

- In the experiment I.843, honeybee colonies (n = 4) were fed by spiked sugar syrup at different concentrations over a period of 9 weeks. For the next spring, all but one treated colonies died while from the control, only one of the four colonies died. A slight overall tendency suggested that the effect may have started earlier with the higher concentration. The endpoint was assessed as 'reliable with minor restrictions'. The estimated exposure levels for the lowest test concentration (40 μg/kg, four of four colonies died) were forager – 1.28–5.12 ng/bee per day, nurse – 1.36–2.0 ng/bee per day, larva – 2.38 ng/larva per developmental period.
- In the experiment I.362, over a 12-week period, spiked diet patties (pollen and sugary solution) were offered to honeybee colonies (n = 10) with different concentrations. For overwintering success, a decreasing trend with increasing concentration was found (although it was statistically different only in case of the highest test concentration). All control hives successfully overwintered. The endpoint was assessed as 'reliable with minor restrictions'. The estimated exposure levels for the lowest test concentration (5 μg/kg, 2 of 10 colonies died) were forager – 0.32–1.28 ng/bee per day, nurse – 0.37–0.53 ng/bee per day, larva – 0.6 ng/larva per developmental period.
- In the experiment I.2017 similar methodology was used as in the experiment I.362 (note: I.2017 and I.362 are from the same publication). Three of the seven control colonies died and four of the seven treated colonies (at each concentration) died for the next spring. The endpoint was assessed as 'reliable with major restrictions'. The estimated exposure levels for the lowest test concentration (5 μg/kg) are the same as reported above for study I.362. Taking the estimated exposure levels for the highest test concentration (100 μg/kg, same effect than at the lowest or at the middle concentration) were forager – 6.4–25.6 ng/bee per day, nurse – 7.45–11.2 ng/bee per day, larva – 12.0–12.1 ng/larva per developmental period.

An overall integration of the eight available and reliable experiments, which investigated the overwintering, is presented below.

Reference	Exposure estimation ng/bee per day (for simplification, it is indicated only for foragers)	Exposure length (day)	Reliability	Description of effect/ deviation from control
I.411	0.032–0.128	33	Reliable with major restrictions	No more than negligible deviation from the control
I.411	0.32–1.28	33	Reliable with major restrictions	Medium negative deviation from the control
I.2017	0.32–25.6	84	Reliable with major restrictions	No clear tendency (negative effect cannot be excluded nor confirmed)
I.362	0.32–1.28	84	Reliable with minor restrictions	Clear tendency for a negative effect
I.1455-II	0.39–1.56	84	Reliable with minor restrictions	No more than negligible negative deviation from the control
I.843	1.28–5.12	63	Reliable with minor restrictions	Clear negative effect
I.163	1.6–6.4	42	Reliable with minor restrictions	Large positive deviation from the control
I.163	3.2–12.8	42	Reliable with minor restrictions	Large negative deviation from the control

Note: the exposure assessment goal for foragers is 2.1–1.6 ng/bee per day (acute and chronic, respectively) and the realistic flowering duration of winter oilseed rape was considered as 10–42 days.

No dose–response pattern could be seen when all the endpoints are considered together. Estimated exposures to honeybee castes of the lower dose of experiment I.411 were too low when compared to the exposure assessment goal. No clear conclusion could be drawn from experiments I.2017. Experiments I.362, I.843 and high dose of I.411 indicated a clear negative effect on honeybee populations after overwintering. The estimated exposure of these experiments was at around or somewhat below the exposure assessment goal. The high dose of the experiment I.163 also indicated a clear negative effect; however, the exposure level of this endpoint was somewhat higher than the exposure assessment goal. In the remaining two experiments, such negative effects were not present. Experiment I.1455-II had only a negligible negative deviation from the control. The estimated exposure of this experiment was comparable, but somewhat below the exposure assessment goal. The low dose of the experiment I.163 had a realistic worst-case exposure regime and resulted in a large-positive deviation from the control. Considering the deviations from the controls in combination with the exposure estimations, it can be concluded that the available data set is contradictory. Nevertheless, it may be considered that the available evidence indicating more than negligible negative effects has more weight. However, two of the four experiments that indicated clear negative effects had considerably longer exposure duration than the realistic flowering period of oilseed rape (I.362 and I.843). When the severity of these two endpoints is taken into consideration, the available evidences become balanced and no clear trend is apparent. Therefore, **this line of evidence is inconclusive**.

F.1.2.2. Succeeding crop

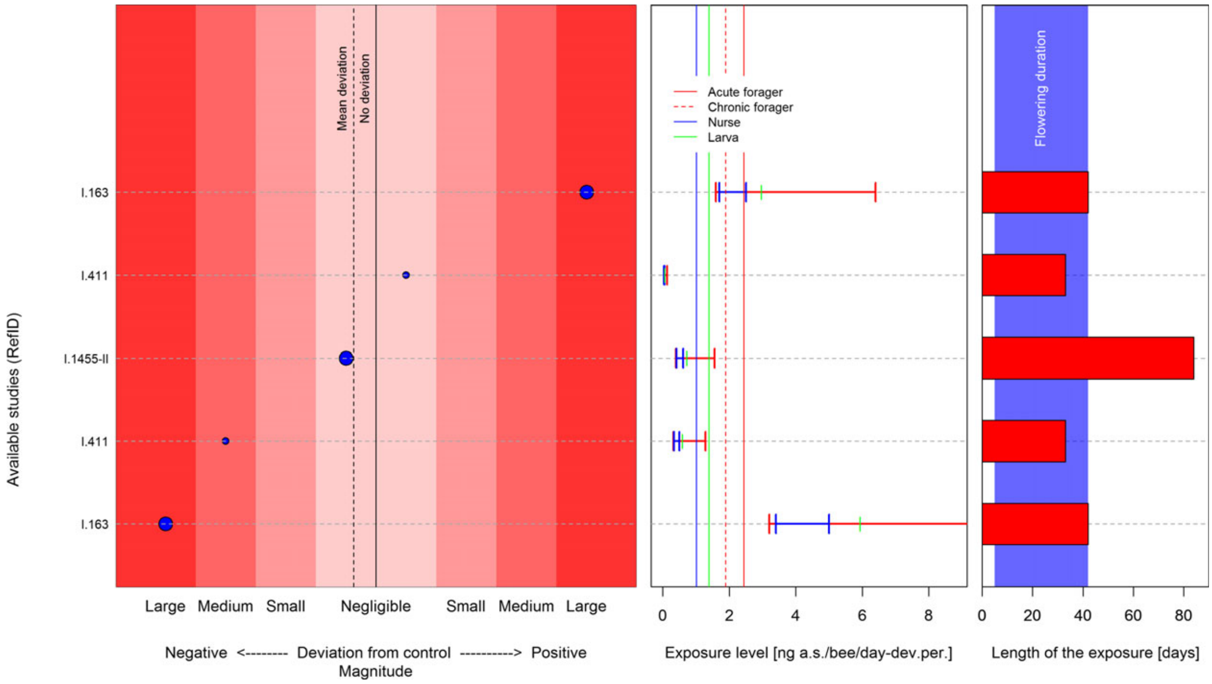

Figure F.7: Summary of the observed deviations for honeybee colony strength after overwintering for the succeeding crop scenario – only the reliable endpoints are indicated in the order of the magnitude of deviation from the control, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

Interpretation for the succeeding crop scenario
The exposure assessment goals for the succeeding crop scenario are only marginally different from the exposure assessment goals for winter oilseed rape (see Section 5.1.1.2). Also, when the exposure length of the experiments is compared to the range of expected flowering period, only marginal differences could be identified between the succeeding crop scenario and for the winter oilseed rape. Therefore, the indications for effects and for lack of effects with the overall balancing as presented for winter oilseed rape above based on colony strength after overwintering is equally applicable for the succeeding crop scenario The integration of the additional experiments and the final conclusion on this line of evidence as presented for winter oilseed rape above is also applicable for the succeeding crop scenario

F.1.3. Mortality in front of the hive (Class 2 endpoint)

One figure is presented below for each of the treated crop scenario (winter oilseed rape) and for the succeeding crop scenario. All of them are based on the same data set (honeybee mortality in front of the hives). The general interpretation is relevant for both figures.

General interpretation

- Altogether 10 endpoints were available, but five of them were considered as non-reliable
- All the five reliable endpoints were considered as reliable with major restrictions
- The biological variability of all the reliable endpoints was very low; all the mean deviations from the controls during the experiments were in the negligible range as well as the mean of the extreme deviations
- Exposure estimation and information on the exposure lengths was available for all the reliable experiments
- Dose–response analysis cannot be performed due to the very low variability between the reliable endpoints

F.1.3.1. Winter oilseed rape

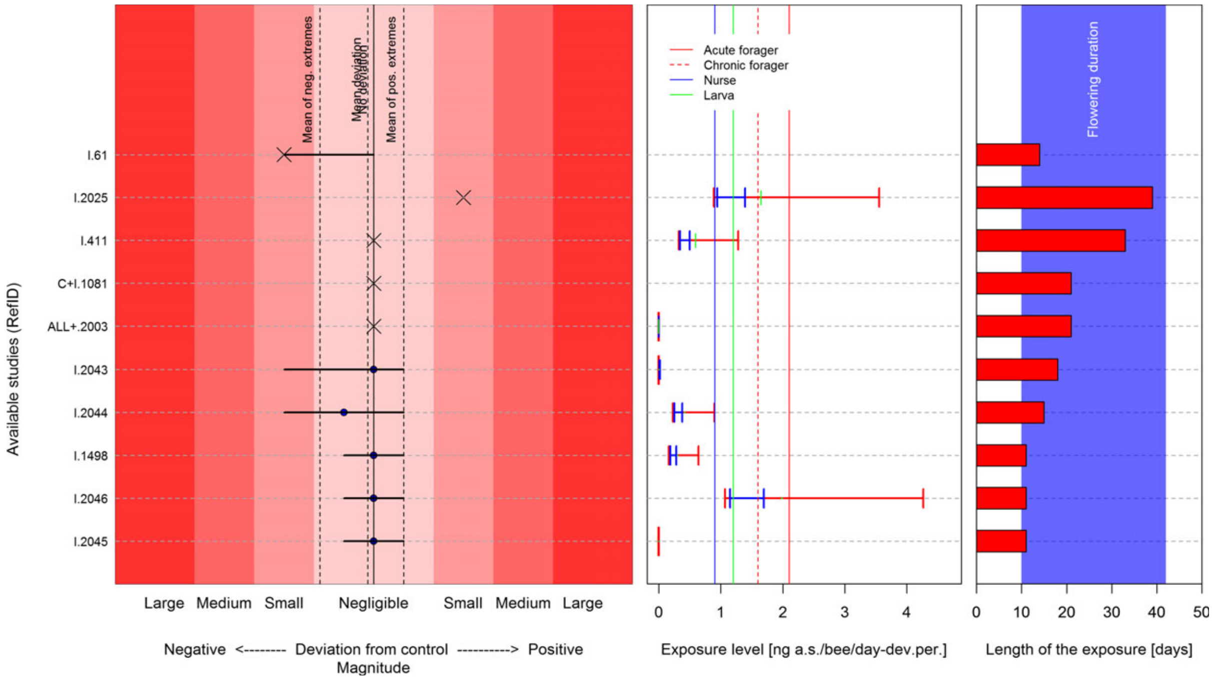

Figure F.8: Summary of the observed deviations for honeybee mortality in front of the hives for the succeeding crop scenario – only the reliable endpoints are indicated, scale for exposure level aligned to the available data

