CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted

European Food Safety Authority (EFSA)

Abstract

The conclusions of EFSA following the peer review of the initial risk assessment carried out by the competent authority of the rapporteur Member State, Germany, for the pesticide active substance imidacloprid are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory ecotoxicological data. The conclusions were reached on the basis of the evaluation of the representative uses of imidacloprid as an insecticide on winter cereals, beet, potato, leafy vegetables and amenity vegetation. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the available studies and literature in the dossier peer reviewed, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

Keywords: imidacloprid, peer review, confirmatory data, risk assessment, pesticide, insecticide

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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. The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013, to restrict the uses of imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing this active substance to professional users. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on:

a) the risk to pollinators other than honeybees;
b) the risk to honeybees foraging in nectar or pollen in succeeding crops;
c) the potential uptake via roots to flowering weeds;
d) the risk to honeybees foraging on insect honey dew;
e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
g) the acute and long-term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen

by 31 December 2014.

In accordance with the specific provision, the applicant, Bayer CropScience, submitted an updated dossier on 19 December 2014, which was evaluated by the designated rapporteur Member State (RMS), Germany, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev. 6.1, the RMS distributed the addendum to the Member States, the applicant and the European Food Safety Authority (EFSA) for comments on 18 January 2016. The RMS collated all comments in the format of a reporting table which was submitted to EFSA on 19 May 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report on 30 May 2016.

Following consideration of the Technical Report, the European Commission requested EFSA to provide scientific and technical assistance on the unresolved issues of the Technical Report and to deliver its conclusions.

On 3 June 2016, the European Commission requested EFSA to organise a peer review of the RMS' evaluation of the confirmatory data submitted in relation to ecotoxicological data and to deliver its conclusions on the risk assessment to bees.

For all the uses for which confirmatory data on imidacloprid have been presented, high risks were identified or could not be excluded, or the risk assessment could not be finalised.

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Background

Imidacloprid was included in Annex I to Directive 91/414/EEC on 1 August 2009 by Commission Directive 2008/116/EC[1], and has been deemed to be approved under Regulation (EC) No 1107/2009[2], in accordance with Commission Implementing Regulation (EU) No 540/2011[3], as amended by Commission Implementing Regulation (EU) No 541/2011[4]. The peer review leading to the approval of imidacloprid was finalised on 29 May 2008 (EFSA, 2008). Upon request from the European Commission, European Food Safety Authority (EFSA) finalised a conclusion 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[5] to restrict the uses of imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing this active substance to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing imidacloprid have been prohibited for crops attractive to bees and for cereals except for uses in permanent glasshouses and for winter cereals. Foliar treatments with plant protection products containing imidacloprid have been prohibited for crops attractive to bees and for cereals with the exception of uses in permanent glasshouses and uses after flowering. Furthermore, the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for imidacloprid, taking into account all uses other than seed treatments and granules including foliar spray uses. EFSA finalised its conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules on 31 July 2015 (EFSA, 2015).

It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on:

a) the risk to pollinators other than honeybees;
b) the risk to honeybees foraging in nectar or pollen in succeeding crops;
c) the potential uptake via roots to flowering weeds;
d) the risk to honeybees foraging on insect honey dew;
e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
g) the acute and long-term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen

by 31 December 2014.

In accordance with the specific provision, the applicant, Bayer CropScience, submitted an updated dossier in 19 December 2014, which was evaluated by the designated rapporteur Member State (RMS), Germany, in the form of an addendum to the draft assessment report (DAR) (Germany, 2015). In compliance with guidance document SANCO 5634/2009-rev. 6.1 (European Commission, 2013), the RMS distributed the addendum to the Member States, the applicant and EFSA for comments on 18 January 2016. The RMS collated all comments in the format of a reporting table which was submitted to EFSA on 19 May 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table and finalised the Technical Report on 30 May 2016 (EFSA, 2016a).

Following consideration of the Technical Report, the European Commission requested EFSA on 3 June 2016 to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to ecotoxicological data and to deliver its conclusions on risk assessment to bees.

[1] 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.
[2] 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 L 309, 24.11.2009, p. 1–50.
[3] 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.
[4] 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.
[5] 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.

The addendum and the reporting table were discussed at the Pesticides Peer Review Meeting on ecotoxicology in June 2016. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report.

A final consultation on the conclusions arising from the peer review took place with the Member States via a written procedure in September 2016.

The conclusions laid down in this report were reached on the basis of the peer review of the RMS's evaluation of the confirmatory data submitted in relation to ecotoxicology. A key supporting document to this conclusion is the peer review report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the reporting table to the conclusion. The peer review report (EFSA, 2016b) comprises the following documents, in which all views expressed during the course of the peer review, including minority views, can be found:

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

Given the importance of the addendum to the DAR (Germany, 2015, 2016) and the peer review report, these documents are considered as background documents to this conclusion.

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

Conclusions of the evaluation

1. Introduction

1.1. Uses

The uses for which confirmatory data on imidacloprid have been presented are the currently registered uses as seed treatment in winter cereals, beet and leafy vegetables, in-planter or in-furrow spray to potato tubers and granular uses on amenity vegetation. A summary of these uses are included in Table 1. A complete list of the assessed uses is presented in Appendix A.

Other uses, including some foliar spray applications, granular application in forest nursery or preplanting tuber treatment on potato which are currently authorised in some Member States were not covered by the confirmatory data set.

Table 1: Summary of the uses considered in this conclusion

Crop	Application type	Seed/tuber treatment rate (range)		Application rate (range) in g a.s./ha
Winter cereals	Seed treatment	27 g a.s./100 kg	0.006 mg a.s./seed[(a)]	48
			0.016 mg a.s./seed[(a)]	
		70 g a.s./100 kg	0.015 mg a.s./seed[(a)]	126
			0.043 mg a.s./seed[(a)]	
Beet	Seed treatment	15 g a.s./100,000 seeds	0.15 mg a.s./seed	15
		90 g a.s./100,000 seeds	0.9 mg a.s./seed	162
Potato	In-planter/ in-furrow spray to tuber	Not relevant		120–180
Leafy vegetables (lettuce, endive)	Seed treatment	114 g a.s./100,000 seeds	1.14 mg a.s./seed	80–104
Leafy vegetables (lettuce, endive, radicchio rosso)	Seed treatment in glasshouse[(b)]	80 g a.s./100,000 seeds	0.8 mg a.s./seed	90–120
		150 g a.s./100,000 seeds	1.2 mg a.s./seed	
Amenity vegetation	Granule	Not relevant		150

a.s.: active substance.

(a): Estimated based on: (i) the substance dose rate per unit, (ii) one unit is 100 kg seeds (iii) the seed weight is range between 21 and 61 g/1,000 seeds as was agreed at the Pesticides Peer Review Meeting 145 (7–9 June 2016).

(b): Treated seeds are used in glasshouse at BBCH 12, the seedlings are transplanted to the open field.

1.2. Risk assessment methodology

The risk assessment of this conclusion was performed according to EFSA (2013b), although the RMS has proposed other methodologies for some parts of the risk assessment (Germany, 2015, 2016).

Based on EFSA (2013b), the risk assessment for seed treatment and granules applications should cover the acute contact exposure and the oral exposure (acute for adult bees, chronic for adult bees and larvae). These assessments should be performed for honeybees, bumble bees and solitary bees by calculating hazard quotient (HQ) and exposure toxicity ratio (ETR) values for the contact and oral risk assessments, respectively, and using a stepwise approach. For honeybees, the oral risk assessment should cover also sublethal effects on development of the hypopharyngeal glands (HPG).

Furthermore, the following risk assessments should be considered: (1) risk for accumulative effects (for honeybees only); (2) risk from exposure to contaminated water (by calculating ETRs, for honeybees only); and (3) risk from the metabolites in pollen and nectar.

The contact and the oral risk assessments should be carried out by considering the exposure from the treated field and surrounding areas.

For *contact exposure via dust particles* (see Section 7), HQs are calculated for the field margin (which covers exposure from contaminated adjacent crop also). The HQ values are then compared to the trigger values given in EFSA (2013b), which differ for honeybees, bumble bees and solitary bees.

For *oral exposure*, ETRs are calculated for the treated crop (Section 8), flowering weeds within the treated field (Section 4), plants in the field margin and adjacent crop (Section 7), and also succeeding crops (Section 3). ETRs are calculated for the acute risk to adult bees, chronic risk to adult bees and chronic risk to bee larvae for honeybees, bumble bees and solitary bees. ETRs represent the estimated exposure divided by the toxicity endpoint (acute adult median lethal dose (LD_{50}), chronic adult median lethal dietary dose (LDD_{50}) and no observed effect concentration at mortality ($NOEC_{mortality}$) for larvae). An overview of the risk assessment schemes according to EFSA (2013b) is provided in Table 2.

