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CONCLUSION ON PESTICIDE PEER REVIEW

# Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering all uses other than seed treatments and granules[1]

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## ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including imidacloprid, as regards the risk to bees, as a follow up of previous mandates received from the European Commission on neonicotinoids. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance imidacloprid are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of all authorised uses of imidacloprid other than seed treatments and granules in Europe (including the foliar spray uses as referred to in recital 7 of Commission Implementing Regulation (EU) No 485/2013). The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as any other relevant data available at national level and made available to EFSA, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.



## KEY WORDS

imidacloprid, peer review, 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 peer review leading to the approval of this active substance was finalised on 29 May 2008 as set out in the EFSA Scientific Report (2008) 148. A specific conclusion was issued by EFSA on 19 December 2012 on the risk assessment for bees as regards the authorised uses applied as seed treatments or granules (EFSA Journal 2013;11(1):3068).

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013, to restrict the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these active substances have been prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering.

With reference to Article 31 of Regulation (EC) No 178/2002 and in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data, in June 2013 the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for the three neonicotinoids (namely clothianidin, imidacloprid and thiamethoxam), taking into account all uses other than seed treatments and granules including foliar spray uses as mentioned in recital 7 of Commission Implementing Regulation (EU) No 485/2013 (i.e. including the uses that may have been withdrawn due to restrictions of Regulation (EU) No 485/2013). This mandate is a follow up of previous mandates received from the European Commission on neonicotinoids to perform an evaluation with regard to the acute and chronic effects on colony survival and development, taking into account effects on bee larvae and bee behaviour, and the effects of sublethal doses on bee survival and behaviour.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing data submitted for the approval of the active substance at EU level and for the authorisation of plant protection products containing imidacloprid at Member State level, taking into account the uses other than seed treatments and granules. In addition, any other relevant data available at national level and made available to EFSA were taken into account and, where relevant, the results of a systematic literature review awarded by EFSA and conducted by the Food and Environmental Research Agency (FERA) on clothianidin, thiamethoxam and imidacloprid, and the risk to bees (EFSA supporting publication 2015:EN-756). The EFSA guidance document on the risk assessment of plant protection products on bees (EFSA Journal 2013;11(7):3295) was used for the current evaluation.

For all the authorised uses, high risks were identified or high risks could not be excluded or the risk assessment could not be finalised. For the authorised uses in permanent greenhouse structures, a low risk to honeybees, bumble bees and solitary bees was concluded for all exposure routes except the risk assessment for honeybees from residues in surface water. The risk assessment for honeybees from residues in surface water could not be finalised with the available information. However, it is noted that pertinent risk assessments were available for two open field spray uses (the EU representative uses in tomato and apple) that indicated a low risk to honeybees.

## TABLE OF CONTENTS

## BACKGROUND

Imidacloprid was included in Annex I to Directive 91/414/EEC[3] on 1 August 2009 by Commission Directive 2008/116/EC[4], and has been deemed to be approved under Regulation (EC) No 1107/2009[5], in accordance with Commission Implementing Regulation (EU) No 540/2011[6], as amended by Commission Implementing Regulation (EU) No 541/2011[7]. The peer review leading to the approval of this active substance was finalised on 29 May 2008 as set out in the EFSA Scientific Report (EFSA, 2008). For the request of the European Commission, a specific conclusion was issued on 19 December 2012 on the risk assessment for bees as regards the authorised uses applied as seed treatments or granules (EFSA, 2013a). In addition, EFSA finalised a conclusion following the submission of confirmatory data concerning the risk assessment for operators and workers, and the risk to birds and mammals (EFSA, 2014a), and a specific conclusion as regards the risk assessment for aquatic organisms (EFSA, 2014b).

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013[8], to restrict the uses of clothianidin, thiamethoxam and imidacloprid, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid have been prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing these active substances have been prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering.

With reference to Article 31 of Regulation (EC) No 178/2002[9] and in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data, and as a follow up of previous mandates on neonicotinoids, on 21 June 2013 the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for the three neonicotinoids (namely clothianidin, imidacloprid and thiamethoxam), in particular with regard to the acute and chronic effects on colony survival and development, taking into account effects on bee larvae and bee behaviour, and the effects of sublethal doses on bee survival and behaviour. With reference to the pending evaluation by EFSA of the foliar uses of these 3 neonicotinoids, as referred to in recital 7 of Commission Implementing Regulation (EU) No 485/2013, with this follow up mandate the European Commission requested EFSA to undertake a review of all uses other than seed treatments and granules, including the uses that may have been withdrawn due to restrictions of Regulation (EU) No 485/2013, for the above mentioned 3 neonicotinoids, including imidacloprid.

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

[4] 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.

[5] 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.

[6] 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.

[7] 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.

[8] 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.

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

A consultation on the evaluation and preliminary conclusions of EFSA on the risk assessment for bees was conducted with Member States via a written procedure in February-March 2015. The draft conclusions drawn by EFSA, together with the points that required further consideration in the assessment, as well as the specific issues raised by Member States following the consultation were discussed at the Pesticides Peer Review Experts' Meeting 129 on ecotoxicology in March 2015. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report. A further consultation on the final conclusions arising from the peer review of the risk assessment for bees took place with Member States via a written procedure in June 2015.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing data submitted for the approval of the active substance at EU level and for the authorisation of plant protection products containing imidacloprid at Member State level, taking into account the uses other than seed treatments and granules. In addition, any other relevant data available at national level and made available to EFSA were taken into account. Where relevant, the results of a systematic literature review conducted by the Food and Environmental Research Agency (FERA) on clothianidin, thiamethoxam and imidacloprid and the risk to bees (Fryday et al, 2015) were considered. This systematic literature review was awarded by EFSA to FERA (contract RC/EFSA/PRAS /2013/03 implementing Framework contract OC/EFSA/SAS/2012 – LOT5 – FWC 2). The overall objective of the systematic literature search was to contribute to producing the evidence base for risk assessment of the three neonicotinoids thiamethoxam, clothianidin and imidacloprid for bees (including honeybees, bumble bees, solitary bees), by performing two systematic reviews to inform exposure assessment and adverse effect characterisation.

The EFSA guidance document on the risk assessment of plant protection products on bees (EFSA, 2013b) was used for the current evaluation.

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. The Peer Review Report (EFSA, 2015) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

- the study evaluation notes[10],
- the report of the scientific consultation with Member State experts
- the comments received on the draft EFSA conclusion.

[10] As no Draft Assessment Report was available in the context of this peer review, the studies and available data submitted by the applicant(s) and / or made available by the Member States were evaluated by EFSA and summarised in a document titled 'study evaluation notes'.

# CONCLUSIONS OF THE EVALUATION

## 1. Introduction

### 1.1. Authorised uses

Imidacloprid was authorised in Member States using a variety of application techniques. These included foliar sprays using standard horizontal boom sprayers, sideward spray techniques, broadcast assisted sprayers and knapsack sprayers. In addition to the foliar spray uses there were a variety of other application techniques which included soil drenches, dipping solutions, irrigation, drip irrigations, rodlets (also known as plant sticks or PIN) and stem applications (brush and trunk injections). An authorised use, submitted by the Member States, was granular formulation and was not covered by this mandate.

The approaches to perform a risk assessment according to EFSA, 2013b for the authorised uses were discussed and agreed at the Peer Review Meeting 129 (March, 2015) (see Sections 1.2 – 1.5).

Several of the GAP tables for the authorised uses lacked sufficient information (e.g. the application technique not stated) to be able to perform any form of risk assessment (see the separate Excel spreadsheet 'Appendix A_Imidacloprid_GAP Table' accompanying this Conclusion, refer to supporting table worksheet, column M). The risk assessment for the authorised non-professional (home garden) uses was discussed at the Pesticides Peer Review Experts' Meeting 129 and it was agreed that, in the context of this mandate, no quantitative risk assessment should be performed but it should be acknowledged that the concentrations in pollen and nectar in treated plants may be comparable to that found in treated agricultural/horticultural plants. The experts agreed that the risk to bees would therefore depend on the scale of use, which is dependent on the Member State conditions and whether the treated plants are kept outdoors or in protected structures.

#### 1.1.1. Foliar spray uses

According to EFSA, 2013b, the risk assessment for foliar sprays 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 Ratios (ETR) values for the contact and oral risk assessments, respectively. For honeybees, the oral risk assessment should cover also sublethal effects on development of the hypopharyngeal glands (HPG).

Furthermore, the following risks should be considered: 1) risk for accumulative effects (for honeybees only); 2) risk from exposure to contaminated water (by calculating ETRs for honeybees, only); 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 and surrounding area. Therefore, depending on the use under evaluation, different exposure scenarios should be considered, i.e. exposure from: the treated crop, weeds within the field, the field margin, the adjacent crop and succeeding crops (including succeeding permanent flowering plants/trees).

According to EFSA, 2013b, where a first-tier risk assessment indicates a high risk then there are several options for performing a higher tier risk assessment either by refining the exposure estimate (tier 2) or by the use of higher tier effect studies (tier 3). An overview of the risk assessment scheme according to EFSA, 2013b is provided in Table 1.

**Table 1:** Overview of the risk assessment scheme according to EFSA, 2013b

<table>
<tr><th></th><th>Honeybee</th><th>Bumble bee</th><th>Solitary bee</th></tr>
<tr><td>First-tier contact risk assessment[3]</td><td>Treated crop<br>Weeds in the field<br>Field margin[2]</td><td>Treated crop<br>Weeds in the field<br>Field margin[2]</td><td>Treated crop<br>Weeds in the field<br>Field margin[2]</td></tr>
<tr><td>First-tier acute oral risk assessment[3]</td><td rowspan="4">Treated crop<br>Weeds in the field<br>Field margin<br>Adjacent crop<br>Succeeding crop[5]</td><td rowspan="3">Treated crop<br>Weeds in the field<br>Field margin<br>Adjacent crop<br>Succeeding crop[5]</td><td rowspan="3">Treated crop<br>Weeds in the field<br>Field margin<br>Adjacent crop<br>Succeeding crop[5]</td></tr>
<tr><td>First-tier chronic oral risk[4] assessment</td></tr>
<tr><td>First-tier larvae risk assessment[4]</td></tr>
<tr><td>First-tier risk assessment for effects on the HPG (sublethal effect)</td><td>Not applicable</td><td>Not applicable</td></tr>
<tr><td>Assessment of accumulative effects</td><td>Required</td><td>Not required[1]</td><td>Not required[1]</td></tr>
<tr><td>Risk assessment for exposure from residues in guttation fluid</td><td>Required</td><td>Not required[1]</td><td>Not required[1]</td></tr>
<tr><td>Risk assessment for exposure from residues in surface water</td><td>Required</td><td>Not required[1]</td><td>Not required[1]</td></tr>
<tr><td>Risk assessment for exposure from residues in puddles</td><td>Required</td><td>Not required[1]</td><td>Not required[1]</td></tr>
<tr><td>Risk assessment for exposure from metabolites</td><td>Required for pollen and nectar consumption</td><td>Required for pollen and nectar consumption</td><td>Required for pollen and nectar consumption</td></tr>
<tr><td>Higher tier risk assessment using refined exposure (tier 2)</td><td>Required if lower tier fails</td><td>Required if lower tier fails</td><td>Required if lower tier fails</td></tr>
<tr><td>Higher tier risk assessment using effects field studies (tier 3)</td><td>Required if lower tier fails</td><td>Required if lower tier fails</td><td>Required if lower tier fails</td></tr>
<tr><td>Uncertainty analysis for higher tier assessment</td><td>Required</td><td>Required</td><td>Required</td></tr>
</table>

1 Assumed to be covered by the assessment for honeybees.
2 Field margin risk assessment for contact exposure also covers the adjacent crop.
3 Risk assessments for formulated products required depending on whether exposure will occur and where the toxicity cannot be predicted on the basis of the active substance.
4 Chronic risk assessment for formulated products (adult and larvae) only required when the product is more acutely toxic and in cases where exposure will occur.
5 The ‘succeeding crop scenario’ includes residues occurring in flowering permanent crops in the successive year.

It is noted that the EFSA 2013b does not include exposure routes such residues in wax or honeydew. As acknowledged in the EFSA 2013b, this could underestimate the risk for certain circumstances (e.g. honeydew from conifer trees).

Several of the authorised uses were to crops/plants for which there is no clear crop categorisation in EFSA, 2013b (e.g. ornamental plants, ornamental trees, tobacco, hazel, palm tree, chestnut, conifers). The experts at the Pesticides Peer Review Experts’ Meeting 129 discussed the appropriate parameters to be used in the first tier risk assessment in those cases. The agreements reached have been reflected in the risk assessments performed as part of this Conclusion (Sections 3.1 and 4.1). Full details of the discussions can be found in Appendix 2 to the meeting report (EFSA, 2015) and a short summary for ornamentals and non-orchard trees is provided in Appendix D to this document.

### 1.1.2. Other application techniques

The risk assessment approach provided in EFSA, 2013b is applicable to all application techniques i.e. the risk assessment as summarised in Table 1 should be considered in the first tier and, where a first tier risk assessment does not demonstrate a low risk, then a tier 2 and/or tier 3 risk assessment should be performed. However, there is no specific tier 1 risk assessment scheme given in EFSA, 2013b for application techniques other than foliar sprays, seed treatments and granules. Therefore, the approach to the risk assessment for the authorised uses of imidacloprid, other than spray applications (e.g. drenches, drip irrigation, dips), was discussed at the Pesticides Peer Review Experts’ Meeting 129.

The experts provided clarifications and definitions for a number of the authorised application techniques. On the basis of the agreed definitions, the potential for exposure to bees via different routes was discussed. The details of the discussions can be found in Appendix 2 to the meeting report (EFSA, 2015) and in Appendix E to this Conclusion. The risk assessment for the authorised uses other than foliar sprays is provided in Section 4.

### 1.1.3. Uses made in protected structures

A number of the authorised uses of imidacloprid were to protected crops/plants. The experts at the Pesticides Peer Review Experts' Meeting 129 discussed the exposure to bees from the protected uses. In order to perform a risk assessment for bees it was necessary to clearly define what is meant by protected uses. For this purpose, it was agreed to use the definitions given in the 'EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from open-protected crops (greenhouses and crops grown under cover) to relevant environmental compartments', (EFSA, 2014c). Full details of the discussions can be found in Appendix 4 of the meeting report (EFSA, 2015).

For the purposes of clarity, in this Conclusion the following terminology is used:

| | |
|---|---|
| **Uses in open-protected structures:** | Crops/plants grown in low mini tunnels, plastic shelters, net shelter/shade house and walk-in tunnels For all these uses exposure to bees may be equivalent to non-protected uses. |
| **Uses in permanent greenhouses**: | Crops/plants grown in a permanent walk-in, static, closed place for crop production with a non-permeable translucent outer shell. For all these uses exposure to bees is limited. |
| **Outdoor field uses**: | Crops/plants grown in the open field without any form of protection (includes orchards, hops, arable field crops etc.). |

Overall, it was agreed that for uses in **open-protected structures** exposure to bees may not differ from that of an outdoor field use (i.e. non-protected uses) as these types of protected structures can be open to the environment. Therefore, a risk assessment should be performed using the same parameters as for outdoor field uses.

It was agreed that, with the exception of the risk to honeybees via water consumption of surface water, no risk assessment for **permanent greenhouses uses** is required.

It should be noted that the experts considered that exposure to bees from foliar spray applications and soil treatments made in permanent greenhouses could not be completely excluded (e.g. bees entering the permanent greenhouse through open vents), but it was agreed that, in most circumstances, exposure to bee populations via this route is likely to be low. The experts considered that this may not be an appropriate assumption in the case of areas with large scale greenhouse production.

The experts noted that it could not be excluded that pollinators would be introduced as part of Integrated Pest Management practices (IPM) in all types of protected crop structure. Therefore, it was agreed that where a high risk is indicated for an equivalent field use, it cannot be excluded that there is also a high risk to IPM pollinators if used.

Member States were requested to provide feedback on whether the authorised uses to protected crops were restricted to permanent greenhouses only. Unless clearly indicated in the GAP table (see separate Excel spreadsheet 'Appendix A_Imidacloprid_GAP Table'), it was assumed that the authorised use could be made to crops/plants grown under any type of protected crop structure (i.e. used in open-protected structures) and therefore a risk assessment has been performed using the same parameters for outdoor field uses.

There were also a number of authorised uses where the applications are made to plants or seedlings, either indoors or in permanent greenhouses, but then with subsequent movement of the plants or seedlings outside. The application techniques for the authorised uses included drenches, watering and immersion application. The exposure to bees from these types of uses was also discussed at the Pesticides Peer Review Experts' Meeting 129. For applications made indoors or in permanent greenhouses, with the exception of exposure via surface water, exposure will only occur once the plants or seedlings have been transplanted to the outdoor field (refer to Appendix 4 of the meeting report for further details). No quantitative risk assessment could be performed for these types of uses as information on the number of plants/seedlings transplanted per hectare was not available. However, as the application rates to the treated plants are similar to that of the outdoor field uses, for attractive flowering plants, it would be reasonable to assume that these types of authorised uses pose a similar risk to bees (via the oral exposure to the treated crop) once the plants are placed in the field.

In addition, there were several authorised uses which were stated to be indoor but it was not clear whether the plants would then be moved outside. It was considered unlikely that these plants (orchards, ornamentals and conifers) would be maintained indoors. Without further clarification no risk assessment could be performed for these uses.

## 1.2. Formulated products

In accordance with EFSA, 2013b guidance document, a risk assessment for the formulated product is required in addition to a risk assessment for the active substance. Therefore, a consideration of the risk posed by the formulated products has been provided in Section 2.

A number of the authorised products containing imidacloprid also contain additional active substances. The name and authorised uses of these products have been summarised in Table 2. No separate risk assessments for these mixtures have been included in this Conclusion as the outcome of the risk assessment would not differ from that of imidacloprid alone. With the exception of 'NTN 33893 75 OD & AE F032640 10' (containing deltamethrin), no formulation toxicity data were available.

**Table 2:** Authorised professional and amateur products containing additional active substances

| Product name | Active substances | Member State | Crop |
|---|---|---|---|
| **Professional products** | | | |
| Confidor Energy | Imidacloprid<br>Deltamethrin | Bulgaria,<br>Spain, Romania | Fruiting and leafy vegetables,<br>tobacco |
| Prestige FS 370<br>Prestige Forte 370 FS | Imidacloprid<br>Pencycuron | Denmark<br>Poland | Potato |
| **Non-professional products** | | | |
| Lizetan plus Zierpflanzenspray, BG Gartenspray, BG Gartenspray Provado, BG Rosen-Schädlingsspray, BG Rosen-Schädlingsspray Provado, BG Spinnmilbenspray, BG Zierpflanzenspray, BG Zierpflanzen Lizetan, Provado Gartenspray | Imidacloprid<br>Methiocarb | Germany | Ornamentals |

### 1.3. Risk mitigation measures for the authorised uses

Where risk mitigation measures were considered to potentially address the risk identified, these have been highlighted. It is noted that the authorised uses in a number of Member States included risk mitigation measures designed to protect bees. These mitigation measures are considered to reduce the risk to bees, for example preventing applications during and just before flowering or preventing applications when flowering weeds are present in the field. The risk assessment included in this Conclusion considers only risk mitigation measures which are included in EFSA, 2013b. It should be acknowledged that further mitigation may be possible in individual Member States.

