CONCLUSION ON PESTICIDES PEER REVIEW

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Peer review of the pesticide risk assessment for the active substance clothianidin 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, Belgium, for the pesticide active substance clothianidin are reported. The context of the peer review was that requested by the European Commission following the submission and evaluation of confirmatory ecotoxicological data concerning the risk assessment for bees. The conclusions were reached on the basis of the evaluation of the representative uses of clothianidin as an insecticide on winter cereals, beet potato, maize/sweet maize, sorghum and forestry nursery. 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.

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

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Correspondence: pesticides.peerreview@efsa.europa.eu

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Summary

Clothianidin was included in Annex I to Directive 91/414/EEC on 1 August 2006 by Commission Directive 2006/41/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 and 1136/2013.

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013, to restrict the uses of clothianidin, 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. 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 honey bees;
b) the risk to honey bees foraging in nectar or pollen in succeeding crops;
c) the potential uptake via roots to flowering weeds;
d) the risk to honey bees 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 applicants, Sumitomo Chemical Agro Europe S.A.S. and Bayer Crop Science, submitted updated dossiers in March 2015 (Bayer Crop Science) and in June 2015 (Sumitomo Chemical Agro Europe S.A.S.), which were evaluated by the designated rapporteur Member State (RMS), Belgium, in the form of an addendum to the draft assessment report (Belgium, 2015a,b). 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 31 August 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 25 November 2015. 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 18 December 2015.

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 23 March 2016, the European Commission requested EFSA to organise a peer review of the evaluation by RMS of the confirmatory data submitted in relation to ecotoxicological data and to deliver its conclusions on the risk assessment for bees.

For all the uses for which confirmatory data on clothianidin 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

Clothianidin was included in Annex I to Directive 91/414/EEC[1] on 1 August 2006 by Commission Directive 2006/41/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 Regulation (EU) No 541/2011[5] and 1136/2013[6]. The peer review leading to the approval of clothianidin was finalised in 2006; the European Food Safety Authority (EFSA) was not involved in this evaluation. Upon request from the European Commission, a specific conclusion on this active substance was finalised by EFSA on 19 December 2012 (EFSA, 2013a) concerning 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[7] to restrict the uses of clothianidin, 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 clothianidin have been prohibited for crops attractive to bees and for cereals except for uses in permanent greenhouses and for winter cereals. Foliar treatments with plant protection products containing clothianidin have been prohibited for crops attractive to bees and for cereals with the exception of uses in permanent greenhouses and uses after flowering. Furthermore, the European Commission requested EFSA to provide a conclusion concerning an updated risk assessment for bees for clothianidin, 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 30 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 honey bees;
b) the risk to honey bees foraging in nectar or pollen in *succeeding crops*;
c) the potential uptake via roots to *flowering weeds*;
d) the risk to honey bees 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 applicants, Sumitomo Chemical Agro Europe S.A.S. and Bayer Crop Science, submitted updated dossiers in March 2015 (Bayer Crop Science) and in June 2015 (Sumitomo Chemical Agro Europe S.A.S.), which were evaluated by the designated rapporteur Member State (RMS), Belgium, in the form of an addendum to the draft assessment report (DAR) (Belgium, 2015a,b). 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 31 August 2015. The RMS collated all comments in the format of a reporting table,

[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.
[2] Commission Directive 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances. OJ L 187, 8.7.2006, p. 24–27.
[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 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 1136/2013 of 12 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid. OJ L 302, 13.11.2013, p. 34–35.
[7] 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.

which was submitted to EFSA on 25 November 2015. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

On 18 December 2015, EFSA published a technical report which summarises the outcome of the consultation process organised by the RMS, Belgium, and presents EFSA's scientific views and conclusions on the individual comments received (EFSA, 2016a).

Following consideration of the Technical Report, the European Commission requested EFSA on 23 March 2016 to organise a peer review of the RMS's evaluation of the confirmatory data submitted in relation to ecotoxicology and to deliver its conclusions on the risk assessment for bees.

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 (Belgium, 2015a,b, 2016a,b) 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 that are supported by the Confirmatory Data of Sumitomo Chemical Agro Europe S.A.S. are the currently registered uses as granular treatment in potato, maize/sweet maize, sorghum and tree nursery. Uses for maize and sweet maize are authorised in France in permanent glasshouse.

The uses that are supported by the Confirmatory Data of Bayer CropScience are the currently registered uses as seed treatment in winter cereals and beets.

A summary of these uses is reported in the Table 1; the complete list is presented in the Appendix A.

No data were provided with this confirmatory data set for other uses, such as some foliar spray applications, that might be currently authorised in some Member States.

Table 1: Summary of the uses considered in this conclusion

Crop	Application type	Seed/granular treatment rate (range)	Application rate (range) in g a.s./ha
Potato	Granule, field	–	70
Maize/sweet maize	Granule, permanent greenhouse	–	50
Sorghum	Granule, field uses	–	
Forestry nursery	Granule, field	1–2 g/plant	
Winter cereals	Seed treatment	27 g a.s./u 0.016–0.006 mg a.s./seed[(a)]	59
		50 g a.s./u 0.03–0.01 mg a.s./seed[(a)]	100

Crop	Application type	Seed/granular treatment rate (range)	Application rate (range) in g a.s./ha
Beet/sugar beet/ fodder beet	Seed treatment	10 g a.s./u 0.1 mg a.s/seed(b)	10
		60 g a.s./u 0.6 mg a.s./seed(b)	108

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): Estimated based on the substance dose rate per unit and that one unit contains 100,000 seeds.

1.2. Risk assessment methodology

The risk assessment was performed according to EFSA (2013b).

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 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 to 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 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 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 higher tier effect studies (Tier 3). According to EFSA (2013b), the fundamental basis for a Tier 3 risk assessment is to design the higher tier studies in a way that 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 as 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 the 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 this version 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 the addendum) should be considered in this risk assessment. After the meeting, the RMS provided an updated risk assessment. (Belgium, 2016a,b). 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 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 the 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 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 final addendum (Belgium, 2016a,b).