Where a first-tier risk assessment indicates a high risk, there are several options to perform a higher tier risk assessment, either by refining the exposure estimate (Tier 2) or by the higher tier effect studies (Tier 3). According to EFSA (2013b), the fundamental basis for the Tier 3 risk assessment is to design the higher tier studies in a way that the studies are sufficiently sensitive to detect biological effects (i.e. cause–effect relationship) in accordance with the specific protection goals (SPG) (i.e. down to 7% reduction in colony size) and in realistic worst case exposure situations (i.e. 90th percentile worst case for the hives at the edge of treated fields in the area of use). In order to demonstrate that the studies achieved the 90th percentile exposure, EFSA (2013b) suggests that an exposure assessment is undertaken by performing residue studies in areas representative of where the active substance will be applied. The level of exposure achieved in the effect field study can then be demonstrated to be representative across a wider area (i.e. if it equates to the 90th percentile exposure level).

At the Pesticides Peer Review Meeting 145 (7–9 June 2016), the assessment methodology to address the risk from dust drift was discussed. The experts noted that the values for dust deposition used in EFSA (2013b) were derived from an outdated version of the draft SANCO Guidance Document for seed treatment (SANCO/10553/2012). In fact, the SANCO/10553/2012 was updated based on more recent and additional data on dust drift (SANCO/10553/2012, January 2014 (European Commission, 2014)), and was therefore considered by the experts as the latest best available knowledge. EFSA further acknowledged that the version considered by the RMS in the addendum for the confirmatory data, has been further updated. The majority of the experts agreed that the new deposition values from SANCO/10553/2012, January 2014 (the version available to RMS at time of drafting of addendum) should be considered in this risk assessment. After the meeting, the RMS provided an updated risk assessment (Germany, 2016). However, EFSA noted that in this risk assessment not only the deposition values were considered, but also a novel approach was applied to the data. This is because the updated versions of the SANCO/10553/2012 suggest that the amount of active substance deposited in the off-field areas through dust drift is in function of the seed dressing quality; while in older versions of the SANCO/10553/2012 and in EFSA (2013b), the deposition values are linked to the in-field application rate. EFSA also pointed out that SANCO/10553/2012 was not yet finalised and this new approach has not been validated.

Furthermore, the integration of a novel approach for estimating the exposure from dust drift deposits into the risk assessment scheme of EFSA (2013b) should also be further validated and agreed within a wider regulatory scientific framework. A proper validation on a case-specific base was considered inadequate and outside of the scope of this conclusion.

Therefore, the outcome of the risk assessment based on EFSA (2013b) was considered to draw a final conclusion.

The risk assessment based on SANCO/10553/2012 as provided by the RMS, is included in the addendum (Germany, 2015, 2016).

Table 2: Overview of the risk assessment scheme according to EFSA (2013b)

	Honeybee (exposure scenarios)	**Bumble bee (exposure scenarios)**	**Solitary bee (exposure scenarios)**
First-tier contact risk assessment	Treated crop[(d)]	Treated crop[(d)]	Treated crop[(d)]
	Weeds in the field[(d)]	Weeds in the field[(d)]	Weeds in the field[(d)]
	Field margin[(a)]	Field margin[(a)]	Field margin[(a)]
First-tier acute oral risk assessment	Treated crop Weeds in the field[(b)] Field margin Adjacent crop Succeeding crop	Treated crop Weeds in the field[(b)] Field margin Adjacent crop Succeeding crop	Treated crop Weeds in the field[(b)] Field margin Adjacent crop Succeeding crop
First-tier chronic oral risk assessment			
First-tier larvae risk assessment			
First-tier risk assessment for effects on the HPG (sublethal effect)		Not applicable	Not applicable
Assessment of accumulative effects	Required	Not required[(c)]	Not required[(c)]
Risk assessment for exposure from residues in guttation fluid	Required	Not required[(c)]	Not required[(c)]
Risk assessment for exposure from residues in surface water	Required	Not required[(c)]	Not required[(c)]
Risk assessment for exposure from residues in puddles	Required	Not required[(c)]	Not required[(c)]
Risk assessment for exposure from metabolites	Required for pollen and nectar consumption	Required for pollen and nectar consumption	Required for pollen and nectar consumption
Higher tier risk assessment using refined exposure (Tier 2)	Required if lower tier fails	Required if lower tier fails	Required if lower tier fails
Higher tier risk assessment using effects field studies (Tier 3)	Required if lower tier fails	Required if lower tier fails	Required if lower tier fails
Uncertainty analysis for higher tier risk assessments	Required	Required	Required

HPG: hypopharyngeal gland.
(a): Field margin risk assessment for contact exposure also covers the adjacent crop.
(b): The 'flowering weeds in field' scenario is not relevant for seed treatment in EFSA (2013b). However, it was considered relevant for this assessment (see section 4).
(c): In EFSA (2013b) it is assumed to be covered by the assessment for honeybees.
(d): Treated crop scenario and Weeds in the field scenario for acute contact exposure is not relevant for seed treatment, but relevant for granules.

In this conclusion, only the aspects of the risk assessment schemes of EFSA (2013b) relevant for the confirmatory data set were used (i.e. risk from accumulative effects, risk from sublethal effects on development of the HPG, risk from exposure to contaminated water except guttation were not considered). Risk assessments were performed by considering the range of the application patterns (minimum and maximum application rates).

2. Toxicity endpoints

In agreement with the experts at the Pesticides Peer Review Meeting 145, the previous EU agreed endpoints were considered for the risk assessments (EFSA, 2015). These endpoints are reported in Appendix B.

According to EFSA (2013b) and in line with the previous conclusion on imidacloprid (EFSA, 2015), to perform a screening risk assessment, surrogate endpoints were agreed for bumble bees (chronic) and solitary bees, assuming that for these species the endpoints for the technical are 10 times lower than those agreed for honeybees. It is noted that for the previous conclusion on imidacloprid (EFSA, 2015), this approach was, however, not considered appropriate by the experts for bumble bee and solitary bee larvae, because only a provisional honeybee larvae endpoint was available.

It is noted that some new acute toxicity data of different formulations were available. Some of these data indicated higher contact toxicity to honeybees compared to the EU agreed endpoint. However, the difference between the toxicity for the formulation and the EU agreed endpoint (for the technical active substance) was less than a factor of 5 (i.e. based on the ratio between the LD_{50} for the technical and the LD_{50} of the formulation expressed as a.s.). Therefore, it was agreed to use the endpoints for the technical.

3. Succeeding crops

In this Section, the risk to honeybees (point b of the confirmatory data requirement) and to pollinators other than honeybees (point a of the confirmatory data requirement) foraging for nectar and pollen is considered.

3.1. Tier 1 risk assessment

A Tier 1 risk assessment based on EFSA (2013b) was performed where agreed toxicity endpoints were available (for honeybees and acute endpoints for bumble bees) and a screening assessment was carried out where only surrogate endpoints were available (adult chronic endpoint for bumble bees and endpoints for solitary bees). No toxicity data were available for bumble bee and solitary bee larvae; therefore, no lower tier risk assessments were performed for those cases.

As a result, for honeybees, a high acute risk and a high chronic risk to adults and larvae were indicated. A high acute risk was indicated for bumble bees and a high chronic risk to adults could not be excluded. Also, a high risk to solitary bees (acute and chronic adult) could not be excluded. This conclusion is relevant for the exposure in the succeeding crop scenario for all the field uses under evaluation (see Appendix A).

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 above 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. Considering the conclusion in Section 8, a low risk was concluded for the succeeding crop scenario for amenity vegetation provided that the amenity vegetation is maintained in the following year. The use in glasshouse includes that the production of seedlings of leafy vegetables (lettuce, endive, radicchio rosso) propagated indoors, where the small plants can subsequently be transplanted to the open field. With this horticultural practice, the transfer of some residues to the planted fields will occur. Therefore, the Tier 1 calculations performed for the field uses on vegetables (lettuce and endive) cover these situations as well. This approach may be considered as worst case.

3.2. Tier 2 exposure characterisation

A number of studies were submitted in which the concentration of imidacloprid in nectar and pollen of bee attractive crops (phacelia, winter oilseed rape, maize, mustard) were measured for succeeding crops grown on soil with a history of imidacloprid use (referred in the addendum (Germany, 2016) as 'natural' soil residue) or for succeeding crops (phacelia, maize, mustard) grown on soils treated with imidacloprid to obtain a theoretical plateau concentration in the soil (referred in the addendum as 'forced' soil residues). The experts at the Pesticides Peer Review Meeting 145 agreed that the most realistic data available in the entire dataset, i.e. the 'natural' soil residues experiments should be considered to address the succeeding crops scenarios for all the uses under evaluation. In these experiments, soil residues measured over the top 15 cm soil layer were from 0.035 to 0.059 mg/kg, i.e. marginally higher than the calculated accumulated soil predicted environmental concentration (PEC) of 0.028 mg/kg[6] for the sugar beet seed treatment use. It is noted that soil residues measured over the top 15 cm soil layer are independent of the Good Agricultural Practice (GAP) 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 $PEC_{plateau}$. Therefore, the highest residue value measured for pollen (2.5 μg a.s./kg) and nectar (3.5 μg a.s./kg) from these 'natural' soil residues experiments should be used to refine the risk. The fact that the natural soil experiments were limited

[6] EFSA (2008), plateau concentration calculated by subtracting the PEC from a single application of 0.156 mg/kg from the accumulated peak concentration of 0.184 mg/kg that was calculated to be present immediately after drilling seeds, accumulation calculated using the single first-order SFO soil DT_{50} of 288 days and an application rate of 117 g/ha every year, with a soil mixing depth of 20 cm and soil bulk density of 1.5 kg/L.

to five trial locations all in France, resulted in the conclusion that the data were insufficient to justify using 90th percentile pollen and nectar residues values for the risk assessment.