### 1.4. Multiple stressors

It is known that there are multiple stressors in the environment which bees are exposed to, as reported in the scientific report of EFSA 'Towards an integrated environmental risk assessment of multiple stressors on bees: review of research projects in Europe, knowledge gaps and recommendations' (EFSA, 2014b). A number of literature papers were provided to EFSA (Aufauvre et al., 2014; Bekele at al., 2015; Betti et al., 2014; Gisder and Genersch, 2015; Goblirsch et al., 2013; Graystock et al., 2014; Khoury et al., 2013; Natsopoulou et al., 2015; Naug, 2014; Perry at al., 2014; Simeunovic et al., 2014; Wolf et al., 2014; Sandrock at al., 2014; Pettis at al., 2012) regarding this issue. Data were also available in the systematic review report (Fryday et al, 2015) indicating the potential for synergistic effects between neonicotinoid pesticide active substances and honeybee disease. At the experts' meeting, it was acknowledged that effects caused by exposure of pesticides can be amplified by other factors impairing the health status of the bees. EFSA, 2014b, recommended developing a holistic approach to account for multiple stressors in the environment. This is currently being developed under the umbrella of the EFSA project MUST-B (EU effort towards the development of a holistic approach for the risk assessment on multiple stressors in bees: http://www.efsa.europa.eu/en/topics/topic/beehealth.htm). No risk assessment scheme accounting for multiple stressors was included in EFSA, 2013b as, currently, there is insufficient knowledge to be able to develop a robust risk scheme. Consequently, this Conclusion focusses on the risk posed by authorised uses of imidacloprid only.

### 1.5. Systematic literature review

A systematic literature review was conducted by the Food and Environmental Research Agency (FERA) on clothianidin, thiamethoxam and imidacloprid and the risk to bees (Fryday et al, 2015). This systematic literature review was awarded by EFSA to FERA (contract RC/EFSA/PRAS /2013/03 implementing Framework contract OC/EFSA/SAS/2012 – LOT5 – FWC 2). The overall objective of the systematic literature search was to contribute to producing the evidence base for risk assessment of the three neonicotinoids thiamethoxam, clothianidin and imidacloprid for bees (including honeybees, bumblebees, solitary bees), by addressing questions to inform on exposure assessment and effect characterisation.

A large number of studies were selected by the systematic literature search for full assessment. A quality assessment of the papers selected for full assessment was performed by Fryday et al., 2015, according to the criteria agreed with the systematic literature search protocol (i.e. reproducibility, appropriateness of study design, repeatability, internal and external validity/risk of bias, precision, conclusions in support of results, characterisation of uncertainty, chemical analysis, test accuracy, controls, replicates, statistical analysis, other information) These studies covered effects assessments (e.g. acute, chronic, sublethal, colony parameters etc.) in laboratory, field, and greenhouse for several bee species as well exposure assessment. For this Conclusion, the systematic literature report was screened for relevant information, in particular:

- Toxicity data (e.g. to check whether there was indication of more adverse effects or to seek for data suitable for tier 1 risk assessment according to EFSA, 2013b when data were missing in the dossier (e.g. chronic data for honeybees, or toxicity studies on bumble bees and solitary bees)).

- Residue studies which could provide information to perform an exposure assessment and tier 2 risk assessment using refined shortcut values.

For higher tier risk assessment, a further consideration of the data included in the systematic literature review can be performed in the future.

## 2. Toxicity

A large number of laboratory toxicity studies were available from different sources, namely:

- Draft Assessment Report of imidacloprid (Germany, 2005)
- EFSA conclusion on imidacloprid from 2008 (EFSA, 2008)
- Review report for the active substance imidacloprid (SANCO/108/08 – rev. 1, 20 June 2008)
- EFSA conclusion on imidacloprid regarding the risk assessments for bees from 2013 (EFSA, 2013a)
- Studies not previously considered by EFSA but made available in the EU and or in MSs' dossiers in the context of this mandate
- Systematic literature review

The assessment of the newer studies, which had not been evaluated for earlier risk assessments, is included in the study evaluation notes (EFSA, 2015). Considerations on the use of the available data from the systematic literature review are included in Section 1.5.

### 2.1. Toxicity to honeybees

<u>Active substance imidacloprid</u>
The available data and assessments were discussed at the Pesticides Peer Review Experts' Meeting 129 and the endpoints to be used for the lower tier risk assessments were agreed.

As regards to the **acute** toxicity, a large number of data were available. An overview of these data is included in Appendix B. The experts at the meeting considered that the EU-agreed endpoints are suitable for the current risk assessment; namely the contact $LD_{50}$ of 0.081 µg/bee and oral $LD_{50}$ of 0.0037 µg/bee.

As regards to the adult **chronic** toxicity, the experts at the meeting agreed that the only available value of 0.00282 µg/bee/day is suitable for the risk assessment. It is noted that for the chronic endpoint, the risk assessment scheme in EFSA, 2013b uses the median lethal dietary dose (LDD50). The endpoint of 0.00282 µg/bee/day is actually a NOED (highest tested dose), and the LDD50 was reported here as greater than value. Therefore, the use of this value is considered as worst-case.

As regards to the toxicity to honeybee **larvae**, the single available study was discussed and some concerns were identified. The main issues were that the exposure duration in the study was shorter than required by EFSA, 2013b and that the actual food consumption was not reported (i.e. it is not known whether all the spiked food that was provided to the larvae had been consumed). The experts at the meeting agreed that, in general, the study is of suitable quality, but the uncertainties discussed above have to be acknowledged. As a result, it was agreed that the endpoint of 0.00528 µg/larvae, originating from this study, can be used in the risk assessment as a provisional regulatory endpoint.

A summary of the endpoints selected for the risk assessment is presented in Section 2.6.

No data for the development of the **hypopharyngeal glands** were available in the regulatory dossiers, but some data were available in the scientific literature. However, none of the available studies concluded an endpoint which fitted in the risk assessment scheme of EFSA, 2013b. Therefore the experts at the meeting considered that no risk assessment for HPG could be performed.

No suitable data for **accumulative effects** on honeybees were available.

It should be noted that toxicity data of formulations (only acute $LD_{50}$ values were available) were also taken into account. A detailed consideration to these data set is included in the next section, below.

Formulated products

A summary of the acute laboratory toxicity data for honeybees on plant protection products available in the dossier can be found in Appendix B. The toxicity data for the formulated products (expressed in terms of active substance) has been compared to the selected endpoints for imidacloprid. In accordance with EFSA, 2013b, where the difference in toxicity is less than a factor of 5, the product is considered to be of comparable toxicity.

As indicated in Appendix B, 'Imidacloprid AL 0.125' and 'Imidacloprid-AE VL 0.0625' are of greater toxicity to honeybees via contact exposure than imidacloprid (based on the endpoints selected for risk assessment). However, since no authorised formulations could be linked to these test items, these data could not be used further.

None of the other formulated products were considered as more acutely toxic by more than a factor of 5. Therefore, no separate risk assessments for these formulated products were considered necessary. However, there was a large number of authorised formulations for which no toxicity data were available or which could not be linked to any of the test item included in Appendix B. The experts at the meeting noted that, in general, bridging (extrapolation of toxicity predictions) from a formulation to another is possible, provided that sufficient information is available. However this information was not available for the current risk assessment to EFSA. Therefore, such cases would require further consideration at Member State level.

Acute toxicity endpoints from the systematic literature review

There were a number of additional 48-hour acute oral endpoints for *Apis mellifera* summarised in the available literature systematic review report (presented as mass a.s./bee). Several studies used technical imidacloprid and the acute 48 oral $LD_{50}$ values reported were: between 41 and > 81 ng a.s./bee (Nauen et al., 2001), 57 ng a.s./bee Suchail (2001a), around 70 ng a.s./bee Suchail (2001b) and 30.6 ng a.s./bee (Decourtye, 2003). A study using 'Confidor 200SL' (17.8% imidacloprid) gave an endpoint of 90.09 ng a.s./bee (Laurino et.al., 2013). These endpoints indicate lower toxicity compared with the acute oral $LD_{50}$ value selected for risk assessment of imidacloprid (3.7 ng a.s./bee). A further study using a formulated product 'Tanrek' (200 g/L imidacloprid) reported an acute oral $LD_{50}$ of 3.1 ng a.s./bee (Illarionov, 2008). However, this product is not included in the list of product authorised in EU as provided by Member States, please refer to the separate Excel spreadsheet 'Appendix A_Imidacloprid_GAP Table'.

There were a number of additional acute contact endpoints for *Apis mellifera* summarised in the available systematic review report of the literature. Nauen et al. (2001) reported a 48h contact $LD_{50}$ of between 42.0 and 74.9 ng a.s./bee and Schmuck (2003) reported values of between 42 and 104 ng a.s./bee. Two additional 24 hour endpoints were also reported: 17.9 ng/bee (Iwasa, 2004) and 40 ng a.s./bee (Stark et al. 1995). These endpoints indicate similar toxicity (i.e. difference < 5) compared with the value selected for risk assessment of imidacloprid (81 ng a.s./bee). A further study using a formulated product 'Tanrek' (200 g/L imidacloprid) reported the acute contact $LD_{50}$ to be 9 ng a.s./bee (Illarionov, 2008), however, none of the authorised uses in the EU are for a product called 'Tanrek'.

### 2.2. Toxicity to bumble bees

Active substance imidacloprid

A few **acute** endpoints for bumble bees were available, which were discussed at the Pesticides Peer Review Experts' Meeting 129. An overview of these data is included in Appendix B. The experts at the meeting agreed that the oral $LD_{50}$ of 0.038 µg/bee and the contact $LD_{50}$ of 0.218 µg/bee are suitable for the current risk assessments.

No **chronic** endpoint for adults and no **larval** toxicity studies were available. According to EFSA, 2013b, the relevant toxicity endpoints for honeybees divided by 10 can be used for the risk assessment (as a screening) for bumble bees. The use of this approach was considered at the meeting. It was noted that the available acute data suggest that the factor of 10 may overestimate the real difference in toxicity between honeybees and bumble bees. However, in this case the dataset was not considered to be robust enough to carry out a solid extrapolation. Therefore, it was agreed that a chronic endpoint using the standard extrapolation factor of 10 should be used in the risk assessment (screening). As regards the larval endpoint, the experts at the meeting agreed that no quantitative larval risk assessment should be performed for bumble bees given the uncertainties around the honeybee larvae endpoint and that it can be predicted in advance that this screening step will result in a high larval risk for all the authorised uses where exposure of bee larvae happens. A summary of the endpoints used in the risk assessment is presented in Section 2.6.

Formulated products
Toxicity data (acute contact and oral $LD_{50}$ values) only for one of the relevant formulations were available. These data indicated that the toxicity of this formulation (Nuprid 200 SC) is not greater to bumble bees than the technical imidacloprid (based on the endpoints selected for risk assessment). No information was available for the other formulations.

## 2.3. Toxicity to solitary bees

Active substance imidacloprid and formulated products
**No toxicity studies** for solitary bees were available in the regulatory dossiers. According to EFSA, 2013b, the relevant toxicity endpoints for honeybees divided by 10 can be used for the risk assessment (as a screening). The use of this approach together with the available toxicity data from the systematic literature search report (Fryday et al, 2015) was discussed at the meeting. In the systematic literature report, three endpoints for non-apis and non-bombus species were available which fitted in the risk assessment scheme of EFSA, 2013b (Kumar et al., 2005; Valdovinos-Nunez et al., 2009; Biddinger et al., 2013). All three endpoints were acute contact $LD_{50}$ values expressed in µg/bee. One of the endpoints referred to *Osmia cornifrons* and the other two to non-European (likely social) bee species with very small body weights (*Melipona beecheii* and *Trigona irridipenis*). The experts at the meeting agreed that the $LD_{50}$ value for *Osmia cornifrons* (3.8 µg/bee) from Biddinger et.al, 2013 could be used in a quantitative risk assessment provided that the methodology of the test complies with EFSA, 2013b. Otherwise a toxicity endpoint extrapolated from honeybees should be used. Therefore the study was further assessed by EFSA after the meeting. The assessment of the published paper revealed that some important aspects of the methodology were unclear; it was not clear whether the treatments were sufficiently replicated and whether the endpoint refers to imidacloprid or to the test item, which was a formulation with only 17.4% imidacloprid. Additionally, in parallel to the contact test with *Osmia cornifrons, Apis mellifera* was also tested for imidacloprid and for another neonicotinoid insecticide. In both cases the tests with honeybees resulted in higher endpoints than the EU-agreed endpoints, which may indicate that the test methodologies differed from the standard regulatory tests (imidacloprid LD50 on *Apis mellifera*: 0.2 µg/bee vs. EU agreed endpoint of 0.081 µg/bee; acetamiprid LD50 on *Apis mellifera*: 64.6 µg/bee vs. EU agreed endpoint of 14.55 µg/bee).

In addition, two acute contact studies for solitary bees (*Megachile rotundata* and *Nomia melanderi*) were available (Stark et al., 1995). $LD_{50}$ values expressed in µg imidacloprid/bee were not reported, but estimations for these values could be done. This resulted for both cases in an estimated $LD_{50}$ of 0.04 µg/bee (a similar toxicity value was established for *Apis mellifera* from this study).

Considering all of these uncertainties, the endpoints from these tests were not considered sufficient for a quantitative risk assessment. As a consequence, the acute and chronic toxicity endpoints derived from the honeybee toxicity values were used in the risk assessment as a screening. However, it was noted that the data summarised above indicated that the contact toxicity of imidacloprid to some solitary bees might be similar than to honeybees.

As regards to the larvae, no surrogate endpoint was derived and no quantitative larval risk assessment was performed in line with the agreement of the experts at the meeting and considering the same reasons as for bumble bee larvae (see Section 2.2).

A summary of the endpoints used in the risk assessment is presented in Section 2.6.

## 2.4. Metabolites of imidacloprid

Please refer to Section 7.

## 2.5. Sublethal effects

A number of studies were available which investigated sublethal effects, including behaviour, locomotion, navigation or orientation. Reviews of sublethal effects were reported in earlier risk assessments including EFSA 2013a. Also, the systematic literature search report (Fryday et al., 2015) included several studies for sublethal effects. For example, Di Prisco et al., 2013 demonstrated that clothianidin at sub-lethal dose (i.e. ≤21 ng a.s./bee topic exposure and 0.1-10 ppb sucrose solution for oral exposure) reduces immune defences and promotes the replication of deformed wing virus. This honeybee immune-suppression is similarly induced by imidacloprid.

Fisher et al., 2014 reported for a significantly shorter length of the vector flight in bees treated at 7.5 and 11.25 imidacloprid ng/bee ($p=0.0242$). The duration of the vector flights did not differ significantly between the control groups and treatment groups. Both imidacloprid treatments resulted in significantly more directional changes compared to controls ($p=0.001$ at 7.5 ng/bee and $p=0.11$ at 11.25 ng/bee) and significantly lower directedness ($p<0.05$). Imidacloprid-treated bees at both doses were less successful in reaching the hive during the final phase of homing ($p<0.05$).

A comprehensive review of sublethal effects of pesticides was reported in EFSA PPR 2012. It has to be noted that EFSA, 2013b, identified issues that must be resolved before sublethal effects, other than HPG for honeybees, can be fully integrated in a risk assessment scheme, such as definition of protection goal and interpretation of the sublethal effects in terms of impact on the colony. EFSA, 2013b provided a proposal for a sublethal risk assessment scheme. However, for the purposes of this Conclusion, it was considered premature to apply such proposal.

## 2.6. Summary of endpoints to be used for the tier 1 risk assessments

Table 3 summarises the toxicity endpoints, which were selected for the use in the tier 1 risk assessments for honeybees, bumble bees and solitary bees. The details of the selections are included in Sections 2.1, 2.2 and 2.3.

**Table 3:** Toxicity endpoints selected for tier 1 risk assessments

| Risk assessment type | Endpoint | Honeybee | Bumble bee | Solitary bee |
|---|---|---|---|---|
| Acute contact | $LD_{50}$ (µg a.s./bee) | 0.081<br>(48h) | 0.218<br>(96h) | 0.0081*** |
| Acute oral | $LD_{50}$ (µg a.s./bee) | 0.0037<br>(48h) | 0.038<br>(96h) | 0.00037*** |
| Chronic (oral) | 10-day $LDD_{50}$<br>(µg a.s./bee/day) | > 0.00282* | > 0.000282*** | > 0.000282*** |
| Larval | NOEC<br>(µg a.s./larva)<br>7days (=22days) | 0.00528<br>as provisional** | No endpoint available or extrapolated | No endpoint available or extrapolated |
| Development of hypopharyngeal glands | NOEChpg<br>(µg a.s./bee/day) | No endpoint available | Not applicable | Not applicable |

*: Endpoint set at the highest concentration tested

**: 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

***: Extrapolated from the endpoint for honeybee by using a factor of 10.

## 3. Risk assessments for products applied as a foliar spray

### 3.1. Tier 1:Risk assessments for honeybee, bumble bee and solitary bees

For contact exposure, Hazard Quotients (HQs) are calculated for the treated crop (during flowering growth stages only), weeds within the field and also for the field margin (which covers also exposure from residues on the adjacent crop). The HQs are calculated as the deposition, depending on the application rate and the scenario, divided by the acute contact $LD_{50}$ value for honeybees, bumble bees and solitary bees. The HQ values are then compared to the trigger values given in EFSA, 2013b, which differ for honeybees, bumble bees and solitary bees and also whether the application is made by a downward spray (from a horizontal boom sprayer) or side and upwards spray (from a broadcast sprayer).

For oral exposure, Exposure Toxicity Ratios (ETRs) are calculated for the treated crop, weeds within the treated field, plants in the field margin, adjacent crop and also succeeding crops (defined as permanent crops in the next year/flowering and succeeding annual crops). ETRs are calculated for the acute risk to adult bees, chronic risk to adult bees and chronic risk to bee larvae for each honeybee, bumble bee and solitary bees. ETRs represents the estimated exposure divided by the toxicity endpoint (acute $LD_{50}$, chronic adult $LC_{50}$, NOEC for larvae and NOEC for HPG; all expressed on mass basis, i.e. mass/bee). The exposure is calculated by the application rate multiplied by the exposure factor (Ef value) and shortcut values (SVs) which are presented in EFSA, 2013b for the different exposure scenarios. The shortcut values account for residue intake for honeybees, bumble bees and solitary bees. Dissipation of the residues is accounted for in the chronic assessments using a default time-weighted average factor (TWA).

In the context of the current assessment, no data were available for HPG therefore the current risk assessment does not include considerations to the development of HPG of honeybees. It is noted that no median effect concentration endpoint was available for imidacloprid for the chronic adult assessments; instead the NOEC value, which was available, was used. For non-*Apis* bees only a few toxicity data were available. Therefore, where no data were available, either no assessment was done or a surrogate endpoint derived from pertinent endpoint for honeybees was used. For details see Section 2.

The shortcut values used in the risk assessment depend on whether the crop produces, and is attractive, to honeybee, bumble bee and solitary bees for, pollen and/or nectar (as summarised in Appendix D of EFSA, 2013b). It should be noted that, for a number of the authorised uses, EFSA, 2013b indicates that there was insufficient information available to fully understand whether the crop is attractive to honeybee, bumble bee and solitary bees for pollen and/or nectar (e.g. alfalfa, artichokes, barley, oat, wheat, rice, aubergines, grapes, melon, olives, potatoes, squash, cotton, tomatoes, hazel, hops, lettuce, pumpkin, quince, sugar beet, tobacco). Therefore, in the first instance, in accordance with EFSA, 2013b, in the current assessment, it has been assumed that these crops are attractive for pollen and/or nectar. However, it is noted that EFSA, 2013b acknowledged that a number of these crops are generally considered to be of low attractiveness for pollen and/or nectar but attractiveness could not be fully excluded, therefore, a conservative approach has been used in this Conclusion. For further details, please refer to Appendix D of EFSA, 2013b. Regarding the attractiveness of potatoes to honeybees, data were provided by Denmark during the Pesticides Peer Review Experts' Meeting 129 indicating that honeybees collect pollen from potatoes (see study evaluation notes, EFSA 2015).

