

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering all uses other than seed treatments and granules¹

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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 thiamethoxam, 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 thiamethoxam 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 thiamethoxam 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.

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KEY WORDS

thiamethoxam, peer review, risk assessment, pesticide, insecticide

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SUMMARY

Thiamethoxam was included in Annex I to Directive 91/414/EEC on 1 February 2007 by Commission Directive 2007/6/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. A specific conclusion was issued by EFSA on 19 December 2012 on the risk assessment for bees as regards the authorised uses applied as seed treatments and granules (EFSA Journal 2013;11(1):3067). In addition, EFSA finalised a specific conclusion following the submission of post-approval data concerning the risk assessment for honeybees (EFSA Journal 2012;10(3):2601).

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 the 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 thiamethoxam 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 could not be excluded, or the risk assessment could not be finalised. It is noted, however, that 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 which could not be finalised.

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BACKGROUND

Thiamethoxam was included in Annex I to Directive 91/414/EEC³ on 1 February 2007 by Commission Directive 2007/6/EC⁴, and has been deemed to be approved under Regulation (EC) No 1107/2009⁵, in accordance with Commission Implementing Regulation (EU) No 540/2011⁶, as amended by Commission Implementing Regulation (EU) No 541/2011⁷. The peer review leading to the approval of this active substance was finalised in 2006, however EFSA was not involved in this evaluation. For the request of the European Commission, 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 and granules (EFSA, 2013a). In addition, EFSA finalised a specific conclusion following the submission of post-approval data concerning the risk assessment for honeybees (EFSA, 2012a).

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013⁸, 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 permanent 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 permanent greenhouses and uses after flowering.

With reference to Article 31 of Regulation (EC) No 178/2002⁹ 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 three 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 the restrictions of Regulation (EU) No 485/2013, for the above mentioned three neonicotinoids, including thiamethoxam.

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 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances. OJ L 43, 15.2.2007, p. 13-18.

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 thiamethoxam 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, 2015a) 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 notes¹⁰,
- 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

Thiamethoxam was authorised in Member States using a variety of application techniques. These included foliar spray applications using standard horizontal boom sprayers, sideward spray techniques and broadcast assisted 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, soil incorporation (of liquid), etc. Some of the authorised products, reported by the Member States, were granular formulations and were 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 Pesticides Peer Review Experts' Meeting 129 (March 2015).

Several of the GAPs for the authorised uses lacked sufficient information to be able to perform any form of risk assessment (e.g. the application technique was not stated or the application rate was not reported in sufficient detail). The authorised uses for which no risk assessment could be performed are indicated in the GAP table (see the separate Excel spreadsheet 'Appendix A_Thiamethoxam_GAP Table' accompanying this Conclusion, refer to supporting worksheets No 1 and 2, column L).

The risk assessment for the authorised non-professional (home garden) uses was discussed at the experts' meeting 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 the treated plants may be comparable to that found in the 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 spray applications should cover the acute contact exposure and the oral exposure (acute for adult bees, chronic for adult bees and larvae). These assessments should be performed for honeybees, bumble bees and solitary bees by calculating Hazard Quotient (HQ) and Exposure Toxicity Ratio (ETR) values for the contact and oral risk assessments, respectively. For honeybees, the oral risk assessment should cover also sublethal effects on development of the hypopharyngeal glands (HPG).

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

The contact and the oral risk assessments should be carried out by considering the exposure from the treated 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 crops 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 below.

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

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

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 are 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) is 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 Guidance Document (EFSA, 2013b) does not include a risk assessment scheme to cover exposure routes such as residues in wax or honeydew. As acknowledged in the EFSA GD (EFSA, 2013b), this could underestimate the risk for certain circumstances (e.g. honeydew from conifer trees).

Several of the authorised uses were on crops/plants for which there is no clear crop categorisation in EFSA, 2013b (e.g. ornamental plants, ornamental trees, tobacco). The experts at the meeting discussed the appropriate parameters to be used in the first-tier risk assessment. The agreements reached have been reflected in the risk assessments performed as part of this Conclusion (see Sections 2.1 and 3.1). Full details of the discussions can be found in Appendix 2 of the meeting report (EFSA, 2015a) and a short summary for ornamentals and non-orchard trees is provided in Appendix C of this document.

1.1.2. Other application techniques

The risk assessment approach provided in EFSA, 2013b is applicable to all application techniques, i.e. each aspect provided 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 or granules. Therefore, the approach to the risk assessment for the authorised uses of thiamethoxam as drenches, drip irrigation and dips, soil incorporation (of liquid), etc. was discussed at the experts' meeting. 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. A summary is provided in Appendix D and full details of the discussions can be found in Appendix 3 of the meeting report (EFSA, 2015a). The risk assessment for the authorised uses other than foliar spray applications is provided in Section 4.