3.3. Tier 2 risk assessment

The default shortcut values proposed in EFSA (2013b) were refined based on the residue levels in pollen and nectar agreed at the Pesticides Peer Review Meeting 145. The calculations of the refined shortcut values were performed with the EFSA SHVAL tool (EFSA, 2014) and were reported in the revised addendum (Germany, 2016). The Tier 2 risk assessments indicated a high risk or that a high risk cannot be excluded for honeybees, bumble bees and solitary bees.

3.4. Higher tier risk assessment

Field effect studies were considered as a line of evidence to address the risk from exposure to succeeding crops scenario. In order to address this, earlier assessments of the available semifield and field effect studies from the Annex I dossier of imidacloprid were quoted (Germany, 2005). These studies have been evaluated and peer reviewed in EFSA (2013a). In the EFSA conclusion (EFSA, 2013a), it was concluded that these studies are insufficient to demonstrate that the risk to bees was low for the use of imidacloprid as a seed treatment in crops such as oilseed rape and sunflower.

Additionally, two field effect studies on bumble bees were submitted for the confirmatory data package. These studies were discussed at the Pesticides Peer Review Meeting 145. It was noted that the statistical power of the study was low. Furthermore, the available information indicated that the exposure of the colonies was low. Therefore, it was agreed that the studies are not sufficient to draw any solid conclusion on the effects of imidacloprid on wild bees.

4. Flowering weeds in the field

In this Section, the risk to honeybees (point c of the confirmatory data requirement) and to pollinators other than honeybees (point a of the confirmatory data requirement) foraging in flowering weeds in the treated field is considered.

4.1. Tier 1 risk assessment

The risk assessment scheme of EFSA (2013b) includes the weed scenario only for spray and granular applications; therefore, these assessments were performed only for the in-planter/in-furrow spray uses in potato and the granular use in amenity vegetation. A Tier 1 risk assessment based on EFSA (2013b), was performed by EFSA where agreed toxicity endpoints were available (for honeybees and acute endpoints for bumble bees) and a screening assessment was carried out where only surrogate endpoints were available (adult chronic endpoint for bumble bees and endpoints for solitary bees). No toxicity data were available for bumble bee and solitary bee larvae; therefore, no lower tier risk assessments were performed for those cases.

As a result, for honeybees a high acute risk (contact and oral) and a high chronic risk to adults and larvae were indicated for the in-planter/in-furrow spray uses in potato. A high acute risk (contact and oral) was indicated for bumble bees and a high chronic risk to adults could not be excluded. Also, a high risk to solitary bees (acute and chronic adult) could not be excluded. It should be noted that the application in potato is performed at the plantation (i.e. BBCH 00-03), when the presence of flowering weeds is unlikely. Therefore, contact exposure of bees is also unlikely. It is also noted that the spray drift from these uses is likely lower compared to any conventional broadcast spraying operations, because the nozzles are directed into the furrow. However, no precise information was available on the GAP or on spray drifts resulting from these uses. Therefore, the risk assessments were conducted considering spray drift emission from conventional broadcast spraying, which can be considered as worst case. As regards the amenity vegetation it was considered that no considerable flowering weeds are present, therefore a low risk was concluded for this scenario.

Due to the persistence of imidacloprid in soil and its systemic properties (i.e. its mobility in plants after uptake by the roots), the experts at the meeting agreed to consider the 'flowering weeds' scenario as relevant also for the seed treatment uses, although not specified as being necessary in EFSA (2013b). A higher tier risk assessment was performed on the basis of the studies submitted with the confirmatory data set.

4.2. Higher tier risk assessment

For the uses as *seed treatment*, a statement assessing the occurrence of flowering weeds in cereals, potato and sugar beet fields was provided. This assessment was performed by analysing a number of herbicide efficacy trials (i.e. control plots) mainly performed in Europe. No flowering weeds were reported for potato and sugar beet fields. In the case of cereals, the flowering weed ground cover exceeded the trigger of 10% in less than 3% of the considered trials. It has to be noted that this analysis focused on only relatively early growth stages of the considered crop (i.e. up to BBCH 40 for cereals, BBCH 20 for beets and BBCH 30 for potatoes). From the data available for clothianidin (EFSA, 2016c) for the granular uses, it was noted that the presence of weeds increases throughout the crop growing season.

Overall, on the basis of the available data, it was concluded that the total ground cover of flowering weeds in potato, winter cereals and sugar beet could be considered generally unlikely to exceed the trigger of 10% suggested in EFSA, 2013. Therefore, the exposure to bees via this scenario could be considered of low relevance for these uses, particularly when weed control is applied.

No such data and assessments were available for the uses in leafy vegetables; therefore a data gap was identified for these uses.

5. Honeydew

In this Section, the risk to honeybees (point d of the confirmatory data requirement) foraging for honeydew is considered.

No new data but statements were provided by the applicant. The reasoned case argued that imidacloprid is intended to control sap sucking insects; therefore at least during the first weeks of the growth of the crop, the exposure of honeybees is likely to be low. Generally, the argumentation provided was agreed by the experts at the Pesticides Peer Review Meeting 145. In the meeting, additional information from the open literature about aphid resistance was also considered.

It was concluded that resistance to imidacloprid by aphids could not be generally excluded. However, on the basis of the available data, the experts agreed that honeydew can be considered as a route of exposure of low relevance for the treated crop scenario for the uses under evaluation.

6. Guttation fluids

In this Section, the risk to honeybees (point e of the confirmatory data requirement) is considered.

6.1. Tier 1 risk assessment

No first-tier risk assessments were performed.

6.2. Tier 2 risk assessment

Studies investigating the occurrence and frequency of guttation, the residue levels in guttation fluid and the effects on honeybees' colonies were provided on winter cereals, sugar beets and potato. The data set was considered not sufficient for selecting the 90th percentile of exposure for each crop as suggested by EFSA (2013b). However, the experts considered that the residue levels from the available studies could be used for performing the Tier 2 risk assessments. In particular, it was agreed to use the highest residue values for the acute exposure assessment, the time-weighted average (twa) values over 5 days for the assessment to larvae and the twa values over 10 days for the chronic assessment to adults.

However, EFSA has considered that the residue analysis of the available studies did not indicate a clear decline of the residue concentrations in the guttation fluids (in the majority of the studies the concentration levels fluctuated over the time). Moreover, in some studies, the sampling period for autumn was too short to derive a twa value. Therefore, the Tier 2 risk assessments were carried out considering only the maximum measured residue levels. These values were 15 mg a.s./L for winter cereals, 0.061 mg a.s./L for beets and 1.98 mg a.s./L for potato.

Overall, based on the Tier 2 ETRs, a high risk was indicated or a high risk cannot be excluded for potatoes, winter cereals and sugar beet.

6.3. Higher tier risk assessment

Higher tier studies were considered. Beside some temporal slight tendency of higher bee mortality compared to the control in some studies, no apparent effects on the honeybee colonies were observed. Concerns were raised by the experts on the use of few studies to address the risk from the exposure to guttation fluids at the higher tier level. For example, it was questioned whether they are representative for worst-case conditions, for different geographic situations, for other crops. Furthermore, the statistical power of the studies was not reported. Therefore, the experts agreed that the available data do not allow drawing a firm conclusion in the light of the recommendations of EFSA (2013b). However, as a general line of evidence the experts noted that guttation fluids might not be the primary route of exposure for bees. Generally, bees using guttation are only rarely observed. Therefore, although robustness of the available studies to assess the effects was questioned and there was uncertainty around the exposure assessment, the experts agreed that the risk from exposure to residues in guttation fluids, for uses under evaluation can be considered of lower relevance.

7. Dust drift in field margins and adjacent crops

In this Section, the risk to honeybees (point f of the confirmatory data requirement) and to pollinators other than honeybees (point a of the confirmatory data requirement) foraging in field margin/adjacent crops is considered.

For granular applications by machinery (outdoors), in the previous EFSA conclusion on imidacloprid (2013a), it was concluded that dust formation and high risk to bees cannot be excluded. In the Pesticides Peer Review Meeting 145, some experts reported experiences indicating that some drift may occur for granular products. No new data were provided to address the confirmatory data requirement. Therefore, it was suggested that, until clear information is provided regarding the machinery to be used, the relevance of the exposure through dust drift should not be excluded for granules. The Tier 1 calculations according to EFSA (2013b) were reported in Appendix B. The HQ and the ETRs indicated a high risk or that a high risk to bees cannot be excluded for granule applications in amenity turf when machinery is used (drop type and rotary type spreaders).

As regards the hand held granular applications, it was agreed that the dust drift from this type of application can be considered as negligible. Therefore, the risk for hand held applications was considered as low.

For the uses as seed treatment, the exposure and risk assessment was performed according to EFSA (2013b) and assuming that a deflector is used during the seed drilling.