In order to perform a first tier risk assessment according to the recommendation of EFSA, 2013b, the authorised uses have been grouped into crop categories given in Table 4 (which correspond to the crop categories used by the EFSA Bee Tool v.2, Appendix Y of EFSA, 2013b, for oral risk assessment). A distinction has been made for the authorised uses which are applied post-flowering of the treated crop only and if the crop is not foraged by bees for pollen and/or nectar. The first-tier risk assessment has then been performed using the highest and lowest authorised 'maximum application rate' for each crop category. In selecting the crop category, where no growth stage has been included in the GAP table submitted by the applicants and verified by Member States, or where the growth stage at the time of the application was not clear, then it has been assumed that the authorised use is for all growth stages after BBCH 10. The same approach was applied for the uses in open-protected structures and is summarised in Table 5.

A field use for in-furrow spraying in potato (seed potato) was also authorised in a single EU Member State. Although this use is not considered as foliar spray (spray to the tubers and to soil), the risk from this use is addressed within this section considering a spray application to potato at BBCH < 10.

The soil $DT_{50}$ of imidacloprid ranges from 99 to 129 days under laboratory conditions (FC, 20°C) and 104 to 228 days under field conditions (non-normalised, 1st order) (EFSA, 2008). These values are greater than the triggers given in EFSA, 2013b of 2 and 5 days for multiple cropping and single cropping scenarios, respectively. Consequently, a risk assessment for succeeding crops has been included.

**Table 4:** Summary of the authorised foliar spray outdoor field uses of imidacloprid grouped according to the categories given in the EFSA Bee Tool[1]

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Type of spray | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| Cereals | No | barley, oat, wheat, rice | Downward spray | 55 | 100 |
| Clovers | No[2] | Alfalfa | Downward spray | 60 | 100 |
| Cotton | Yes, post flowering | Cotton | Downward spray | 100 | 100 |
| Fruiting vegetables group 1 | No | Cucumbers, melons, watermelons, peppers, zucchini (courgette), Gherkins | Downward spray | 45 | 225 |
| | Yes, post flowering | Cucumbers, melons, watermelons, peppers, zucchini (courgette), Squashes and others | | 100 | 150 |
| Fruiting vegetables group 2 | No | Tomato, Eggplant (Aubergine) | Downward spray | 45 | 225 |
| | Yes, post flowering | | | 150 | 250 |
| Tobacco (grouped with fruiting vegetables group 2) | No | Tobacco | Downward spray | 33.75 | 3500 |
| Grapes | No | Grapes, Grape vine, vine nurseries, rootstock vineyards | Side/upward spray | 56 | 112 |
| | Yes, post flowering | | | 70 | 200 |
| Hops | No | Hops | Side/upward spray | 98 | 165 |
| | Yes, post flowering | | | 100 | 100 |
| Leafy vegetables | No | Artichoke (cardoon), Brassicas flowering, (Cauliflower, broccoli), Brassicas flowering (head, leafy, kohlrabi), Brussels sprouts, Cabbage | Downward spray | 27 | 160 |

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Type of spray | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| | Yes, harvested prior to flowering | Artichoke (cardoon), Brassicas flowering, (Cauliflower, broccoli), Brassicas flowering (head, leafy, kohlrabi), Brussels sprouts, Cabbage | Downward spray | 27 | 160 |
| Lettuce | No | Lettuce, Scarole | Downward spray | 100 | 150 |
| | Yes, harvested prior to flowering | Lettuce, Scarole | | 100 | 150 |
| | Yes, post flowering | Lettuce, corn salad, radicchio, eskariol salad, kres salad | | 100 | 100 |
| Oilseed rape | No | Oilseed rape | Downward spray | 55 | 56 |
| Olives | Yes, post flowering | Olives | Side/upward spray | 20 | 125 |
| Orchards group 1 | No | Almond, Apple, Apricot, Nectarine, Peach, Cherry, Pear Plum, Quince, Pome fruit, Stone fruit | Side/ upward spray | 35 | 151 |
| | Yes, post flowering | Almond, Apple, Apricot, Nectarine, Peach, Cherry, Pear Plum, Pome fruit, Stone fruit | | 35 | 180 |
| Orchards group 2 | No | Citrus group | Side/upward spray | 150 | 301 |
| | Yes, post flowering | | | 140 | 600 |
| Orchards group 3 | No | Hazel | Side/upward spray | 100 | 100 |
| Ornamentals, ornamental trees | No | Forestry and ornamentals | Side/upward spray (can also be a downward | 100 | 150 |

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Type of spray | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| | | (herbaceous and woody); Non agricultural crops: forestry, ornamentals; Ornamental plants; Ornamentals bush; Ornamentals Palms; Ornamentals, ornamental trees; Rose | spray; with lack of information side/ upward spray was assumed) | | |
| | Yes, post flowering or non flowering varieties | Ornamentals, Ornamental plants (not intended for consumption), Ornamentals (non flowering varieties), Rose | | 100 | 300 |
| Non orchard trees | No | Horse chestnut | Side/upward spray | 225 | 225 |
| | Yes, post-flowering or not foraged by bees for nectar and pollen | Buckeye tree, Conifers | Side/upward spray | 70 | 225 |
| Potatoes | No[3] | Potatoes | Downward spray | 30 | 350 |
| | Yes, post flowering | | | 60 | 60 |
| Pulses | No | Bean (dry, green) | Downward spray | 225 | 225 |
| | Yes, post flowering | Bean (dry, green), Peas (dry, green) | | 100 | 100 |
| Sugar beet | No | Sugar beet | Downward spray | 100 | 100 |

[1]: Crop grouping has been done according to the categories in the EFSA Bee Tool v.2 (Appendix Y of EFSA, 2013b), for the risk assessment for oral exposure. For the purposes of the contact risk assessment the same groupings were used with the exception that orchard group 3 was merged with orchard group 1. For some uses (e.g. ornamentals, tobacco) the grouping was identified and agreed by the experts at the meeting PPR 129. Category non-orchard tree (ornamental trees, as well) is based on category Orchards 1.
[2]: It is assumed that alfalfa will flower again after cutting
[3]: This includes the use as in-furrow tuber treatment

**Table 5:** Summary of the authorised foliar spray uses of imidacloprid made in open-protected structures grouped according to the categories given in the EFSA Bee Tool[1]

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Type of spray | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| Fruiting vegetables group 1 | No | Cucumbers, melons, peppers, zucchini (courgette), Gherkins and others, Curcurbits | Downward spray | 60 | 450 |
| | Yes, post flowering | Cucumbers, melons, watermelons, peppers, zucchini (courgette), Squashes and others, Paprika, Pumpkin | | 150 | 250 |
| Fruiting vegetables group 2 | No | Tomato, Eggplant (Aubergine) | Downward spray | 60 | 450 |
| | Yes, post flowering | Tomato, Eggplant | | 150 | 250 |
| Tobacco (grouped with fruiting vegetables group 2) | No | Tobacco | Downward spray | 100 | 5000 |
| Grapes | No | Grape | Side/ upward spray | 100 | 100 |
| Lettuce | No | Lettuce and similar | Downward spray | 100 | 100 |
| | Yes, harvested prior to flowering | | | | |
| Ornamentals, ornamental trees | No | Ornamentals (herbaceous and woody, bush) | Side/ upward spray (can also be a downward spray; with lack of information side/ upward spray was assumed) | 70 | 630 |
| | Yes, post flowering or non flowering varieties | Ornamentals, Ornamental plants (not intended for consumption), Ornamentals (non flowering varieties) | | 100 | 350 |

| **Crop grouping**[1] | **Can exposure to nectar and or pollen on the treated crop/plant be excluded?** | **Authorised uses** | **Type of spray** | **Lowest 'maximum application rate' g a.s./ha** | **Highest 'maximum application rate' g a.s./ha** |
|---|---|---|---|---|---|
| Non orchard trees | Yes, not foraged by bees for nectar and pollen | Conifers | Side/ upward spray | 70 | 70 |
| Pulses | No | Bean (dry, green) | Downward spray | 140 | 225 |

[1] Crop grouping has been done according to the categories in the EFSA Bee Tool v.2 (Appendix Y of EFSA, 2013b), for the risk assessment for oral exposure. For the purposes of the contact risk assessment the same groupings were used with the exception that orchard group 3 was merged with orchard group 1. For some uses (e.g. ornamentals, tobacco) the grouping was identified and agreed by the experts at the meeting PPR 129. Category non-orchard tree (ornamental trees, as well) is based on category Orchards 1.

### 3.1.1. First-tier contact and oral risk assessment for honeybees, bumble bees and solitary bees

3.1.1.1. Treated crop (uses in outdoor field and open-protected structures)

The calculated ETR values and the HQ values for the treated crop scenarios are presented in a separate spreadsheet 'Appendix B_Imidacloprid_Risk assessment spreadsheet' accompanying this Conclusion. Where no reliable toxicity endpoint was available (i.e. for larvae of bumble bees and solitary bees and for HPG development of honeybees) no ETR calculations were performed.

On the basis of the first-tier risk assessment, a high **oral** risk to honeybees and bumble bees from foraging on pollen and/or nectar from the treated crop was indicated for all authorised uses when applications are made either before or during flowering (in case of hazel nut, hops and potato, some risk categories of some uses indicated a low risk, while high risk was identified for other risk categories). Furthermore, a high oral risk to solitary bees could not be excluded on the basis of the screening assessment, assuming that the endpoints for solitary bees (acute adult and chronic adult scenarios) are ten times lower than the endpoints for honeybees, for all of the authorised uses when applications are made either before or during flowering. For all of the authorised uses a low oral risk was indicated for all bee species for post-flowering growth stages as nectar and pollen are no longer present.

A high acute **contact** risk to honeybees and bumble bees was indicated for all of the authorised uses when applications are made during flowering. Furthermore, a high acute contact risk to solitary bees could not be excluded on the basis of the screening assessment for all of the authorised uses when applications are made during flowering. A low contact risk to all bee species was concluded for the situations when the applications are performed before or after the flowering period.

For the authorised uses to **leafy vegetables and lettuce,** it was not specified whether the vegetables are always harvested before flowering or whether they may be allowed to produce flowers (e.g. in the case they are grown for seed production). Therefore, a risk assessment including flowering growth stages has been included. If the **crop is harvested before flowering** there is **low risk to bees** from contact exposure and foraging pollen and nectar directly from the treated crop.

It is noted that for two crops - cotton, olives - only post-flowering applications were authorised in the EU Member States (see the separate Excel spreadsheet 'Appendix A_Imidacloprid_GAP Table' accompanying this Conclusion).

It is also noted that some ornamentals were indicated as **non-flowering varieties**. Moreover conifer trees were considered **as non-attractive** to bees for pollen and nectar. Therefore, **low risk to bees** was concluded for these plants from contact exposure and foraging pollen and nectar directly on the treated crop.

A summary of the risk assessment for the treated crop scenario is presented in Table 6.

**Table 6:** Summary of the risk from the treated crop depending on the timing of the spray application

| Timing of the spray application | Oral route of exposure | Contact route of exposure |
|---|---|---|
| Before flowering (BBCH 0 – 59) | Low risk for the situations when the crop is harvested before flowering (leafy vegetables, lettuce), for non-flowering ornamental varieties and for conifers.<br>High risk to honeybees and bumble for all the other cases. Screening assessment did not exclude a high risk to solitary bees for all the cases other than explained above. | Low risk to honeybees, bumble bees and solitary bees. |
| During flowering (BBCH 60- 69) | High risk to honeybees and bumble bees except conifers.<br>Screening assessment did not exclude a high risk to solitary bees except conifers. | High risk to honeybees and bumble bees except conifers.<br>Screening assessment did not exclude a high risk to solitary bees except conifers. |
| After flowering (BBCH ≥70) | Low risk to honeybees, bumble bees and solitary bees. | Low risk to honeybees, bumble bees and solitary bees. |

#### 3.1.1.2. Weeds within the treated field (uses in outdoor field and open-protected structures)

The acute oral and contact risk assessment for honeybees, bumble bees and solitary bees foraging on weeds in the treated crop was performed using the risk assessment scheme in EFSA, 2013b. The resulting ETR and HQ values are presented in a separate spreadsheet 'Appendix B_Imidacloprid-Risk assessment spreadsheet' accompanying this Conclusion. Where no reliable toxicity endpoint was available (i.e. for larvae of bumble bees and solitary bees and for HPG development of honeybees) no ETR and HQ values were calculated. On the basis of the assessments, a high oral and contact risk to honeybees and bumble bees was indicated for all of the authorised uses and for all growth stages. Furthermore, a risk to solitary bees could not be excluded on the screening assessment, assuming that the endpoints used for solitary bees (acute adult and chronic adult scenarios) are ten times lower than the endpoints for honeybees. Risk mitigation measures to prevent the weeds within the treated crop from flowering would result in a low risk. It is important to note that the removal of the flowering weeds would need to be continued for the whole season to prevent residues in pollen and nectar in newly emerged flowers. It has also to be noted that the recommendation 'remove weeds before flowering' is likely to have undesired side effects such as removing a source of nectar and pollen, which in turn may impact on honeybees, solitary bees and bumble bees. Further data would be needed to determine the wider impact of such risk mitigation. Member States may wish to consider the wider implications of this risk mitigation measure before implementation on product labels.

#### 3.1.1.3. Field margin and adjacent crop (uses in outdoor field and open-protected structures)

The risk assessment for the field margin and adjacent crop scenario for the oral and contact routes of exposure have been performed by calculating the application rate which results in a low risk to bees (rounded down to the nearest whole gram per hectare) and where reliable toxicity endpoints were available (no reliable toxicity endpoints were available for larvae of bumble bees and solitary bees and for HPG development of honeybees). These 'limit rates' are then compared with the authorised foliar spray uses of imidacloprid. The calculation of the 'limit rates' have been performed for the six relevant spray drift scenarios according to the risk assessment scheme in EFSA, 2013b, such as arable field crops, orchard-early, orchard-late, grapevine-early, grapevine-late and hops. The calculations were repeated for honeybees, bumble bees and solitary bees for the oral and contact assessments. The chronic adult risk assessments results in the lowest 'limit rates' and therefore drives the outcome of the risk assessment and have been summarised in Table 7. Furthermore, only the lower 'limit rate' for either the field margin or adjacent crop were reported in Table 7. The detailed calculations are included in the separate spreadsheet ‘Appendix B_Imidacloprid-Risk assessment spreadsheet’ accompanying this Conclusion. It should be noted that some assessments for bumble bees and solitary bees have been performed using a surrogate endpoint by taking the honeybee toxicity endpoint divided by 10. Since for bumble bees, non-surrogate endpoints are available (acute contact and acute oral $LD_{50}$ values), the calculations for the acute oral risk assessments were also included in Table 7 (this scenario drives the risk assessment for the non-surrogate endpoints). The ‘limit rates’ have not been calculated for honeybee HPG as no endpoint was available and therefore the limit rates should not be regarded as conclusive of the level of mitigation required to protect honeybees. It is also noted that the chronic endpoint that was available, is a NOED rather than a median effect concentration/dose.

EFSA, 2013b indicates that it is possible to mitigate the risk to bees from exposure from residues in the field margin and adjacent crop by the use of spray drift reduction. According to the FOCUS Landscape and Mitigation guidance document (FOCUS, 2007), the maximum possible mitigation for spray-drift is 95% which can be achieved through no spray buffer zones and/or drift reduction technology. The ‘limit rates’ have been determined assuming no mitigation and 95% spray drift mitigation.

**Table 7:** 'Limit rates', assuming 0% and 95% spray drift mitigation, which indicate to achieve a low risk to honeybees, bumble bees and solitary bees from exposure in the field margin and adjacent crop. Please note that some risk schemes (e.g. sublethal HPG effects) are not included due to insufficient information.

| Crop group and application type | Authorised uses | | | 'Limit rate' (highest application rate which results in a low risk to bees for the selected endpoints) (g a.s./ha) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Crops/plants | | Range of authorised application rates (g a.s./ha) | Honeybee (oral $LDD_{50}$ = 0.00282 µg a.s./bee) | | Bumble bee (surrogate oral $LDD_{50}$ = 0.000282 µg a.s./bee and acute oral $LD_{50}$ = 0.038 µg a.s./bee) | | Solitary bee (surrogate oral $LDD_{50}$ = 0.000282 µg a.s./bee) | |
| | | | | **0 % mitigation** | **95% mitigation** | **0 % mitigation** | **95% mitigation** | **0 % mitigation** | **95% mitigation** |
| Arable field crop, downward spray | Outdoor-field | Barley, oat, wheat, rice, alfalfa, cotton, cucumbers, melons, watermelons, peppers, zucchini (courgette), gherkins, squashes and others, tomato, eggplant (aubergine), tobacco, artichoke (cardoon), brassicas flowering, (cauliflower, broccoli), brassicas flowering (head, leafy, kohlrabi), Brussels sprouts, cabbage lettuce, scarole, corn salad, radicchio, eskariol salad, kres salad, oilseed rape, potatoes, bean (dry, green), peas (dry, green) sugar beet | 27 – 600 (3500 for tobacco) | 4 | 88 | <1<br>2 | <1<br>44 | <1 | 1 |
| | Open-protected | Cucumbers, melons, peppers, zucchini (courgette), gherkins and others, curcurbits watermelons, squashes and others, paprika, pumpkin tomato, eggplant (aubergine), tobacco, lettuce and similar, bean (dry, green) | 60 – 450 (5000 for tobacco) | | | | | | |
| Orchards group 1 and 3 early Side/ upward spray | Outdoor-field | Almond, apple, apricot, nectarine, peach, cherry, pear plum, quince, pome fruit, stone fruit, hazel, forestry, ornamentals (herbaceous and woody), non-agricultural crops: forestry, ornamentals, ornamental plants, ornamentals bush, ornamental palms, ornamentals, ornamental trees, rose | 35 - 300 | <1 | 6 | <1<br><1 | <1<br>3 | <1 | <1 |
| | Open-protected | Ornamentals | 70 - 630 | | | | | | |

| Crop group and application type | Authorised uses | | | 'Limit rate' (highest application rate which results in a low risk to bees for the selected endpoints) (g a.s./ha) | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Crops/plants | | Range of authorised application rates (g a.s./ha) | **Honeybee** (oral $LDD_{50}$ = 0.00282 µg a.s./bee) | | **Bumble bee** (surrogate oral $LDD_{50}$ = 0.000282 µg a.s./bee and acute oral $LD_{50}$ = 0.038 µg a.s./bee) | | **Solitary bee** (surrogate oral $LDD_{50}$ = 0.000282 µg a.s./bee) | |
| | | | | **0 % mitigation** | **95% mitigation** | **0 % mitigation** | **95% mitigation** | **0 % mitigation** | **95% mitigation** |
| Orchards group 1, 2 and 3 late Side/ upward spray | Outdoor Field | Olives, Almond, Apple, Apricot, Nectarine, Peach, Cherry, Pear Plum, Quince, Pome fruit, Stone fruit, Citrus group, Hazel, Forestry and ornamentals (herbaceous and woody); Non agricultural crops: forestry, ornamentals; Ornamental plants; Ornamentals bush; Ornamentals Palms; Ornamentals, ornamental trees; Rose, Horse chestnut, Buckeye tree, Conifers | 20 –600 | <1 | 13 | <1<br><1 | <1<br>7 | <1 | <1 |
| | Open-protected | Ornamentals and conifers | 70 - 630 | | | | | | |
| Hops Side/ upward spray | Outdoor Field | Hops | 98 – 165 | <1 | 9 | <1<br><1 | <1<br>5 | <1 | <1 |
| Vines early (BBCH <20) Side/ upward spray | Outdoor-field | Grapes, Grape vine, vine nurseries, rootstock | 56 - 112 | 4 | 86 | <1<br>2 | <1<br>45 | <1 | 1 |
| | Open-protected | Grape | 100 | | | | | | |
| Vines late (BBCH ≥20) Side/ upward spray | Outdoor-field | Grapes, Grape vine, vine nurseries, rootstock | 56 - 112 | 1 | 28 | <1<br><1 | <1<br>15 | <1 | <1 |
| | Open-protected | Grape | 100 | | | | | | |

In summary, for those risk scenarios that can be assessed with the currently available information, for the field margin/adjacent crop scenario for foliar spray uses:

- It is possible to mitigate the risk to honeybees and bumble bees for some of the arable field uses
- For all uses to orchards, hops and vines, a high risk to bumble bees is indicated even with 95% spray drift mitigation
- For all uses to orchards and hops, a high risk to honeybees is indicated even with 95% spray drift mitigation
- For late growth stages and some early growth stages uses in vines, a high risk to honeybees is indicated even with 95% spray drift mitigation. However, it is possible to mitigate the risk to honeybees for some uses to vines sprayed in early growth stages.
- The screening assessments indicated that a high risk could not be excluded for bumble bees and solitary bees for all authorised uses (it is noted that for bumble bees, non-screening assessments are also available)

#### 3.1.1.4. Succeeding crops (uses in outdoor fields and open-protected structures)

The oral risk assessment for honeybees, bumble bees and solitary bees foraging on the succeeding crops was performed using the risk assessment scheme in EFSA, 2013b and with the available toxicity endpoints (see Section 2). The resulting ETR values are presented in a separate spreadsheet 'Appendix B_Imidacloprid_Risk assessment spreadsheet' accompanying this Conclusion. Where no reliable toxicity endpoint was available (i.e. for larvae of bumble bees and solitary bees and for HPG development of honeybees) no risk assessment could be performed. A low oral risk to honeybees was only indicated for some risk categories of the authorised use to hazel nut, hops and olives and for a single scenario for bumble bees for olives. However, for other categories a high risk was indicated even for these crops, as well as for all other crops for all risk categories. Therefore, a high oral risk to honeybees and bumble bees was indicated for all of the authorised uses. Furthermore, a high oral risk to solitary bees could not be excluded on the basis of the screening assessment, assuming that the endpoints for solitary bees (acute adult and chronic adult scenarios) are ten times lower than the endpoints for honeybees.