Interpretation for the treated crop scenario for the winter oilseed rape use	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The maximum negative deviation from the controls was larger than negligible in two experiments and the exposure regimes of these two experiments represented the lower end of the realistic exposure situations (or even below for I.2043)	The maximum negative deviation from the controls was not larger than negligible in three experiments. One of these experiments (I.2046) had exposure estimations which are in the range of the exposure assessment goal. The exposure lengths of this study fell in the realistic range of the flowering period, although tend to be at the lower edge of this range
	Considering the mean deviations from the control, all the reliable studies fell in the negligible range. Only one of these experiments (I.2046) had exposure estimations which are in the range of the exposure assessment goal
The available evidence indicating not more than negligible deviation from the control has somewhat lower weight than has the evidence indicating more than negligible negative deviation from the control. This is because only one experiment with appropriate exposure indicated negligible effect, while in two experiments with mild exposure regime, a temporal negative deviation was indicated. All the endpoints had low reliability, but the biological variability was low Overall, this indicates a **weak evidence for larger than negligible effect**	

F.1.3.2 Succeeding crop

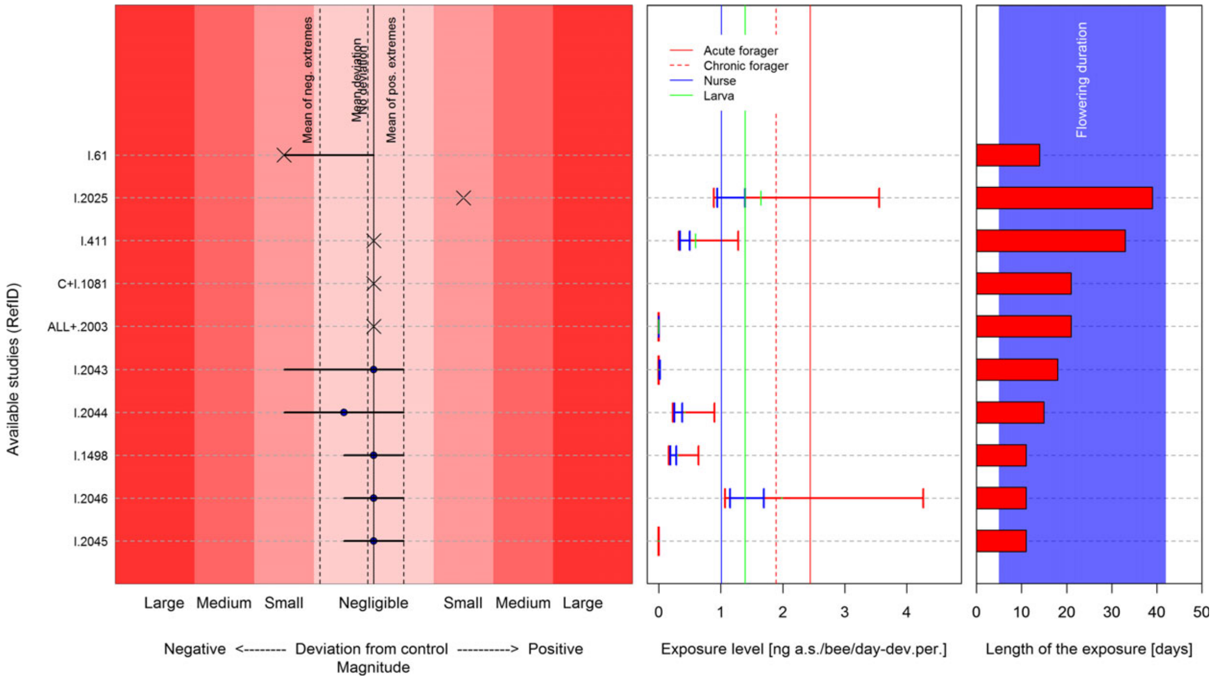

Figure F.9: Summary of the observed deviations for honeybee forager mortality in front of the hives for the succeeding crop scenario – all endpoints are indicated, scale for exposure level aligned to the available data

Interpretation for the succeeding crop scenario
The exposure assessment goals for the succeeding crop scenario are only marginally different from the exposure assessment goals for winter oilseed rape (see Section 5.1.1.2). Also, when the exposure length of the experiments is compared to the range of expected flowering period, only marginal differences could be identified between the figures for the succeeding crop scenario and for the winter oilseed rape. Therefore, the indications for effects and for lack of effects with the overall balancing as presented for winter oilseed rape is equally applicable for the succeeding crop scenario

F.1.4. Brood abundance (Class 2 endpoint)

Three figures are presented below for the treated crop scenario (winter oilseed rape) and one for the succeeding crop scenario. All of them are based on the same data set (brood abundance of honeybee colonies), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for all figures for honeybee brood abundance.

F.1.4.1. Winter oilseed rape

General interpretation
• Altogether 22 endpoints were available, but eight of them were considered as non-reliable • All the 14 reliable endpoints were considered as reliable with major restrictions • The biological variability of several reliable experiments was considerable high, in some cases fluctuated both negatively and positively relative to the control • There was also variability between the studies. The mean deviation from the control ranged from medium negative to medium positive. The number of endpoints on both the negative and the positive sides were balanced and all had the same reliability score. The mean of the mean overall deviations during the duration of the studies is in the negligible range. This line is very close to the zero line and the lines of the extreme deviations are also close to the edges of the negligible deviation range

General interpretation

- Exposure estimation was available for all of them and also, information on the exposure lengths was available for all reliable studies
- No dose–response pattern could be seen when all reliable experiments are considered
- Within the experiments with more than one test concentration, a dose–response trend could be observed (considering the mean effects)

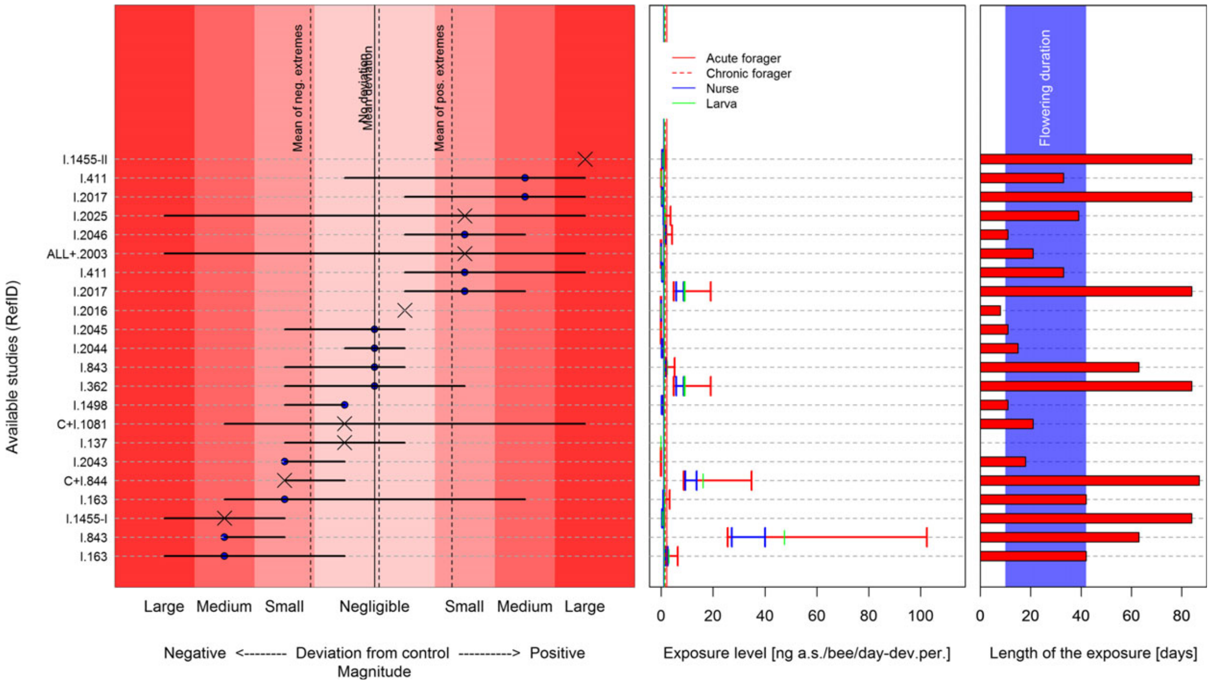

Figure F.10: Summary of the observed deviations for honeybee brood abundance for seed treatment use to winter oilseed rape – all available endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the available data

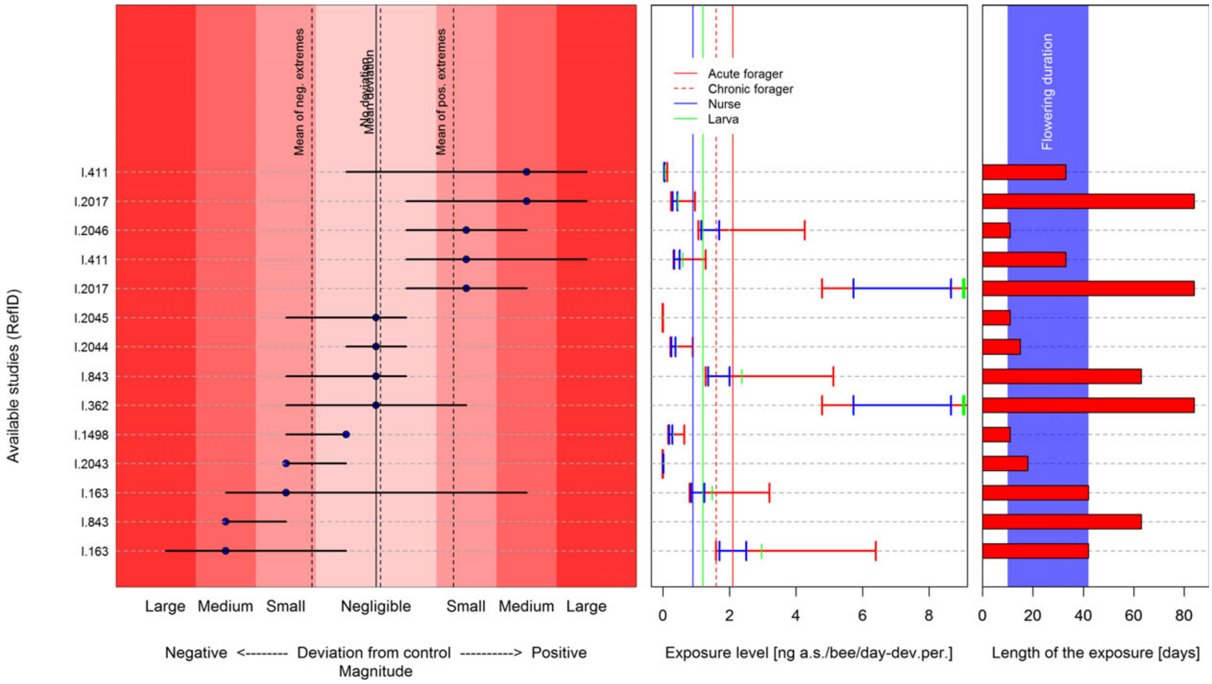

Figure F.11: Summary of the observed deviations for honeybee brood abundance for seed treatment use to winter oilseed rape – only the reliable endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