7.1. Tier 1 risk assessment

Considering the highest application rate, a high contact and oral risk was indicated or a high risk could not be excluded for honeybees, bumble bees and solitary bees for the use on *winter cereals*. As regards the lowest application rate, a low risk was concluded only for the acute contact route of exposure for honeybees and bumble bees and for honeybee larvae considering the oral route of exposure. In all the other cases (acute contact for solitary bees, acute and chronic oral for honeybees, bumble bees and solitary bees), a high risk was indicated or a high risk could not be excluded.

For *beet*, a low risk from acute contact exposure to honeybees, bumble bees and solitary bees (both lowest and highest application rates) was concluded according to EFSA (2013b).

As regards the oral route of exposure, the lowest application rate indicated a low risk to honeybees (acute, chronic and larvae) and solitary bees (acute and chronic). For bumble bees also, a low risk was concluded for the acute and the larval scenarios, but a high risk could not be excluded for the chronic adult scenario. For the highest application rate, a low acute risk was concluded for honeybees, bumble bees and solitary bees and a low risk was concluded for honeybee larvae. Also, a low risk was concluded for the chronic adult scenario for honeybees, but a high risk could not be excluded for bumble bees and solitary bees. Up to the application rate of 17.8 g/ha, a low risk could be concluded for solitary bees.

For the *outdoor uses on leafy vegetables* (both lowest and highest application rates), a high risk was indicated or a high risk could not be excluded for honeybees, bumble bees and solitary bees.

No quantitative risk assessments were conducted for the field margin/adjacent crops scenarios for the *glasshouse use on leafy vegetables* as the contamination of off-field areas was considered to be negligible from this use (although some exposure cannot be excluded). The *in-planter and in-furrow*

uses for potatoes were not considered relevant for this point as no dust formation was expected from the proposed application techniques.

7.2. Higher tier risk assessment

The applicant submitted studies in which the dust drift ground deposition was assessed in winter cereals. No Heubach active substance values were provided for these studies; only some values on the dustiness of the used seed batches from two studies on winter barley were reported. In addition, the experts argued that results from individual studies investigating few varieties of seeds might not be sufficient to overrule the available default dust deposition values in EFSA (2013b).

A single study to assess potential effects on honeybee colonies during and after vacuum-pneumatic sowing operation of coated sugar beet pills was also available for sugar beet. It was noted that the concentration of the active substances and the dust deposition in this study was very low. However, the above argumentation for winter cereals regarding the quality of the study and the concerns for overruling the current available dust deposition values was acknowledged. Therefore, the conclusion on the risk assessment for sugar beet was based on the results of the Tier 1 calculations.

In the Pesticides Peer Review Meeting 145, it was considered that EFSA (2013b) suggests selecting the sowing machine at the EU level that delivers 90th percentile exposure based on ranking of dust emission and area of use, in order to ensure that the machine used for experimental measurement covers the 90th percentile exposure. The experts noted that there is indeed no information as to whether the machinery used in all the studies covers the 90th percentile of exposure. It was, however, acknowledged that, it is at present very difficult to perform such an assessment.

Overall, it was agreed that these studies alone are not sufficient for estimating the exposure from dust deposition and it was considered that no refined risk assessment can be performed.

8. Treated crop

In this Section, the risk to honeybees (point g of the confirmatory data requirement) and to pollinators other than honeybees (point a of the confirmatory data requirement) foraging for pollen and nectar in the treated field is considered.

8.1. Tier 1 risk assessment

A Tier 1 risk assessment based on EFSA (2013b) was performed where agreed toxicity endpoints were available (for honeybees and acute endpoints for bumble bees) and a screening assessment was carried out where only surrogate endpoints were available (adult chronic endpoint for bumble bees and endpoints for solitary bees). No toxicity data were available for bumble bee and solitary bee larvae; therefore, no lower tier risk assessments were performed for those cases.

As a result, for the use on *potato* the risk from oral exposure to honeybee larvae was concluded to be low. However, a high risk was indicated or a high risk could not be excluded for adult honeybees, bumble bees and solitary bees. Also, a high risk could not be excluded from oral exposure to bumble bees and solitary bees for the use on *winter cereals*. The risk to honeybees from the use on winter cereals is depending on the seed dressing rate, which ranged between 0.006 and 0.043 mg/seed for the authorised uses in the Member States (estimated). A low risk for the treated crop scenario was concluded for the uses up to a seed dressing rate of 0.007 mg/seed. Where the seed dressing rate was higher, a high risk was indicated by the calculated ETRs (at least for the chronic adult scenario) (see Appendix B).

For the uses as seed treatment for *beet and leafy vegetables* (lettuce, endive, radicchio rosso), it was concluded that this scenario is only relevant if the crops are grown for seed production. However, in the GAP table available in the addendum (Germany, 2016), this information was not reported. In the Member States where uses as seed treatment of beets are authorised, this issue should be further considered in case these crops are grown for seed production.

Amenity vegetation was considered as being unattractive to bees. However, in the GAP table available in the addendum, no information was reported on the species composition of the turf or whether the vegetation is cut continuously. In the Member States where granular uses on amenity vegetation are authorised, this issue should be further considered.

According to EFSA (2013b), contact exposure is only relevant when the crop is in flowering stage at the time of the application. Therefore, this route of exposure is relevant only for the uses on amenity vegetation. However, amenity vegetation was considered as being unattractive to bees. In the Member

States where granular uses on amenity vegetation are authorised, this issue should be further considered.

8.2. Tier 2 risk assessment

As no data were available to refine the risk, the Tier 2 risk assessments could not be performed.

8.3. Higher tier risk assessment

Field effect studies were considered as a line of evidence to address the risk from exposure to the treated crop scenario. In order to address this, earlier assessments of the available semifield and field effect studies from the dossier of imidacloprid were quoted (Germany, 2005). These studies had been evaluated and peer reviewed in earlier procedures (EFSA, 2013a) and EFSA had concluded that these studies are insufficient to demonstrate that the risk to bees was low for the use of imidacloprid as a seed treatment in crops such as oilseed rape and sunflower.

Additionally, two field effect studies on bumble bees were submitted for the confirmatory data package. These studies were discussed at Pesticides Peer Review Meeting 145. It was noted that the statistical power of the studies was low. Furthermore, the available information indicated that the exposure of the colonies was low. It was therefore agreed that the studies are not sufficient to draw any solid conclusion on the effects of imidacloprid on wild bees.

9. Overall conclusion and data gaps

On the basis of the available data, the following conclusions were drawn and data gaps were identified:

- For all the uses, only a screening risk assessment could be performed for bumble bees for the adult chronic scenario and for solitary bees for the acute (contact and oral) and chronic adult scenarios with surrogate endpoints; no data, including surrogate endpoints on bumble bee and solitary bee larvae were available. Overall, a data gap was identified to provide all the relevant toxicity endpoints (data gap).
- With the exception of the uses on amenity turf, the risk from exposure to the *succeeding crop* scenario was indicated as high or high risk could not be excluded (data gap).
- For the uses on potatoes, cereals, beet and amenity vegetation, the exposure via the *flowering weeds* was considered as not relevant. However, further data should be provided for the uses in leafy vegetable (data gap).
- The exposure via *honeydew* was considered not relevant for the uses for which confirmatory data on imidacloprid have been presented.
- For the uses under evaluation, the exposure via *guttation fluids* was concluded as not the primary route of exposure for bees.
- For the uses as seed treatment on winter cereals, outdoor uses on leafy vegetables and granular uses on amenity turf with machinery, the risk from exposure via *dust* was indicated as high or high risk could not be excluded (data gap). For the use in beet, the risk was indicated as low for honeybees, but high risk could not be excluded for bumble bees and solitary bees (data gap). For the indoor use on leafy vegetables (seedling production) and the hand held granular use on amenity turf, a low risk was concluded from exposure to dust drift.
- For the uses on winter cereals and potatoes, the risk from the exposure of bees via 'pollen' in the *treated crop* was indicated as high or high risk could not be excluded (data gap). However, it is noted that up to a seed dressing rate of 0.007 mg/seed, the risk to honeybees from the winter cereals use was considered as low. The risk from the other uses was considered as low. However, further consideration will be needed at the Member States level, when beet or leafy vegetables are grown for seed production.

10. Particular conditions proposed for the uses evaluated

Some aspects of the risk assessment were considered to be addressed by the application of mitigation measures, such as:

- The risk to honeybees from exposure to dust drift was assessed as low for seed treatment of beet considering that a deflector is used during the sowing.

- The risk to bees from exposure to nectar and pollen in the treated crop of beet and leafy vegetables was assessed as low considering that the crops are harvested before flowering.
- The risk to bees from in-field exposure to nectar and pollen from the uses on amenity turf was assessed as low considering that the turf consists of species of generally low attractiveness to bees, the turf is established for several years and well maintained (i.e. regularly cut to short, weed control is applied when necessary).

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

The assessments are considered not finalised when there were no data or when only a screening level assessment could be performed. The issues that could not be finalised are marked with an 'X' in Table 3.

The risks identified are marked with an 'R' in Table 3. Risks have been identified where any of the parts of the risk assessment for each risk scenario according to EFSA (2013b) indicated a high risk.