It is should be noted that the risk assessment scheme for the succeeding crop scenario in EFSA, 2013b has been developed to be protective of a number of agricultural practices, e.g. including situations for crops such as lettuce when applications can be made to late growth stages and then succeeding, attractive crop is planted very shortly after harvest. For other situations such as crops where applications are made only during early growth stages with a long growing season, or permanent crops, it is likely that the risk is overestimated and it may be possible to further refine the parameters used in the risk assessment (e.g. refining the shortcut values in a tier 2 assessment taking into account residue decline in soil).

No risk assessment for contact exposure in succeeding crops is needed according to EFSA, 2013b.

## 3.2. Tier 2: risk assessment (oral) honeybee, bumble bee, solitary bees

EFSA, 2013b suggests a number of options to refine tier 1 risk assessments. For these refinements further data are required. For example, valid residue data could potentially be used for refining the default shortcut values (SVs) which are used in the oral risk assessment. An overview of the available residue data on imidacloprid is presented in Appendix C.

The imidacloprid regulatory dossier included seven studies reporting residue data on the active substance (i.e. imidacloprid) and/or its metabolites. Two studies reported only residues in matrices non relevant for bees (i.e. alfalfa leaves, different parts of the rice plant). In another multi-year study (Kemp and Rogers, 2002), the experimental design was considered unclear, particularly for the timing between imidacloprid application and sample collection. The measurements reported in the study were not further considered.

The four remaining studies reported residue values for bee-relevant matrices. However, residue data from matrices sampled in-hive (pollen, nectar) were not considered suitable to refining the risk assessment according to EFSA, 2013b. Measurements considered relevant for this Conclusion (pollen and nectar from foragers) for foliar spray uses are summarised in Table 8.

**Table 8:** Available imidacloprid residue data on bee-relevant matrices for foliar spray

| **Crop/ location** | **BBCH at application** | **Type[3]** | **Matrix** | **Maximum RUD (mg/kg)[1]** | **Minimum RUD (mg/kg)[1]** | **DAT[2]** |
|---|---|---|---|---|---|---|
| Apple Spain | 10-11 | F | Pollen from forager bees (also traps) | < LOQ | < LOQ | 18 |
| Apple Spain | 10-11 | F | Nectar from forager bees | < LOQ | < LOQ | 18 |
| Apple Spain | 10-11 | SF | Pollen from forager bees | 0.73 | 0.38 | 13 |
| Apple Spain | 10-11 | SF | Nectar from forager bees | 0.07 | < LOQ | 13 |

[1]Maximum and minimum RUD (residue unit dose) refer to the same sampling date (usually the first available sampling)
[2]Days After Treatment: interval (days) between treatment and sample collection
[3] F – Field; SF - Semi-Field

One field and one semi-field (tunnel) study were carried out under similar conditions; both were performed in South-Eastern Spain, in spring 2008, with an application on apples at BBCH 10-11. Despite these similar conditions maximum residues in the semi-field study were generally higher.
This is a confirmation that, in field studies, forager bees may collect pollen and nectar outside the treated area.

Other studies reporting measurements of imidacloprid residues were found by the systematic open literature review (Fryday et al, 2015). The outcome of the review was screened using several criteria. Studies were retained only if the application technique was relevant for the uses included in this Conclusion. In addition, the studies were screened retaining only those reporting residues measured in certain bee-relevant matrices (i.e. guttation fluid, nectar, pollen, water). It is noted that some residues in other bee-relevant matrices (e.g. beebread, dew, honey, propolis, etc) were also reported, but not considered for this assessment as no risk assessment methodology is included in EFSA 2013b. The availability of information on the application rate - in order to express residues as RUD - was also a selection criterion.

One relevant study with four trials for foliar spray use was identified at the end of the screening process, reporting residues measurement on pollen and nectar. These values are reported in Table 9.

**Table 9:** Imidacloprid relevant residue data from the systematic open literature review for foliar spray

| Reference | Crop/ location | BBCH at application | Type[1] | Matrix | Maximum RUD (mg/kg) | Minimum RUD (mg/kg) | DAT[2] |
|---|---|---|---|---|---|---|---|
| Byrne et al. (2014) | Citrus California, USA | Fall treatment | F | Nectar from flowers | 0.05[3] | 0.002[3] | Not known |
| Byrne et al. (2014) | Citrus California, USA | Fall treatment | F | Nectar from forager bees | 0.03[3] | <LOQ[3] | Not known |
| Byrne et al. (2014) | Citrus California, USA | Fall treatment | F | Nectar from new comb | 0.03[3] | 0.01[3] | Not known |
| Byrne et al. (2014) | Citrus California, USA | Fall treatment | F | Pollen from forager bees (traps) | 0.02 | 0.02 | Not known |

1: F – Field; SF - Semi-Field

2: Days After Treatment: interval (days) between treatment and sample collection. Not known: indicates that it was not clear when the sample was taken in relation to the treatment day

3: Approximated RUDs: concentration values (expressed as ng/mL) were inferred from box-plots. Conversion to mg/kg was performed assuming a worst-case nectar density of 1 g/cm$^3$.

In comparison to the variety of crops and geographic location of the authorised uses (refer to the separate Excel spreadsheet 'Appendix A_Imidacloprid_GAP Table' accompanying this Conclusion), the available residue data are very limited. Furthermore, the representativeness of the studies in relation to worst-case or 90$^{th}$ percentile exposure is very uncertain (see study evaluation notes; EFSA, 2015a).

According to EFSA, 2013b (Appendix G), to perform a tier 2 assessment it is necessary to have data from at least five representative fields in the area of use of the substance with minimal alternative bee pasture in the landscape. Furthermore, the application should be made at the relevant growth stage of the crop. In the Pesticide Peer Review Meeting 129, all experts agreed that the available residue data are not robust and abundant enough to perform a tier-2 risk assessment refining the exposure levels. The available data for imidacloprid are therefore not considered sufficient to perform a robust tier 2 assessment for any of the intended use.

## 3.3. Tier 3: higher tier risk assessment using effects studies honeybee, bumble bee, solitary bees

A high number of semi-field and field studies were available. In most of them the effects of spray applications on honeybees were studied; one particular trial was available for drip irrigation. Two studies were available for drench application on bumble bees. The studies for uses other than spray application are evaluated in Section 4. Some feeding studies (spiked food offered to small honeybee colonies in field/semi-field conditions) were also available. Some of these studies had already been evaluated in earlier risk assessments (Germany, 2005; EFSA, 2013a), some others are evaluated first time for this risk assessment at EU level (see EFSA, 2015a). The feeding studies were not reconsidered here since a relatively high number of higher tier studies were available that used more realistic application regimes. Moreover, these studies had severe shortcomings against the requirement of EFSA, 2013b. Nevertheless, these studies are summarised in the study evaluations notes (EFSA, 2015), under the study numbers of 13, 21, 37, 38 and 81.

### 3.3.1. Higher tier effects studies performed with honeybees and foliar sprays

All of the available higher tier effect studies performed with honeybees have been considered (see study evaluation notes, EFSA, 2015) in relation to EFSA, 2013b. A brief summary of the observations is given in Appendix B.

The fundamental basis for higher tier risk assessment according to EFSA, 2013b is to design higher tier effect studies which are able to address the specific protection goals (SPG) for worst case exposure (90$^{th}$ percentile worst case for the hives at the edge of treated fields in the area of use) and to ensure that the studies are sufficiently sensitive in order to detect biological effects (i.e. cause effect relationship) to meet the SPG for the level of effect (7 % reduction in colony). In order to demonstrate that the studies have achieved the 90$^{th}$ percentile exposure, EFSA, 2013b suggests that an exposure assessment 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 90$^{th}$ percentile exposure level). Insufficient residue data were available to perform an exposure assessment for any of the authorised uses of imidacloprid. An alternative approach would be to have a sufficient number of suitable higher tier effects studies, which are also considered to be able to address the exposure SPG. The number of studies required would depend on numerous factors, such as the representative GAP, the area where the active substance will be applied, the quality of the exposure assessment within the studies and the consistency of results. However, the available higher tier effects studies for imidacloprid were not suitable to be able to assess whether they met the exposure SPG.

The second critical aspect of the usefulness of higher tier effects studies for a risk assessment in accordance with EFSA, 2013b is to ensure that the studies are sufficiently sensitive in order to detect biological effects to meet the SPG for the level of effect (e.g. 7% reduction in colony strength of honeybees). Several criteria are given in the guidance document, which are essential for such an assessment (e.g. an assessment of the power of detection).

EFSA, 2013b also recommended several improvements to the methodology used for higher tier effects studies e.g. increase the size of field/cage, increase the distance between the test fields and the control, to include overwintering success, improvements to the measurements of mortality and colony strength.

Moreover, EFSA 2013b indicates that semi-field studies are of limited usefulness in terms of assessment against the protection goals (e.g. due to the small colony size and short study duration). It is suggested that they may provide some information for specific aspects of the risk assessment, such as forager mortality.

None of the available studies fulfilled the criteria of EFSA 2013b. It is noted that all of the studies were performed prior to the publication of EFSA 2013b. In evaluating these studies deficiencies in the study design, beyond those identified on the basis of the new elements introduced by EFSA 2013b, were also highlighted. Several studies had severe limitations which question their reliability for any form of risk assessment.

On the basis of the available data set, as a general observation, differences from control on foraging activity and forager mortality were noted at the tested application rates, crops and growth stages (including when applications made a number of days before flowering) for the majority of the studies.

### 3.3.2. Higher tier effects studies performed with bumble bees, solitary bees and foliar sprays

No tier 3 studies for bumble bees and solitary bees were available in the regulatory dossiers for foliar spray applications.

## 3.4. Uncertainty analysis

As tier 2 or tier 3 refined risk assessments could not be performed, no uncertainty analysis could be done.

## 4. Risk assessments for products applied as drenches, drip irrigation and other application methods

The risk assessment approach provided in EFSA, 2013b is applicable to all application techniques, however, there is no specific scheme given in EFSA, 2013b for application techniques other than foliar sprays, seed treatments and granules (i.e. no exposure factors and shortcut values are available). Therefore, the exposure to bees for the authorised uses, as drenches, drip irrigation, dips and soil incorporated, was discussed at the Pesticides Peer Review Experts' Meeting 129. The outcome of the discussions can be found in Appendix 4 to the meeting report (EFSA, 2015) and in Appendix E to this Conclusion.

It is noted that for all application techniques, oral exposure via pollen and nectar in the treated crop is anticipated. A risk assessment for the treated crops scenario has therefore been performed (Section 4.1). In the absence of specific shortcut value for drenches, drip irrigation and dips the shortcut values for 'incorporated granules' were used as a surrogate (i.e. the growth stages was restricted to <10). For authorised uses for pre-emergent growth stages (BBCH <10), the use of 'incorporated granules' is considered to be a reasonable assumption. A number of the authorised uses included applications to later growth stages (e.g. via drenches, drip and irrigation). In these cases, it is considered that the shortcut values for 'incorporated granules' is likely to underestimate the risk to bees, given the possibility for foliar contamination and the shorter time between the application and the flowering of the crop/plant.

In line with the approach to the risk assessment for standard foliar spray uses, in order to perform a risk assessment, the authorised uses have been grouped into crop categories given in Table 10-11 which correspond to the crop categories used by the EFSA Bee Tool EFSA Bee Tool v.2 (Appendix Y of EFSA, 2013b), for oral risk assessment. A distinction has been made for the authorised uses which are applied post-flowering of the treated crop only.

**Table 10:** Summary of the authorised outdoor field uses of imidacloprid applied using other application techniques grouped according to the categories given in the EFSA Bee Tool[1]

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Application methods | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| Fruiting vegetables group 1 | No | Cucumber, melon, watermelon, pepper, zucchini (courgette), gherkins and other | Irrigation and drip irrigation | 140 | 150 |
| Fruiting vegetables group 2 | No | Aubergine (eggplant), tomato, tobacco | Drip irrigation, irrigation, watering/pouring | 140 | 640 |
| Grasses | No | Grasses | Drench, watering/pouring | 150 | 150 |
| Leafy vegetables | No | Broccoli, cabbage , head cabbage, cauliflower | Drench, drip irrigation, watering/pouring | 100 | 250 |
| | Yes, harvested prior to flowering | Broccoli, cabbage , head cabbage, cauliflower | Drench, drip irrigation, watering/pouring | 100 | 250 |
| Lettuce | No | Lettuce | Drench, drip irrigation, irrigation, | 140 | 140 |
| | Yes, harvested prior to flowering | Lettuce | Drench, drip irrigation, irrigation, | 140 | 140 |
| Ornamentals | No | Ornamental bulbs | Dip application | 210 | 210 |
| Ornamental trees | No | Palm trees | Root irrigation | 2000 | 2000 |
| Pulses | No | Bean green and bean dry | Drip irrigation | 140 | 140 |
| Strawberries | No | Strawberries | Irrigation | 150 | 150 |
| | Yes, post flowering | | Irrigation | 150 | 150 |
| Non-orchard tree | Yes, not foraged by bees for nectar and pollen | Conifer seedlings[2] | Knapsack sprayer (spot treatment) | 70 | 70 |

[1] Crop grouping has been performed according to the categories in the EFSA Bee Tool v.2 (Appendix Y of EFSA, 2013b), for the risk assessment for oral exposure. For some uses (e.g. ornamentals, tobacco) the grouping was identified and agreed by the experts at the meeting PPR 129. Category non-orchard tree (ornamental trees, as well) is based on category Orchards 1.
[2]: Conifers were considered as not attractive for pollen.

**Table 11:** Summary of the authorised uses of imidacloprid made in open-protected structures applied using other application techniques grouped according to the categories given in the EFSA Bee Tool[1]

| Crop grouping[1] | Can exposure to nectar and or pollen on the treated crop/plant be excluded? | Authorised uses | Application methods | Lowest 'maximum application rate' g a.s./ha | Highest 'maximum application rate' g a.s./ha |
|---|---|---|---|---|---|
| Fruiting vegetables group 1 | No | Bell pepper, cucumber, cucurbits, melon, watermelon, pepper, zucchini (courgette), Gherkins and other | Irrigation and drip irrigation | 20 | 313.6 |
| Fruiting vegetables group 2 | No | Aubergine (eggplant), tomato, tobacco | Drench, drip irrigation, irrigation, watering/pouring | 140 | 640 |
| Leafy vegetables | No | Chinese cabbage | Watering | 190.4 | 190.4 |
| | Yes, harvested prior to flowering | Chinese cabbage | Watering | 190.4 | 190.4 |
| Lettuce | No | Lettuce | Watering | 190.4 | 190.4 |
| | Yes, harvested prior to flowering | Lettuce | Watering | 190.4 | 190.4 |
| Ornamentals | No | Ornamental | Drip irrigation, irrigation, | 140 | 784 |
| Ornamental trees | No | Palm trees | Drip irrigation | 2000 | 2000 |
| Pulses | No | Bean green and bean dry | Drip irrigation | 140 | 140 |
| Strawberries | No | Strawberries | Irrigation | 150 | 150 |
| | Yes, post flowering | | Irrigation | 150 | 150 |

[1] Crop grouping has been performed according to the categories in the EFSA Bee Tool v.2 (Appendix Y of EFSA, 2013b), for the risk assessment for oral exposure. The grouping of category ornamentals and ornamental trees was agreed by the experts at the meeting PPR 129.

In addition to the uses summarised in Table 11, there were three crops/plants (citrus seedlings, hops and palm trees) where applications were made via stem treatment (brush, trunk injection). No quantitative risk assessment could be performed for these types of uses as no first tier parameters were available. However, since the application rates were in the same range to that of the foliar spray uses, it would be reasonable to assume that these type of authorised uses pose a similar or even higher risk to bees (via the oral exposure to the treated crop). However, provided that further information is available (e.g. residue levels in plant/pollen and nectar, residue decline), a more precise exposure estimation and risk assessment could be performed.

### 4.1. Tier 1: risk assessment for honeybees, bumble bees and solitary bees (uses in outdoor field and open-protected structures)

The calculated ETR values are presented in a separate spreadsheet 'Appendix B_Imidacloprid_Risk assessment spreadsheet' accompanying this Conclusion. Where no reliable toxicity endpoint was available (i.e. for larvae of bumble bees and solitary bees and for HPG development of honeybees) no ETR calculations were performed.

On the basis of the first-tier risk assessment, a high risk to honeybees and bumble bees from foraging on pollen and/or nectar in the treated crop was indicated for all of the authorised uses when applications are made either before or during flowering (in case of lettuce and some uses of fruiting vegetables, the risk for the larva scenario was low, but not for adult bees). Furthermore, a high oral risk to solitary bees could not be excluded on the basis of the screening assessment i.e. assuming that the endpoints for solitary bees (acute adult and chronic adult scenarios) are ten times lower than the endpoints for honeybees. For the authorised uses of post-flowering growth stages of strawberry a low oral risk is indicated for the treated crop scenario for all bee species as nectar and pollen are no longer present.

For the authorised uses **to leafy vegetables and lettuce**, it was not specified whether the vegetables are always harvested before flowering or whether they may be allowed to produce flowers (e.g. in the case they are grown for seed production). Therefore, a risk assessment including flowering growth stages has been included. If the **crop is harvested before flowering** there is **a low risk to bees** from foraging pollen and nectar directly on the treated crop. Conifer trees were considered **as non-attractive** to bees for pollen and nectar. Therefore, a **low risk to bees** was concluded for these plants from foraging pollen and nectar directly from the treated crop

The experts at the meeting agreed that, for the authorised uses as soil incorporation, drenches, irrigation, drip irrigation and dips, exposure to bees from weeds in the treated field and succeeding crop is possible (see Table 23, Appendix E). Nevertheless, risk mitigation measures to prevent the weeds within the treated field from flowering would result in a low risk to bees for this scenario. For the authorised uses applied as dips, drip irrigation and drenches to pots for the field margin and the adjacent crop scenarios, it was agreed at the expert meeting that exposure to bees via drift is unlikely (see Table 23, Appendix E) and therefore a low risk was concluded. For the authorised uses as soil incorporation, drenches (excluding to pots) and irrigation the experts considered that exposure could occur and therefore a risk assessment is required. A risk assessment for the succeeding crop scenario, for the field margin and the adjacent crop scenarios for soil incorporation uses, drenches and irrigation should be performed, taking into account the specific conditions in the Member States. This information was not available to EFSA.