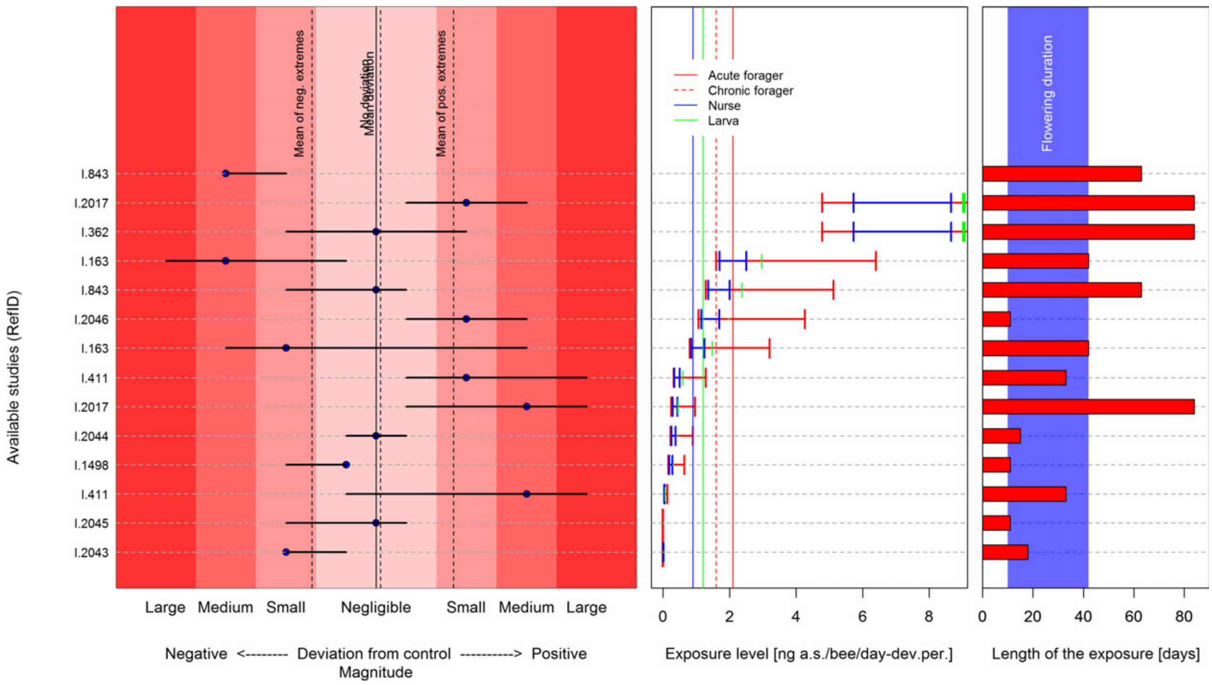

Figure F.12: Summary of the observed deviations for honeybee brood abundance for seed treatment use to winter oilseed rape – only the reliable endpoints are indicated in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the exposure assessment goals (zoom into the relevant part)

Interpretation for the treated crop scenario for the winter oilseed rape use	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The maximum negative deviation from the controls was larger than negligible in eight experiments. Three of these experiments had low estimated exposure compared to the exposure assessment goal in combination with exposure lengths which represent the lower end of the realistic range of the flowering period. An additional experiment from this set (low dose of I.163) had a realistic worst-case exposure regime	The maximum negative deviation from the controls was not larger than negligible in six experiments. One of these experiments (high dose of I.2017) had a very severe exposure regime and another one had a realistic worst-case exposure estimation (I.2046). In addition, another one (low dose of I.2017) had a relatively low estimated exposure, but in combination with a very long exposure duration
Considering the mean deviations from the control, it was more than negligible in the negative direction in case of four experiments The exposure regimes in three of these four experiments were not unrealistically severe and one of these had a very low exposure estimation when compared to the exposure assessment goal	Ten experiments indicated negligible or positive mean deviation from the control. Although, some of them represented a rather low exposure regime, four of them had higher or comparable exposure estimation than the exposure assessment goal. Three of these four had an exposure period considerable longer than the realistic flowering period. An additional experiment (low dose of I.2017) with lower exposure estimate than the exposure assessment goal also had a long exposure period
The available evidence indicating not more than negligible deviation from the control has somewhat more weight than has the evidence indicating more than negligible negative deviation from the control This is because a slightly higher number of experiments with a realistic or severe exposure regime indicated an overall negligible (or even positive) deviation from the control, while slightly fewer experiments with realistic or mild exposure regime indicated more than negligible negative deviation from the control. There was a considerable biological variability and all the endpoints had low reliability Overall, this indicates a **weak evidence for negligible effect**	

F.1.4.2. Succeeding crop

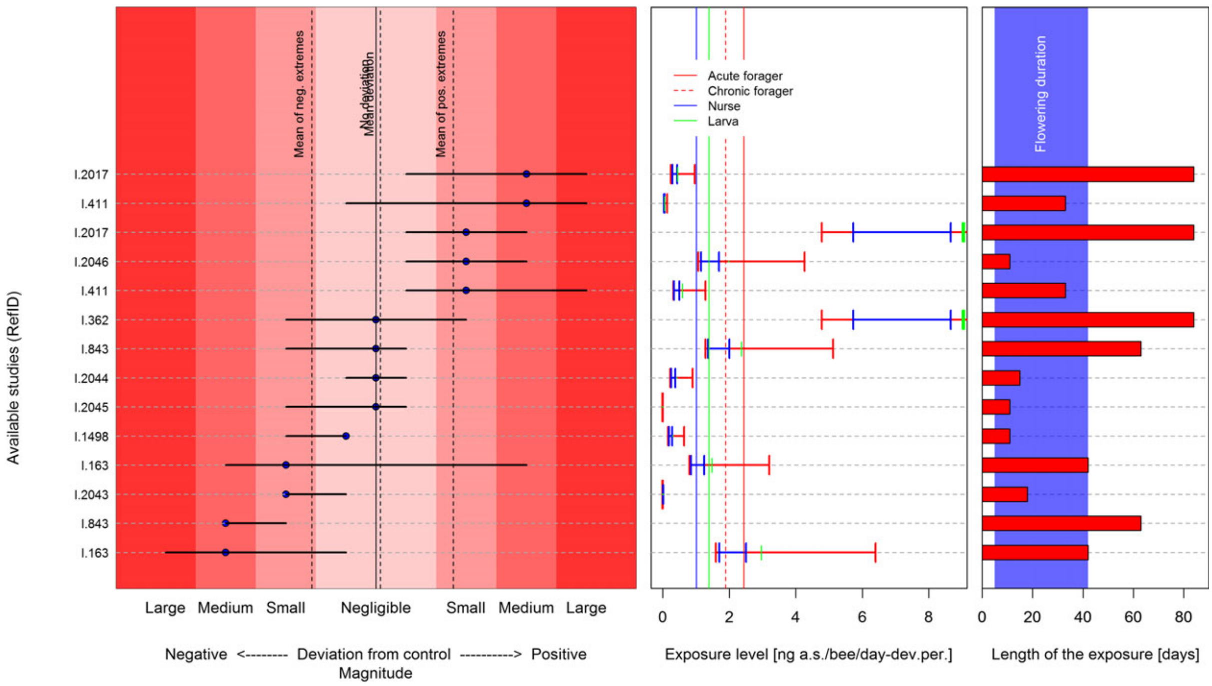

Figure F.13: Summary of the observed deviations for honeybee brood abundance for the succeeding crop scenario – only the reliable endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

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Interpretation for the succeeding crop scenario
The exposure assessment goals for the succeeding crop scenario are only marginally different from the exposure assessment goals for winter oilseed rape (see Section 5.1.1.2). Also, when the exposure length of the experiments is compared to the range of expected flowering period, only marginal differences could be identified between the figures for the succeeding crop scenario and for the winter oilseed rape. Therefore, the indications for effects and for lack of effects with the overall balancing as presented for winter oilseed rape above is equally applicable for the succeeding crop scenario

F.1.5. Homing success (Class 2 endpoint)

Two figures are presented below for the treated crop scenario (winter oilseed rape) and one for the succeeding crop scenario. All of them are based on the same data set (homing success of honeybee foragers), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for all figures for homing success.

General interpretation

- Six endpoints were available from three experiments; all were considered as reliable with major restrictions
- These endpoints were derived from three studies; from each of them, results from two test concentrations are presented. In all cases, the highest test concentration indicating no or the smallest deviation from the control and the next higher test concentration was selected.
- Exposure estimation was available for all the endpoints
- When all the six endpoints are considered, some, but not entirely clear dose–response pattern is indicated (note: for one study, range of doses are indicated; it is considered that the lower edge of the ranges are more relevant since the homing flight experiments do not lasts all day long)
- Within each experiment, a dose–response trend was observed

F.1.5.1. Winter oilseed rape

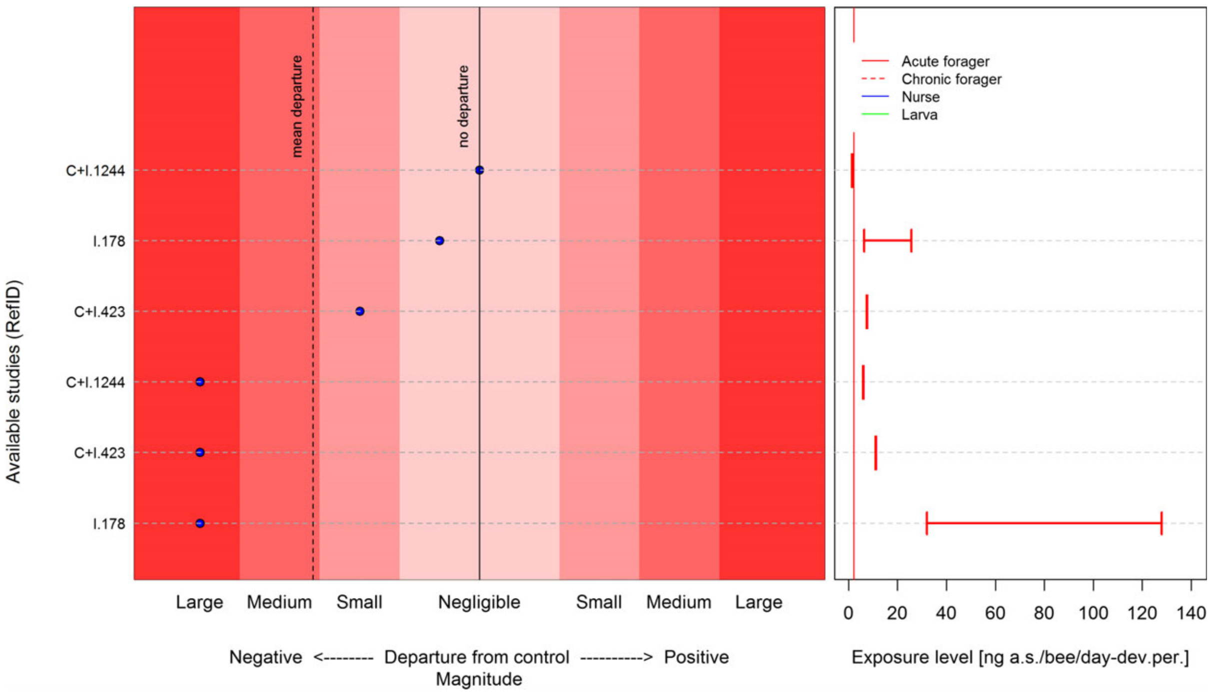


Figure F.14: Summary of the observed deviations for homing success of honeybee foragers for seed treatment use to winter oilseed rape – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the available data

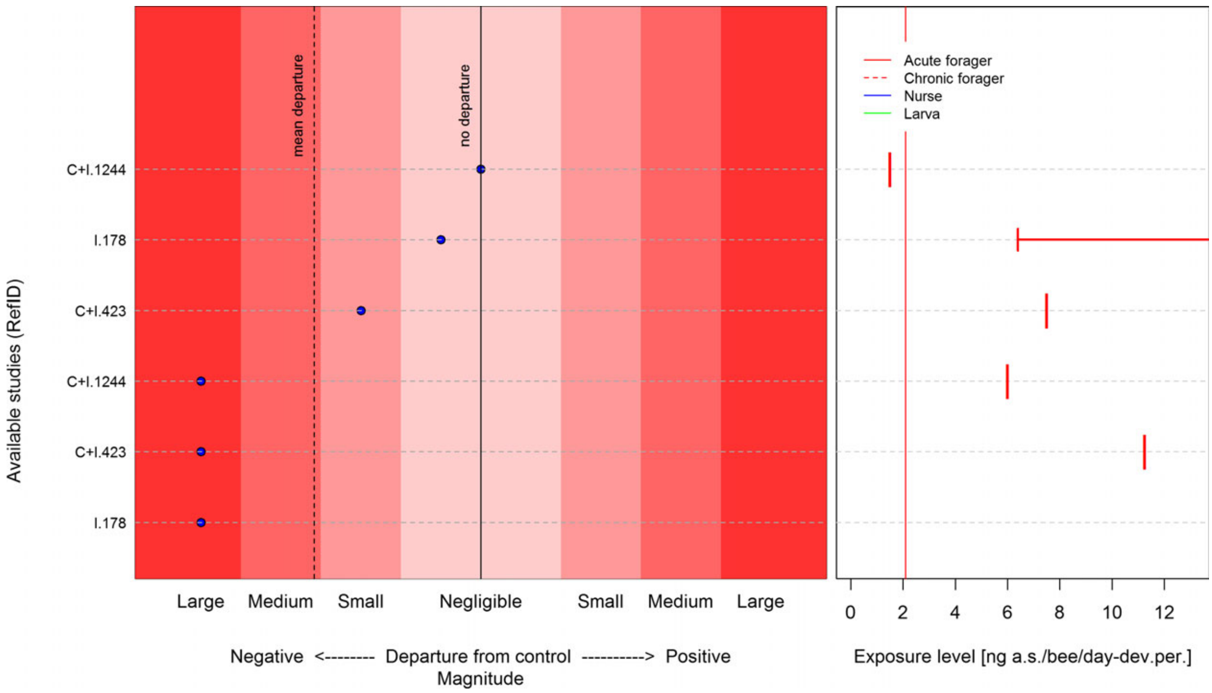


Figure F.15: Summary of the observed deviations for homing success of honeybee foragers for seed treatment use to winter oilseed rape – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the exposure assessment goal (zoom in to the relevant part)