Table 3: Summary of concerns for each scenario according to the risk assessment scheme in EFSA (2013b) accounting for particular conditions proposed to be taken into account to manage the risks identified. The table does not cover authorised uses that were not covered by the confirmatory data package

Categories				Honeybee							Bumble bee						Solitary bee					
Crop/plant	Use type	Application		Treated crop scenario	Weed scenario	Field margin[a]	Adjacent crop [a]	Succeeding crop	Guttation fluid	Honeydew	Treated crop scenario	Weed scenario	Field margin[a]	Adjacent crop [a]	Succeeding crop	Honeydew	Treated crop scenario	Weed scenario	Field margin[a]	Adjacent crop [a]	Succeeding crop	Honeydew
Winter cereals	Seed treatment	48 g a.s./ha; 0.006 mg a.s./seed	Risk identified			R	R	R					R	R	R							
			Assessment not finalised								X		X	X	X		X		X	X	X	
		126 g a.s./ha; 0.043 mg a.s./seed	Risk identified	R		R	R	R					R	R	R							
			Assessment not finalised								X		X	X	X		X		X	X	X	
Beet	Seed treatment	15 g a.s./ha; 0.15 mg a.s./seed	Risk identified					R							R							
			Assessment not finalised										X	X	X				X	X	X	
		162 g a.s./ha; 0.9 mg a.s./seed	Risk identified					R							R							
			Assessment not finalised										X	X	X				X	X	X	
Potato	In-planter or in-furrow use only	120 g a.s./ha	Risk identified	R				R			R				R							
			Assessment not finalised								X				X		X				X	
		180 g a.s./ha	Risk identified	R				R			R				R							
			Assessment not finalised								X				X		X				X	
Amenity vegetation	Granules machinery application	150 g a.s./ha	Risk identified			R	R						R	R								
			Assessment not finalised										X	X					X	X		
	Granules hand held application	150 g a.s./ha	Risk identified																			
			Assessment not finalised																			

Categories				Honeybee							Bumble bee						Solitary bee					
Crop/plant	Use type	Application		Treated crop scenario	Weed scenario	Field margin(a)	Adjacent crop (a)	Succeeding crop	Guttation fluid	Honeydew	Treated crop scenario	Weed scenario	Field margin(a)	Adjacent crop (a)	Succeeding crop	Honeydew	Treated crop scenario	Weed scenario	Field margin(a)	Adjacent crop (a)	Succeeding crop	Honeydew
Leafy vegetables	Seed treatment field/open protected structure	80 g a.s./ha; 0.8 mg a.s./ seed	Risk identified			R	R	R					R	R	R							
			Assessment not finalised		X							X	X	X	X			X	X	X	X	
		104 g a.s./ha; 1.14 mg a.s./ seed	Risk identified			R	R	R					R	R	R							
			Assessment not finalised		X							X	X	X	X			X	X	X	X	
	Seed treatment in greenhouse for seedling production	90 g a.s./ha; 0.8 mg a.s./ seed	Risk identified					R							R							
			Assessment not finalised		X							X			X			X			X	
		120 g a.s./ha; 1.2 mg a.s./ seed	Risk identified					R							R							
			Assessment not finalised		X							X			X			X			X	

a.s.: active substance.
R = High risk identified. A high risk has been highlighted if any of the parts of the risk assessment for each risk scenario according to EFSA (2013b) indicated high risk.
X = Risk assessment not finalised due to the lack of data or when only a screening level assessment could be performed.
(a): Related to dust drift, not related to spray drift from the in-planter or in-furrow use on potato.

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Abbreviations

a.s.	active substance
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
DT_{90}	period required for 90% dissipation (define method of estimation)
dw	dry weight
ETR	exposure toxicity ratio
ETR_{acute}	exposure toxicity ratio for acute exposure
$ETR_{chronic}$	exposure toxicity ratio for chronic exposure
ETR_{larvae}	exposure toxicity ratio for larvae
ETR_{HPG}	exposure toxicity ratio for effects on honeybee hypopharyngeal glands
f(twa)	time-weighted average factor
GAP	Good Agricultural Practice
HPG	hypopharyngeal glands
HQ	hazard quotient
$HQ_{contact}$	hazard quotient for contact exposure
LD_{50}	lethal dose, median; dosis letalis media
LDD_{50}	lethal dietary dose; median
NOEC	no observed effect concentration
NOEL	no observed effect level
PEC	predicted environmental concentration
PEC_{air}	predicted environmental concentration in air

PEC_{gw}	predicted environmental concentration in groundwater
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PHI	preharvest interval
SFO	single first-order
SPG	specific protection goal
TER	toxicity exposure ratio
TER_A	toxicity exposure ratio for acute exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TMDI	theoretical maximum daily intake
W/S	water/sediment
WG	water-dispersible granule

Appendix A – List of the representative uses evaluated

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Winter wheat rye, triticale	FR	Gaucho	F	*Agriotes* sp. *Macrosiphum avenae* *Metopolophium dirhodum* *Rhopalosiphum padi* *Zabrus tenebrioides*	FS	350	Seed treatment	00	1	na	na	0.07	0.126	na	Sowing rate: 1.8 dt seeds/ha Product dose rate: 0.2 L/dt
Winter barley	FR	Gaucho	F	*Agriotes* sp. *Macrosiphum avenae* *Metopolophium dirhodum* *Rhopalosiphum padi* *Zabrus tenebrioides*	FS	350	Seed treatment	00	1	na	na		0.112	na	Sowing rate: 1.6 dt seeds/ha Product dose rate: 0.2 L/dt
Winter wheat	PL	Astep 225 FS	F	*Aphis* sp.	FS	175	Seed treatment	00	1	na	na	0.035	0.088	na	Sowing rate: 2.5 dt/seeds ha Product dose rate: 0.2 L/dt
Winter barley,	PL	Astep 225 FS	F	*Aphis* sp.	FS	175	Seed treatment	00	1	na	na	0.035	0.063	na	Sowing rate: 1.8 dt/ha Product dose rate: 0.2 L/dt
Winter wheat Winter barley	HU	Yunta Quattro	F	*Agriotes* sp. *Echeandia* sp. *Oscinis frit*	FS	166.7	Seed treatment	00	1	na	na	0.033	0.067	na	Sowing rate: 2 dt seeds/ha Product dose rate: 0.2 L/dt
Winter wheat	RO	Yunta Quattro	F	*Agriotes* sp. *Hylemya coarctata* *Zabrus tenebrioides*	FS	166.7	Seed treatment	00	1	na	na	0.027	0.059	na	Sowing rate: 2.2 dt seeds/ha Product dose rate: 0.16 L/dt

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Winter barley	RO	Yunta Quattro	F	*Agriotes* sp. *Hylemya coarctata* *Zabrus tenebrioides*	FS	166.7	Seed treatment	00	1	na	na	0.027	0.048	na	Sowing rate: 1.8 dt seeds/ha Product dose rate: 0.16 L/dt
Beet	BE	Gaucho 70 WS, Gaucho R 70 WS	F	*Chaetocnema* spp. *Atomaria linearis* *Agriotes* spp. *Scutigerella immaculata* *Pegomyia hyoscyami* *Pegomya betae* *Blaniulus guttulatus* Aphididae	WS	700	Seed treatment	00	1	na	na	0.09	0.117	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100000 Product dose rate 0.13 kg/u
Beet	CZ	Gaucho 70 WS	F	Elateridae sp. *Aphis fabae* *Myzus persicae* *Atomaria linearis* *Chaetocnema concinna* *Chaetocnema tibialis* *Pegomya hyoscyami* *Bothynoderes punctiventris*	WS	700	Seed Treatment	00	1	na	na	0.09	0.109	na	Sowing rate 1.2 unit seeds/ha Product dose rate 0.13 kg/u
Beet	DK	Gaucho 70 WS	F	Aphididae *Thrips* *Atomaria linearis* *Pegomya betae*	WS	700	Seed treatment	00	1	na	na	0.06	0.066	na	Sowing rate 1.1 unit seeds/ha 1 u = 100,000 Product dose rate 0.085 kg/u

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Beet	FI	Gaucho 70 WS	F	*Thrips* *Lygus* spp. *Chaetocnema tibialis*	WS	700	Seed Treatment	00	1	na	na	0.06	0.06	na	Sowing rate 1.0 unit seeds/ha 1 u = 100,000 Product dose rate 0.085 kg/u
Beet	DE	Gaucho WS	F	*Echeandia* sp. *Atomaria linearis* *Pegomya hyoscyami* *Agriotes* sp.	WS	700	Seed Treatment	00	1	na	na	0.09	0.117	na	Sowing rate 1.3 unit seeds/ha 1 u = 100,000 Product dose rate 0.13 kg/u
Beet	HE	Gaucho	F	Elateriidae *Cassida seraphina* *Pegomya* spp. *Tanymecus* spp. *Cleonus* sp. Aphididae, e.g. *Aphis fabae* *Myzus persicae* Wireworms, e.g. *Agriotes* spp. *Chaetocnema* sp.	WS	700	Seed treatment	00	1	na	na	0.088	0.140	na	Sowing rate 1.6 unit seeds/ha 1 u = 100,000 Product dose rate 0.125 kg/u
Beet	IT	Gaucho	F	*Blaniulus* spp. *Agriotes* spp. *Chaetocnema tibialis* *Atomaria linearis* *Tipula* spp. *Pegomya hyoscyam* Aphididae, e.g. *Aphis fabae* *Myzus persicae*	WS	700	Seed Treatment	00	1	na	na	0.09	0.135	na	Sowing rate 1.5 unit seeds/ha 1 u = 100,000 Product dose rate 0.13 kg/u