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 glands.
(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 EFSA (2013b) risk assessment schemes 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 for the field uses, were performed by considering the range of the application patterns (minimum and maximum application rate), where relevant. For the uses as granules in maize

and sweet corn in permanent glasshouse, the risk assessment was not deemed to be necessary. However, at the Member State level, exposure via consumption of contaminated water, as the only potential route of exposure from this use, should be further considered. No risk assessment could be performed for the use in forestry nursery. No sufficient information was available in the Good Agricultural Practice (GAP) table to determine the application rate in g a.s./ha and thus to perform a Tier 1 risk assessment. Nevertheless, no higher tier studies were available for this use and no extrapolation from other available studies was possible due to differences in agronomic practices.

2. Toxicity endpoints

The endpoints to be used for risk assessments were discussed and agreed at the Pesticides Peer Review Meeting 145. It was noted that the difference between oral toxicity for the formulation and the technical 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 for all the acute risk assessments to honeybees.

According to EFSA (2013b) and in line with the previous conclusion of clothianidin (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 of clothianidin (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.

The endpoints selected for risk assessment are reported in Appendix B. The previous EU agreed acute (oral and contact) endpoints for honeybees were maintained (EFSA, 2015). New acute contact and oral endpoints were provided for bumble bees.

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 in nectar or pollen is considered.

3.1. Tier 1 risk assessment

A Tier 1 risk assessment, based on the EFSA (2013b), was performed for honeybees and bumble bees (acute) and a screening assessment was carried out for bumble bees and solitary bees with surrogate endpoints. No data were available for bumble bee and solitary bee larvae. No data were available to perform a Tier 1 risk assessment for forestry nursery use.

A high risk was indicated to honeybees (acute, chronic and to larvae) and bumble bees (acute), while a high chronic risk to bumble bees and high acute and chronic risk to solitary bees was not excluded with the screening assessment. This conclusion was relevant for the exposure in the succeeding crop scenario for all the field uses under evaluation, except for forestry nursery (see Appendix A).

3.2. Tier 2 exposure characterisation

A number of studies were submitted in which the concentration of clothianidin in nectar and pollen for bee attractive crops (phacelia, maize or mustard) could be measured for succeeding crops grown on soils with a history of clothianidin use (referred to in the addendum (Belgium, 2016a,b) as 'natural' soil residues) or for succeeding crops grown on soils treated with clothianidin to obtain a theoretical plateau concentration (referred to in the addendum as 'forced' soil residues). The experts at the Pesticides Peer Review Meeting 145 agreed that the most realistic data available of the entire data set (both granular applications and seed treatments) should be considered in order to address the succeeding crops scenarios for all the uses under evaluation (except for forestry nursery). The residue levels measured under 'natural exposure' conditions were considered the most representative of the accumulation over years. However, as the geographical spread of the available studies was limited, instead of the 90th percentile values recommended by EFSA (2013b), the highest residue values measured for pollen (1.5 μg a.s./kg) and nectar (0.6 μg a.s./kg) were agreed to be used to refine the risk assessment.

3.3. Tier 2 risk assessment

The default shortcut values proposed in the EFSA (2013b) were refined based on the above residue levels in pollen and nectar. The calculations of the refined shortcut values were performed with the EFSA SHVAL tool (EFSA, 2014) and were reported in the revised addendum (Belgium, 2016a,b). The Tier 2 risk assessments indicated that the acute risk to honeybees and the risk to honeybee larvae were low. However, the chronic risk to honeybees and the acute risk to bumble bees were still indicated as high, while a high chronic risk to bumble bees and high acute and chronic risk to solitary bees were not excluded, based on the screening assessment with a refined exposure. This conclusion is relevant for the exposure in the succeeding crop scenario for all the field uses under evaluation (except for forestry nursery) (see Appendix A).

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. The majority of the studies were performed in maize and were already evaluated in the previous conclusion of clothianidin (EFSA, 2013a). No new elements were provided triggering a re-evaluation of these studies, except for a review of the long-term (3-year) honeybee field study performed in France with a granular formulation (Thompson, 2011; Peer Review Report of EFSA, 2013a). This review was discussed at the Pesticides Peer Review Meeting 145. It was noted that the statistical power of the study was low. Furthermore, it was noted that the variability partitioning observed in this study may not represent the real natural variability. Overall, it was agreed that the re-analysis provided did not address the concerns already identified in the previous conclusion (EFSA, 2013a), where the study was considered not sufficient to draw a firm conclusion on the cause–effect relationship. In addition, it was argued that studies on maize are of low representativeness for succeeding crops that produce nectar.

As the higher tier risk assessment for the succeeding crops, also a large monitoring study on oilseed rape performed in Germany was considered. The rationale was that the exposure level for bees on treated oilseed rape crops should represent a worst case for the succeeding crops, and therefore, the biological observations on bees in this monitoring study can be extrapolated to other scenarios. The experts considered that this argumentation might be reasonable for honeybees and bumble bees. However, the study should be carefully evaluated before drawing firm conclusions on any possible extrapolation of the results on honeybees and bumble bees to scenarios other than the treated crop (i.e. succeeding crops, but also field margin and treated crop other than oilseed rape). For solitary bees, the experts considered that the extrapolation to other crops or scenarios could not be reliably performed because the conditions in the study were likely not worst case for these species. EFSA noted that the complete study report package including statistical analysis (MDD) has been re-submitted in the context of the EFSA open call for data, as indicated by the Applicant in the reporting table (BCS comment 5(50)) on confirmatory data on clothianidin (EFSA, 2016a). Therefore, these data will be in depth evaluated under the mandate for the review of clothianidin.[8]

Overall, the available higher tier risk assessment could not be considered suitable to further address the risk.

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

For the uses as *granules*, a Tier 1 risk assessment based on EFSA (2013b), was performed by EFSA for honeybees and bumble bees (acute) and a screening assessment was carried out for bumble bees and solitary bees with surrogate endpoints. No data were available for bumble bee and

[8] EFSA-Q-2015-00771. Request for EFSA to provide scientific and technical assistance (EFSA Conclusion) in accordance with Article 21 of Regulation (EC) No 1107/2009 to perform an evaluation of neonicotinoids (clothianidin) as regards the risk to bees (seed treatment and granules uses).

solitary bee larvae. Tier 1 calculations were only performed for uses as granules in potatoes and sorghum. Tier 1 calculations were not relevant for the uses in maize/sweet maize in permanent glasshouse.