Interpretation for the treated crop scenario for the winter oilseed rape use
The estimated exposure levels considerably exceed the exposure assessment goal for winter oilseed rape in all, but one case. These five endpoints included the lower test concentration from the experiment I.178, which indicated a negligible deviation from the control. The only endpoint that had an estimated exposure level close but slightly below the exposure assessment goal indicated no deviation from the control. The endpoints were classified as reliable with major restrictions Overall, this indicates a **weak evidence for negligible effect**

F.1.5.2. Succeeding crop

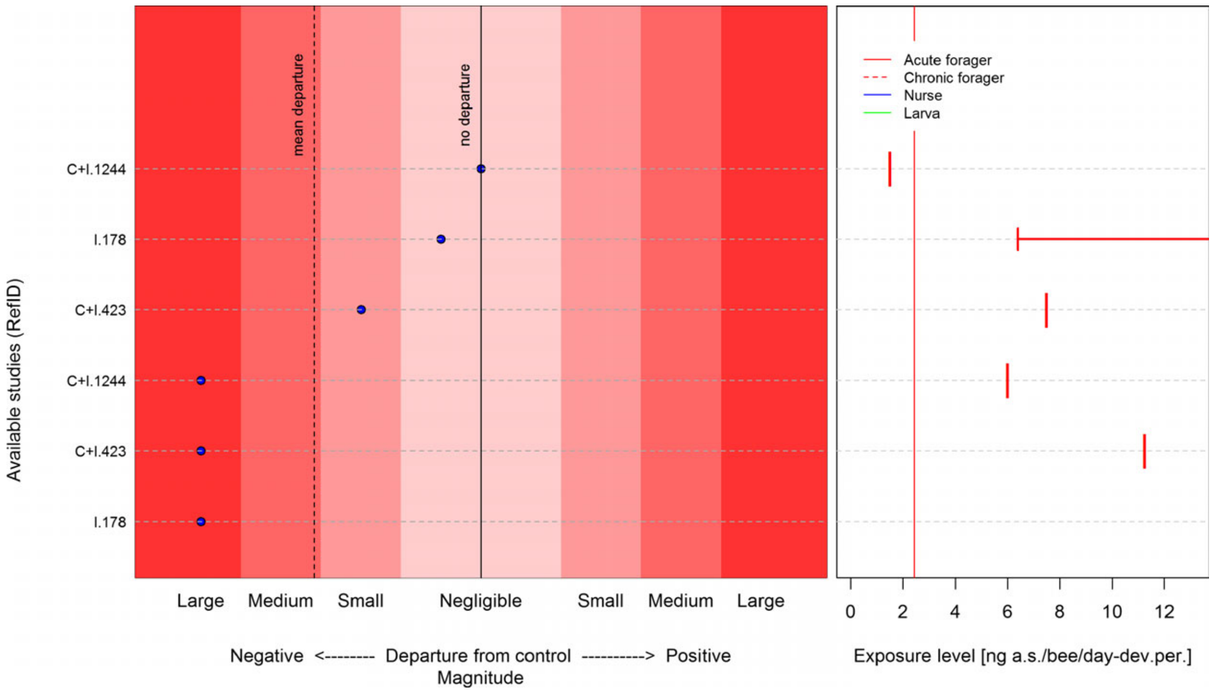


Figure F.16: Summary of the observed deviations for homing success of honeybee foragers for the succeeding crop scenario – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the exposure assessment goal (zoom in to the relevant part)

Interpretation for the succeeding crop scenario
The exposure assessment goal for the succeeding crop scenario is only marginally different from the exposure assessment goal for winter oilseed rape (see Section 5.1.1.2). Therefore, the interpretation of the available evidences and the conclusion as presented for winter oilseed rape above are also applicable for the succeeding crop scenario

F.2. Bumblebees

F.2.1. Queen production (Class 1 endpoint)

Two figures are presented below for the succeeding crop scenario. Both are based on the same data set (queen production of queenright bumblebee colonies), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for both figures.

General interpretation
• Six reliable endpoints were available, all were assessed as reliable with major restrictions • There was a high variability between the experiments. The deviation from the control ranged from large positive to large negative • Exposure estimation was available for all, but one and information on the exposure lengths was available for all experiments • No dose–response pattern could be seen when all endpoints are considered

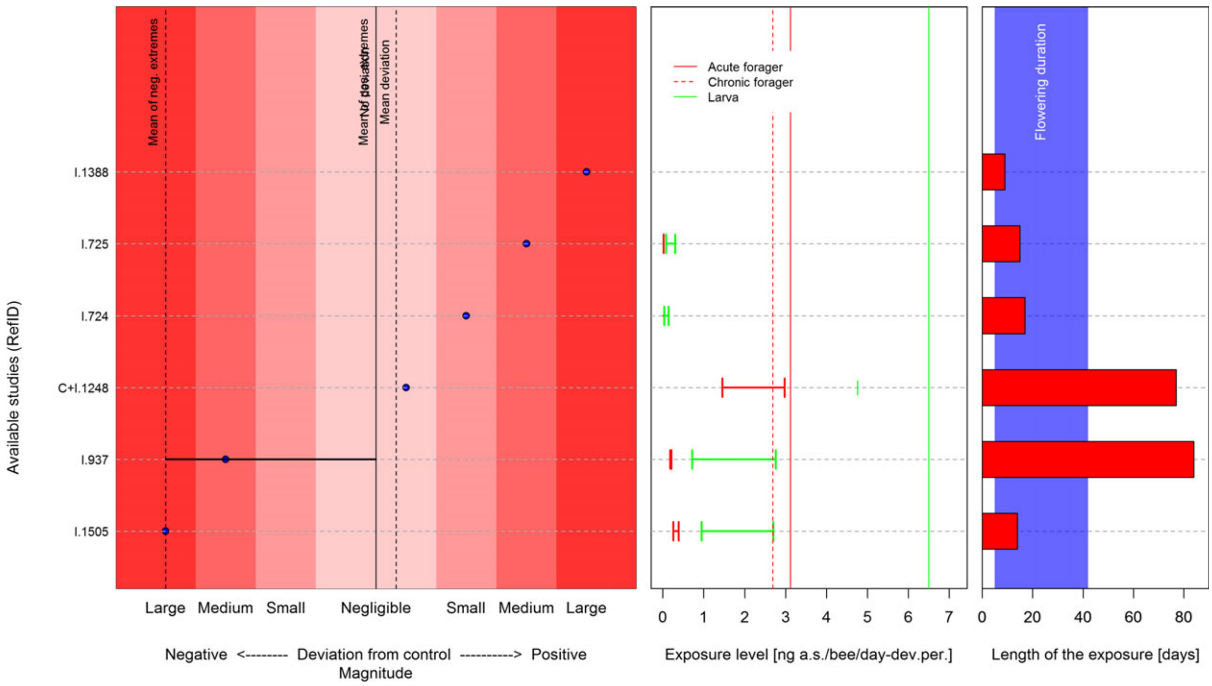


Figure F.17: Summary of the observed deviations for queen production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the available data

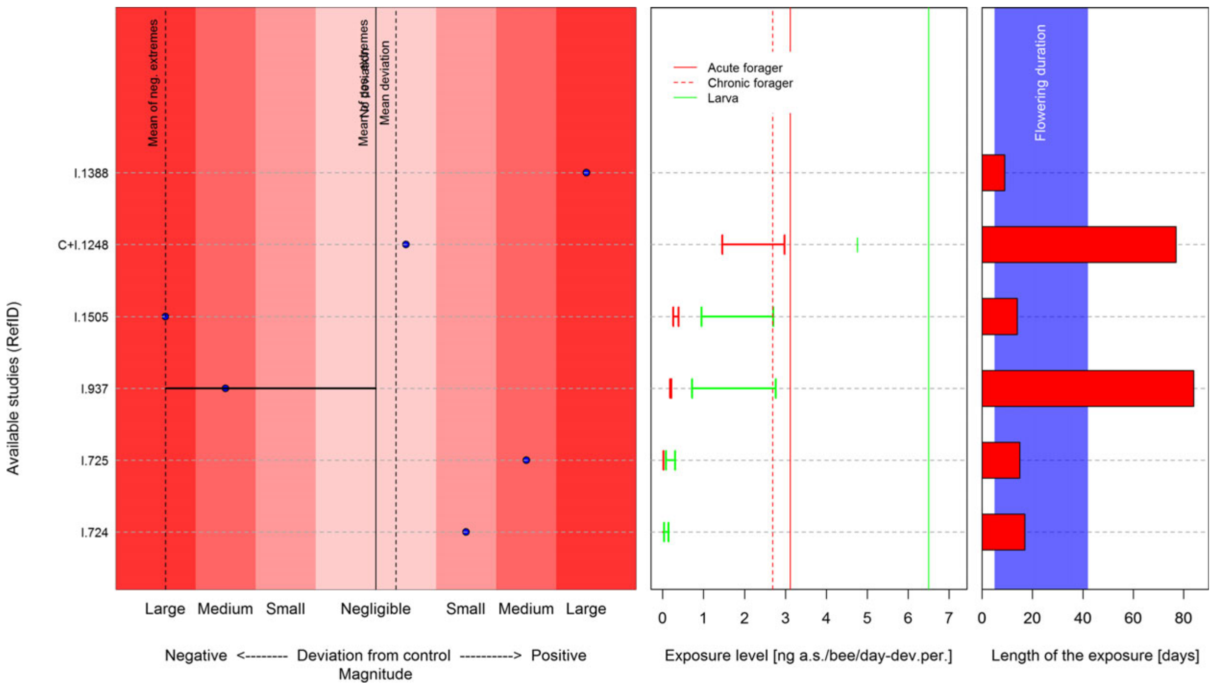


Figure F.18: Summary of the observed deviations for queen production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the available data

Interpretation of the line of evidence	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
Two endpoints indicated more than negligible negative deviation from the control. Although one of them had an unrealistically long exposure (when compared to the realistic range of the flowering period of any succeeding crop), the other one had a realistic exposure length falling to the lower end of the range of the flowering period of succeeding crops. The estimated exposures of both of them were well below the exposure assessment goals	Three experiments with exposure estimation indicated positive deviation from the control. Although two of them had too low exposure levels, the exposure estimations of one of them (C+I. 1248) was reasonable close to the exposure assessment goals (but were somewhat below) in combination with a very long exposure length that was far beyond the realistic range of the flowering period of any succeeding crop
The available evidence indicating not more than negligible deviation from the control has less weight than has the evidence indicating more than negligible negative deviation from the control One experiment with appropriate exposure indicated negligible effect and also only one experiment with rather mild exposure regime resulted in a large negative deviation from the control. However, there was another endpoint with low exposure level indicating similar results. This experiment (I.937) was not considered to be suitable to fully support the negative trend due to its very long exposure length. However, it was considered as a weak indication for a likely negative effect at realistic exposure situation	
Overall, this indicates a **weak evidence for larger than negligible effect**	

F.2.2. Worker production (Class 1 endpoint)

Two figures are presented below for the succeeding crop scenario. Both are based on the same data set (worker production of queenright bumblebee colonies), but with slightly different setups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for both figures.