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Beet	SK	Gaucho	F	Elateridae sp. *Aphis fabae* *Atomaria linearis* *Chaetocnema concinna* *Chaetocnema tibialis* *Myzus persicae* *Pegomya hyoscyami* *Bothynoderes punctiventris*	WS	700	Seed treatment	00	1	na	na	0.09	0.117	na	Sowing rate 1.3 unit seeds/ha 1 u = 100,000 Product dose rate 0.13 kg/u
Beet	SE	Gaucho	F	Aphididae *Onychirus* ssp. *Atomaria linearis* *Pegomya betae*	WS	700	Seed treatment	00	1	na	na	0.06	0.06	na	Sowing rate 1.0 unit seeds/ha 1 u = 100,000 Product dose rate 0.085 kg/u
Beet	ES	Gaucho	F	*Aubeonymus mariaefranciscae* *Chaetocnema tibialis* Aphididae	WS	700	Seed treatment	00	1	na	na	0.09	0.162	na	Sowing rate 1.8 unit seeds/ha 1 u = 100,000 Product dose rate 0.13 kg/u
Beet	BE	Imprimo	F	*Echeandia sp.* *Pegomya hyoscyami* *Atomaria linearis* *Blaniulus* sp. *Scutigerella* sp. *Agriotes* sp.	FS	400	Seed treatment	00	1	na	na	0.09	0.117	na	Sowing rate 1.0 unit seeds/ha Product dose rate 0.225 kg/u
Beet	DK	Imprimo FS 417.78	F	*Aphis fabae* *Pegomya hyoscyami* *Myzus persicae* *Atomaria linearis*	FS	400	Seed treatment	00	1	na	na	0.09	0.09	na	Sowing rate 1.0 unit seeds/ha Product dose rate 0.225 kg/u

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Beet	FR	Imprimo	F	*Agriotes* sp. *Aphis fabae* *Atomaria linearis* *Aulacorthum solani* *Blaniulus guttulatus* *Macrosiphum euphorbiae* *Myzus ascalonicus* *Myzus persicae* *Pegomya hyoscyami*	FS	400	Seed treatment	00	1	na	na	0.09	0.117	na	Sowing rate 1.3 unit seeds/ha 1 u = 100,000 Product dose rate 0.225 kg/u
Beet	BE	Montur forte	F	*Chaetocnema* spp *Atomaria linearis* *Agriotes* ssp. *Pegomyia betae* *Scutigerella immaculate* *Blaniulus guttulatus* Aphids *Thrips*	FS	150	Seed treatment	00	1	na	na	0.015	0.0195	na	Sowing rate 1.3 unit seeds/ha 1 u = 100,000 Product dose rate 0.1 kg/u
Beet	DK	Montur forte FS 230	F	*Atomaria linearis* *Pegomya betae* Aphids *Thrips*	FS	150	Seed treatment	00	1	na	na	0.015	0.015	na	Sowing rate 1.0 unit seeds/ha Product dose rate 0.1 kg/u
Beet	PL	Montur forte	F	*Atomatia linearis,* *Chaetocnema concina,* *Pegomyia hyocyami,* *Aphis fabae*	FS	150	Seed treatment	00	1	na	na	0.015	0.018	na	Sowing rate 1.2 unit seeds/ha Product dose rate 0.1 kg/u
Potato	DK	Amigo		Aphididae *Empoasca* spp.	FS	350	Seed treatment	00	1	na	na	0.006	0.12	na	Tuber density: 20 dt/ha Product dose rate: 0.017 L/dt

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Potato	FI	Amigo	F	Aphididae *Empoasca* spp.	FS	350	Seed treatment	00	1	na	na	0.006	0.12	na	Tuber density: 20 dt/ha Product dose rate: 0.017 L/dt
Potato	ES	Escocet	F	*Leptinotarsa decemlineata* *Agriotes* spp. Aphididae	FS	350	In-furrow	00	1	na	75–100 L/ha	0.0088	0.175	na	Tuber density: 20 dt/ha Product dose rate: 0.5 L/ha
Potato	SE	Amigo	F	Aphididae *Empoasca* spp.	FS	350	Seed treatment	00	1	na	na	0.006	0.12	na	Tuber density: 20 dt/ha Product dose rate: 0.017 L/dt
Potato	AT	Monceren G	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Thanatephorus cucumeris*	FS	120	In-planter	00–03	1	na	6–8 L/dt	0.007	0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt
Potato	AT	Monceren G	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Thanatephorus cucumeris*	FS	120	In-furrow	00–03	1	na	60–80 L/day		0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06L/dt
Potato	AT	Monceren G	F	*Aphis* sp. *Leptinotarsa decemlineata* *Thanatephorus cucumeris*	FS	120	In-furrow	00–03	1	na	0.6–0.8 L/dt		0.18	na	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Potato	BU	Monceren G	F	F *Aphis* sp. *Leptinotarsa decemlineata* *Thanatephorus cucumeris* *Agriotes* sp.	FS	120	In-furrow	00–03	1	na	na		0.18	na	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	CZ	Monceren G	F	*Aphis* sp. *Leptinotarsade cemlineata* *Thanatephorus cucumeris*	FS	120	In-furrow	00–03	1	na	60–80 L/ha		0.18	na	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	DK	Prestige FS 370	F	*Aphis* sp., Virus, *Empoasca* sp. *Leptinotarsa decemlineata* *Lygus* sp	FS	120	In-planter	00–03	1	na	0.2–0.4 L/dt	0.054	0.12	na	Tuber density: 22 dt/ha Product dose rate: 0.045 L/dt
Potato	DK	Prestige FS 370	F	*Aphis* sp., Virus, *Empoasca* sp. *Leptinotarsa decemlineata* *Lygus* sp.	FS	120	In-furrow	00–03	1	na	60–70 L/ha		0.12	na	Tuber density: 22 dt/ha Product dose rate: 1 L/ha
Potato	DE	Monceren G	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Thanatephorus cucumeris*	FS	120	In-furrow	00	1	na	na		0.18	na	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	EE	Monceren G	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Agriotes* sp. *Melolontha* sp.	FS	120	In-planter	00–03	1	na	1.5–2.0 L/dt	0.007	0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Potato	HU	Monceren	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Agriotes* sp. *Melolontha* sp.	FS	400	In-furrow	00–03	1	na	50–80 L/ha		0.18	na	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	LV	Monceren G	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Agriotes* sp. *Melolontha* sp.	FS	120	In-planter	00–03	1	na	1.5–2.0 L/dt	0.007	0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt
Potato	LT	Monceren	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata* *Agriotes* sp. *Melolontha* sp.	FS	120	In-planter	00–03	1	na	1.5–2.0 L/dt	0.007	0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt
Potato	PL	Prestige forte	F	*Aphis* sp., Virus, *Leptinotarsa decemlineata*	FS	120	In-planter	00–03	1	na	2.0 L/dt	0.007	0.18	na	Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt
Potato	PL	Prestige forte	F	*Aphis sp., Virus, Leptinotarsa decemlineata*	FS	120	In-furrow	00–03	1	n.a.	25–50 L/ha	n.a.	0.18	n.a.	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	RO	Monceren	F	*Aphis sp., Virus, Leptinotarsa decemlineata*	FS	120	In-furrow	00–03	1	n.a.	30–60 L/ha	n.a.	0.18	n.a.	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha
Potato	SK	Monceren	F	RHISZO, LPTNDE, *Aphis* sp., Virus	FS	120	In-furrow	00–03	1	n.a.	50–80 L/ha	n.a.	0.18	n.a.	Tuber density: 25 dt/ha Product dose rate: 1.5 L/ha

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Potato	SE	Prestige forte	F	RHIZSO, *Aphis* sp., Virus, EMPOSP, LPTNDE, LYGUSP	FS	120	In-planter	00–03	1	na	02–0.4 L/dt	0.007	0.18		Tuber density: 25 dt/ha Product dose rate: 0.06 L/dt
Potato	SE	Prestige forte	F	RHIZSO, *Aphis* sp., Virus, EMPOSP, LPTNDE, LYGUSP	FS	120	In-furrow	00–03	1	na	60–70 L/ha		0.18		Tuber density: 25 dt/ha Product dose rate: 1.5 L/dt
Lettuce	BE	Gaucho 70 WS	F	*Aphis* sp.	WS	700	Seed treatment	00	1	na	na	0.1037	0.1037		Sowing rate: 1.3 u/ha 1 u = 100,000 seeds Product dose rate: 0.114 kg/u
Endive Scarole (broad-leaf endive)	BE	Gaucho 70 WS	F	*Aphis* sp.	WS	700	Seed treatment	00	1	na	na	0.0798	0.0798		Sowing rate: 1.0 u/ha 1 u = 100,000 seeds Product dose rate: 0.114 kg/u
Brassica, flowering	NL	Gaucho Tuinbouw	G*	*Thrips tabaci*	WS	700	Seed treatment as dummy pill** or as phytodrip	00	1	na	na		0.0900		Sowing rate: 0.6 u/ha 1 u = 100,000 seeds Dose rate: 0.215 kg Pdt/u
Brassica, head	NL	Gaucho Tuinbouw	G*	*Thrips tabaci*	WS	700	Seed treatment as dummy pill** or as phytodrip	00	1	na	na	na	0.0900		Sowing rate: 0.6 u/ha 1 u = 100,000 seeds Dose rate: 0.215 kg Pdt/u