On the basis of the available Tier 1 calculations, for the uses in potatoes and sorghum, a high risk was indicated to honeybees (acute, chronic and to larvae) and bumble bees (acute), while a high chronic risk to bumble bees and high acute and chronic risk to solitary bees was not excluded with the screening assessment. No data were available to perform a Tier 1 risk assessment for forestry nursery use.

Due to the persistence of clothianidin in soil and its systemic properties, the experts at the meeting agreed to consider the 'flowering weeds' scenario as relevant also for *seed treatment*, although is 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 granules*, a large-scale monitoring study was submitted to assess the weeds population present in maize and potato fields, at different crop growth stages. No data were available for the uses on sorghum and forestry nursery. Extrapolation from the available data was considered appropriate from maize to sorghum. However, due to different agronomic practices this extrapolation could not be performed for the use in forestry nursery, therefore a data gap was identified for this use.

At the Pesticides Peer Review Meeting 145, it was agreed that a rough estimation of the total weed ground cover at the field sites monitored in this study should be considered in order to draw a conclusion on the relevance of the weed scenario in relation to the trigger of 10% weed coverage, as suggested in EFSA (2013b). However, no data were reported in the study to perform such estimation. Nevertheless, the information available showed a relatively low occurrence of weeds in potato and maize fields.

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 beets 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. From the data provided 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 for both granular application in potato and sorghum and for the seed treatment uses in winter cereals and sugar beet could be considered generally unlikely to exceed the trigger of 10% suggested in EFSA (2013b). Therefore, the exposure to bees via this scenario could be considered of low relevance for these uses, particularly when weed control is applied. Further data would be needed for the use as granule in forestry nursery.

5. Honeydew

In this Section, the risk to honeybees (point d of the confirmatory data requirement) foraging in nectar or pollen was considered.

For the uses as *granules*, the applicant did not provide any data regarding the presence of honeydew, specifically in clothianidin-treated crops. However, the large scale monitoring study submitted for weeds and mentioned in the above section, was also aimed at determining the presence of honeydew in potato and maize during the growing season. The study showed a limited occurrence of honeydew. Therefore, the experts at the Pesticides Peer Review Meeting 145 concluded that honeydew can be considered as a not relevant route of exposure.

For the uses as *seed treatment*, statement papers were provided by the applicant. The reasoned case argued that clothianidin is intended to control sap sucking insects; therefore, at least during the first weeks of crop's growth, 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. During the meeting, additional information from the open literature about aphid resistance was also considered. It was concluded that resistance to clothianidin by aphids could not be generally excluded.

Overall, on the basis of the available data, showing the low occurrence of honeydew, the experts agreed that honeydew can be considered as a low relevance route of exposure for all the field uses under evaluation, i.e. potato, sorghum, winter cereals, sugar beets and forestry nursery.

6. Guttation fluids

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

6.1. Tier 1 risk assessment

The first-tier calculations were not performed because measured values of clothianidin in guttation water were available to perform a Tier 2 risk assessment.

6.2. Tier 2 risk assessment

Studies investigating the occurrence and frequency of guttation and the effects on honeybees were provided. 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 level 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; the TWA values over 10 days for the chronic assessment to adults.

For the uses as *granules* in potatoes, a new study was available. The study focused on the effects on honeybee colonies from exposure to the guttation fluid used as a source of water, when clothianidin is applied in-furrows at sowing of potato seeds. The other studies provided were already considered in EFSA, 2015 and evaluated as not suitable for risk assessment. The residue values from the new study to be used for Tier 2-ETR calculations were: 1.317 mg a.s./L (max residue), 0.917 mg a.s./L (5-day TWA) and 0.391 mg a.s./L (10-day TWA). The risk assessment performed with these values indicated a high risk (acute, chronic and to larvae) for potatoes. For the uses as granules in maize, the available residue levels were: 9.109 mg a.s./L (max residue), 4.943 mg a.s./L (5-day TWA) and 3.446 mg a.s./L (10-day TWA). However, the Tier 2-ETRs were not calculated because for uses in permanent glasshouse, as the exposure is not relevant. For the uses as granules in sorghum and forestry nursery, no data were provided.

For the uses as *seed treatment* in winter cereals and beets, new studies were provided. The residue values from these studies to be used for Tier 2-ETR calculations were, for winter cereals: 13 mg a.s./L (max residue), 5.84 mg a.s./L (5-day TWA) and 5.53 mg a.s./L (10-day TWA). For sugar beet, based on the limited number of samples available, there was no indication that clothianidin concentration in guttation fluid declines over time. Therefore, the maximum available residue value of 0.327 mg a.s./L was used for the Tier 2-ETRs.

Overall, based on the Tier 2-ETRs, a high risk (acute, chronic and to larvae) was indicated for potatoes, winter cereals and sugar beet (see Appendix B).

6.3. Higher tier risk assessment

Higher tier studies were considered (i.e. a new study for the use as granules in potatoes and five studies for the seed treatment of winter cereals and sugar beet). Beside some temporal slight tendency of higher bee mortality compared with the control in some studies, no apparent effects on the honeybee colonies were observed. Several concerns were raised by the experts on the use of few studies to address the risk from the exposure to guttation fluids at higher tier level. For example, it was questioned whether the studies may be not representative of worst-case conditions, or different geographic situations, or 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 the guttation fluids may 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 on potatoes, winter cereals and beets can be considered of low relevance. No data were available for sorghum and forestry nursery uses and for extrapolation of data from other crops.

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 the uses as *granules* in the previous EFSA conclusion on clothianidin (EFSA, 2013a), it was concluded a low risk resulting from the exposure to dust deposition assuming that there is no air-flow in the application machinery when the granule are applied in furrow. At the Pesticides Peer Review Meeting 145, some experts reported experiences indicating that some dust drift may occur for granular products. Therefore, it was suggested that, at the Member State level, the relevance of the exposure through dust drift should not be excluded for granules, until further information is provided with regard to the transplanting/sowing machinery to be used.

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

7.1. Tier 1 risk assessment

For *winter cereals* (both lowest and highest application rates), a high risk was indicated to honeybees (acute, chronic and to larvae), bumble bees (acute) or a high risk could not be excluded for bumble bees (chronic) and solitary bees, based on the HQ and the ETR values according to EFSA (2013b).