1.1.3. Uses made in protected structures

A number of the authorised uses of thiamethoxam were on protected crops/plants. The experts at the meeting 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, 2014a). Full details of the discussions can be found in Appendix 4 of the meeting report (EFSA, 2015a).

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 consumption of surface water, no risk assessment for **permanent greenhouse 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 structures. Therefore it was agreed, 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, 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 as for outdoor field uses.

There were also a number of authorised uses where the applications are made to plants or seedlings, either indoor or in permanent greenhouses, but then with subsequent movement of the plants or seedlings outside. The application techniques for the authorised uses included drips, dips, seedling dumping¹¹ and drenches. The exposure to bees from these types of uses was also discussed at the Pesticides Peer Review Experts' Meeting 129. For applications made indoor 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 Appendices 3 and 4 of the meeting report for further details; EFSA, 2015a). 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 rate to the treated plants is 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, vegetables and ornamentals) would be maintained indoors. Without further clarification no risk assessment could be performed for these uses.

1.2. Formulated products

In accordance with the EFSA, 2013b guidance document, a consideration of the need for a specific risk assessment for the formulated product is required. Therefore a consideration has been provided in Section 2.

A number of the authorised products containing thiamethoxam also contain additional active substances (abamectin, chlorantraniliprole, difenoconazole or lambda-cyhalothrin). 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 thiamethoxam alone. With the exception of 'Voliam Flexi' (A-15645A) (containing thiamethoxam and chlorantraniliprole), no formulation toxicity data were available for comparison.

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

Product name	Active substances	Member State	Authorised use
Professional products			
Axoris rovarölő permet dísznövényekhez ¹	Thiamethoxam Abamectin	Hungary	Ornamentals
COMPO AXORIS Sprej proti hmyzu		Czech Republic	Ornamentals
EFORIA 045 ZC	Thiamethoxam Lambda-cyhalothrin	Greece Romania	Alfalfa, artichoke, bell pepper, broccoli, cauliflower, cherry, cotton, lettuce and/or salad, watermelon, nectarine, olives, peach, bell pepper, plum, potato tobacco, tomato, courgette (zucchini)
EFORIA 065 ZC		Estonia Hungary Latvia Lithuania Poland	Barley (spring and winter), rye, triticale, wheat (spring and winter), cereal group, wheat group, rape, lettuce

¹¹ Seedling dumping: 'seedlings dipped in the product (or a solution of the product) before planting in the field', see Appendix D.

Product name	Active substances	Member State	Authorised use
Professional products			
EFORIA		Italy	Apricot, aubergine, bell pepper, cherry, citrus, lettuce and/or salad, melon/water melon, nectarine, peach, plum, potato, tobacco, tomato.
LUZINDO	Thiamethoxam Chlorantraniliprole	Italy Hungary	Apricot, grape group, peach tree group
LUZINDO 40 WG		Cyprus Greece	Apricot, grape, nectarine, peach
VOLIAM FLEXI		France	Grape, non-specified
Non-professional products			
AXORIS EASY +	Thiamethoxam Abamectin	France	Ornamentals
AXORIS ENDOM SPRAY		Greece	Ornamentals
AXORIS INSECTICIDA POLIVALENTE AL		Spain, Portugal	Ornamentals
AXORIS QUICK-SPRAY		Belgium Luxembourg The Netherlands	Ornamentals
AXORIS SPREJ		Slovenia	Ornamentals
COMPO Axoris Insekten-frei AF		Germany	Ornamentals
COMPO Axoris Pronto Uso		Italy	Ornamentals
AXORIS TRIPLE	Thiamethoxam Abamectin	Belgium France Luxembourg	Ornamentals
COM 302 11 IAF AL	Difenoconazole	Portugal	Ornamentals
AXORIS INSECTICIDA POLIVALENTE AL	Thiamethoxam Chlorantraniliprole	Spain, Portugal	Ornamentals

¹ Professional and non-professional product

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 already included risk mitigation measures designed to protect bees. These mitigation measures are considered to potentially 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 et 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 et al., 2014; Simeunovic et al.,

2014; Wolf et al., 2014; Sandrock et al., 2014; Pettis et al., 2012). Data were also available in the systematic literature 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 scheme. Consequently, this Conclusion focusses on the risk posed by the authorised uses of thiamethoxam 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, bumble bees, solitary bees), by addressing questions to inform on exposure assessment and adverse 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 as 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 dossiers (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

Data from the dossiers, the previous EU evaluation of thiamethoxam (Spain, 2001; European Commission, 2006) and the systematic literature search were considered in this section.