General interpretation
• Nine reliable endpoints were available, all, but one was assessed as reliable with major restrictions • There was a high variability between the experiments. The deviation from the control ranged from large positive to medium negative • Exposure estimation was available for all, but one and information on the exposure lengths was available for all experiments • No dose–response pattern could be seen when all endpoints are considered

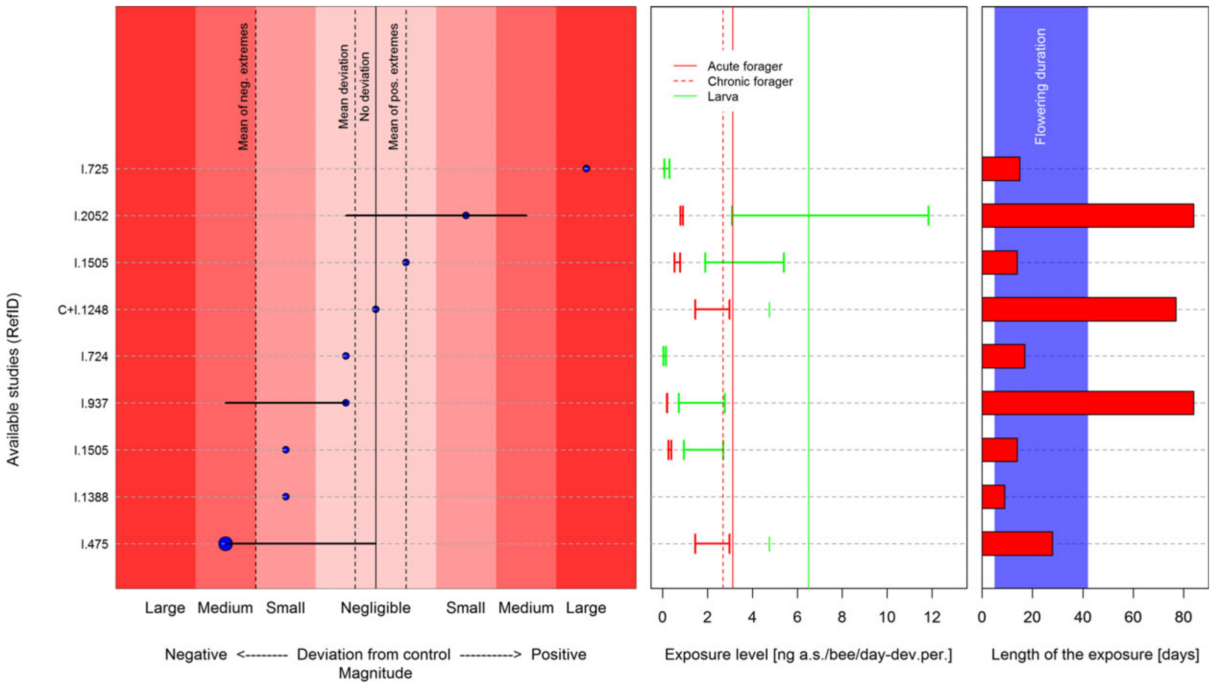


Figure F.19: Summary of the observed deviations for worker production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the available data

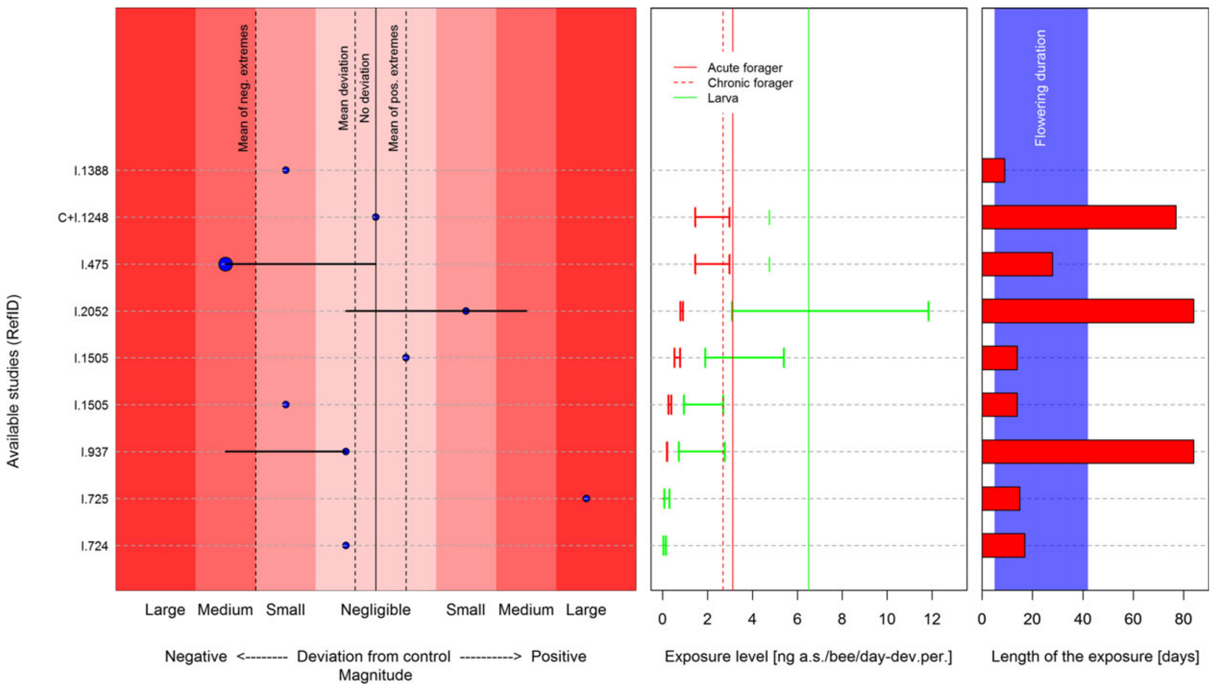


Figure F.20: Summary of the observed deviations for worker production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the available data

Interpretation of the line of evidence	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The maximum negative deviation from the controls was larger than negligible in two experiments out of the three, where the effect was studied at more than one observation day. In both cases, the exposure levels were below the exposure assessment goals, although one of them had a very long exposure period	The maximum negative deviation from the controls was not larger than negligible in one out of those three experiments, where the effect was studied at more than one observation day. When compared to the exposure assessment goal, this experiment had a realistic exposure level for the larvae in combination with a very long exposure period
The mean deviation from the control was negative and larger than negligible in three experiments and two of them had exposure estimations (lower dose of I.1505, I.475). The exposure estimation for both of them was lower than the exposure assessment goal in combination with exposure lengths falling in the realistic range of the flowering period of any succeeding crop. One of these experiments was considered as reliable with minor restrictions	Six endpoints indicated negligible mean deviation from the control or positive deviation from the control. Although three of them had too low estimated exposure, in case of the other three (C+I.1248, high dose of I.1505, I.2052) at least the estimations for larvae were close to or overlapped the respective exposure assessment goal. Moreover, two of these three had very long exposure period
	Results from the two test concentrations of experiment I.1505 are not consistent; the lower dose resulted in the negative deviation from the control indicating some uncertainties to consider this deviation as true effect
The available evidence indicating not more than negligible deviation from the control has not more, neither less weight than has the evidence indicating more than negligible negative deviation from the control. Although the available evidence indicating more than negligible negative deviations based on maximum deviations has slightly more weight than has the evidence indicating not more than negligible deviation, overall this type of evidence has a low weight (three experiments only). Considering the mean deviations, two experiments with appropriate exposure indicated a clear negative deviation from the control. One of them had higher reliability than all the other endpoints, while the other one bears some uncertainties. On the other hand, three experiments could be considered as evidence indicating no negative deviation from the controls. However, two of them had somewhat low exposure levels (but reasonable close to the exposure assessment goal at least for larvae) and the third one had a high enough exposure level only for larvae. The lengths of the exposure of these experiments were either realistic or considerable longer than the realistic range of the flowering period of any succeeding crop. No clear trend could be seen when all these positive and negative elements were balanced	
Therefore, **this line of evidence is inconclusive**	

F.2.3. Drone production (Class 1 endpoint)

Two figures are presented below for the succeeding crop scenario. Both are based on the same data set (drone production of queenright bumblebee colonies), but with slightly different set-ups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for both figures.

General interpretation
• Six reliable endpoints were available, all were assessed as reliable with major restrictions • There was variability between the experiments. The deviation from the control ranged from medium positive to large negative • Exposure estimation and information on the exposure lengths was available for all experiments • No dose–response pattern could be seen when all endpoints are considered

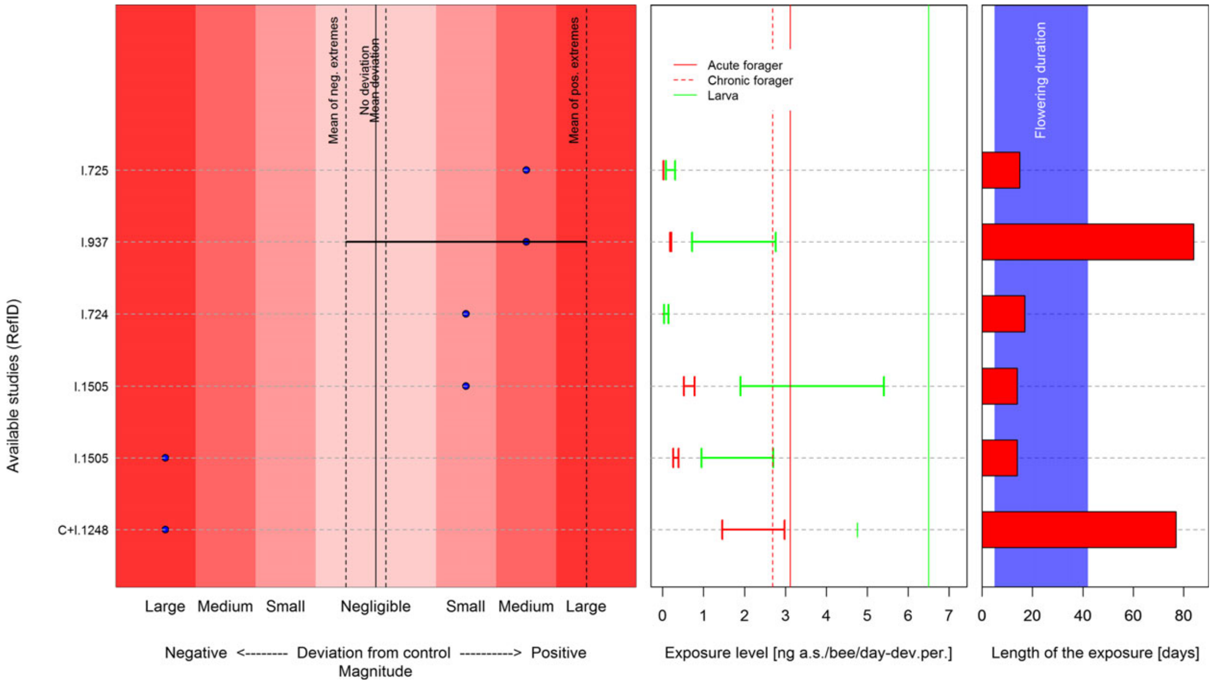


Figure F.21: Summary of the observed deviations for drone production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of deviation from control, scale for exposure level aligned to the available data