### 4.2. Tier 2: risk assessment (oral) honeybee, bumble bee, solitary bees

EFSA, 2013b suggests a number of options to refine tier 1 risk assessments. For these refinements further data are required. For example, valid residue data could potentially be used for refining the default shortcut values (SVs) which are used in the oral risk assessment.

The imidacloprid regulatory dossier included seven studies reporting residue data on the active substance (i.e. imidacloprid) and/or its metabolites. Two studies reported only residues in matrices non relevant for bees (i.e. alfalfa leaves, different part of the rice plant). In another multi-year study (Kemp and Rogers, 2002), the experimental design was considered unclear, particularly for the timing between imidacloprid application and sample collection. The measurements reported in the study were not further considered.

The four remaining studies reported residue values for bee-relevant matrices. However, residue data from matrices sampled in-hive (pollen, nectar) were not considered suitable to refining the risk assessment according to EFSA, 2013b. Measurements considered relevant for this Conclusion for uses other that foliar spray were available only in one study. This was performed by drip irrigation in tomato in Spain. The measured maximum residue levels (RUD values) in pollen from foragers were between 0.35 – 0.18 mg/kg 47 days after the treatment.

A dissipation rate was derived from this study. Residue data were fitted with a single first order (SFO) kinetic model by EFSA, resulting in a $DT_{50}$ of 12.6 days. The fitting was visually acceptable. However, this dissipation rate is probably not a good representation of a true $DT_{50}$ in the pollen, as imidacloprid is applied as drip irrigation. The observed decay curve may be a combination of dissipation in soil, continuous uptake from roots, transport to flowers and true decay in the pollen.

Other studies reporting measurements of imidacloprid residues were found in the systematic open literature review (Fryday et al, 2015). The outcome of the review was screened using several criteria. Studies were retained only if the application technique was relevant for the uses included in this Conclusion. In addition, the studies were screened retaining only those reporting residues measured in bee-relevant matrices (i.e. guttation fluid, nectar, pollen, water) relevant for these assessments. The availability of information on the application rate - in order to express residues as RUD - was also a selection criterion.

Three relevant studies (with different trials) for uses other that foliar spray, were identified at the end of the screening process, reporting residues measurement on nectar, and guttation fluid. These are reported in Table 12.

**Table 12:** Imidacloprid relevant residue data from the systematic open literature review

| Reference | Crop/ location | BBCH at application | Type[1] | Application technique | Matrix | Max. RUD (mg/kg) | Min. RUD (mg/kg) | DAT[2] |
|---|---|---|---|---|---|---|---|---|
| Byrne et al. (2014) | Citrus California, USA | Pre-flowering (end of February) | F | Watering can to soil | Nectar from flowers | 0.07[3] | <LOQ[3] | 55-57 |
| Byrne et al. (2014) | Citrus California, USA | Post-flowering (September) | F | Watering can to soil | Nectar from flowers | 0.08[3] | 0.005[3] | 227-232 |
| Byrne et al. (2014) | Citrus California, USA | Post-flowering (September) | SF | Watering can to soil | Nectar from flowers | 0.04[3] | 0.01[3] | 232 |
| Byrne et al. (2014) | Citrus California, USA | Post-flowering (September) | SF | Watering can to soil | Nectar from forager bees | 0.04[3] | 0.004[3] | 232 |
| Byrne et al. (2014) | Citrus California, USA | Post-flowering (September) | SF | Watering can to soil | Nectar from new comb | 0.10[3] | 0.04[3] | 232 |
| Hoffman& Castle (2012) | Cantaloupe Arizona, USA | ~60 | F | Drip | Guttation Fluid | 2.54 | 9.73 | 4 |
| Hoffman& Castle (2012) | Cantaloupe Arizona, USA | Unknown | F | Drench | Guttation Fluid | 88.51 | ≤0.18 | 5 |
| Paine et al. (2011) | Eucalyptus California, USA | Post-flowering (July) | F | Soil injection[4] | Nectar from flowers | RUD not quantified due to lack of an application rate per area. Mean concentration = 286 ppb | | ~150 |

[1]: F – Field; SF - Semi-Field
[2]: Days After Treatment: interval (days) between treatment and sample collection
[3]: Approximated RUDs: concentration values (expressed as ng/mL) were inferred from box-plots. Conversion to mg/kg was performed assuming a worst-case nectar density of 1 g/cm$^3$.
[4]: Application rate in this study was 2.0 g a.i./2.54 cm trunk diameter

In comparison to the variety of crops and geographic location of the authorised uses, the available residue data are very limited (see separate Excel spreadsheet ‘Appendix A_Imidacloprid_GAP table’ accompanying this Conclusion). Furthermore, the representativeness of the studies in relation to worst-case or 90$^{th}$ percentile exposure is very uncertain (see study evaluation notes; EFSA, 2015a).

According to EFSA, 2013b (Appendix G), to perform a tier 2 assessment it is necessary to have data from at least five representative fields in the area of use of the substance with minimal alternative bee pasture in the landscape. Furthermore, a suitable residue data set would take into account different types of application methods according to the authorised uses and different growth stages of the crop when applications are made. In the Pesticide Peer Review Meeting 129, all experts agreed that the available residue data are not robust and abundant enough to perform a tier-2 risk assessment refining the exposure levels. The available data for imidacloprid are therefore not considered sufficient to perform a robust tier 2 assessment for any of the intended use.

### 4.3. Tier 3: higher tier risk assessment using effects studies honeybee, bumble bee, solitary bees

The available higher tier effects studies have been evaluated according to the criteria given in EFSA, 2013b and are summarised in the study evaluation notes (EFSA, 2015).

#### 4.3.1. Higher tier effects studies performed with honeybees using application techniques other than foliar sprays

Only one field study was available for honeybees, where 2 drip irrigations with the application rates of 140 g imidacloprid/ha were done in a melon field in Sicily (Italy). This study has been evaluated and is summarised in the study evaluations notes (EFSA, 2015). The study was not considered sufficient for risk assessment in accordance with EFSA, 2013b. A brief summary of the observations is given in Appendix B. A discussion on the requirements of EFSA, 2013b is included in Section 3.3.1, above.

#### 4.3.2. Higher tier effects studies performed with bumble bees and solitary bees using application techniques other than foliar sprays

There were two studies performed with bumble bees in home gardens in Germany. In both studies flowering *Lobelia erinus* were drenched by an imidacloprid formulation and bumble bee colonies foraging on the plants were monitored. This studies have been evaluated and are summarised in the study evaluations notes (EFSA, 2015). The studies were not considered sufficient for risk assessment in accordance with EFSA, 2013b. A brief summary of the observations is given in Appendix B. A discussion on the requirements of EFSA, 2013b is included in Section 3.3.1, above.

No tier 3 studies for solitary bees were available in the regulatory dossiers for uses other than foliar spray applications.

### 4.4. Uncertainty analysis and conclusions

As tier 2 or tier 3 refined risk assessments could not be performed, no uncertainty analysis could be done.

## 5. Accumulative effects

According to EFSA, 2013b, an assessment of the potential of accumulative effects to honeybees is required. In the case that a substance is demonstrated to have accumulative effects then higher tier risk assessment is required. No toxicity data investigating accumulative effects was available and therefore no assessment could be performed.

## 6. Risk assessment from exposure to contaminated water

EFSA, 2013b proposes that the risk to honeybees from exposure to contaminated water, via guttation fluid, surface water and puddles, should be considered. It is noted that other potential routes of exposure (e.g. exposure via drinking the water formed in the irrigation point when the formulation is applied via drip irrigation) are not covered by the exposure scenarios given in EFSA 2013b.

### 6.1. Assessment of the risk from exposure via residues in guttation fluid

EFSA, 2013b proposes a screening assessment to assess the risk to honeybees via guttation fluid on the treated crop. The risk assessments for the authorised uses as foliar sprays are included in Table 13.

**Table 13:** Screening risk assessment for honeybees via guttation fluid on the treated crop

| | **Step** | **Assessment** | |
|---|---|---|---|
| 1 | Check whether exposure is negligible. | • Permanent greenhouse uses are considered to result in negligible exposure to honeybees from exposure to guttation fluid<br>• For all other uses exposure could occur | |
| 2 | Check whether guttation occurs for <10% of location/calendar year combinations. | No information available to perform this step. | |
| 3 | Calculate ETR based on conservative assumptions. | Water solubility imidacloprid = 0.613 g/L (= 0.613 µg/µL) at pH 5.5, 20 °C (EFSA, 2008). | |
| 3a | $ETR_{acute}$ adult honeybees = W*PEC/$LD_{50}$<br><br>$LD_{50}$ = acute oral $LD_{50}$ (µg a.s./bee)<br>W = water uptake of adult honeybees = 11.4 µL/bee<br>PEC = concentration in guttation fluid in µg/µL and is assumed to be:<br>100% of the water solubility for acute assessment | Acute oral $LD_{50}$ = 0.0037 µg a.s./bee<br>PEC = 0.613 µg/µL<br>W = 11.4 µL/bee | **Screening ETR = 1889**<br>Which is greater than the trigger of 0.2 |
| 3b | $ETR_{chronic}$ honeybees = W*PEC/$LDD_{50}$<br><br>$LDD_{50}$ = chronic lethal dietary dose ($LC_{50}$ expressed in µg a.s./bee per day)<br>W = water uptake of adult honeybees = 11.4 µL/bee<br>PEC = concentration in guttation fluid in µg/µL and is assumed to be:<br>54% of the water solubility for chronic assessment | Chronic adult $LDD_{50}$ >0.00282 µg a.s./bee/day<br>PEC = 0.331 µg/µL<br>W = 11.4 µL/bee | **Screening ETR < 1338**<br>Which is greater than the trigger of 0.03 |
| 3c | $ETR_{larvae}$ honeybees = W*PEC/$NOEL_{larvae}$<br><br>$NOEL_{larvae}$ = NOEC for larvae expressed in µg a.s./larvae per developmental period<br>W = water uptake of larvae over 5 days = 111 µL/larvae per 5 days<br>PEC = concentration in guttation fluid in µg/µL and is assumed to be:<br>72% of the water solubility for chronic assessment | Chronic larvae NOEC = 0.00528 µg a.s./bee/ developmental period<br>PEC = 0.441 µg/µL<br>W = 111 µL/bee | **Screening ETR = 9279**<br>Which is greater than the trigger of 0.2 |
| 3d | $ETR_{HPG}$ honeybees = W*PEC/$NOEL_{HPG}$<br><br>$NOEL_{HPG}$ = NOEC based on HPG development expressed in µg a.s./bee per day<br>W = water uptake of adult honeybees = 11.4 µL/bee<br>PEC = concentration in guttation fluid in µg/µL and is assumed to be:<br>54% of the water solubility for chronic assessment | No suitable endpoint available for assessment. | |
| 4 and 5 | Refine exposure calculation<br>Step 4 and 5 of the EFSA, 2013b risk assessment scheme suggests that the exposure estimate could be refined by using 90$^{th}$ percentile measured residues in guttation fluid occurring on the crop. Alternatively, the 90$^{th}$ percentile scenario soil pore water concentrations could also be calculated and used as an approximation of the concentration in guttation fluid. | No data for these assessments were available for the authorised uses of imidacloprid. | |

As indicated in Table 13, the screening step was not sufficient to demonstrate a low acute risk to honeybees for the uses when bees can be exposed to contaminated guttation fluid.

As acknowledged by EFSA, 2013b, little information exists to understand the potential risk to honeybees from exposure to residues of pesticides in guttation fluid applied as foliar sprays. For an informative risk assessment further information is needed as to when guttation occurs in crops. Further knowledge is also needed to understand the extent that honeybees use guttation fluid.

The exposure data base in the available systematic literature review or from the dossier did not reveal any data giving measurements of concentrations of imidacloprid occurring in guttation fluid following foliar spray applications. For other uses (drench and drip application), only two studies were available from the USA.

With the information available, the risk assessment for honeybees exposed to residues of imidacloprid occurring in guttation fluid cannot be finalised.

However, for the authorised uses in permanent greenhouses, no exposure to bees from residues in guttation fluid is anticipated and therefore there is no risk to bees via this route of exposure.

### 6.2. Assessment of the risk from exposure via residues in surface water

According to EFSA (2013b) a risk assessment for honeybees from the consumption of residues in surface water should be performed. The assessment should use the aquatic exposure assessment calculated according to FOCUS as currently performed for the risk assessment for aquatic organisms. No agreed FOCUS surface water exposure assessment is available for each of the authorised uses of imidacloprid. However, an aquatic exposure assessment is available in EFSA (2014b) for the two representative foliar spray uses summarised in Table 14.

**Table 14:** Representative uses of imidacloprid for which a surface water exposure assessment is available in EFSA 2014b

| Crop | Member State | Growth stage | Number of applications | Interval between applications | Maximum application rate g a.s./ha |
|---|---|---|---|---|---|
| Apple | Northern and Southern Europe | 1. BBCH 10<br>2. BBCH 69/71 or latest 14 d prior to harvest | 1<br>1 | - | 1st 70<br>2nd 105 |
| Tomato | Southern Europe | At infestation | 2 | 14 | 100 |

The available FOCUS step 3 PEC values for the representative uses to apple and tomatoes are summarised in Table 15. The exposure to honeybees has then been calculated by considering a daily water consumption of 11.4 µL/bee per day for adult honeybees and a five day water consumption of 111 µL/honeybee larvae per 5 days. ETR values have then been calculated using the available acute oral, chronic oral and chronic larvae toxicity endpoints given in Table 3. On the basis of the assessment, a low risk to honeybees (with the exception of HPG) is demonstrated for the representative uses to apples and tomatoes using FOCUS step 3 exposure estimates. No assessment of effects to honeybee HPG could be performed as no toxicity endpoint was available.

**Table 15:** First tier risk assessment for honeybees from consumption of residues of imidacloprid in surface water (FOCUS step 3) for the representative uses to apples and tomatoes

| Scenario | Water body | $PEC_{sw;max}$ (µg a.s./L) | Exposure to adult honeybees µg a.s./bee per day | Exposure to honeybee larvae µg a.s./bee per 5 days | Acute oral $LD_{50}$ µg a.s./bee | Acute ETR | Trigger for acute adult | Chronic $LDD_{50}$ µg a.s./bee/day | Chronic ETR | Trigger for chronic adult | Larvae NOEL morality µg a.s./larva | Larvae ETR | Trigger for larvae |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Apples (1st application 70 g a.s./ha or 105 g a.s./ha)** | | | | | | | | | | | | | |
| D3 | ditch | 5.429 | 0.000062 | 0.000603 | 0.0037 | 0.017 | 0.2 | >0.00282 | <0.022 | 0.03 | 0.00528 | 0.114 | 0.2 |
| D4 | pond | 0.334 | 0.000004 | 0.000037 | | 0.001 | | | <0.001 | | | 0.007 | |
| D4 | stream | 5.204 | 0.000059 | 0.000578 | | 0.016 | | | <0.021 | | | 0.109 | |
| D5 | pond | 0.357 | 0.000004 | 0.000040 | | 0.001 | | | <0.001 | | | 0.008 | |
| D5 | stream | 5.173 | 0.000059 | 0.000574 | | 0.016 | | | <0.021 | | | 0.109 | |
| R1 | pond | 0.330 | 0.000004 | 0.000037 | | 0.001 | | | <0.001 | | | 0.007 | |
| R1 | stream | 4.425 | 0.000050 | 0.000491 | | 0.014 | | | <0.018 | | | 0.093 | |
| R2 | stream | 5.821 | 0.000066 | 0.000646 | | 0.018 | | | <0.024 | | | 0.122 | |
| R3 | stream | 6.187 | 0.000071 | 0.000687 | | 0.019 | | | <0.025 | | | 0.130 | |
| R4 | stream | 4.395 | 0.000050 | 0.000488 | | 0.014 | | | <0.018 | | | 0.092 | |
| **Tomatoes (2 applications of 100 g a.s./ha)** | | | | | | | | | | | | | |
| D6 | ditch | 0.627 | 0.000007 | 0.000007 | 0.0037 | 0.002 | 0.2 | >0.00282 | <0.003 | 0.03 | 0.00528 | 0.013 | 0.2 |
| R2 | stream | 1.298 | 0.000015 | 0.000015 | | 0.004 | | | <0.005 | | | 0.027 | |
| R3 | stream | 2.856 | 0.000033 | 0.000033 | | 0.009 | | | <0.012 | | | 0.060 | |
| R4 | stream | 3.037 | 0.000035 | 0.000035 | | 0.009 | | | <0.012 | | | 0.064 | |

### 6.3. Assessment of the risk from exposure via residues in puddles

In the absence of agreed PECrunoff values for the authorised uses, the risk to honeybees consuming residues in puddles could not be assessed. For the authorised uses in permanent greenhouses no exposure to residues in puddles are expected to be present and therefore the risk to bees via this route of exposure was considered as low.

## 7. Risk posed by metabolites

According to EFSA, 2013b each metabolite should be considered which exceeds 10 % TRR or 0.01 mg/kg identified in the plant metabolism studies. However, where data on occurrence of metabolites in pollen and nectar are available, the assessment should focus on these metabolites. Data on occurrence of metabolites in pollen and nectar and toxicity data for honeybees were available and assessed in Germany, 2005. The relevant data for toxicity from Germany, 2005 are summarised in Table 16.

**Table 16:** Available laboratory toxicity data (oral $LD_{50}$) for honeybees for imidacloprid plant metabolites

| Name of metabolite | Acute oral $LD_{50}$ expressed in µg/bee |
|---|---|
| 5-Hydroxy-(M01) | 0.159 |
| Olefine-(M06) | > 0.036 |
| 4,5-Dihydroxy-(M03) | > 0.049 |
| Guanidine-(M09) | ca. 93.2 |
| Nitrosimine-(M07) | 0.080 |
| 6-Chloro-nicotinic acid (M14) | > 121.5 |
| 6-Chloro-picolylamin | > 119.8 |

Moreover, other types of toxicity studies indicated that the urea metabolite is not more toxic to honeybees than imidacloprid.

All metabolite toxicity tests (for oral $LD_{50}$) were conducted in the same research laboratory. The parent compound was tested in the same facility in parallel to facilitate a comparative assessment of the metabolites. The reported approximated $LD_{50}$ value for the parent compound was 0.041 µg/bee. As shown in Table 16, metabolites guanidine-(M09), 6-Chloro-nicotinic acid (M14) and 6-Chloro-picolylamin are clearly less toxic (with some orders of magnitude) to honeybees than imidacloprid. However, metabolites 5-Hydroxy-(M01), Olefine-(M06), 4,5-Dihydroxy-(M03) and Nitrosimine-(M07) need to be considered further. The experts at the Pesticides Peer Review Experts' Meeting 129 concluded that the first tier risk assessment for metabolites is covered by the assessment with the parent. It was also noted that once further data are available, separate risk assessments could be performed for the metabolites (e.g. second tier assessments considering residue data).

## 8. Overall conclusion of the risk assessment

Where a risk assessment could be performed, a high risk to honeybees and bumble bees was indicated in the available first-tier risk assessments for all authorised foliar uses and for the majority of uses other than foliar sprays, except those used in permanent greenhouse structures:

- No data were available for the development of hypopharyngeal gland of honeybees. For non-*Apis* bees only a few toxicity data were available. Where no data were available, either no assessments were done or a surrogate endpoint derived from pertinent endpoint for honeybees was used. Also, no assessments could be performed for a numerous aspects due to lack of data (accumulative effects; risk to honeybees from contaminated water via guttation fluid, puddles and surface water; risk assessment of relevant metabolites and assessment of toxicity of a number of the authorised formulated products).