For *sugar beets*, the HQs indicated a low risk from acute contact exposure to honeybees, bumble bees and solitary bees (both lowest and highest application rates) according to EFSA (2013b).

The ETRs, for both the lowest and the highest application rate, indicated a low risk from oral exposure for honeybees (acute, chronic and to larvae) for both the field margin and adjacent crops. For bumble bees, the ETRs indicated a low acute risk for both the field margin and adjacent crops, but a high chronic risk was not excluded. For solitary bees, the ETRs indicated a low acute and chronic risk for the field margin and a low acute risk for adjacent crops. A high chronic risk was, however, not excluded for adjacent crops.

7.2. Higher tier risk assessment

The applicant submitted studies in which the dust drift ground deposition was assessed in winter cereals. No Heubach a.s. values were provided for these studies; only some values on the dustiness of 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 dust deposit default values in the 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.

At the Pesticides Peer Review Meeting 145, the experts considered the suggestion given in the EFSA (2013b), i.e. to select the sowing machine at the EU level that delivers 90th percentile (based on ranking of dust emission and area of use), in order to ensure the machine used for experimental measurement covers the 90th percentile of exposure. The experts noted that there is indeed no information whether the machinery used in all studies covers the 90th percentile of exposure. It was furthermore acknowledged that 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 could 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 in pollen and/or nectar in the treated field is considered.

8.1. Tier 1 risk assessment

For the uses *as granules* in potato, the Tier 1-ETRs indicated a high risk from oral exposure to honeybees (acute, chronic and to larvae) and bumble bees (acute); while the chronic risk to bumble bees and the acute and chronic risk to solitary bees could not be excluded based on screening assessment. For sorghum, the Tier 1-ETRs indicated a high risk from oral exposure to honeybees (chronic) and bumble bees (acute); while the chronic risk to bumble bees and the acute and chronic risk to solitary bees could not be excluded based on screening assessment. However, the acute risk to honeybees and the risk to larvae were indicated as low. For the uses in maize and sweet corn, the risk was considered as low because the currently authorised uses evaluated in this conclusion are grown in permanent structures. No data and no Tier 1 risk assessment for the use in forestry nursery were provided, therefore a data gap was identified for this use.

As regards the oral exposure, the uses as *seed treatment* of winter cereals and beets, the applicant argued that the treated crop scenario is unlikely to have an effect on colony or population level. However, given that EFSA (2013b) considered that further data should be provided to exclude collection of pollen by honeybees, bumble bees and solitary bees; at the Pesticides Peer Review Meeting 145, it was agreed that exposure through ingestion of contaminated nectar and pollen should be assessed. An oral risk assessment was provided with the revised addendum (Belgium, 2016a,b). For the uses in winter cereals (lowest and highest application rate), the Tier 1-ETRs indicated a high risk from oral exposure to honeybees (chronic) and bumble bees (acute); while the chronic risk to bumble bees and the acute and chronic risk to solitary bees could not be excluded based on screening assessment. However, the acute risk to honeybees and the risk to larvae were indicated as low. For the uses as seed treatment in beets (lowest and highest application rate), it was concluded that this scenario is only relevant, where beets are grown for seed production. However, since in the GAP table available with the Addendum this information was not reported, in the Member States where the uses as seed treatment of beets are authorised to be grown for seed production, this issue should be further considered.

8.2. Tier 2 risk assessment

In line with the conclusion for the exposure scenario of succeeding crops, the experts at the Pesticides Peer Review Meeting 145 agreed that the highest available residue values in nectar and pollen should be used to refine the risk assessment. Data were available for *granular* application in potato and maize. However, the risk for maize and sweet corn grown in permanent glasshouse was considered not relevant, therefore only the refinement for potatoes was considered in this conclusion. The highest residue level in pollen of 31 μg a.s./kg, obtained from a study where clothianidin was applied at a rate of 80 g a.s./ha, was selected to refine the risk assessment. The default shortcut values proposed in EFSA (2013b) were refined based on this residue level. The calculations of the refined shortcut values were performed with the EFSA SHVAL tool (EFSA, 2014) and were reported in the revised addendum (Belgium, 2016a,b). The Tier 2 risk assessments indicated a low acute risk to honeybees and a low risk to honeybee larvae. However, the chronic risk to on honeybees and the acute risk to bumble bees was still indicated as high; while the chronic risk to bumble bees and the acute and chronic risk to solitary bees could not be excluded based on screening assessment with a refined exposure.

No data on measured residues in pollen from sorghum was available; no measured residue data were available also for winter cereals. Therefore, a Tier 2 risk assessment could not be performed.

8.3. Higher tier risk assessment

No new higher tier data was provided to further address the risk for the granular uses in potato. For the uses as seed treatment in winter cereals, no specific higher tier data was available. Extrapolation of biological observations from the large monitoring study on oilseed rape might be considered, when the study will be in depth evaluated, as discussed in Section 3.

9. Overall conclusion and data gaps

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

9.1. Field uses

- For all the field uses, only a screening risk assessment was performed for bumble bees (chronic) and solitary bees (acute and chronic) 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).
- For all the field uses considered, in the *succeeding crop* scenario, a high risk was identified or high risk could not be excluded. Further data should be provided for the granular uses in forestry nursery (data gap).
- For the uses in potatoes, sorghum, cereals and beets, the exposure via the *flowering weeds* was considered not relevant, due to the low coverage in field of flowering weeds. However, further data should be provided for the granular uses in forestry nursery (data gap).
- For the uses in potatoes, sorghum, cereals and beets, the exposure via *honeydew* was deemed to be as not relevant.
- For the uses in potatoes, cereals and beet, the exposure via *guttation fluids* was concluded as not the primary route of exposure for bees. However, further data should be provided for the granular uses in sorghum and forestry nursery (data gap).
- For the uses as granules, the exposure from *dust* in the field margin and adjacent crop should be further considered at the Member State level. For the uses as seed treatment of winter cereals, the risk from exposure via *dust* was indicated as high; for the uses in sugar beets, the risk was indicated as low for honeybees; however, a high risk to bumble bees and solitary bees was not excluded (data gap).
- For the use as granules in sorghum, the risk from the exposure via 'pollen' in *treated crops* was indicated as high or could not be excluded. For the uses in potatoes and winter cereals, the risk was indicated as high for honeybees; the risk to bumble bees and solitary bees could not be excluded (data gap). For the uses in sugar beets, the treated crop scenario was not considered relevant. Further consideration at the Member States level will be necessary, when beets are grown for seed production.