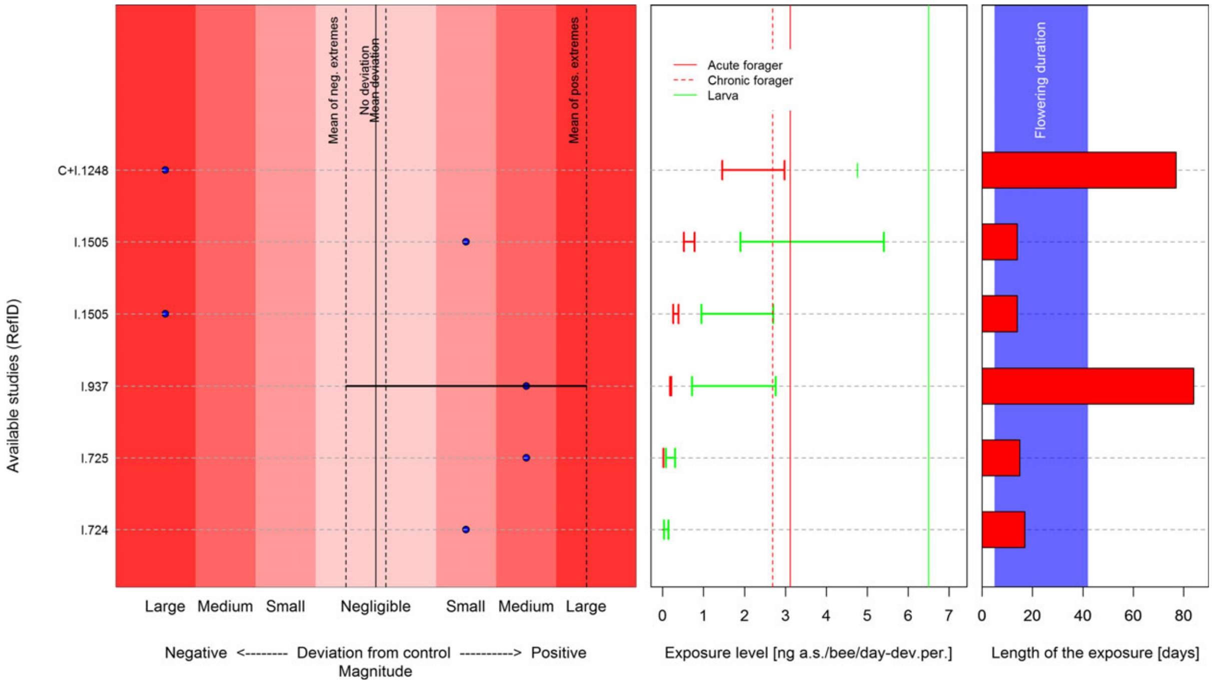


Figure F.22: Summary of the observed deviations for drone production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the available data

Interpretation of the line of evidence	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The deviation from the control was large negative for two experiments and the exposure estimation was lower than the exposure assessment goal in both cases. Although the exposure length was too long for one of these experiments, the exposure lengths of the other one (lower dose of I.1505) was in the realistic range of the flowering period of any succeeding crop	Four endpoints indicated a positive mean deviation from the control. Although all of them had too low estimated exposure, in one case (high dose of I.1505) at least the estimations for larvae were close to the respective exposure assessment goal and another one had a very long exposure period
	Results from the two test concentrations of experiment I.1505 are not consistent; the lower dose resulted in the negative deviation from the control indicating some uncertainties to consider this deviation as true effect
The available evidence indicating not more than negligible deviation from the control has not more neither less weight than has the evidence indicating more than negligible negative deviation from the control. Two experiments with low exposure level indicated a clear negative deviation from the control. One of them had too long exposure length, while the other one bears some uncertainties. On the other hand, two experiments could be considered bearing some evidences that indicate no negative deviations from the controls. However, both of them had relatively mild exposure regimes. Overall, all the available evidences have very low weight and no clear trend could be seen when they were balanced	
Therefore, **this line of evidence is inconclusive**	

F.2.4. Reproductive output of queenless microcolonies (Class 1 endpoint)

One figure is presented below for the succeeding crop scenario.

The endpoints in the available experiments with queenless microcolonies were reported in different ways: (1) brood production (i.e. drone brood cells) or (2) drone production (number of adult drones) or (3) both of these two reported separately or (4) both of the two, but reported as a combined endpoint (brood cell + adults). Because of this and since all brood cells contain male larvae in this type of study, when both endpoints were reported separately, they were summed up.

General interpretation
• Altogether seven endpoints were available, but two of them were considered as non-reliable • All the five reliable endpoints were considered as reliable with major restrictions • The variability between the reliable endpoints was rather low; the deviations from the control ranged from small to large negative • Exposure estimation and information on the exposure lengths was available for all the reliable experiments • Meaningful dose–response analysis cannot be performed due to the low variability between the reliable endpoints

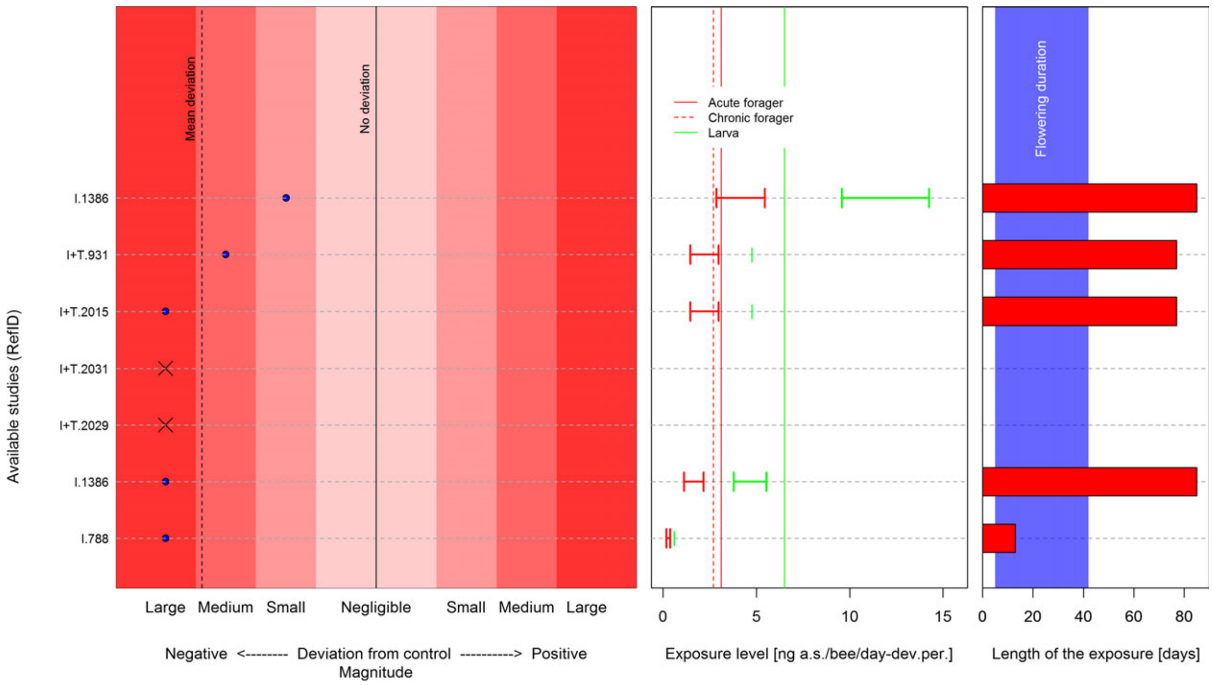


Figure F.23: Summary of the observed deviations for drone production of queenless bumblebee colonies for the succeeding crop scenario

Interpretation of the line of evidence	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
All endpoints have larger than negligible negative deviation from the control, three of the five have large deviations, and there are no endpoints with negligible or positive deviation from the control	The experiment with the highest exposure estimation (above the exposure assessment goal) and longest exposure period indicated the smallest deviation from the control, while all the other experiments with milder exposure regime had larger deviations from the control
One of the experiments (I.788) had a low exposure level in combination with a realistic exposure length compared to the range of the flowering period of succeeding crops (in fact the exposure length was at the lower end of this range). Although the length of exposure was too long for three other endpoints, the exposure levels of these experiments were also lower than the exposure assessment goal	
The available evidence indicating not more than negligible deviation from the control has less weight than has the evidence indicating more than negligible negative deviation from the control This is because there were a number of endpoints with relatively low exposure levels and one of them with a realistic exposure length, which endpoints indicated clearly negative deviations from the control. In addition, no endpoint exists, which would indicate negligible or positive deviation from the control	
Overall, this indicates a **moderate evidence for larger than negligible effect**	

F.2.5. Brood production (Class 1 endpoint)

Three figures are presented below for the succeeding crop scenario. Both are based on the same data set (brood production of queenright bumblebee colonies), but with slightly different set-ups in order to help the interpretation of the data. These differences are explained in the title of the figures. The general interpretation is relevant for both figures.

General interpretation
• Twelve reliable endpoints were available, all but one were assessed as reliable with major restrictions • There was some variability between the experiments. The deviation from the control ranged from medium positive to large negative • Exposure estimation and information on the exposure lengths was available for all experiments • No dose–response pattern could be seen when all endpoints are considered

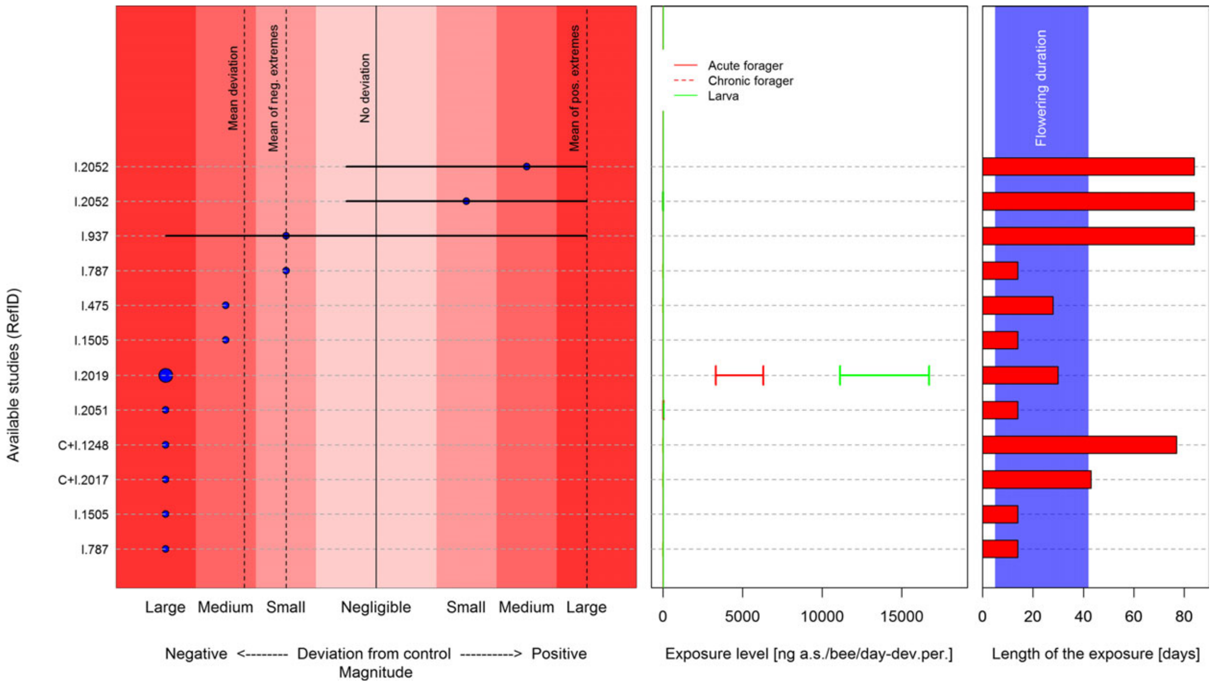


Figure F.24: Summary of the observed deviations for brood production of bumblebees for the succeeding crop scenario – endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the available data