2.1. Toxicity to honeybees

Acute toxicity of the active substance and metabolite clothianidin (CGA322704)

Table 3 summarises the acute laboratory toxicity data for honeybees for thiamethoxam and the metabolite clothianidin (CGA322704) which were available in the dossiers.

Table 3: Available laboratory toxicity data for honeybees for thiamethoxam and the metabolite clothianidin (CGA322704)

Test substance	Toxicity endpoint	Species	Value ¹	Reference
Acute oral toxicity				
thiamethoxam	Acute oral LD ₅₀	<i>Apis mellifera</i>	0.005 µg a.s./bee	European Commission (2006)
metabolite clothianidin (CGA322704)	Acute oral LD ₅₀	<i>Apis mellifera</i>	0.00379 µg/bee ²	European Commission (2005)
Acute contact toxicity				
thiamethoxam	Acute contact LD ₅₀	<i>Apis mellifera</i>	0.024 µg a.s./bee	European Commission (2006)
metabolite clothianidin (CGA322704)	Acute contact LD ₅₀	<i>Apis mellifera</i>	0.0275 µg/bee	European Commission (2006)

¹ Values highlighted in **bold** were used for risk assessment.

² An acute oral LD₅₀ value of 0.0168 µg/bee for the metabolite clothianidin was indicated in the Review Report for thiamethoxam (European Commission, 2006). However, as this value was an order of magnitude higher than the acute oral LD₅₀ reported in the Review Report (European Commission, 2005) for the active substance clothianidin, the latter value has been reported in Table 3.

Acute toxicity of the formulated products

Table 4 summarises the acute laboratory toxicity data for honeybees for formulated products which were available in the dossiers. A comparison has been made of the toxicity of the formulated products (expressed in terms of thiamethoxam) to that of thiamethoxam. 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.

Table 4: Available laboratory toxicity data for honeybees for formulated products and a comparison with the toxicity of thiamethoxam

Test substance	Toxicity endpoint	Toxicity of product	Toxicity of the a.s.	Factor ¹	Product more toxic than the a.s. ²	Reference
Acute oral toxicity						
'Actara 25 WG' (A9558C)	Acute oral LD ₅₀	0.0178 µg formulation/bee (= 0.00445 µg a.s./bee)	0.005 µg a.s./bee	1.1	No	Muniz (2011b) Study evaluation notes ³
'A15645A' 20% w/w thiamethoxam and 20% w/w chlorantraniliprole	Acute oral LD ₅₀	0.080 µg formulation/bee (= 0.0016 µg a.s./bee ⁴)		3.1	No	Warmers (2007) Study evaluation notes ³
'Actara 240 SC' (A9795B)	Acute oral LD ₅₀	0.00309 µg a.s./bee		1.6	No	Vinall (2007) Study evaluation notes ³
'A9549C' 75% w/w thiamethoxam	Acute oral LD ₅₀	0.00668 µg a.s./bee		0.7	No	Kling (2011) Study evaluation notes ³

Test substance	Toxicity endpoint	Toxicity of product	Toxicity of the a.s.	Factor ¹	Product more toxic than the a.s. ²	Reference
Acute contact toxicity						
'Actara 25 WG' (A9558C)	Acute contact LD ₅₀	0.093 µg formulation/bee (= 0.02325 µg a.s./bee)	0.024 µg a.s./bee	1.0	No	Muniz (2011a) Study evaluation notes ³
'A15645A' 20% w/w thiamethoxam and 20% w/w chlorantraniliprole	Acute contact LD ₅₀	0.085 µg formulation/bee (= 0.017 µg a.s./bee ⁴)		1.4	No	Warmers (2007) Study evaluation notes ³
'Actara 240 SC' (A9795B)	Acute contact LD ₅₀	0.0198 µg a.s./bee		1.2	No	Vinall (2007) Study evaluation notes ³
'Actara 75 WG' (A-9549C) 75% w/w thiamethoxam	Acute contact LD ₅₀	0.46 µg a.s./bee		0.1	No	Patnaude (2007) Study evaluation notes ³

¹ The factor is the ratio between the LD₅₀ of the product (in terms of a.s.) and the LD₅₀ of the active substance.

² The product is considered to be more toxic to bees than the active substance, when the LD₅₀ of the product is more than 5 times lower than the LD₅₀ of the active substance (i.e. the factor is > 5).

³ Study evaluation notes; EFSA, 2015a.