- For uses before flowering, or to flowering crops/plants, a high risk to honeybees and bumble bees foraging on the treated crop was indicated. For uses to post-flowering crops, crops harvested before flowering or plants not foraged by bees, a low risk for the treated crop scenario was concluded.

- Where a risk assessment could be performed, a high risk to honeybees and bumble bees from foraging on weeds in the treated field was indicated unless risk mitigation measures are used to ensure there are no flowering weeds.

- For a number of authorised uses a high risk to honeybees and bumble bees was indicated for the field margin and adjacent crop scenarios even with 95% spray drift mitigation. However, for several authorised uses, it is possible to mitigate the risk to honeybees and bumble bees for these scenarios. For the authorised uses as drip irrigation, drenches to pots and dips exposure to bees is unlikely and therefore a low risk was concluded. For the authorised uses as soil incorporation, drenches (excluding to pots) and irrigation, exposure in the field margin and adjacent crop could not be excluded and the risk assessment was not finalised.

- With the exception of a few authorised uses to non-attractive permanent crops, a high risk to honeybees and bumble bees was indicated for the succeeding crop/plant scenario.

- No higher tier risk assessment could be performed as no suitable exposure assessment was available and none of the available higher tier effect studies were considered sufficient in accordance with the EFSA, 2013b guidance document.

- For several authorised uses, no risk assessment could be performed owing to insufficient information provided to EFSA.

- No quantitative risk assessment was performed for the authorised uses indicated as home garden only. It was considered that concentrations in pollen and nectar in treated plants may be comparable to treated agricultural/horticultural plants. The risk to bees was therefore considered to depend on the scale of use which is dependent on Member State conditions.

For the authorised uses in permanent greenhouse structures, a low risk to honeybees, bumble bees and solitary bees was concluded for all exposure routes except the risk assessment for honeybees from residues in surface water. The risk assessment, for honeybees from residues in surface water, could not be finalised with the available information. However, it is noted that pertinent risk assessments were available for two open field spray uses (the EU representative uses in tomato and apple) that indicated a low risk to honeybees.

## 9. Monitoring data

Information on monitoring activities was provided by two Member States (Austria and Hungary).

In particular **Austria** informed the experts' meeting regarding the monitoring program in 2012 and 2013) (follow up to 'MELISSA'). Samples from suspected bee poisoning incidents were collected (bees, beebread) and analysed for clothianidin, thiamethoxam, imidacloprid and fipronil (Girsch and Moosbeckhofer, 2012 Moosbeckhofer and Mayr, 2013).

<u>Results spring/summer season 2012</u>: From 69 samples (38 bee samples, 31 beebread samples) collected in spring/summer 2012 from suspected bee poisoning incidents in 28 samples a contamination with one of the 4 substances was detected. This is related to 51 % of apiaries where residue analyses were positive (totally around 600 hives). All 4 substances were detected with clothianidin being the most frequently found active substance. The max. residue of clothianidin in

dead bee matrix was 0.0054 mg a.s./kg. The max. residue of imidacloprid in dead bee matrix was 0.0056 mg a.s./kg. The max. residue of thiamethoxam in bee bread was 0.0012 mg a.s./kg.

The source of contamination is not known (spray treatment, biocide use, other).

Results in spring/summer 2013: in 14 out of 74 apiaries (around 1500 hives) with suspected poisoning one of the substances was detected. A total of 107 samples were analysed (41 bee samples, 66 bee bread samples). In 7 samples clothianidin was detected with a max. residue level found of 0.0026 mg/kg. In 3 samples imidacloprid was detected with a max. residue level found of 0.0014 mg/kg. Thiamethoxam was not detected.

The source of contamination is not known (spray treatment, biocide use, other). The samples were also analysed for other pesticides and in several samples pesticide a.s. were detected.

Hungary reported that cropped fields, which had been treated (spray or seed dressing) according to the label, were monitored for residues in the flower of the crops (and soil samples for seed dressing) (Jordán László, 2014). The study was conducted by the Hungarian authority (Nemzeti Élelmiszerlánc-biztonsági Hivatal) in 5 Hungarian counties in 2013.

Results: Imidacloprid was investigated only in crops associated with seed dressing. For clothianidin and thiamethoxam from over sprayed crops, the following residue levels were reported:

- Thiamethoxam in winter oilseed rape flower (maximum values): <1 – 4.7 µg/kg flower; clotianidin as metabolite of thiamethoxam <1 – 3.2 µg g/kg flower. The pesticide applications in these fields (5 fields) were done at BBCH 30 with 20 g a.s./ha.

- Clothianidin in apple flower (maximum values): 13.9 – 95.4 µg/kg flower when the applications (4 fields) were at BBCH 09 (5 mm leave bud) and 1268 µg/kg when the application (1 field) was at 'red sprout' stage (off-label use). The application rate was 75 g a.s./ha in both cases.

It has to be noted that at the Pesticides Peer Review Experts' Meeting 97 (EFSA 2013a) the experts discussed the use of monitoring data for risk assessment. It was considered that it can be difficult to use monitoring data directly in risk assessment due to the fact that there are many influential parameters in the monitoring data that cannot be fully understood (pesticide exposure, climatic conditions, presence of disease, farming practices, etc.). Furthermore, it is difficult to link exposure and observed effects in monitoring data (i.e. causality). It was also noted that monitoring data may not provide a complete picture as, in some cases, not all parameters are investigated (e.g. use of veterinary medicines). Overall, it was considered that monitoring data are of limited use for risk assessment but may be useful to provide feedback for risk managers to consider prevention measures.

The issue was not further discussed within the context of this Conclusion. However, EFSA notes that monitoring studies, if specifically designed, could inform the level of risk or provide feedback on risk assessment methodology and further developments are expected in future ('MUST-B' EU effort towards the development of a holistic approach for the risk assessment on multiple stressors in bees: http://www.efsa.europa.eu/en/topics/topic/beehealth.htm).

## 10. List of data gaps identified during the assessment

This is a list of the data gaps identified during this specific peer review process.

- Information to address the risk to honeybees, bumble bees and solitary bees for the pertinent exposure scenarios (contact and/or oral exposure from the treated crop and/or field margin and/or adjacent crop and/or succeeding crop) (relevant for all outdoors field uses and uses in open-protected structures)

- Information to address the risk to honeybees from exposure to contaminated water (surface-water and/or puddles and/or guttation fluid) (relevant for all outdoors field uses, uses in open-protected structures and uses in permanent greenhouses)

- Information to address the risk to honeybees for 5-Hydroxy-(M01), Olefine-(M06), 4,5-Dihydroxy-(M03) and Nitrosimine-(M07) metabolites of imidacloprid (relevant for all outdoors field uses and for uses in open-protected structures)

# 11. Particular conditions proposed to be taken into account to manage the risk(s) identified

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

- To prevent weeds in the field from flowering (relevant for all bee species and all outdoors field uses and uses in open-protected structures; see Section 3).

- To reduce the drift in the field margins and adjacent crops (relevant for honeybees and bumble bees for some uses, see Table 7 in Section 3.1.1.3). It is noted that the level of mitigation should not be regarded as conclusive of that required to protect honeybees and bumble bees as not all aspects of the risk assessments could be performed (e.g. HPG).

# 12. Concerns

## 12.1. Issues that could not be finalised

The assessments are considered not finalised due to lack of data (i.e. HPG for honeybees) or when only a screening level assessment could be performed (i.e. contaminated water consumption for honeybees, oral and contact assessments for solitary bees, chronic oral adult, chronic oral larvae for bumble bees). The issues that could not be finalised are marked with an 'X' in the overview table in Section 13.

## 12.2. Critical areas of concern

The risks identified are marked with an 'R' in the overview table in Section 13. 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 (i.e. honeybee acute oral adult, acute contact adult, chronic oral adult, chronic oral larvae; bumble bees acute oral adult, acute contact adult). See Table 17.

## 13. Overview of the concerns identified for the uses of imidacloprid other than seed treatments and granules

**Table 17:** Summary of concerns for each scenario according to the risk assessment scheme in EFSA, 2013b and particular conditions proposed to be taken into account to manage the risks identified

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 a high risk: honeybee acute oral adult, acute contact adult, chronic oral adult, chronic oral larvae; bumble bees acute oral adult, acute contact adult)
R(1) = High risk identified for some of the uses (a high risk has been highlighted if any of the parts of the risk assessment for each risk scenario according to EFSA, 2013b indicated a high risk: honeybee acute oral adult, acute contact adult, chronic oral adult, chronic oral larvae; bumble bees acute oral adult, acute contact adult). A low risk can be concluded for some of the uses provided that 95 % risk mitigation of spray drift is applied. Refer to Table 7.
R(2) = High risk identified except for conifers and non-flowering varieties of ornamental plants provided that those plants are permanent plants (a high risk has been highlighted if any of the parts of the risk assessment for each risk scenario according to EFSA, 2013b indicated a high risk: honeybee acute oral adult, acute contact adult, chronic oral adult, chronic oral larvae; bumble bees acute oral adult, acute contact adult)
X = Risk assessment not finalised due to lack of data (i.e. HPG for honeybees) or when only a screening level assessment could be performed (i.e. contaminated water consumption for honeybees, oral and contact assessments for solitary bees, chronic oral adult, chronic oral larvae for bumble bees).
X(1) = Risk assessment not finalised due to lack of data (i.e. HPG for honeybees) or when only a screening level assessment could be performed (i.e. contaminated water consumption for honeybees, oral and contact assessments for solitary bees, chronic oral adult, chronic oral larvae for bumble bees) except for conifers.
X(2) = Risk assessment not finalised except where exposure could be excluded (for the authorised uses as dips, drip irrigation and drenches to pots).

The table does not reflect authorised uses where there was insufficient information in the GAP to perform a risk assessment including where the use was indicated as indoors but it was not clear whether the treated crop/plant would be moved outdoors and including when the crop was considered as unknown (Appendix A_Imidacloprid_GAP table; supporting table, Column M, Column N and Column W). In addition, the table does not reflect authorised uses indicated as home garden only (see Section 1.1 and the separate Excel spreadsheet ‘Appendix A_Imidacloprid_GAP table; supporting table, Column R). Also, in lack of specific risk assessment schemes, no quantitative risk assessment was conducted and included in this table where applications were via stem treatment (citrus seedlings, hops and palm trees; see Section 4).

| Crop/plant | Use in outdoor, open-protected structures or in permanent greenhouse | Flowering stage | | Honeybee | | | | | | | | Bumble bee | | | | | Solitary bee | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] | Guttation fluid | Surface water | Puddles | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] |
| **Foliar spray uses (not including spot treatment by knapsack sprayer on conifers) and in-furrow spray uses in potato** | | | | | | | | | | | | | | | | | | | | | |
| Arable field crops[1] | Outdoor and semi-protected uses | Pre-flowering and Flowering | Risk identified | R | | R(1) | R(1) | R | | | | R | | R(1) | R(1) | R | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering | Risk identified | | | R(1) | R(1) | R | | | | | | R(1) | R(1) | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |
| | | Crops harvested before flowering | Risk identified | | | R(1) | R(1) | R | | | | | | R(1) | R(1) | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |
| Orchards[1] | Outdoor uses | Pre-flowering and Flowering | Risk identified | R | | R | R | R | | | | R | | R | R | R | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering | Risk identified | | | R | R | R | | | | | | R | R | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | - | | X | X | X | | | X | X | X |
| Grapes | Outdoor and semi-protected uses | Pre-flowering and Flowering | Risk identified | R | | R | R | R | | | | R | | R | R | R | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering | Risk identified | | | R | R | R | | | | | | R | R | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |

| Crop/plant | Use in outdoor, open-protected structures or in permanent greenhouse | Flowering stage | | Honeybee | | | | | | | | Bumble bee | | | | | Solitary bee | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] | Guttation fluid | Surface water | Puddles | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] | Treated crop scenario | Weed scenario with mitigation | Field margin with 95% mitigation | Adjacent crop with 95% mitigation | Succeeding crop scenario[2] |
| Hops | Outdoor uses | Pre-flowering and Flowering | Risk identified | R | | R | R | R | | | | R | | R | R | R | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering | Risk identified | | | R | R | R | | | | | | R | R | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |
| Ornamentals[1] | Outdoor and semi-protected uses | Pre-flowering and Flowering | Risk identified | R | | R | R | R | | | | R | | R | R | R | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering or non-flowering varieties | Risk identified | | | R | R | R(2) | | | | | | R | R | R | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |
| Non-orchard trees[1] | Outdoor and semi-protected uses | Pre-flowering and Flowering | Risk identified | R | | R | R | R | | | | R | | R | R | | | | | | |
| | | | Assessment not finalised | X | | X | X | X | X | X | X | X | | X | X | X | X | | X | X | X |
| | | Post flowering or specie not attractive to bees | Risk identified | | | R | R | R(2) | | | | | | R | R | | | | | | |
| | | | Assessment not finalised | | | X | X | X(1) | X | X | X | | | X | X | X(1) | | | X | X | X(1) |
| Fruiting vegetables and ornamentals | Use in permanent greenhouse | Pre-flowering | Risk identified | | | | | | | | | | | | | | | | | | |
| | | | Assessment not finalised | | | | | | | X | | | | | | | | | | | |
| **Other application techniques: drench, drip irrigation, irrigation, watering/pouring, spot treatment by knapsack sprayer** | | | | | | | | | | | | | | | | | | | | | |
| Arable field crops, grasses and ornamentals | Outdoor and semi-protected uses | Pre-flowering and Flowering | Risk identified | R | | | | | | | | R | | | | | | | | | |
| | | | Assessment not finalised | X | | X(2) | X(2) | X | X | X | X | X | | X(2) | X(2) | X | X | | X(2) | X(2) | X |

| Crop/plant | Use in outdoor, open-protected structures or in permanent greenhouse | Flowering stage | | Honeybee | | | | | | | | Bumble bee | | | | | Solitary bee | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | **Treated crop scenario** | **Weed scenario with mitigation** | **Field margin with 95% mitigation** | **Adjacent crop with 95% mitigation** | **Succeeding crop scenario[2]** | **Guttation fluid** | **Surface water** | **Puddles** | **Treated crop scenario** | **Weed scenario with mitigation** | **Field margin with 95% mitigation** | **Adjacent crop with 95% mitigation** | **Succeeding crop scenario[2]** | **Treated crop scenario** | **Weed scenario with mitigation** | **Field margin with 95% mitigation** | **Adjacent crop with 95% mitigation** | **Succeeding crop scenario[2]** |
| | | Post flowering or crops harvested before flowering | Risk identified | | | | | | | | | | | | | | | | | | |
| | | | Assessment not finalised | | | X | X | X | X | X | X | | | X | X | X | | | X | X | X |
| Conifer seedlings | Outdoor use | All (not attractive to bees) | Risk identified | | | | | | | | | | | | | | | | | | |
| | | | Assessment not finalised | | | X | X | | X | X | X | | | X | X | | | | X | X | |
| Fruiting vegetables and ornamentals | Use in permanent greenhouse | Pre-flowering | Risk identified | | | | | | | | | | | | | | | | | | |
| | | | Assessment not finalised | | | | | | | X | | | | | | | | | | | |

[1]: a detailed list of crops can be found in Table 7, in Section 3.1.1.3, where 'Ornamentals' and 'Non-orchard trees' are grouped with 'Orchards'

[2]: The 'succeeding crop' scenario includes an assessment from the risk to bees from residues occurring in flowering permanent crops in the successive year

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## APPENDICES

### APPENDIX A – SUMMARY OF AUTHORISED USES OTHER THAN SEED TREATMENTS AND GRANULES IN THE EU, INCLUDING USES REFERRED TO IN RECITAL 7 OF COMMISSION IMPLEMENTING REGULATION (EU) NO 485/2013 (THAT MAY ALSO INCLUDE USES WHICH MAY HAVE BEEN WITHDRAWN AND/OR NO LONGER AUTHORISED IN THE MEMBER STATES DUE TO THE RESTRICTIONS OF REGULATION (EU) NO 485/2013)

Please refer to the separate Excel spreadsheet **'Appendix A_Imidacloprid_GAP table'** accompanying this Conclusion.

## APPENDIX B - OVERVIEW OF THE AVAILABLE TOXICITY STUDIES AND TIER-1 AND TIER-3 RISK ASSESSMENTS

**Table 18:** Overview of the available acute toxicity data for imidacloprid technical and formulated for honeybee and bumble bee

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| Imidacloprid -AE VL 0.0625 | *Apis mellifera* | | contact | 96 | | 0.0020 | 40.5 | Bruhnke, C.<br>2001<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | mellifera | contact | 48 | | 0.0067 | | Suchail, S.; Guez, D.; Belzunces, L. P. 2000<br>DAR, not valid | publication; had been considered as invalid |
| Technical | *Apis mellifera* | caucasica | contact | 48 | | 0.0128 | | Suchail, S.; Guez, D.; Belzunces, L. P.<br>2000<br>DAR, not valid | publication; had been considered invalid |
| Imidacloprid AL 0.125 | *Apis mellifera* | | contact | 96 | | 0.0150 | 5.4 | Bruhnke, C.<br>2001<br>Study evaluation notes, EFSA 2015 | |
| Imidacloprid SL 200 | *Apis mellifera* | | contact | 72 | | 0.0173** | 4.7 | Schmitzer, S.<br>2001<br>DAR | |
| Imidacloprid SL 200 | *Apis mellifera* | | contact | 72 | | 0.0177 | 4.6 | Schmitzer S.(8)<br>2006<br>Study evaluation notes, EFSA 2015 | |
| Imidacloprid 700 g/kg WG | *Apis mellifera* | | contact | 72 | | 0.0190 | 4.3 | Schmitzer S. (9)<br>2006<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 24 | | 0.0300 | | Ruzhong, G.; Rui, C.; Liangyan, C.<br>1999<br>DAR | only cited, but had been not evaluated |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0420 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R.<br>2001<br>DAR | publication, only cited, but had been not evaluated |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0429 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R.<br>2001<br>DAR | publication, only cited, but had been not evaluated |

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| Technical | *Apis mellifera* | carnica | contact | 48 | | 0.0429 | | Wilhelmy, H. 2000 DAR | non-GLP |
| NTN 33893 240FS | *Apis mellifera* | | contact | 24 | | 0.0439 | 1.8 | Mayer, D. F.; Lunden, J. D.; Husfloen, M. R. 1991 DAR | |
| Imidacloprid SL 200 | *Apis mellifera* | | contact | 96 | 0.246 | 0.0450 | 1.8 | Barth, M. 2001 DAR | |
| Imidacloprid 70% WDG | *Apis mellifera* | | contact | 96 | 0.07 | 0.0490 | 1.7 | Marvania, T.G. 2007 Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 72 | | 0.0490 | | Thompson, H. M. 2000 DAR | non-GLP |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0500 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R. 2001 DAR | publication, only cited, but had been not evaluated |
| Confidor SC 200 | *Apis mellifera* | | contact | 48 | 0.29 | 0.0542 | 1.5 | Schmitzer, S. 1995 DAR | |
| Kohinor 700 WG | *Apis mellifera* | | contact | 96 | | 0.0570 | 1.4 | Bruhnke, C. 2008 Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0610 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R. 2001 DAR | publication, only cited, but had been not evaluated |
| Confidor SL 200 | *Apis mellifera* | | contact | 96 | | 0.0610 | 1.3 | Halsall, N. 2004 Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | *carnica* | contact | 96 | | 0.0690 | | Barth, M. 2000 DAR | non-GLP |