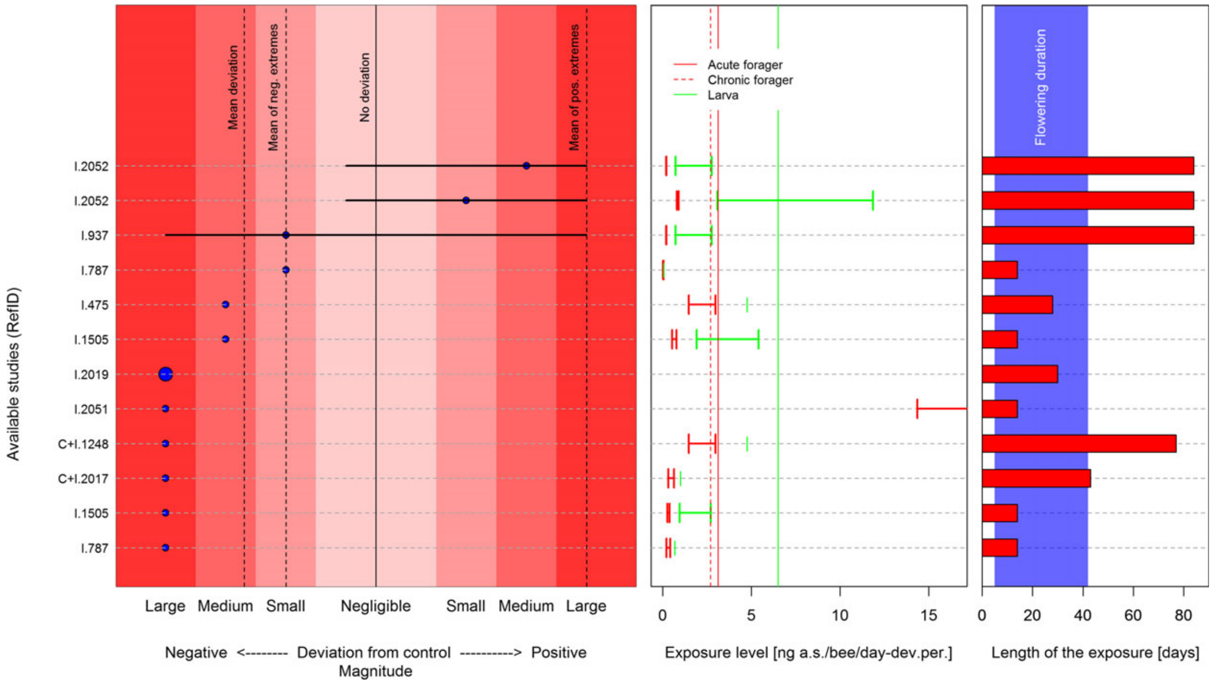


Figure F.25: Summary of the observed deviations for brood production of bumblebees for the succeeding crop scenario – endpoints are indicated in the order of the magnitude of mean deviation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

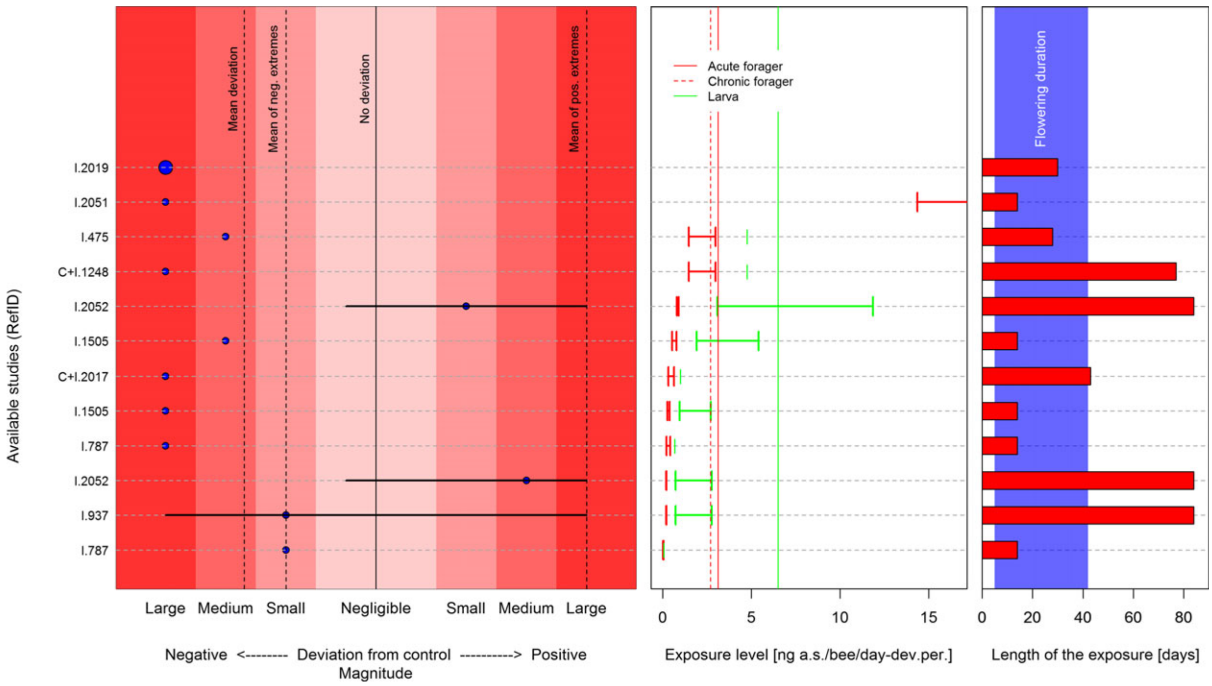


Figure F.26: Summary of the observed deviations for brood production of bumblebees for the succeeding crop scenario – endpoints in the order of the magnitude of the exposure estimation, scale for exposure level aligned to the exposure assessment goals (zoom in to the relevant part)

Interpretation of the line of evidence	
Indications for larger than negligible effect	**Indications for lack of larger than negligible effect**
The maximum negative deviation from the controls was larger than negligible in one experiment out of the three, where the effect was studied at more than one observation day. The exposure level was below the exposure assessment goals, although it had a very long exposure period	The maximum negative deviation from the controls was not larger than negligible in two of those three experiments, where the effect was studied at more than one observation day; these two endpoints are originating from the same experiment, they are two test concentrations Although the results from the two test concentrations are not consistent in terms of dose–response trend, they provide an indication for not more than negligible deviation from the control at realistic exposure level for the larvae (high dose) compared to the exposure assessment goal in combination with a very long exposure period
The mean deviation from the control was larger than negligible in 10 experiments and the exposure estimation for eight of them was lower than the exposure assessment goal. For five of these experiments, the exposure lengths fell in the realistic range of the flowering period of any succeeding crop	Only two endpoints (from the same experiment) indicated no negative mean deviation from the control. Although one of them had too low estimated exposure, for the others the exposure estimations for larvae overlapped the respective exposure assessment goal. Moreover, both of them had a very long exposure period
The available evidence indicating not more than negligible deviation from the control has less weight than has the evidence indicating more than negligible negative deviation from the control This is because only two endpoints (from the same experiment) indicated no negative deviation from the controls and only one of them had a high enough exposure level and this was only for the larvae. Nevertheless, the lengths of the exposure of these experiments were considerable longer than the realistic range of the flowering period of any succeeding crop. On the other hand, a number of experiments indicated clearly negative deviations from the control. Five of these experiments had a mild exposure regime	
Overall, this indicates a **moderate evidence for larger than negligible effect**	

F.2.6. Colony strength (Class 1 endpoint)

Only two endpoints were available for colony strength. The deviation from the control in the experiment I.2004 ranged from negligible to large negative deviation and the median effect (over the study duration) was assessed as a medium negative effect. The endpoint was considered as fully reliable. The estimated exposure level was 1.83–3.73 ng/bee per day for workers and 5.95 ng/larva per developmental period for larva (the exposure assessment goal for workers is 2.69–3.12 ng/bee per day and for larvae is 6.5 ng/larva per developmental period). The length of the exposure was at the higher end, but within the realistic range of the flowering period of any succeeding crop.

The deviation from the control in the experiment C+I.2017 was a large-negative deviation. The endpoint was considered reliable with major restrictions. The estimated exposure level was 0.31–0.63 ng/bee per day for workers and 0.99 ng/larva per developmental period for larva (the exposure assessment goal for workers is 2.69–3.12 ng/bee per day and for larvae is 6.5 ng/larva per developmental period). The length of the exposure was higher than the realistic range of the flowering period of any succeeding crop, but only with 1 day.

Overall, this indicated a **strong evidence for larger than negligible effect.**

F.2.7. Emergence rate (Class 2 endpoint)

Only one endpoint was available for emergence rate (I.2004). The deviation from the control bridged from large positive to large negative and the median effect (over the study duration) was assessed as a medium-negative effect. The estimated exposure level was 1.83–3.73 ng/bee per day for workers and 5.95 ng/larva per developmental period for larva (the exposure assessment goal for workers is 2.69–3.12 ng/bee per day and for larvae is 6.5 ng/larva per developmental period). The endpoint was considered as fully reliable. The length of the exposure was at the higher end, but within the realistic range of the flowering period of any succeeding crop.

This indicated a **moderate evidence for larger than negligible effect.**

F.2.8. Mating ability of the new queens (Class 2 endpoint)

Only one endpoint was available for mating ability (I.1388). This experiment, which was a field study on sunflower, indicated a negligible (negative) deviation from the control. The endpoint was considered as reliable with major restrictions. No exposure estimation was possible. The length of the exposure was 9 days.

Due to the lack of information on the exposure of the single endpoint that was available, this **line of evidence is considered to be inconclusive**.

Appendix G – List of study references

Exp. ID	Doc.ID distiller	Author	Study title	Year	Type	Appendix to EFSA (2018a)	File name
110403 CAN/US	N/A	Scott-Dupree, CD; Spivak, MS; Bruns, G; Blenskinsop, C; Nelson, S	The impact of Gaucho and TI-435 seed-treated Canola on honeybees, *Apis mellifera* L	2001	Residues	Study evaluation notes	EFSA (2013a)
All+.2003	1080	Pohorecka K, Skubida P, Miszczak A, Semkiw P, Sikorski P, Zagibajlo K, et al.	Residues of Neonicotinoid Insecticides in Bee Collected Plant Materials from Oilseed Rape Crops and their Effect on Bee Colonies	2012	Field	M	All + field
All+.1080	1080	Pohorecka K, Skubida P, Miszczak A, Semkiw P, Sikorski P, Zagibajlo K, et al.	Residues of Neonicotinoid Insecticides in Bee Collected Plant Materials from Oilseed Rape Crops and their Effect on Bee Colonies	2012	Residues	M	All + Residues
All+.1084	1084	Poquet Y, Kairo G, Tchamitchian S, Brunet J-L, Belzunces LP	Wings as a new route of exposure to pesticides in the honeybee	2015	Lab	M	All + Lab
C+I.1081	1081	Pohorecka K, Skubida P, Semkiw P, Miszczak A, Teper D, Sikorski P, et al.	Effects of exposure of honeybee colonies to neonicotinoid seed	2013	Field	G	C+I_Field
C+I.1244	1244	Schneider CW, Tautz J, Gruenewald B, Fuchs S	RFID Tracking of Sublethal Effects of Two Neonicotinoid Insecticides on the Foraging Behavior of *Apis mellifera*	2012	Colony feeders	G	C+I_Colony feeders
C+I.1248	1248	Scholer J, Krischik V	Chronic Exposure of Imidacloprid and Clothianidin Reduce Queen Survival, Foraging, and Nectar Storing in Colonies of *Bombus impatiens*	2014	Colony feeders	G	C+I_Colony feeders
C+I.2017	926	Moffat C, Pacheco JG, Sharp S, Samson AJ, Bollan KA, Huang J, et al.	Chronic exposure to neonicotinoids increases neuronal vulnerability to mitochondrial dysfunction in the bumblebee (*Bombus terrestris*)	2015	Colony feeders	G	C+I_Colony feeders
C+I.423	423	Fischer J, Mueller T, Spatz A-K, Greggers U, Gruenewald B, Menzel R	Neonicotinoids Interfere with Specific Components of Navigation in Honeybees	2014	Colony feeders	G	C+I_Colony feeders
C+I.844	844	Lu C, Warchol KM, Callahan RA	Sub-lethal exposure to neonicotinoids impaired honeybees winterization before proceeding to colony collapse disorder	2014	Colony feeders	G	C+I_Colony feeders