⁴ Calculated assuming all toxicity is from thiamethoxam only.

As none of the above formulated products are more acutely toxic than thiamethoxam by more than a factor of 5, no separate risk assessments for the formulated products indicated in Table 4 are considered necessary. For the authorised products not listed in Table 4, it is necessary to consider their toxicity and the appropriateness of the risk for the active substance.

Acute toxicity endpoints from the systematic literature review

There were three additional 48-hour acute oral endpoints for *Apis mellifera* summarised in the available systematic review of the literature (presented in either µg a.s./bee or ng a.s./bee). Two were for a formulated product 'Actara 25 WG' (25% w/w thiamethoxam) and the LD₅₀ values were 0.00427 µg a.s./bee (Laurino et al., 2013) and 0.004411 µg a.s./bee (Laurino et al., 2011), which are in line with the values summarised in Table 3. The third endpoint is for a formulated product 'Aktara VDG' (250 g/L thiamethoxam) and the LD₅₀ was 0.034 µg a.s./bee (Illarionov et al., 2008). This shows lower toxicity compared with the acute oral endpoints summarised in Table 3; however, without further details of the formulation (e.g. presence of co-formulants) the reason for the difference in toxicity is not known.

There are four additional acute contact endpoints for *Apis mellifera* summarised in the available systematic review of the literature. The first is for a formulated product 'Aktara VDG' (250 g/L thiamethoxam) and the LD₅₀ was 0.0025 µg a.s./bee (Illarionov et al., 2008). This shows higher toxicity compared with the acute contact endpoints summarised in Table 3; however, without further details of the formulation (e.g. presence of co-formulants) the reason for the higher toxicity is not known. It is noted that there may be an error in the quoted contact and oral toxicity endpoints from Illarionov et al., 2008 (i.e. the contact and oral values may be the wrong way around). Moreover, none of the authorised uses in the EU are for a product called 'Aktara VDG'. The other three endpoints were for thiamethoxam and were 0.0061 µg a.s./bee (Kumar et al., 2005; 24-hour endpoint), 0.0299 µg a.s./bee (Iwasa et al., 2004; 24-hour endpoint) and 0.05116 µg a.s./bee (Badiou-Beneteau et

al., 2012), indicating lower or comparable toxicity with respect to the endpoint given in Table 3 (0.024 µg a.s./bee).

Chronic toxicity to honeybees, assessment of the hypopharyngeal glands (HPG) and accumulative toxicity

Two chronic oral toxicity studies with thiamethoxam were available in the dossiers, Belzunces (2002) (see study evaluation notes in EFSA, 2013a) and Kling (2012) (see study evaluation notes; EFSA, 2015a). Neither of the studies included an assessment of the HPG nor an assessment of accumulative effects. Both studies followed similar methodology whereby the honeybees were offered contaminated food for 10 hours per day for 10 days. During the remaining 14 hours the honeybees were offered uncontaminated food. In order to perform a risk assessment according to EFSA, 2013b, a chronic toxicity endpoint, where the honeybees were offered contaminated food continuously for 10 days, is needed. Consequently, the available chronic toxicity endpoints are not considered suitable for risk assessment in accordance with EFSA, 2013b.

Chronic toxicity endpoints from the systematic literature review

A paper giving information on the sublethal effects and mortality following an 11-day exposure period was included in the systematic literature review (Aliouane et al., 2009). The paper was discussed at the experts' meeting and in particular whether it was possible to calculate a chronic LDD₅₀ (Lethal Dietary Dose) value for use in the risk assessment. The experts proposed that if a suitable toxicity endpoint could be derived, then an illustrative assessment could be performed. However, EFSA has evaluated the study in relation to the methodology given in Appendix O of EFSA, 2013b and has concluded that the study methodology is not sufficient to derive a toxicity value for use in a chronic risk assessment according to EFSA, 2013b (study evaluation notes; EFSA, 2015a). Therefore, no chronic or sublethal risk assessment, or an assessment for accumulative effects for honeybees could be performed.

Toxicity of the active substance to larvae

Two laboratory studies investigating the toxicity of thiamethoxam to honeybee larvae were available in the dossiers (Overmyer and Huang (2012) and Giffard (2009) (study evaluation notes; EFSA, 2015a). The study by Giffard (2009) included an assessment of mortality after pupation and emergence, however the study was non-GLP and several deficiencies were noted. The study of Overmyer and Huang (2012) was broadly in line with EFSA, 2013b and gave a NOEC_{mortality} of 6.25 µg a.s./g diet. The endpoints from both studies were only available in terms of concentration (µg a.s./g diet). For a risk assessment according to EFSA, 2013b it is necessary to have the endpoint expressed in terms of the actual dose consumed (µg a.s./larva per developmental period, NOEL_{mortality}). It was agreed at the experts' meeting that, for the study of Overmyer and Huang (2012), it was not possible to estimate the endpoint in terms of the actual dose consumed, using the nominal amount of food given to the larvae, as the larvae were fed an excessive amount of contaminated diet per day. Therefore, to assume that all of the contaminated diet was consumed by the larvae would underestimate the toxicity.