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0749 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R.<br>2001<br>DAR | publication, only cited, but had been not evaluated |
| NTN 33893 200 OD | *Apis mellifera* | | contact | 96 | | 0.0780 | 1.0 | Halsall, N.<br>2004<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 48 | | 0.0810 | | Cole, J. H.<br>1990<br>DAR | |
| Technical | *Apis mellifera* | | contact | 96 | | 0.0962 | | Schmitzer, S. (4)<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 48 | | 0.1040 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R.<br>2001<br>DAR | publication, only cited, but had been not evaluated |
| Nuprid 200 SC | *Apis mellifera* | | contact | 72 | | 0.1130 | 0.7 | Warmers C. (11)<br>2007<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | contact | 72 | | 0.1310 | | Ruijter, A. de<br>1999<br>DAR | |
| NTN 33893 75 OD & AE F032640 10 | *Apis mellifera* | | contact | 48 | 2.218 | 0.166 | 2.05 | Barth, M.<br>2004<br>Study evaluation notes, EFSA 2015 | formulation includes deltametrin; the endpoint expressed in µg a.i./bee is only an estimation |
| Confidor WG 70 | *Apis mellifera* | | contact | 48 | 0.35 | 0.2426 | 0.3 | Schmitzer, S.<br>1995<br>DAR | |
| Imidacloprid 20% SL | *Apis mellifera* | | contact | 96 | | 0.3020 | 0.3 | Kling, A.<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | | oral | 48 | | 0.0019 | | Schmitzer, S. (4)<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Imidacloprid 700 g/kg WG | *Apis mellifera* | | oral | 72 48 | | 0.0025 | 1.5 | Schmitzer S. (9)<br>2006<br>Study evaluation notes, EFSA 2015 | |

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| Technical | *Apis mellifera* | | oral | 48 | | 0.0037 | | Cole, J. H.<br>1990<br>DAR | |
| Imidacloprid SL 200 | *Apis mellifera* | | oral | 72 | | 0.0040 | 0.9 | Schmitzer S.(8)<br>2006<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | *mellifera* | oral | 48 | | 0.0048 | | Suchail, S.; Guez, D.; Belzunces, L. P.<br>2000<br>DAR | |
| Imidacloprid SL 200 | *Apis mellifera* | | oral | 96 | | 0.0053*** | 0.7 | Schmitzer, S.<br>2001<br>DAR | |
| Technical | *Apis mellifera* | *caucasica* | oral | 48 | | 0.0065 | | Suchail, S.; Guez, D.; Belzunces, L. P.<br>2000<br>DAR | |
| Imidacloprid 70% WDG | *Apis mellifera* | | oral | 96 | 0.013 | 0.0091 | 0.4 | Marvania, T.G.<br>2007<br>Study evaluation notes, EFSA 2015 | |
| Imidacloprid -AE VL 0.0625 | *Apis mellifera* | | oral | 96 | | 0.0110 | 0.3 | Bruhnke, C.<br>2001<br>Study evaluation notes, EFSA 2015 | |
| Confidor WG 70 | *Apis mellifera* | | oral | 48 | 0.0167 | 0.0116 | 0.3 | Schmitzer, S.<br>1995<br>DAR | |
| Confidor SC 200 | *Apis mellifera* | | oral | 38 | 0.103 | 0.0193 | 0.2 | Schmitzer, S.<br>1995<br>DAR | |
| Technical | *Apis mellifera* | mellifera | oral | 24 | | >0.021 | | Ruijter, A. de<br>1999<br>DAR | |
| Technical | *Apis mellifera* | | oral | 48 | | 0.0301 | | Decourtye, A.<br>2000<br>DAR | |
| Technical | *Apis mellifera* | carnica | oral | 48 | | >0.0347 | | Wilhelmy, H.<br>2000<br>DAR | |

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| Technical | *Apis mellifera* | | oral | 96 | | 0.0370 | | Suchail, S.; Guez, D.; Belzunces, L. P.<br>2001<br>DAR | |
| Technical | *Apis mellifera* | | oral | 96 | | 0.0409 | | Schmitzer, S.<br>1999<br>DAR | |
| Technical | *Apis mellifera* | | oral | 48 | | 0.0410 | | Nauen, R.; Ebbinghaus-Kintscher, U.; Schmuck, R.<br>2001<br>DAR | |
| Technical | *Apis mellifera* | | oral | 72 | | >0.045 | | Thompson, H. M.<br>2000<br>DAR | |
| Imidacloprid SL 200 | *Apis mellifera* | | oral | 96 | 0.29 | 0.0530 | 0.1 | Barth, M.<br>2001<br>DAR | |
| NTN 33893 200 OD | *Apis mellifera* | | oral | 96 | | 0.0570 | 0.1 | Halsall, N.<br>2004<br>Study evaluation notes, EFSA 2015 | |
| Confidor SL 200 | *Apis mellifera* | | oral | 96 | | 0.0600 | 0.1 | Halsall, N.<br>2004<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Apis mellifera* | carnica | oral | 48 | | 0.0703 | | Barth, M.<br>2000<br>DAR | |
| Imidacloprid AL 0.125 | *Apis mellifera* | | oral | 96 | | 0.0710 | 0.1 | Bruhnke, C.<br>2001<br>Study evaluation notes, EFSA 2015 | |
| Nuprid 200 SC | *Apis mellifera* | | oral | 96 | | 0.1100 | 0.0 | Warmers C. (11)<br>2007<br>Study evaluation notes, EFSA 2015 | |
| Kohinor 700 WG | *Apis mellifera* | | oral | 96 | | 0.1100 | 0.0 | Bruhnke, C.<br>2008<br>Study evaluation notes, EFSA 2015 | |

| Substance tested | Species | Subspecies | Exposure type | Exposure duration [hours] | LD50 | | Ratio * | Authors Year Reference | Note |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | µg form./bee | µg a.s./bee | | | |
| NTN 33893 75 OD & AE F032640 10 | Apis mellifera | | oral | 48 | 2.401 | 0.180 | 0.0 | Barth, M.<br>2004<br>Study evaluation notes, EFSA 2015 | formulation includes deltametrin; the endpoint expressed in µg a.i./bee is only an estimation; the exposure period lasted only for 1 hour |
| Imidacloprid 20% SL | *Apis mellifera* | | oral | 96 | | 0.3335 | 0.0 | Kling, A.<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Bombus terrestris* | | contact | 96 | | 0.2180 | | Gimeno, C.(5)<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Nuprid 200 SC | *Bombus terrestris* | | contact | 96 | 4.64 | 0.8300 | | Bocksch, S<br>2007<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Bombus terrestris* | | contact | | | 2.5000 | | Tasei, J. N.<br>2003<br>DAR | data from a review of a book |
| Technical | *Bombus terrestris* | | oral | 96 | | 0.0380 | | Gimeno, C.(5)<br>2008<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Bombus terrestris* | | oral | | | 0.0400 | | Tasei, J. N.<br>2003<br>DAR | data from a review of a book |
| Nuprid 200 SC | *Bombus terrestris* | | oral | 72 | 0.257 | 0.0460 | | Bocksch, S<br>2007<br>Study evaluation notes, EFSA 2015 | |
| Technical | *Bombus terrestris* | | oral | 72 | | 0.1500 | | Ruijter, A. de<br>1999<br>DAR | data considered not accurate; LD50 should be between 0.1 and 0.01 µg/bumble bee |

*The factor is the ratio between the LD50 of imidacloprid and the LD50 the formulation (as test substance). This factor was calculated only for honeybee. For oral, LD50 of imidacloprid 0.0037 µg/bee was considered and for contact, LD50 of imidacloprid 0.081 µg/bee was considered. A test substance is considered as more toxic to bees than imidacloprid, when the $LD_{50}$ of the test substance (expressed in active substance equivalent) is more than 5 times lower than the $LD_{50}$ of imidacloprid (i.e. the factor is > 5)

** A 48hours LD50 (contact) of 0.0422 µg a.s./bee is available from the same study

*** A 48hours LD50 (oral) of 0.0056 µg a.s./bee is available from the same study

**2) Risk assessment**

**Contact Hazard Quotients (HQs), Oral Exposure Toxicity Ratios (ETRs) and Limit Rates for the field margin and adjacent crop scenario. Please refer to the separate Excel spreadsheet 'Appendix B_Imidacloprid-Risk assessment spreadsheet' accompanying this Conclusion.**

**Table of contents of the spread sheet:**

| | | | | |
|---|---|---|---|---|
| 1 | Oral | Foliar spray | outdoor field | flowering crops/plants |
| 2 | Oral | Foliar spray | outdoor field | post flowering crops/plants |
| 3 | Oral | Foliar spray | outdoor field | non-flowering or crops/plants not foraged by bees |
| 4 | Oral | Foliar spray | open-protected | flowering crops/plants |
| 5 | Oral | Foliar spray | open-protected | post flowering crops/plants |
| 6 | Oral | Foliar spray | open-protected | non-flowering or crops/plants not foraged by bees |
| 7 | Contact | Foliar spray | outdoor field | flowering crops/plants |
| 8 | Contact | Foliar spray | outdoor field | post flowering crops/plants |
| 9 | Contact | Foliar spray | outdoor field | non-flowering or crops/plants not foraged by bees |
| 10 | Contact | Foliar spray | open-protected | flowering crops/plants |
| 11 | Contact | Foliar spray | open-protected | post flowering crops/plants |
| 12 | Contact | Foliar spray | open-protected | non-flowering or crops/plants not foraged by bees |
| 13 | Oral | Other application | outdoor field | flowering crops/plants |
| 14 | Oral | Other application | open-protected | flowering crops/plants |
| 15 | Oral/Contact | Limit rate, field margin, adjacent crop for foliar spray uses | | |

**3) Summary of observations in available tier 3 effects studies**

- Higher tier effects studies performed with honeybees and foliar sprays

Table 19 gives an overview on the available higher tier effect studies. In this table only clear differences between the treatments and the controls, which were observed in the studies, were included. In the the table only the tested application rates and timing has been included, but not the level of exposure achieved. For further details, the study evaluation notes should be consulted (EFSA, 2015).

**Table 19:** Overview of observed differences from control in the available higher tier effects studies for spray uses (in series of application rates; several studies had more than one application rates, which are considered as individual trials and reported in a separate row)

| Application rate in g a.i./ha | Crop | Timing of application (aging before exposure) | Difference from control observed* | Reference (study number in evaluation notes) | Remark[1] |
|---|---|---|---|---|---|
| **Semi-field studies** | | | | | |
| 0.6 | *Phacelia* | in full flowering | reduced foraging activity at day 1, which was statistically not significant | Bakker, 2001 (7) | |
| 1.0 | *Phacelia* | in full flowering | reduced foraging activity for 2 days, some sub-lethal effects | Hecht-Rost, 2008 (146) | |
| 1.2 | *Phacelia* | in full flowering | reduced foraging activity at day 1, which was statistically not significant | Bakker, 2001 (7) | |
| 2 | *Phacelia* | in full flowering | significantly reduced foraging activity at day 1 | Bakker, 2001 (7) | |
| 4 | *Phacelia* | in full flowering | significantly reduced foraging activity at day 1 | Bakker, 2001 (7) | |
| 9 | *Phacelia* | in full flowering | significantly reduced foraging activity at day 1 | Bakker, 2001 (7) | |
| 14 | *Phacelia* | in full flowering | significantly reduced foraging activity for 2 days | Bakker, 2001 (7) | |

| Application rate in g a.i./ha | Crop | Timing of application (aging before exposure) | Difference from control observed* | Reference (study number in evaluation notes) | Remark[1] |
|---|---|---|---|---|---|
| 14 | *Phacelia* | in full flowering | reduced foraging activity for 5 days, some sub-lethal effects, increased forager mortality for 3 days | Hecht-Rost, 2008 (146) | |
| 21 | *Phacelia* | 1-4 days before exposure | significantly reduced foraging activity for a couple of days. Significantly higher forager mortality in some repetitions. | Bakker, 2003 (8) | |
| 35 | *Phacelia* | 1-4 days before exposure | significantly reduced foraging activity for a couple of days (more clear for shorter aging). significantly higher forager mortality in some repetitions. | Bakker, 2003 (8) | Queen loss in 2 out of 12 repetitions (combinations). |
| 35 | *Phacelia* | in full flowering | reduced foraging activity for 5 days, some sub-lethal effects, increased forager mortality for 3 days | Hecht-Rost, 2008 (146) | SPG for forager mortality breached |
| 105 | apple | 29 days before exposure | No apparent effects were noted | Schur, 2001 (97) | |
| 105 | apple | 10 days before exposure | reduced foraging activity during the study, somewhat higher forager mortality for 2 days | Bocksch, 2008 (156) | |
| 105 | apple | 9 days before exposure | significantly reduced foraging activity for 3 days | Bocksch, 2009 (144) | Residues in foragers were found. |
| 150 | apple | 14 days before exposure | significantly reduced foraging activity, but only in some days, some sub-lethal effects for 2-5 days, significantly increased forager mortality in the 8 days post exposure | Kriszan, 2011 (147) | |
| 150 | apple | 9 days before exposure | significantly reduced foraging activity for 5 days, somewhat higher mortality, some elevated decrease in colony strength, some transient delay in egg laying | Bocksch, 2009 (144) | Residues in foragers were found. |

| **Application rate in g a.i./ha** | **Crop** | **Timing of application (aging before exposure)** | **Difference from control observed*** | **Reference (study number in evaluation notes)** | **Remark[1]** |
|---|---|---|---|---|---|
| 300 | citrus | 9 days before exposure (start of flowering) | Clear and considerable reduced foraging activity and some increased adult mortality. A transient decrease in colony strength (with recovery) was noted. | Bocksch, 2011 (142) | |
| **Field studies** | | | | | |
| 74 | Spring oilseed rape | in flowering | Clear and considerable reduced foraging activity for a couple of days. Clear and considerable increased adult mortality for 3 days. | Schur, 2003 (138) | The formulation contained deltamethrin (cca 10 g/ha was used). The application was made after bee flight. SPG for forager mortality breached. |
| 105 | apple | 35 days before exposure | No apparent effects were noted | Schur, 2001 (96) | |
| 105 | apple | 11 days before exposure | somewhat lower foraging on apple during the study (significant for 1 day), somewhat higher mortality for 1 day | Bocksch, 2009 (143) | Traces of residues in pollen from foragers found. |
| 80-160 | apple | 15-20 days before exposure | somewhat higher forager mortality | Schmidt, 1995 (128) | |
| 120 | apple | 8 days before the exposure | somewhat higher forager mortality, some repellence were noted | Schmidt, 1995 (128) | |

| Application rate in g a.i./ha | Crop | Timing of application (aging before exposure) | Difference from control observed* | Reference (study number in evaluation notes) | Remark[1] |
|---|---|---|---|---|---|
| 150 | apple | 11 days before exposure | reduced foraging on apple during the study, which was significant on some days, somewhat higher mortality for 2 days | Bocksch, 2009 (143) | Traces of residues in pollen from foragers found. |
| 150 | melon | in flowering | considerable reduced foraging activity for 2 days. Clear and considerable increased adult mortality for 2 days.<br>Repellence and other sub-lethal symptoms. | Bocksch, 2011 (141) | The application was made during bee flight.<br>SPG for forager mortality breached.<br>Pollen analysis revealed < 1 to 5 % melon pollen. |

*only those observations are listed here, which could be judged with high certainty as a real difference from the control by the study evaluator (EFSA). Where statistical analysis was available, it was considered only as supplemental information for the assessments. Nevertheless, in several cases 'significant' is used to describe a difference. This means that a statistical analysis was undertaken by the study authors for the interpretation of the results. Here the results of this statistical analysis are reflected. As indicated earlier, these statistical analyses are not in line with the pertinent requirements of EFSA, 2013b.
[1]all studies do not meet the requirements of EFSA 2013b.

- Higher tier effects studies performed with honeybees using application techniques other than foliar sprays

Only one study was available (Bocksch, 2011; study number 141 in the study evaluation notes; EFSA, 2015) for honeybees. In this field study 2 drip irrigations with the application rates of 140 g imidacloprid/ha were done in a melon field in Sicily (Italy). The first application was done before the flowering and second application during flowering and bee-flight. The application window was 10 days and the water volume was 25,000-30,000 L/ha. No apparent differences between control and treated groups were seen in this study. However, as other field studies, this study did not fulfil the requirements of EFSA, 2013b (e.g. no assessment of overwintering success, small field size, lack of statistical analysis). The level of exposure was estimated by pollen identification using pollen traps. These assessments revealed a large dilution from other pollen sources (weeds, wild plants, palms). The ratio of melon pollen was only 2 and 12 % on the days when these analyses were conducted.

- Higher tier effects studies performed with bumble bees using application techniques other than foliar sprays

Two studies were available in the dossier (study number 164 and 168 in the, study evaluation notes; EFSA, 2015), which were performed with bumble bees in home gardens in Germany. In both studies the soil substrate of flowering *Lobelia erinus* grown in pots were drenched by an imidacloprid formulation (15 or 22.5 mg imidacloprid/litre soil substrate). Bumble bee colonies were put in the gardens and monitored. Several deficiencies were noted with the methodology of these studies e.g. lack of residue analysis, lack of investigation for the statistical analysis. Moreover, it was clear that the bees intensively visited different not-treated flowering ornamentals in the gardens therefore the dilution of residues was likely very high.

Similarly to Table 19, a brief overview of these studies is included in Table 20, below

**Table 20:** Overview of difference from control effects in the available higher tier effects studies on bumble bees

| **Application** | **Crop** | **Difference from control observed*** | **Reference (study number in evaluation notes)** | **Remark** |
|---|---|---|---|---|
| 22.5 mg/litre soil substrate by drenching | Ornamental *Lobelia erinus* in pots | reduced foraging activity, which was statistically not significant (repellence) | Schmidt, 2003 (164) | Non-GLP |
| 15 mg/litre soil substrate by drenching | Ornamental *Lobelia erinus* in pots | signs for repellence, significantly higher forager mortality | Maus, at. al, 2003 (168) | Reduced hive development, which was influenced by parasitism |

* only those observations are listed here, which could be judged with high certainty as a real difference from the control by the study evaluator (EFSA). Statistical analyses were available, but they were considered only as supplemental information for the assessments. Here the results of this statistical analysis are reflected. As indicated earlier, these statistical analyses are not in line with the pertinent requirements of EFSA, 2013b.