9.2. Glasshouse uses (permanent structure)

- For the uses as granules in maize/sweet corn in permanent glasshouse, all the aspects of the risk assessment within the confirmatory data requirement, could be considered of low relevance due to the low exposure.

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 for honeybees from exposure to dust drift was assessed as low for seed treatment of beets, providing that deflector is applied during the sowing.
- A low risk can be concluded from dust exposure for granular uses, assuming that that there is no air-flow in the application machinery when the granules are applied in the furrow.
- The risk from exposure to nectar and pollen in the treated crop for seed treatment of beets was assessed as low providing beets are harvested before flowering.

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

The assessments are considered not finalised when there was no data or when only a screening level assessment could be performed (e.g. bumble bees and solitary bees). 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	Adjacent crop	Succeeding crop	Guttation fluid	Honeydew	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Honeydew	Treated crop scenario	Weed scenario	Field margin	Adjacent crop	Succeeding crop	Honeydew
Potatoes	Granule	70 g a.s./ha	Risk identified	R				R			R				R							
			Assessment not finalised								X				X		X				X	
Sorghum	Granule Field/open protected structure	50 g a.s./ha	Risk identified	R				R			R				R							
			Assessment not finalised						X		X				X		X				X	
Maize/ sweet corn	Granule permanent glasshouse	50 g a.s./ha	Risk identified																			
			Assessment not finalised																			
Forestry nursery	Granule	1–2 g/plant (planting hole) 4 g/m	Risk identified																			
			Assessment not finalised	X	X			X	X		X	X			X		X	X			X	
Winter cereals	Seed treatment	59–100 g a.s./ha	Risk identified	R		R	R	R			R		R	R	R							
			Assessment not finalised								X		X	X	X		X		X	X	X	
Beets, sugar beets, fodder beets	Seed treatment	10 g–108 g a.s./ha	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.

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Abbreviations

a.s.	active substance
DAR	draft assessment report
DT_{50}	period required for 50% dissipation (define method of estimation)
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 hypopharygeal 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
MDD	minimum detectable difference
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
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
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/ha min–max	kg a.s./ha min–max		
Winter wheat, winter barley, rye, triticale, spelt, oats	BE	Argento	F	EHD	FS	250	Seed treatment	00	1	na	na		0.090	na	Sowing rate: 1.8 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 kg/u
Winter barley, winter rye, winter triticale	CZ	Deter	F	APHISP, PSAMAL	FS	250	Seed treatment	00	1	na	na		0.080	na	Sowing rate: 1.6 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 kg/u
Winter wheat, winter barley	HU	Yunta Quattro	F	AGRISP, EHD, OSCIFR	FS	166.7	Seed treatment	00	1	na	na		0.06668	na	Sowing rate: 2.0 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.03334 kg/u
Winter wheat, winter barley, winter oat, triticale, rye, durum wheat	IE	Redigo Deter	F	AGRISP, APHIFA, ARIOSP, DEROSP	FS	250	Seed treatment	00	1	na	na		0.100	na	Sowing rate: 2.0 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 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/ha min–max	kg a.s./ha min–max		
Wheat, barley	RO	Yunta Quattro	F	AGRISP, HYLECO, HYLESP, OSCIFR, ZABUTE	FS	166.7	Seed treatment	00	1	na	na		0.05867	na	Sowing rate: 2.2 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.02667 kg/u
Winter wheat, winter barley, winter rye, triticale, durum wheat	SK	Deter	F	APHIFA	FS	250	Seed treatment	00	1	na	na		0.100	na	Sowing rate: 2.0 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 kg/u
Winter wheat, winter barley, winter oat, rye, triticale, durum wheat	UK	Deter	F	ACB, AGRISP, APHIFA	FS	250	Seed treatment	00	1	na	na		0.100	na	Sowing rate: 2.0 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 kg/u
Winter wheat, winter barley, winter oat, rye, triticale, durum wheat	UK	Redigo Deter	F	AGRISP, APHIFA, ARIOSP, DEROSP	FS	250	Seed treatment	00	1	na	na		0.100	na	Sowing rate: 2.0 unit seeds/ha 1 u = 100 kg Active substance dose rate: 0.050 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/ha min–max	kg a.s./ha min–max		
Sugar beet Fodder beet	AT	Poncho Beta	F	AGRISP ATOMLI APHIFA MYZUPE PEGOHY PHYESP	FS	400	Seed treatment	00	1	na	na		0.060	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Beet	BE	Poncho	F	AGRISP ATOMLI CHAESP EHD PEGOHY PEGOSP	FS	600	Seed treatment	00	1	na	na		0.090	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Beet	BE	Janus	F	AGRISP ATOMLI BLANSP SCUTSP	FS	100	Seed treatment	00	1	na	na		0.015	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Beet	BE	Poncho Beta	F	AGRISP ATOMLI BLANSP SCUTSP TIPUSP HALCSP	FS	400	Seed treatment	00	1	na	na		0.090	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	HR	Poncho FS 600 Rot	F	ATOMLI EHD EMB PEGOHY	FS	600	Seed treatment	00	1	na	na		0.072	na	Sowing rate: 1.2 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 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/ha min–max	kg a.s./ha min–max		
Beet Fodder beet	CZ	Janus	F	ATOMLI	FS	100	Seed treatment	00	1	na	na		0.011	na	Sowing rate: 1.1 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Beet Fodder beet	CZ	Poncho Beta	F	ATOMLI APHIFA CHAETI CHAECO EMB	FS	400	Seed treatment	00	1	na	na		0.066	na	Sowing rate: 1.1 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	DK	Janus	F	ATOMLI PHDCSP	FS	100	Seed treatment	00	1	na	na		0.010	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Sugar beet	DK	Mundus	F	CHAEAR PEGOSP PHYESP	FS	300	Seed treatment	00	1	na	na		0.030	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.030 kg/u
Sugar beet	DK	Poncho Beta	F	ATOMLI AGRISP PHDCSP	FS	400	Seed treatment	00	1	na	na		0.060	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 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/ha min–max	kg a.s./ha min–max		
Sugar beet	FI	Poncho Beta	F	ATOMLI AGRISP PHDCSP	FS	400	Seed treatment	00	1	na	na		0.060	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Fodder beet	DE	Poncho Ungefaerbt	F	AGRISP ATOMLI APHISP PEGOHY	FS	600	Seed treatment	00	1	na	na		0.078	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Beet	DE	Janus	F	ATOMLI PEGOHY	FS	100	Seed treatment	00	1	na	na		0.013	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Beet Fodder beet	DE	Mundus	F	ATOMLI APHDSP PEGOHY	FS	300	Seed treatment	00	1	na	na		0.039	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.030 kg/u
Beet	DE	Poncho Beta	F	ATOMLI AGRISP APHISP BRACSP PEGOHY	FS	400	Seed treatment	00	1	na	na		0.078	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 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/ha min–max	kg a.s./ha min–max		
Sugar beet	HE	Janus	F	AGRISP CHAETI	FS	100	Seed treatment	00	1	na	na		0.0154	na	Sowing rate: 1.54 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Sugar beet	HU	Poncho Beta	F	AGRISP CLEOPL MELOME	FS	400	Seed treatment	00	1	na	na		0.078	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	IT	Poncho Bianco	F	AGRISP ATOMLI CHAETI	FS	600	Seed treatment	00	1	na	na		0.045	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.030 kg/u
Sugar beet	IT	Poncho Bianco	F	APHIFA MYZUPE	FS	600	Seed treatment	00	1	na	na		0.090	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	IT	Poncho Beta	F	AGRISP ATOMLI	FS	400	Seed treatment	00	1	na	na		0.045	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.030 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/ha min–max	kg a.s./ha min–max		
Sugar beet	IT	Poncho Beta	F	CHAETI	FS	400	Seed treatment	00	1	na	na		0.0675	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.045 kg/u
Sugar beet	IT	Poncho Beta	F	APHIFA MYZUPE PEGOHY	FS	400	Seed treatment	00	1	na	na		0.090	na	Sowing rate: 1.5 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Fodder beet	NL	Poncho Beta	F	APHIFA AGRISP ATOMLI BLANGU BRACSP SCUTIM MYZUPE MYZUAS PEGOSP TIPUSP	FS	400	Seed treatment	00	1	na	na		0.060	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	PL	Janus	F	APHIFA ATOMLI EMB HYLERA PHYESP	FS	100	Seed treatment	00	1	na	na		0.010	na	Sowing rate: 1.0 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 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/ha min–max	kg a.s./ha min–max		
Sugar beet	PL	Mundus	F	AGRISP APHIFA ATOMLI CHAECO EMA PEGOHY	FS	300	Seed treatment	00	1	na	na		0.036	na	Sowing rate: 1.2 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.030 kg/u
Sugar beet	RO	Poncho Beta	F	AGRISP CHAEBR CLEOPU TANYDI	FS	400	Seed treatment	00	1	na	na		0.084	na	Sowing rate: 1.4 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Beet	SK	Poncho	F	APHISP ATOMLI LEMASP PHYESP	FS	600	Seed treatment	00	1	na	na		0.0546	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.042 kg/u Once per 2 years
Beet	SK	Janus	F	APHISP ATOMLI PHYESP	FS	100	Seed treatment	00	1	na	na		0.013	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.010 kg/u
Beet Fodder beet	SK	Poncho Beta	F	APHISP ATOMLI LEMASP PHYESP	FS	400	Seed treatment	00	1	na	na		0.078	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u Once per 3 years