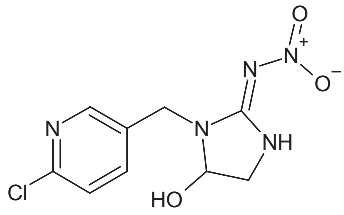
Exp. ID	Doc.ID distiller	Author	Study title	Year	Type	Appendix to EFSA (2018a)	File name
C*I.1324	1324	Staffel J; Lückmann J	Assessment of Potential Impacts on Honeybee Colony Development, their Hibernation Performance and Concurrent Monitoring of Aerial Dust Drift During the Sowing Operation of Poncho Beta Plus - Treated Sugar Beet Pills with Typical Commercial Vacuum-Pneumatic Sowing Technology, Directly Adjacent to Full-Flowering Phacelia tanacetifolia in Germany	2014	Field	H	C*I Field
E 370 1548-8	N/A	Schmuck, R; Schoening, R; Schramel, O	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. Laacher Hof 1999	1999	Residues	Study evaluation notes	EFSA (2013a)
E 370 1553-4	N/A	Schmuck, R; Schoening, R; Schramel, O	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effect of these residues on foraging honeybees	2007	Residues	N/A	EFSA (2013a)
I.1094	1094	Probsting A	Determination of Side-effects of SeedOprid 600 FS coloured treated Seeds of Winter Oil-Seed Rape on Honeybees (*Apis mellifera* L.) in the field in Germany 2011/2012	2012	Residues	E	I residues
I.1095	1095	Probsting A	Determination of Side-effects of SeedOprid 600 treated Seeds of Spring Oil-Seed Rape on Honeybees (*Apis mellifera* L.) in the Field in Germany 2011	2011	Residues	E	I residues
I.137	137	Belien T, Kellers J, Heylen K, Keulemans W, Billen J, Arckens L, et al.	Effects of sublethal doses of crop protection agents on honeybee (*Apis mellifera*) global colony vitality and its potential link with aberrant foraging activity	2009	Colony feeders	E	I colony feeders
I.1386	1386	Tasei JN, Lerin J, Ripault G	Sub-lethal effects of imidacloprid on bumblebees, *Bombus terrestris* (Hymenoptera: Apidae), during a laboratory feeding test	2000	Colony feeders	E	I colony feeders
I.1388	1388	Tasei JN, Ripault G, Rivault E	Hazards of imidacloprid seed coating to *Bombus terrestris* (Hymenoptera: Apidae) when applied to sunflower	2001	field	E	I field
I.1455 - Part I and II	1455	van der Steen JC, Hok-Ahin and Cornelissen B	De invloed van imidacloprid en de interactie met gereduceerd stuifmeelaanvoer op de vitaliteit en de overwintering van bijenvolken. Translation from Dutch: The influence of imidacloprid and the interaction with reduced pollen supply on the vitality and overwintering of honeybee colonies	2014	Colony feeders	E	I colony feeders

Exp. ID	Doc.ID distiller	Author	Study title	Year	Type	Appendix to EFSA (2018a)	File name
I.1498	1498	Wehner A	Determination of Side-effects of SeedOprid 600 FS coloured treated Seeds of Sunflower on Honeybees (*Apis mellifera* L.) in the Field in Italy 2012	2013	Field	E	2.I field
I.1505	1505	Whitehorn PR, O'Connor S, Wackers FL, Goulson D	Neonicotinoid Pesticide Reduces Bumblebee Colony Growth and Queen Production	2012	Colony feeders	E	I colony feeders
I.163	163	Bocksch S	Honeybee brood and colony level effects following Imidacloprid intake via treated artificial diet in a field study in North Carolina	2014	Colony feeders	E	I colony feeders
I.178	178	Bortolotti L, Montanari R, Marcelino J, Medrzycki P, Maini S, Porrini C	Effects of sub-lethal imidacloprid doses on the homing rate and foraging activity of honeybees	2003	Colony feeders	E	I colony feeders
I.2004	201	Bryden J, Gill RJ, Mitton RAA, Raine NE, Jansen VAA	Chronic sublethal stress causes bee colony failure	2013	Colony feeders	E	I colony feeders
I.2016	553	Hecht-Rost	A residue study with Nuprid 600 FS treated maize seed, investigating residues in crops, soil and honeybee products in Germany 2007	2009	Semifield	E	I semifield
I.2017	362	Dively GP, Embrey MS, Kamel A, Hawthorne DJ, Pettis JS	Assessment of Chronic Sublethal Effects of Imidacloprid on Honeybee Colony Health	2015	Colony feeders	E	I colony feeders
I.2019	501	Gradish AE, Scott-Dupree CD, Shipp L, Harris CR, Ferguson G	Effect of reduced risk pesticides for use in greenhouse vegetable production on *Bombus impatiens* (Hymenoptera: Apidae)	2010	Colony feeders	E	I colony feeders
I.2020	340	Decourtye A, Lacassie E, Pham-Delegue MH	Learning performances of honeybees (*Apis mellifera* L) are differentially affected by imidacloprid according to the season	2003	Lab	E	I Lab
I.2025	1243	Schmuck R, Schoning R, Stork A, Schramel O	Risk posed to honeybees (*Apis mellifera* L. Hymenoptera) by an imidacloprid seed dressing of sunflowers	2001	Colony feeders	E	I colony feeders
I.2043	1092	Probsting A	Determination of Side-effects of SeedOprid 600 FS coloured treated Seeds of Maize on Honeybees (*Apis mellifera* L.) in the Field in Germany 2011	2011	Field	E	I field
I.2044	1093	Probsting A	Determination of Side-effects of SeedOprid 600 FS coloured treated Seeds of Sunflower on Honeybees (*Apis mellifera* L.) in the Field in Germany 2011	2011	Field	E	I field
I.2045	1094	Probsting A	Determination of Side-effects of SeedOprid 600 FS coloured treated Seeds of Winter Oil-Seed Rape on Honeybees (*Apis mellifera* L.) in the field in Germany 2011/2012	2012	Field	E	I field

Exp. ID	Doc.ID distiller	Author	Study title	Year	Type	Appendix to EFSA (2018a)	File name
I.2046	1095	Probsting A	Determination of Side-effects of SeedOprid 600 treated Seeds of Spring Oil-Seed Rape on Honeybees (*Apis mellifera* L.) in the Field in Germany 2011	2011	Field	E	I field
I.2051	787	Laycock I, Cresswell JE	Repression and Recuperation of Brood Production in *Bombus terrestris* Bumblebees Exposed to a Pulse of the Neonicotinoid Pesticide Imidacloprid	2013	Colony feeders	E	I colony feeders
I.2052	937	Morandin LA, Winston ML	Effects of novel pesticides on bumblebee (Hymenoptera: Apidae) colony health and foraging ability	2003	Colony feeders	E	I colony feeders
I.362	362	Dively GP, Embrey MS, Kamel A, Hawthorne DJ, Pettis JS	Assessment of Chronic Sublethal Effects of Imidacloprid on Honeybee Colony Health	2015	Colony feeders	E	I colony feeders
I.411	411	Faucon JP, Aurieres C, Drajnudel P, Mathieu L, Ribiere M, Martel AC, et al.	Experimental study on the toxicity of imidacloprid given in syrup to honeybee (*Apis mellifera*) colonies	2005	Colony feeders	E	I colony feeders
I.462	462	Gels JA, Held DW, Potter DA	Hazards of insecticides to the bumblebees *Bombus impatiens* (Hymenoptera: Apidae) foraging on flowering white clover in turf	2002	Semifield	E	I semifield
I.475	475	Gill RJ, Ramos-Rodriguez O, Raine NE	Combined pesticide exposure severely affects individual- and colony-level traits in bees	2012	Colony feeders	E	I colony feeders
I.545	545	Hatjina F, Papaefthimiou C, Charistos L, Dogaroglu T, Bouga M, Emmanouil C, et al.	Sublethal doses of imidacloprid decreased size of hypopharyngeal glands and respiratory rhythm of honeybees *in vivo*	2013	Lab	E	I Lab
I.724: Monceren BB (1)	724	Klein O	A Field Study to Evaluate Effects of Monceren G on the Bumblebee (*Bombus terrestris* L; Hymenoptera, Apidae) in Potato in Southern Germany in 2014	2014	Field	E	I field
I.725: Monceren (BB2)	725	Klein O	Field Study to Evaluate Effects of Monceren G on the Bumblebee (*Bombus terrestris* L; Hymenoptera, Apidae) in Potato in Southern Germany in 2014	2014	Field	E	I field
I.787	787	Laycock I, Cresswell JE	Repression and Recuperation of Brood Production in *Bombus terrestris* Bumblebees Exposed to a Pulse of the Neonicotinoid Pesticide Imidacloprid	2013	Colony feeders	E	I colony feeders
I.788	788	Laycock I, Lenthall KM, Barratt AT, Cresswell JE	Effects of imidacloprid, a neonicotinoid pesticide, on reproduction in worker bumblebees (*Bombus terrestris*)	2012	Colony feeders	E	I colony feeders
I.843	843	Lu C, Warchol KM, Callahan RA	In situ replication of honeybee colony collapse disorder	2012	Colony feeders	E	I colony feeders

Exp. ID	Doc.ID distiller	Author	Study title	Year	Type	Appendix to EFSA (2018a)	File name
I.848	848	Lückmann J, Staffel J (L mentioned in Appendix to EFSA, 2018a)	Assessment of Potential Impacts on Honeybee Colony Development, their Hibernation Performance and Concurrent Monitoring of Aerial Dust Drift During the Sowing Operation of Imidacloprid FS 350A G - Treated Winter Barley with Typical Commercial Pneumatic So	2014	Field	E	I field
I.937	937	Morandin LA, Winston ML	Effects of novel pesticides on bumblebee (Hymenoptera: Apidae) colony health and foraging ability	2003	Colony feeders	E	I colony feeders
I+T.2015	931	Mommaerts V, Reynders S, Boulet J, Besard L, Sterk G, Smagghe G	Risk assessment for side effects of neonicotinoids against bumblebees with and without impairing foraging behaviour	2010	Colony feeders	L	I+T. Colony feeder
I+T.2029	1341	Sterk G, Heuts F, Merck N, Bock J	Sensitivity of non-target arthropods and beneficial fungal species to chemical and biological plant protection products: results of laboratory and semifield trials	2003	Colony feeders	L	I+T. Colony feeder
I+T.2031					Colony feeders	L	I+T. Colony feeder
I+T.931	931	Mommaerts V, Reynders S, Boulet J, Besard L, Sterk G, Smagghe G	Risk assessment for side effects of neonicotinoids against bumblebees with and without impairing foraging behaviour	2010	Colony feeders	L	I+T. Colony feeder
I*T.583	583	Henry M, Cerrutti N, Aupinel P, Decourtye A, Gayrard M, Odoux J-F, et al.	Reconciling laboratory and field assessments of neonicotinoid toxicity to honeybees	2015	Field	K	T*I field

Appendix H – Used compound codes

Code/trivial name	Chemical name/SMILES notation	Structural formula
5-OH-imidacloprid	(2*E*)-1-[(6-chloropyridin-3-yl)methyl]-5-hydroxy-*N*-nitroimidazolidin-2-imine [O-][N+](=O)/N=C2\NCC(O)N2Cc1cnc(Cl)cc1	
Imidacloprid olefin	(2E)-1-[(6-chloropyridin-3-yl)methyl]-*N*-nitro-1,3-dihydro-2*H*-imidazol-2-imine [O-][N+](=O)/N=C2\NC=CN2Cc1cnc(Cl)cc1