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Brassica, leafy	NL	Gaucho Tuinbouw	G*	*Thrips tabaci*	WS	700	Seed treatment as dummy pill** or as phytodrip	00	1	na	na	na	0.0900		Sowing rate: 0.6 u/ha 1 u = 100,000 seeds Dose rate: 0.215 kg Pdt/u
Lettuce	NL	Gaucho Tuinbouw	G*	*Thrips tabaci*	WS	700	Seed treatment as dummy pill** or as phytodrip	00	1	na	na	na	0.0800–0.1080		Planting rate: 100,000–135,000 plts/ha Dose rate: 0.114 kg Pdt/100,000 seeds
Lettuce	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.1200		Planting rate: 100,000 plts/ha Dose rate: 0.171 kg Pdt/100,000 seeds
Endive	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.1200		Planting rate: 100,000 plts/ha Dose rate: 0.171 kg Pdt/100,000 seeds
Endive	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.0890		Sowing rate: 111.100 plts/ha Dose rate: 0.114 kg Pdt/100,000 plts

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Lettuce	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.0800–0.1080		Planting rate: 100,000–135,000 plts/ha Dose rate: 0.114 kg Pdt/ 100,000 seeds
Lettuce	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.1200		Planting rate: 100,000 plts/ha Dose rate: 0.171 kg Pdt/ 100,000 seeds
Lettuce (Sugar loaf)	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.1200		Planting rate: 100,000 plants/ ha Dose rate: 0.171 kg Pdt/ 100,000 seeds
Lettuce (sugar loaf)	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.0890		Sowing rate: 111.100 plts/ha Dose rate: 0.114 kg Pdt/ 100,000 plts
Radicchio rosso	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.1200		Planting rate: 100,000 plts/ha Dose rate: 0.171 kg Pdt/100, 000seeds
Radicchio rosso	NL	Gaucho Tuinbouw	G*	Aphididae	WS	700	Seed treatment as dummy pill** or as phytodrip***	00	1	na	na	na	0.0890		Sowing rate: 111.100 plts/ha Dose rate: 0.114 kg Pdt/ 100,000 plts

Crop and/or situation[a]	Country	Product name	F G or I[b]	Pests or group of pests controlled[c]	Formulation		Application				Application rate per treatment			PHI (day)[l]	Remarks[m]
					Type[d–f]	Conc. of a.s.[i]	Method kind[f–h]	Growth stage and season[j]	Number min–max[k]	Interval between applications (min)	kg a.s./hL min–max	Water L a.s./dt min–max	kg a.s./ha min–max		
Managed amenity turf (golf courses, sport grounds, commercial and residential lawns,. . .)	DK, DE, IE, ES	Merit Turf	F	Cheafer grubs & Leather jacket	GR	5	Spread uniformly over the area with normally used granular application equipment (e.g. hand held, drop type and rotary type spreaders)	January to December	1	na	na	na	0.150		Apply as a granule at 30 Kg/ha, immediately followed by sufficient irrigation to move the active ingredient through the thatch, wetting the top inch of soil

a.s.: active substance.
(a): For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b): Outdoor or field use (F), glasshouse application (G) or indoor application (I).
(c): e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e): GCPF Codes – GIFAP Technical Monograph No 2, 1989.
(f): All abbreviations used must be explained.
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants – type of equipment used must be indicated.
(i): g/kg or g/L.
(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application.
(k): The minimum and maximum number of application possible under practical conditions of use must be provided.
(l): PHI: minimum preharvest interval.
(m): Remarks may include: Extent of use/economic importance/restrictions.
*: Nursery, seeds are sown in trays and then, at BBCH stage 12, plants are planted out in field.
**: Dummy pill: Treated dead seeds are sown together with untreated alive seeds at ratio 1 to 1.
***: Phytodrip: Drench application on seeds of a low volume of product during sowing.

Appendix B – List of end points for the active substance and the representative formulation

Toxicity endpoints selected for lower tier risk assessments or for screening assessment

Risk assessment type	Endpoint	Honeybee	Bumble bee	Solitary bee
Acute contact	LD_{50} (µg a.s./bee)	0.081 (48 h)	0.218 (96 h)	0.0081[(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

(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.

Contact exposure and exposure to consumption of contaminated pollen and nectar

Tier 1 risk assessment based on EFSA (2013b)

Winter cereals 48 g a.s./ha (seed treatment)

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	5.9–**58.7***	14	2.2–**21.8***	2.3	**58.7**	2.6

Values are presented in bold when they exceed the trigger value.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013).

48 g a.s./ha, 0.006 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.02	0.2	0.005	0.036	**0.16**	0.04
	Field margin	**0.48**	0.2	**0.08**	0.036	**2.95**	0.04
	Adjacent crop	**0.47**	0.2	**0.07**	0.036	**3.55**	0.04
	Next crop	**9.08**	0.2	**1.14**	0.036	**63.57**	0.04
Chronic	Treated crop	0.026–**0.07***	0.03	**0.64**	0.0048	**0.21**	0.0054
	Field margin	**0.49**	0.03	**9.94**	0.0048	**3.88**	0.0054
	Adjacent crop	**0.47**	0.03	**8.09**	0.0048	**4.66**	0.0054
	Next crop	**9.19**	0.03	**132.77**	0.0048	**83.40**	0.0054
Larva	Treated crop	0.002	0.2	–	0.2	–	0.2
	Field margin	0.20–**1.98****	0.2	–	0.2	–	0.2
	Adjacent crop	0.19–**1.92****	0.2	–	0.2	–	0.2
	Next crop	**3.64**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: The higher value was calculated by a worst case seed dressing rate of 0.016 mg/seed obtained by assuming a seed weight of 61 g/1,000 seeds.
**: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013b).

Winter cereals 126 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**15.4**	14	**5.7**	2.3	**154.0**	2.6

Values are presented in bold when they exceed the trigger value.

126 g a.s./ha, 0.043 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.14	0.2	0.034	0.036	**1.16**	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
	Next crop	**23.84**	0.2	**2.98**	0.036	**166.86**	0.04
Chronic	Treated crop	**0.183**	0.03	**4.57**	0.0048	**1.52**	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
	Next crop	**24.13**	0.03	**348.51**	0.0048	**218.94**	0.0054
Larva	Treated crop	0.02	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
	Next crop	**9.55**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.

Beet (seed treatment) 15 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	0.01	14	0.002	2.3	0.1	2.6

15 g a.s./ha, 0.15 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop**	**28.38**	0.2	**3.55**	0.036	**198.65**	0.04
	Field margin	0.0005	0.2	0.0001	0.036	0.003	0.04
	Adjacent crop	0.0005	0.2	0.0001	0.036	0.003	0.04
	Next crop	**2.84**	0.2	**0.36**	0.036	**19.86**	0.04
Chronic	Treated crop**	**28.72**	0.03	**414.89**	0.0048	**260.64**	0.0054
	Field margin	0.0005	0.03	**0.01**	0.0048	0.0037–**0.045***	0.0054
	Adjacent crop	0.0005	0.03	**0.01**	0.0048	0.0045–**0.05***	0.0054
	Next crop	**2.87**	0.03	**41.49**	0.0048	**26.06**	0.0054

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Larva	Treated crop**	**11.36**	0.2	–	0.2	–	0.2
	Field margin	0.0002	0.2	–	0.2	–	0.2
	Adjacent crop	0.0002	0.2	–	0.2	–	0.2
	Next crop	**1.14**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013b).
**: Not relevant when beet are not grown for seed production.

Beet 162 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	0.1	14	0.02	2.3	0.6–**6***	2.6

Values are presented in bold when they exceed the trigger value.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013b).

162 g a.s./ha, 0.9 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop**	**170**	0.2	**21**	0.036	**1,192**	0.04
	Field margin	0.005	0.2	0.008	0.036	0.03–**0.3***	0.04
	Adjacent crop	0.005	0.2	0.007	0.036	0.037–**0.37***	0.04
	Next crop	**31**	0.2	**4**	0.036	**214**	0.04
Chronic	Treated crop**	**172**	0.03	**2,489**	0.0048	**1,563**	0.0054
	Field margin	0.005–**0.05***	0.03	**0.1**	0.0048	**0.04**	0.0054
	Adjacent crop	0.005–**0.05***	0.03	**0.09**	0.0048	**0.05**	0.0054
	Next crop	**31**	0.03	**448**	0.0048	**281**	0.0054
Larva	Treated crop**	**68**	0.2	–	0.2	–	0.2
	Field margin	0.002	0.2	–	0.2	–	0.2
	Adjacent crop	0.002	0.2	–	0.2	–	0.2
	Next crop	**12**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: The higher value reflects a scenario sowing without deflector as considered in EFSA (2013b).
**: Not relevant when beet are not grown for seed production.