## APPENDIX C- AVAILABLE RESIDUE DATA ON IMIDACLOPRID

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Pollen (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Pollen (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Pollen (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Pollen (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Pollen (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Nectar (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Nectar (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Nectar (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Nectar (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Nectar (from foragers) | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Admire 240 F | 204 | in-furrow (drench?) | Potato/Clover? | Canada | Unripened Honey | na[1] | 0.010 | < | 0.002 | Kemp JR, Rogers REL | 2002 | M-061850-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Nectar (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 49 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 55 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid OD 200 AG | 200 | Drip irrigation | Watermelon | Spain | Pollen (from combs) | 62 | 0.005 | < | 0.001 | Bocksch S | 2011 | M-401652-01-1 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 8 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 18 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 25 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 8 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 18 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 25 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from foragers) | 18 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from foragers) | 25 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from foragers) | 18 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from foragers) | 25 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from foragers) | 18 | 0.095 | < | 0.01 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 18 | 0.080 | < | 0.012 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from foragers) | 25 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 25 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from combs) | 18 | 0.095 | < | 0.01 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from combs) | 18 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from combs) | 25 | 0.029 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from combs) | 25 | 0.020 | < | 0.003 | Bocksch S | 2008 | Eurofins_S08-00779 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 7 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from combs) | 27 | 0.020 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00779 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from foragers) | 13 | 0.095 | < | 0.01 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from foragers) | 17 | 0.095 | < | 0.01 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Nectar (from foragers) | 27 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from foragers) | 13 | 0.067 | | 0.01 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from foragers) | 13 | 0.067 | < | 0.01 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Nectar (from foragers) | 17 | 0.067 | < | 0.01 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from foragers) | 27 | 0.029 | < | 0.003 | Bocksch S | 2009 | Eurofins_S08-00778 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid 200 SL | 105 | Foliar spray | Apple | Spain | Pollen (from foragers) | 13 | 0.381 | | 0.04 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 17 | 0.333 | | 0.05 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 13 | 0.667 | | 0.1 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 13 | 0.733 | | 0.11 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid 200 SL | 150 | Foliar spray | Apple | Spain | Pollen (from foragers) | 17 | 0.400 | | 0.06 | Bocksch S | 2009 | Eurofins_S08-00778 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 42 | 0.327 | | 0.049 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.187 | | 0.028 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.293 | | 0.044 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.180 | | 0.027 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.220 | | 0.044 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.310 | | 0.062 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.190 | | 0.038 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.348 | | 0.139 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 47 | 0.265 | | 0.106 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.200 | | 0.03 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.133 | | 0.02 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.270 | | 0.054 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.175 | | 0.035 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.175 | | 0.035 | Bocksch S | 2012 | M-428259-01-1 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.223 | | 0.089 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.133 | | 0.053 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 50 | 0.180 | | 0.072 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.133 | | 0.02 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.087 | | 0.013 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.100 | | 0.015 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.120 | | 0.024 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.075 | | 0.015 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.105 | | 0.021 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.078 | | 0.031 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.085 | | 0.034 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 55 | 0.063 | | 0.025 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.113 | | 0.017 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.107 | | 0.016 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.140 | | 0.021 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.160 | | 0.032 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.135 | | 0.027 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.100 | | 0.02 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.155 | | 0.062 | Bocksch S | 2012 | M-428259-01-1 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.165 | | 0.066 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 57 | 0.103 | | 0.041 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.093 | | 0.014 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.107 | | 0.016 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.093 | | 0.014 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.115 | | 0.023 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.075 | | 0.015 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.065 | | 0.013 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.155 | | 0.062 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.105 | | 0.042 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 63 | 0.078 | | 0.031 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.080 | | 0.012 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.056 | | 0.0084 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.059 | | 0.0088 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.070 | | 0.014 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.055 | | 0.011 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.045 | | 0.0089 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.118 | | 0.047 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.095 | | 0.038 | Bocksch S | 2012 | M-428259-01-1 |

| Formulation | Rate [g a.s/ha] | Application type | Crop | Country | Matrix | Application /Collection interval [Days] | RUD (mg/kg) | Op. | Residue value [mg a.s/kg] | Authors | Study year | Study ID |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 69 | 0.040 | | 0.016 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.067 | | 0.01 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.065 | | 0.0097 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.041 | | 0.0061 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.105 | | 0.021 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.050 | | 0.01 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.049 | | 0.0098 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.078 | | 0.031 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.065 | | 0.026 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 76 | 0.058 | | 0.023 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.087 | | 0.013 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.073 | | 0.011 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.070 | | 0.014 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 200 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.042 | | 0.0084 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.090 | | 0.036 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 400[2] | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 84 | 0.058 | | 0.023 | Bocksch S | 2012 | M-428259-01-1 |
| Imidacloprid OD 200 | 150 | Drip irrigation | Tomato | Spain | Pollen (from foragers) | 97 | 0.037 | | 0.0056 | Bocksch S | 2012 | M-428259-01-1 |

[1] The design of the study was not clearly reported: application, crops, and time between application and collection were missing or not transparent

[2] Rate: 2x200 g a.s./ha, 14 days interval

## APPENDIX D – SUMMARY OF THE APPROACH TO THE RISK ASSESSMENT FOR ORNAMENTALS

The risk assessment for bees from the authorised uses on ornamentals, ornamental trees and non-orchard trees was discussed at the Pesticides Peer Review Experts' Meeting 129 (March 2015). It was noted that the authorised uses to ornamentals can be to a large variation of types of ornamental plants but, for the purposes of the current risk assessment, the approach summarised in Table 21 was agreed.

**Table 21:** Approach to risk assessment for authorised foliar spray uses on ornamental plants, ornamental trees and non-orchard trees

| **Scenario** | **Risk assessment** |
|---|---|
| Treated crop | Exposure depends on whether the plants or trees are attractive and applications are made pre- or during the flowering period.<br>If the type of ornamental plant or tree is not stated then it should be assumed they are attractive to bees for pollen and nectar collection.<br>For attractive ornamental small plants, the use of the treated crop scenario for oilseed rape would be a reasonable surrogate (for both oral and contact risk assessment).<br>For non-attractive ornamental plants and applications made post-flowering, no risk assessment for the treated crop scenario is required (for both oral and contact risk assessment).<br>For attractive trees, the use of early orchard scenario can be used.<br>For the assessment of imidacloprid, none of the authorised uses on ornamentals were clearly only to small plants and therefore it is assumed that applications could also be made to ornamental trees. The early orchard scenario was therefore assumed. The early orchard scenario was also assumed for the non-orchard trees. |
| Weeds within the treated field | Exposure depends on the amount of interception by the ornamental plant or tree.<br>If the ornamental plant growth stage is not specified then it should be assumed that applications can be made to small/young ornamental plants which provide little or no interception.<br>If the growth stage for trees is not specified then it should be assumed that applications can be early orchards.<br>For the assessment of imidacloprid, only a few of the authorised uses to ornamentals specified the growth stage when applications would be made. For practicality reasons the early orchard scenario was assumed where 20% intercept by the plants is used. It should, however, be noted that for small plants and seedlings the calculated ETR values for the weed scenario underestimate the risk to bees as it would be more appropriate to assume little or no intercept by the plants. The early orchard scenario was also assumed for the non-orchard trees. |
| Field margin<br>Adjacent crop | Exposure depends on the application method and the size of the plants or trees.<br><u>Ornamentals:</u><br>If applications are restricted to growth stages with plants smaller than 50 cm then the spray drift values for standard agricultural field crops (e.g. cereals) should be used.<br>For ornamental plants greater than 50 cm in height the spray drift values late vines should be used.<br>If the application method and type of ornamental plant is not stated in the GAP then it is assumed that all types of application methods can be used and applications can be made to all types of plants including ornamental trees. In these cases, the spray drift values early orchards should be used. |

| | |
|---|---|
| | Non-orchard trees<br>For small trees (e.g. conifers), the late grape scenario should be used. For larger trees the early orchard scenario is used. If the size of the tree is not specified then it assumed that applications can be made to large trees.<br>For the assessment of imidacloprid, none of the authorised uses on ornamentals specified the size of the plants to which applications would be made, therefore, the early orchard scenario was used. The early orchard scenario was also assumed for the non-orchard trees. |
| Succeeding crop/plants | Exposure to bees from residues in nectar and pollen in succeeding ornamental plants may occur.<br>For trees exposure in the succeeding year depends on whether the tree is attractive to bees (in line with the treated crop scenario).<br>For the assessment of imidacloprid, the early orchard scenario was used for ornamentals, ornamental trees and non-orchard trees. |
| Guttation fluid | Exposure to bees from residues in guttation fluid from plants or trees may occur if the plants or trees produce guttation fluid. |
| Surface water | Exposure to bees from residues in surface water may occur. |
| Puddles | Exposure to bees from residues in puddles may occur. |

## APPENDIX E – SUMMARY OF THE APPROACH TO THE RISK ASSESSMENT FOR APPLICATION TECHNIQUES OTHER THAN FOLIAR SPRAYS

Many of the authorised uses of imidacloprid use application techniques other than standard foliar spray techniques. The risk to bees from these uses was discussed at the Pesticides Peer Review Experts' Meeting 129. The experts provided clarification and definitions for a number of the application techniques; these are summarised in Table 22. On the basis of the agreed definitions, the potential for exposure to bees via different routes was discussed and is summarised in Table 22.

**Table 22:** Definition of methods of applications other than foliar sprays (professional non foliar spray application techniques, outdoor uses)

| Application group | Definition agreed at the Pesticides Peer Review Meeting 129 |
|---|---|
| **Aerial spraying** | **Definition**<br>*"Spraying crops from an agricultural aircraft"*<br><br>**Comments**<br>Agricultural aircraft are highly specialized, purpose-built aircraft. Today's agricultural aircraft is often powered by a turbine engine of up to 1500 hp and can carry as much as 800 gallons (more than 3000 L) of crop protection product. Helicopters are sometimes used. |
| **Brush/injection** | **Stem injection definition**<br>*"The stem injection method involves drilling or cutting through the bark into the sapwood tissue in the trunks of woody weeds and trees. The product is immediately placed into the hole or cut. The aim is to reach the sapwood layer just under the bark (the cambium growth layer), which will transport the chemical throughout the plant."*<br><br>**Brush application definition**<br>*"The product is applied directly on different part of the plants (usually the stem) by using a brush."* |
| **Stem application** | **Definition**<br>**"***The product is applied the stem by means of spraying equipment***"**<br><br>**Comments**<br>This application was originally grouped with the brush/injection because it was wrongly assumed that the application to the stem was performed by brushing or injection. |
| **Dip** | **Definition**<br>*"Plants roots of seedlings or bulbs dipped in the product (or a solution of the product) before planting in the field."*<br><br>**Comments**<br>A distinction should be made if soil surrounding the roots is also dipped into the product or just the bulb/roots.<br>For most uses it should be assumed that some soil attached to the roots is also dipped into the product, while for all uses in NL (bulbs) no soil is attached. However, for bulb dipping some amount of the active substance could be released to the soil after transplantation, and being taken up by weeds.<br>Sometimes plant trays are dipped in the product. |

| Application group | Definition agreed at the Pesticides Peer Review Meeting 129 |
| --- | --- |
| **Drench+irrigation** | **Definition**<br>*"Application of the product together with water. The target of the application is the soil rather than the canopy of the plant."*<br><br>**Comments**<br>For professional uses drenching can be via a boom sprayer without the use of nozzles. In this case, there is no atomisation of the liquid and the majority of the liquid reaches the soil<br>The outcome of any evaluation with this application techniques is pending on the height and the accuracy of the device used for the application. |
| **Drench into pot** | **Comments**<br>See definition for "Drench", except for the presence of pots. |
| **Drip irrigation** | **Definition**<br>*"Water and pesticide are dripped slowly to the roots of plants, either onto the soil surface or directly onto the root zone, through a network of valves, pipes, tubing, and emitters. It is done through narrow tubes that deliver water directly to the base of the plant."*<br><br>**Comments**<br>The specific application "Nursery drip application over the top of plants" is actually more similar to drench application except the product is applied directly over the plants. The application is performed in greenhouses (pre-flowering) and then the plants are transplanted. |
| **In-furrow** | **Definition**<br>*"Application of liquid formulations together with the seed along the line drawn by the plough."*<br><br>**Comments**<br>Some MSs confirmed that the formulation is applied as a liquid and not as granules |
| **Knapsack spray** | **Definition**<br>*"Application by means of a sprayer consisting of a handheld nozzle supplied from a pressurized reservoir that is carried on the back like a knapsack"* |
| **Soil incorporation** | **Comments**<br>Most of the uses are likely to be non-professional. However, some of them are professional e.g. Thiamethoxam – ACTARA (liquid formulation), NL, UK, BG on potatoes and vegetables.<br>For NL this application equals in-furrow. |
| **Stuck into soil/substrate (PIN)** | **Definition**<br>*"A solid object (rodlets, sticks, PIN) placed directly in the soil, beside the plants."*<br><br>**Comments**<br>Most uses are non-professional. Professional uses are just in protected environment. No information was available to say if plants are then transplanted, but some MSs clarified that plants can be transplanted after the treatment. |

**Table 23:** Potential exposure to bees from different types of application techniques

| | Contact | | | Oral | | | | | Contaminated water | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Treated crop** | **Weeds (treated field)** | **Field margin** | **Treated crop** | **Weeds (treated field)** | **Field margin** | **Adjacent crop** | **Succeeding crop** | **Guttation fluid** | **Surface water** | **Puddles** |
| Aerial spraying | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Brush/injection | N | N | N | Y | N | N | N | Y (1) | Y | N | N |
| Stem application | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |
| Dip | N | N | N | Y | Y (2) | N | N | Y | Y | Y | Y |
| Drench+irrigation | N if it is just above the ground Y if the crop is touched (7) | Y if it is above the weeds height N otherwise | N (3) | Y | Y | Y (4) | Y (4) | Y | Y | Y | Y |
| Drench into pot | N if it is just above the ground Y if the crop is touched | N | N | Y | Y (5) | N | N | Y (5) | Y | Y (5) | Y (5) |
| Drip irrigation | N | N | N | Y | Y (6) | N | N | Y | Y | Y | Y |
| In-furrow/ soil incorporation | N | N | N | Y | Y | Y (4) | Y (4) | Y | Y | Y (4) | Y |
| Knapsack spray | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y |

| | Contact | | | Oral | | | | | Contaminated water | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **Treated crop** | **Weeds (treated field)** | **Field margin** | **Treated crop** | **Weeds (treated field)** | **Field margin** | **Adjacent crop** | **Succeeding crop** | **Guttation fluid** | **Surface water** | **Puddles** |
| Stuck into soil/substrate | N | N | N | Y | Y | Y (4) | Y (4) | Y | Y | Y (4) | Y |

N: No/low exposure

Y: Exposure likely to occur

(1) it was assumed that the product would not go into the soil, while for permanent crops it may be present in the plants the following year. Some MSs pointed out that the product can also go downward to the root and the soil. However, some studies on imidacloprid show that the substance goes upward and only minimal downward and it is not released to the soil. This was confirmed by experts having experience with efficacy studies. Assuming application to permanent crop the exposure cannot be excluded.

(2) See definitions.

(3) No drift is assumed from this kind of applications

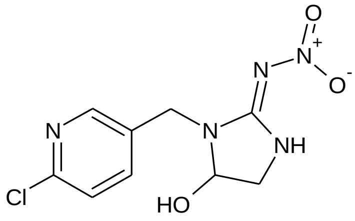
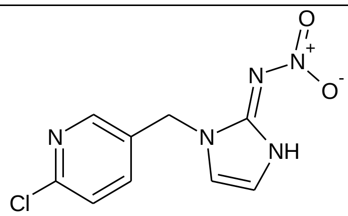
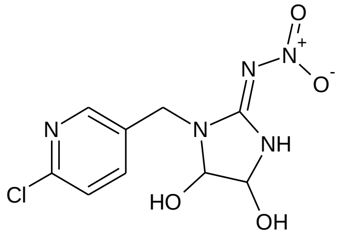
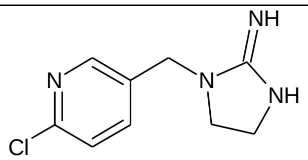
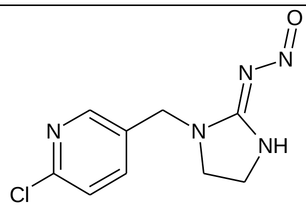
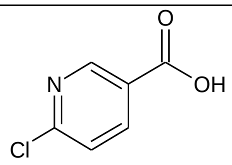
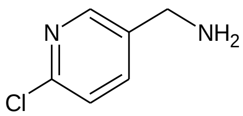
(4) Route of exposure might be possible via runoff.

(5) Only if transplanted

(6) Weeds can take up liquid from the soil (they can be very close to the crop plants)

(7) Exposure to solitary bees and bumblebees via exposure to the soil is possible but it is not covered by EFSA (2013b) (for foliar sprays)

## APPENDIX F – USED COMPOUND CODE(S)

| Code/Trivial name | Chemical name/SMILES notation* | Structural formula* |
|---|---|---|
| 5-Hydroxy-(M01) | (2*E*)-3-[(6-chloropyridin-3-yl)methyl]-2-(nitroimino)imidazolidin-4-ol<br><br>[O-][N+](=O)/N=C2\NCC(O)N2Cc1cnc(Cl)cc1 |  |
| Olefine-(M06) | (2*E*)-1-[(6-chloropyridin-3-yl)methyl]-*N*-nitro-1,3-dihydro-2*H*-imidazol-2-imine<br><br>[O-][N+](=O)/N=C2\NC=CN2Cc1cnc(Cl)cc1 |  |
| 4,5-Dihydroxy-(M03) | (2*E*)-1-[(6-chloropyridin-3-yl)methyl]-2-(nitroimino)imidazolidine-4,5-diol<br><br>[O-][N+](=O)/N=C2\NC(O)C(O)N2Cc1cnc(Cl)cc1 |  |
| Guanidine-(M09) | 1-[(6-chloropyridin-3-yl)methyl]imidazolidin-2-imine<br><br>Clc2ncc(CN1CCNC1=N)cc2 |  |
| Nitrosimine-(M07) | (2*E*)-1-[(6-chloropyridin-3-yl)methyl]-*N*-nitrosoimidazolidin-2-imine<br><br>Clc2ncc(CN1CCN/C1=N\N=O)cc2 |  |
| 6-Chloro-nicotinic acid (M14) | 6-chloronicotinic acid<br><br>OC(=O)c1cnc(Cl)cc1 |  |
| 6-Chloro-picolylamin | 1-(6-chloro-3-pyridinyl)methanamine<br><br>NCc1cnc(Cl)cc1 |  |

* ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)

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## ABBREVIATIONS

| | |
|---|---|
| µg | microgram |
| a.s. | active substance |
| AF | assessment factor |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| bw | body weight |
| CAS | Chemical Abstract Service |
| COM | European Commission |
| d | day |
| DM | dry matter |
| $DT_{50}$ | period required for 50 percent disappearance (define method of estimation) |
| $DT_{90}$ | period required for 90 percent disappearance (define method of estimation) |
| dw | dry weight |
| EAC | environmentally acceptable concentration |
| $EbC_{50}$ | effective concentration (biomass) |
| $EC_{50}$ | effective concentration |
| EEC | European Economic Community |
| Ef | exposure factor |
| $ER_{50}$ | emergence rate/effective rate, median |
| $ErC_{50}$ | effective concentration (growth rate) |
| ETR | exposure to toxicity ratio |
| EU | European Union |
| FC | Filed Capacity |
| FIR | Food intake rate |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| g | gram |
| GAP | good agricultural practice |
| GM | geometric mean |
| GS | growth stage |
| h | hour(s) |
| ha | hectare |
| HQ | hazard quotient |
| HPG | hypopharyngeal gland |
| IPM | Integrated Pest Management practices |
| L | litre |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LOAEL | lowest observable adverse effect level |
| LOEC | lowest observable effect concentration |
| LOER | lowest observable effect rate |
| LOD | limit of detection |
| LOQ | limit of quantification |
| m | metre |
| MAF | multiple application factor |
| mg | milligram |
| mL | millilitre |
| mm | millimetre |
| MTD | maximum tolerated dose |
| MWHC | maximum water holding capacity |
| ng | nanogram |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |

| | |
|---|---|
| NOER | no observed effect rate |
| OM | organic matter content |
| Pa | Pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_{air}$ | predicted environmental concentration in air |
| $PEC_{gw}$ | predicted environmental concentration in ground water |
| $PEC_{sed}$ | predicted environmental concentration in sediment |
| $PEC_{soil}$ | predicted environmental concentration in soil |
| $PEC_{sw}$ | predicted environmental concentration in surface water |
| pH | pH-value |
| PHI | pre-harvest interval |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| $P_{ow}$ | partition coefficient between *n*-octanol and water |
| ppm | parts per million ($10^{-6}$) |
| ppp | plant protection product |
| PT | proportion of diet obtained in the treated area |
| $r^2$ | coefficient of determination |
| RUD | residue per unit dose |
| SD | standard deviation |
| SFO | single first-order |
| SPG | specific protection goal |
| SSD | species sensitivity distribution |
| SV | shortcut values |
| $t_{1/2}$ | half-life (define method of estimation) |
| 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 |
| TLV | threshold limit value |
| TRR | total radioactive residue |
| TWA | time weighted average |
| UV | ultraviolet |
| W/S | water/sediment |
| w/v | weight per volume |
| w/w | weight per weight |
| WHO | World Health Organization |
| wk | week |
| yr | year |