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/ha min–max	kg a.s./ha min–max		
Sugar beet	SI	Poncho FS 600 Rot	F	APHISP ATOMLI EMB PEGOHY	FS	600	Seed treatment	00	1	na	na		0.084	na	Sowing rate: 1.4 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet	ES	Poncho FS 600 Rot	F	AGRISP CHAETI EHD	FS	600	Seed treatment	00	1	na	na		0.108	na	Sowing rate: 1.8 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Sugar beet Fodder beet	UK	Poncho Beta	F	AGRISP ANURHE APHIFA ATOMLI MYZUPE PEGOHY PHYESP PSYICH	FS	400	Seed Treatment	00	1	na	na		0.078	na	Sowing rate: 1.3 unit seeds/ha 1 u = 100,000 Active substance dose rate: 0.060 kg/u
Potato	BU	Santana 0.7G	F	*Wireworms*	GR	0,7%	Soil application	00	1	n.a.	n.a.	n.a.	0.07	n.a.	Minor use registration
Maize	FR	Cheyenne or Santana	G	*Wireworms*	GR	0,7%	Soil application	00	1	n.a.	n.a.	n.a.	0.05	n.a.	
Sweet maize				*Wireworms*	GR	0,7%	Soil application	00	1	n.a.	n.a.	n.a.	0.05	n.a.	
Sorghum			F	*Wireworms*	GR	0,7%	Soil application	00	1	n.a.	n.a.	n.a.	0.05	n.a.	Sowing forbidden between the 1st of January and the 30th of June

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/ha min–max	kg a.s./ha min–max		
Forestry nursery	HU	Santana 1G Or Cheyenne 1G	F	Soil pests	GR	1%	Soil application	00	1	n.a.	n.a.	n.a.	1–2 g/plant (planting hole) 4 g/m	n.a.	

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.

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

PEC soil

Granular application

Method of calculation	Soil DT_{50} (d): 305.4 (worst case from field dissipation studies at 20°C* as reported in the Review Report SANCO/10533/05). Kinetics: SFO Tool: ESCAPE 2.0 (8 October 2011) with constant conditions *Note: According to the current practice, DT_{50} not normalised to reference conditions (20°C and pF 2) should be used for PEC_{soil} calculations
Application data	Crop: potato Depth of soil layer: 5 cm (and 20 cm as tillage depth) Soil bulk density: 1.5 g/cm^3 % plant interception: 0 (no crop interception) Number of applications: 1 Application rate: 70 g a.s./ha
Plateau concentration ($PEC_{plateau}$)	Final background concentration in total soil over 20 cm: 0.0181 mg/kg (estimated to occur after 10 years without crop rotation)