Potatoes (in-planter and in-furrow uses) 120 g a.s./ha

(these uses were evaluated as spray DW – BBCH < 10, as agreed at the Pesticides Peer Review Meeting 145)

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Treated crop	0	42	0	7	0	8
Weeds	**1,481**	42	**551**	7	**14,815**	8
Field margin	41.5	42	**15**	7	**415**	8

Values are presented in bold when they exceed the trigger value.

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**0.4**	0.2	**0.09**	0.036	**3**	0.04
	Weeds	**120**	0.2	**21**	0.036	**746**	0.04
	Field margin	**1**	0.2	**0.2**	0.036	**7**	0.04
	Adjacent crop	**0.8**	0.2	**0.1**	0.036	**6**	0.04
	Next crop	**22.7**	0.2	**2.8**	0.036	**159**	0.04
Chronic	Treated crop	**0.4**	0.03	**9**	0.0048	**3**	0.0054
	Weeds	**89**	0.03	**1,808**	0.0048	**705**	0.0054
	Field margin	**0.8**	0.03	**17**	0.0048	**7**	0.0054
	Adjacent crop	**0.6**	0.03	**10**	0.0048	**6**	0.0054
	Next crop	**17**	0.03	**239**	0.0048	**150**	0.0054
Larva	Treated crop	0.04	0.2	–	0.2	–	0.2
	Weeds	**43**	0.2	–	0.2	–	0.2
	Field margin	**0.4**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.28**	0.2	–	0.2	–	0.2
	Next crop	**8**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.

Potatoes (in-planter and in-furrow uses) 180 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Treated crop	0	42	0	7	0	8
Weeds	**2,222**	42	**826**	7	**22,222**	8
Field margin	**62**	42	**23**	7	**622**	8

Values are presented in bold when they exceed the trigger value.

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**0.6**	0.2	**0.14**	0.036	**4.9**	0.04
	Weeds	**180**	0.2	**31**	0.036	**1,119**	0.04
	Field margin	**1.7**	0.2	**0.3**	0.036	**10**	0.04
	Adjacent crop	**1.2**	0.2	**0.2**	0.036	**9**	0.04
	Next crop	**34**	0.2	**4.3**	0.036	**239**	0.04
Chronic	Treated crop	**0.6**	0.03	**14**	0.0048	**4.6**	0.0054
	Weeds	**133**	0.03	**2,711**	0.0048	**1,058**	0.0054
	Field margin	**1.2**	0.03	**24.9**	0.0048	**10**	0.0054
	Adjacent crop	**0.9**	0.03	**15**	0.0048	**9**	0.0054
	Next crop	**25**	0.03	**359**	0.0048	**225**	0.0054
Larva	Treated crop	0.06	0.2	–	0.2	–	0.2
	Weeds	**64**	0.2	–	0.2	–	0.2
	Field margin	**0.6**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.4**	0.2	–	0.2	–	0.2
	Next crop	**12**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.

Leafy vegetables: lettuce, endive (seed treatment) – outdoor 80 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**16.8**	14	**6.2**	2.3	**167.9**	2.6

Values are presented in bold when they exceed the trigger value.

80 g a.s./ha, 0.8 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**2.59**	0.2	**18.95**	0.036	**1,059.46**	0.04
	Field margin	**1.34**	0.2	**0.23**	0.036	**8.35**	0.04
	Adjacent crop	**1.33**	0.2	**0.19**	0.036	**9.98**	0.04
	Next crop	**15.14**	0.2	**1.89**	0.036	**105.95**	0.04
Chronic	Treated crop*	**3.40**	0.03	**85.11**	0.0048	**28.37**	0.0054
	Field margin	**1.38**	0.03	**28.12**	0.0048	**10.96**	0.0054
	Adjacent crop	**1.33**	0.03	**22.75**	0.0048	**13.10**	0.0054
	Next crop	**15.32**	0.03	**221.28**	0.0048	**139.01**	0.0054
Larva	Treated crop*	**0.30**	0.2	–	0.2	–	0.2
	Field margin	**0.56**	0.2	–	0.2	–	0.2
	Adjacent crop	**0.54**	0.2	–	0.2	–	0.2
	Next crop	**6.06**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: Not relevant when leafy vegetables are not grown for seed production.

Leafy vegetables: lettuce, endive (seed treatment) – outdoor 104 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin	**21.8**	14	**8.1**	2.3	**218.3**	2.6

Values are presented in bold when they exceed the trigger value.

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

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**2.59**	0.2	**18.95**	0.036	**1,059.46**	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
	Next 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
	Next crop	**19.91**	0.03	**287.66**	0.0048	**180.71**	0.0054

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Larva	Treated crop*	**0.30**	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
	Next crop	**7.88**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: Not relevant when leafy vegetables are not grown for seed production.

Leafy vegetables: lettuce, endive, radicchio rosso (seed treatment) – glasshouse 90 g a.s./ha, 0.8 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**2.59**	0.2	**18.95**	0.036	**1,059.46**	0.04
	Next crop	**17.03**	0.2	**2.13**	0.036	**119.19**	0.04
Chronic	Treated crop*	**3.40**	0.03	**85.11**	0.0048	**28.37**	0.0054
	Next crop	**17.23**	0.03	**248.94**	0.0048	**156.38**	0.0054
Larva	Treated crop*	**0.30**	0.2	–	0.2	–	0.2
	Next crop	**6.82**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: Not relevant when leafy vegetables are not grown for seed production.

Leafy vegetables: lettuce, endive, radicchio rosso (seed treatment) – glasshouse 120 g a.s./ha, 1.2 mg a.s./seed

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop*	**3.89**	0.2	**28.42**	0.036	**1,589.19**	0.04
	Next crop	**22.70**	0.2	**2.84**	0.036	**158.92**	0.04
Chronic	Treated crop*	**5.11**	0.03	**127.66**	0.0048	**42.55**	0.0054
	Next crop	**22.98**	0.03	**331.91**	0.0048	**208.51**	0.0054
Larval	Treated crop*	**0.45**	0.2	–	0.2	–	0.2
	Next crop	**9.09**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.
*: Not relevant when leafy vegetables are not growth for seed production.

Amenity vegetation – granules, application with machinery 150 g a.s./ha

Acute contact exposure – **HQ**

Scenario	BBCH	Honeybee		Bumble bee		Solitary bee	
		HQ	Trigger	HQ	Trigger	HQ	Trigger
Treated crop	≥ 10	**185.2**	14	**68.8**	2.3	**1,851.9**	2.6
Weeds	≥ 10	**185.2**	14	**68.8**	2.3	**1,851.9**	2.6
Field margin	All stages	**177.8**	14	**66.1**	2.3	**1,777.8**	2.6

Values are presented in bold when they exceed the trigger value.

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

Category	Scenario	BBCH	Honeybee		Bumble bee		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
	Next crop	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
	Next crop	All stages	**28.72**	0.03	**414.89**	0.0048	**260.64**	0.0054
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
	Next crop	All stages	**11.36**	0.2	–	0.2	–	0.2

Values are presented in bold when they exceed the trigger value.

Tier 2 Risk assessment for the oral route of exposure

Succeeding crop scenario (for the uses on cereals, potato, beet, amenity vegetation and leafy vegetables (lettuce, endive, radicchio rosso))

Bee type	Category	Tier 2 SV (µg/bee or µg/bee per day or µg/larva)	ETR	Trigger
Honeybee forager	Acute	0.00244	**0.659459**	> 0.2
Honeybee forager	Chronic	0.00189	**< 0.670213**	> 0.03
Honeybee larva	Larva	0.00139	**0.263258**	> 0.2
Bumble bee adult	Acute	0.00312	**0.082105**	> 0.036
Bumble bee adult	Chronic	0.00269	**< 9.539007**	> 0.0048
Solitary bee adult	Acute	0.00171	**4.621622**	> 0.04
Solitary bee adult	Chronic	0.00171	**< 6.06383**	> 0.0054

Values are presented in bold when they exceed the trigger value.

Exposure to guttation fluid

Tier 2 Risk assessment

Winter cereals (seed treatment)

Bee type	Category	Water consumption (µL/bee or µL/larva)	Measured concentration in guttation fluid (µg/µL)	ETR	Trigger
Honeybee forager	Acute	11.4	0.015	**46.2**	> 0.2
Honeybee forager	Chronic	11.4		**< 60.6**	> 0.03
Honeybee larva	Larva	111		**315.3**	> 0.2

Beet (seed treatment)

Bee type	Category	Water consumption (µL/bee or µL/larva)	Measured concentration in guttation fluid (µg/µL)	ETR	Trigger
Honeybee forager	Acute	11.4	0.000061	0.19	> 0.2
Honeybee forager	Chronic	11.4		**< 0.25**	> 0.03
Honeybee larva	Larva	111		**1.28**	> 0.2

Values are presented in bold when they exceed the trigger value.

Potatoes (in-planter, in-furrow uses and preplanting tuber treatment)

Bee type	Category	Water consumption (µL/bee or µL/larva)	Measured concentration in guttation fluid (µg/µL)	ETR	Trigger
Honeybee forager	Acute	11.4	0.00198	**6.1**	> 0.2
Honeybee forager	Chronic	11.4		**< 8.0**	> 0.03
Honeybee larva	Larva	111		**41.6**	> 0.2

Values are presented in bold when they exceed the trigger value.