Seed treatment

Method of calculation	Soil DT_{50} (d): 305.4 (worst case from field dissipation studies at 20°C* as reported in the Review Report SANCO/10533/05). Kinetics: SFO Tool: ESCAPE 2.0 (8 October 2011) with constant conditions *Note: According to the current practice, DT_{50} not normalised to reference conditions (20°C and pF 2) should be used for PEC_{soil} calculations
Application data	Crop: winter cereals Depth of soil layer: 5 cm (and 20 cm as tillage depth) Soil bulk density: 1.5 g/cm^3 % plant interception: 0 (no crop interception)
	Number of applications: 1 Application rate: 100 g a.s./ha
Plateau concentration ($PEC_{plateau}$)	Final background concentration in total soil over 20 cm: 0.0181 mg/kg (estimated to occur after 15 years without crop rotation)

Toxicity endpoints selected for risk assessments or for screening assessment

Risk assessment type	Endpoint	Honeybees	Bumble bees	Solitary bees
Acute contact	48-h LD_{50} µg a.s./bee (technical)	0.0275	0.1483	0.00275[(a)]
Acute oral	48-h LD_{50} µg a.s./bee technical	0.00379	0.001911	0.000379[(a)]
Chronic	10-day LDD_{50} µg a.s./bee per day (technical)	0.00138 (based on actual food consumption)	0.000138[(a)]	0.000138[(a)]
Larvae	7-day NOEL mortality µg a.s./larva per development period (technical)	0.00528 (provisional endpoint because of 3 days exposure and nominal food consumption)	No endpoint available	No endpoint available
Development of hypopharyngeal glands	NOEL (µg a.s./bee per day)	No endpoint available	Not relevant	Not relevant

(a): Surrogate endpoint by using the honeybee toxicity endpoint divided by a factor of 10.

TIER 1 risk assessment based on EFSA (2013b)

Potatoes 70 g a.s./ha (granules)

Acute, chronic and larvae oral exposure – **TIER 1-ETRs**

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	**0.222**	0.2	**1.099**	0.036	**1.842**	0.040
	Weeds	**1.939**		**71.429**		**127.105**	
	Next crop	**12.929**		**32.967**		**90.263**	
Chronic	Treated crop	**0.609**	0.03	**15.217**	0.0048	**5.072**	0.0054
	Weeds	**4.109**		**897.826**		**350.000**	
	Next crop	**27.391**		**395.652**		**248.551**	
Larva	Treated crop	**0.027**	0.2	No data	0.2	No data	0.2
	Weeds	**0.795**		No data		No data	
	Next crop	**5.303**		No data		No data	

Sorghum 50 g a.s./ha (granules)

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

Category	Scenario	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.158	0.2	**0.785**	0.036	**1.316**	0.040
	Weeds	**14.644**		**51.020**		**90.789**	
	Next crop	**9.235**		**23.548**		**64.474**	
Chronic	Treated crop	**0.435**	0.03	**10.870**	0.0048	**3.623**	0.0054
	Weeds	**2.935**		**641.304**		**250.000**	
	Next crop	**19.565**		**282.609**		**177.536**	
Larva	Treated crop	0.019	0.2	No data	0.2	No data	0.2
	Weeds	**0.568**		No data		No data	
	Next crop	**3.788**		No data		No data	

Forestry nursery (granules)

Not data available, data gap.

Winter cereals (wheat, barley, rye, triticale, spelt, oats) (seed treatment) 100 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin[a]	**36.0**	14	**6.7**	2.3	**360.0**	2.6

(a): The HQs include the application of deflectors.

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

Category	Scenario[a]	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.03[b]	0.2	**0.16**	0.036	**0.26**	**0.04**
	Field margin	**0.97**		**3.37**		**5.99**	
	Adjacent crop	**0.96**		**2.81**		**7.20**	
	Next crop	**18.47**		**47.10**		**128.95**	
Chronic	Treated crop	**0.09**	0.03	**2.17**	0.0048	**0.72**	0.0054
	Field margin	**2.08**		**42.33**		**16.50**	
	Adjacent crop	**2.02**		**34.43**		**19.83**	
	Next crop	**39.13**		**565.22**		**355.07**	
Larva	Treated crop	0.00[b]	0.2	No data	0.2	No data	0.2
	Field margin	**0.41**		No data		No data	
	Adjacent crop	**0.40**		No data		No data	
	Next crop	**7.58**		No data		No data	

(a): For field margin and adjacent crops, the ETRs include the application of deflectors.
(b): The ETRs were calculated assuming the seed dressing rate of 0.01 mg a.s/seed, which represents the best case situation. The ETRs assuming a weight of 61 g seed/1,000 (i.e. worst case 0.03 mg a.s./seed) were still below the triggers.

Winter cereals (wheat, barley, rye, triticale, spelt, oats) (seed treatment) 59 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin[a]	**21.2**	14	**3.9**	2.3	**212.4**	2.6

(a): The HQs include the application of deflectors.

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

Category	Scenario[a]	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop	0.02[b]	0.2	**0.09**	0.036	**0.16**	**0.04**
	Field margin EFSA (2013)	**0.57**		**1.99**		**3.54**	
	Adjacent crop	**0.57**		**1.66**		**4.25**	
	Next crop	**10.90**		**27.79**		**76.08**	

Category	Scenario[a]	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Chronic	Treated crop	**0.05**	0.03	**1.30**	0.0048	**0.43**	0.0054
	Field margin EFSA (2013b)	**1.23**		**24.97**		**9.74**	
	Adjacent crop	**1.19**		**20.32**		**11.70**	
	Next crop	**23.09**		**333.48**		**209.49**	
Larva	Treated crop	0.00[b]	0.2	No data	0.2	No data	0.2
	Field margin EFSA (2013b)	**0.24**					
	Adjacent crop	**0.24**					
	Next crop	**4.47**					

(a): For field margin and adjacent crops, the ETRs include the application of deflectors.
(b): The ETRs were calculated assuming a seed dressing rate of 0.006 mg a.s/seed, which represents the best case situation. The ETRs assuming a weight of 61 g seed/1,000 (i.e. worst case 0.016 mg a.s./seed) were still below the triggers.

Beets, sugar beet, fodder beet (seed treatment) 108 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin[a]	0.1	14	0.0	2.3	1.2	2.6

(a): The HQs include the application of deflectors.

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

Category	Scenario[a]	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[b]	**110.82**	0.2	**282.57**	0.036	**773.68**	0.04
	Field margin	0.00		0.01		0.02	
	Adjacent crop	0.00		0.01		0.02	
	Next crop	**19.95**		**50.86**		**139.26**	
Chronic	Treated crop[b]	**234.78**	0.03	**3,391.30**	0.0048	**2,130.43**	0.0054
	Field margin	0.01		**0.14**		0.05	
	Adjacent crop	0.01		**0.12**		**0.07**	
	Next crop	**42.26**		**610.43**		**383.48**	
Larva	Treated crop[b]	**45.45**	0.2	No data	0.2	No data	0.2
	Field margin	0.00					
	Adjacent crop	0.00					
	Next crop	**8.18**					

(a): For field margin and adjacent crops, the ETRs include the application of deflectors.
(b): Not relevant when beets are not growth for seed production. The ETRs were calculated assuming the seed dressing rate of 0.1 mg a.s./seed.

Beets, sugar beet, fodder beet (seed treatment) 10 g a.s./ha

Acute contact exposure – **HQ**

Scenario	Honeybee		Bumble bee		Solitary bee	
	HQ	Trigger	HQ	Trigger	HQ	Trigger
Field margin[a]	0.0	14	0.0	2.3	0.1	2.6

(a): The HQs include the application of deflectors.

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

Category	Scenario[a]	Honeybee		Bumble bee		Solitary bee	
		ETR	Trigger	ETR	Trigger	ETR	Trigger
Acute	Treated crop[b]	**18.47**	0.2	**47.10**	0.036	**128.95**	0.04
	Field margin	0.00		0.00		0.00	
	Adjacent crop	0.00		0.00		0.00	
	Next crop	**1.85**		**4.71**		**12.89**	
Chronic	Treated crop[b]	**39.13**	0.03	**565.22**	0.0048	**355.07**	0.0054
	Field margin	0.00		**0.01**		0.0050	
	Adjacent crop	0.00		**0.01**		**0.006**	
	Next crop	**3.91**		**56.52**		**35.51**	
Larva	Treated crop[b]	**7.58**	0.2	No data	0.2	No data	0.2
	Field margin	0.00		No data		No data	
	Adjacent crop	0.00		No data		No data	
	Next crop	**0.76**		No data		No data	

(a): For field margin and adjacent crops, the ETRs include the application of deflectors.
(b): Not relevant when beets are not growth for seed production. The ETRs were calculated assuming the seed dressing rate of 0.1 mg a.s./seed.

TIER 2 – risk assessment based on EFSA (2013b) (SHVAL Tool)

TIER 2-ETRs for potatoes

Treated crop scenario

Bee type	Category	Tier 2 SV (µg/bee or µg/bee per day or µg/larva)	Toxicity endpoint	ETR	Trigger
Honeybee	Acute	0.00465	0.00379	0.086	> 0.2
Honeybee	Chronic	0.00465	0.00138	**0.327**	> 0.03
Honeybee	Larva	0.00078	0.00528	0.010	> 0.2
Bumble bee	Acute	0.01174	0.001911	**1.10**	> 0.036
Bumble bee	Chronic	0.01174	0.000138	**15.2**	> 0.0048
Solitary bee	Acute	0.00395	0.000379	**0.430**	> 0.04
Solitary bee	Chronic	0.00395	0.000138	**5.955**	> 0.0054

TIER 2-ETRs - succeeding crop scenario (relevant for all the uses under evaluation, except for forestry nursery)

Bee type	Category	Tier 2 SV (µg/bee or µg/bee per day or µg/larva)	Toxicity endpoint	ETR	Trigger
Honeybee	Acute	0.00042	0.00379	0.11	> 0.2
Honeybee	Chronic	0.00032	0.00138	**0.232**	> 0.03
Honeybee	Larva	0.00024	0.00528	0.04	> 0.2
Bumble bee	Acute	0.00057	0.001911	**0.2983**	> 0.036
Bumble bee	Chronic	0.00049	0.000138	**3.5507**	> 0.0048
Solitary bee	Acute	0.00030	0.000379	**0.79**	> 0.04
Solitary bee	Chronic	0.00030	0.000138	**2.174**	> 0.0054

TIER 2 - Estimation based on EFSA (2013b)

TIER 2-ETRs Guttation

Acute adult oral exposure					
Crop	W (µL/bee per day)	PEC (µg/µL)	48-h $LD_{50,oral}$ (µg a.s/bee)	ETR	Trigger
Potatoes	11.4	0.001317	0.00379	**4.0**	> 0.2
Chronic adult exposure					
Crop	W (µL/bee per day)	PEC (µg/µL)	10-day LDD_{50} (µg a.s/bee per day)	ETR	Trigger
Potatoes	11.4	0.000917	0.00138	**7.6**	> 0.03
Larval exposure					
Crop	W (µL/bee per day)	PEC (µg/µL)	7-day NOEL (µg a.s./larva per development period)	ETR	Trigger
Potatoes	111	0.000391	0.00528	**8.2**	> 0.2

Acute adult oral exposure						
Crop	Season	W (µL/bee per day)	PEC (µg/µL)	$LD_{50,oral}$ (µg a.s/bee)	ETR	Trigger
Winter cereals	Autumn	11.4	0.0130	0.00379	**39.1**	> 0.2
	Spring	11.4	0.00039	0.00379	**1.17**	> 0.2
Sugar beet	–	11.4	0.000327	0.00379	**0.98**	> 0.2
Chronic adult exposure						
Crop	Season	W (µL/bee per day)	PEC (µg/µL)	LDD_{50} (µg a.s/bee per day)	ETR	Trigger
Winter cereals	Autumn	11.4	0.00553	0.00138	**45.7**	> 0.03
	Spring	11.4	0.00039	0.00138	**3.22**	> 0.03
Sugar beet	–	11.4	0.000327	0.00138	**2.70**	> 0.03
Larval exposure						
Crop	Season	W (µL/bee per day)	PEC (µg/µL)	NOED (µg a.s./larva per development period)	ETR	Trigger
Winter cereals	Autumn	111	0.00584	0.00528	**122.8**	> 0.2
	Spring	111	0.00039	0.00528	**8.19**	> 0.2
Sugar beet	–	111	0.000327	0.00528	**6.87**	> 0.2