2.2. Sublethal effects and other studies performed with honeybees

Two studies investigating sublethal effects (return-flight ability) of thiamethoxam and metabolite clothianidin (CGA322704) to honeybees were available in the dossiers (Werner von der Ohe (2001); see study evaluation notes in EFSA, 2013a). The studies were not performed according to GLP. The methodology used to determine the return-flight ability (using colour coding of the bees) was not as sophisticated as the study by Henry et al., 2012 (considered in EFSA, 2012b) where the use of RFID (radio-frequency identification) was employed. In the study of Werner von der Ohe (2001) with thiamethoxam the study author proposed that the NOEL for return-flight ability was 25 µg/kg sucrose solution (equivalent to 3.03 ng a.s./bee). However, it is noted that, at 25 µg/kg sucrose solution, 2 out of 11 bees had not returned within 24 hours compared to 100% of the control bees. It is therefore questionable whether the NOEL was 25 µg/kg sucrose solution. All bees returned at 0.1, 1 and

10 µg/kg sucrose solution and therefore the NOEL is considered to be 10 µg/kg sucrose solution (equivalent to 1.13 ng a.s./bee). It is noted that very few bees were used during the study, which creates some uncertainty with regard to the robustness of the results.

A number of additional studies were available in the literature investigating sublethal effects, including behaviour, locomotion, navigation or orientation. For example, Hassani et al., (2008) investigated sublethal behavioural effects of contact and oral exposure of thiamethoxam at doses of 0.1, 0.5 and 1 ng a.s./bee. At the tested doses no significant effects were observed on the locomotor activity, proboscis extension reflex (PER) and olfactory learning ability. Aliouane et al., (2009) also investigated effects on honeybee locomotor activity, water and sucrose responsiveness and learning abilities (PER). In contrast to Hassani et al., (2008), the authors concluded that contact exposure to thiamethoxam induced either a significant decrease of olfactory memory 24 hours after learning at 0.1 ng/bee, or a significant impairment of learning performance with no effect on memory at 1 ng/bee. Responsiveness to antennal sucrose stimulation was significantly decreased for high sucrose concentrations in honeybees treated orally with thiamethoxam (1 ng/bee).

A comprehensive review of sublethal effects of pesticides was reported in the EFSA PPR Panel, 2012 and data were also available in the systematic literature search report (Fryday et al., 2015). 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 the protection goal and the 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.

2.3. Toxicity to bumble bees

Table 5 summarises the acute laboratory toxicity data for bumble bees for thiamethoxam which were available.

Table 5: Available laboratory toxicity data for bumble bees for thiamethoxam

Test substance	Toxicity endpoint	Species	Value	Reference
Acute oral toxicity				
'Actara 25 WG'	Acute oral LD ₅₀	<i>Bombus terrestris</i>	0.02 µg formulation/bee (0.005 µg a.s./bee)	European Commission (2006)
Acute contact toxicity				
'Actara 25 WG'	Acute contact LD ₅₀	<i>Bombus terrestris</i>	0.11 µg formulation/bee (0.0275 µg a.s./bee)	European Commission (2006)

No acute toxicity data were available for technical thiamethoxam and therefore the risk assessment was performed using the endpoints for the formulated product, but expressed in terms of active substance. It is noted that 'Actara 25 WG' is of comparable toxicity to technical thiamethoxam to honeybees (Table 4), which may support the use of the bumble bee endpoint for 'Actara 25 WG' for the active substance risk assessment.

Toxicity endpoints from the systematic literature review

No suitable 10-day chronic toxicity study with bumble bees was available in the dossiers. A chronic toxicity study, performed for 11 weeks, was included in the systematic review (Mommaerts et al., 2010). Mommaerts et al., (2010) determined an 11-week LC₅₀ of thiamethoxam to *Bombus terrestris* to be 0.12 ppm thiamethoxam in sugar solution (95% CI: 0.04-0.38 ppm). However, an 11-week exposure period is considered to be too severe relative to the risk assessment scheme in EFSA, 2013b,

which requests that a 10-day LC₅₀ value should be used. It is noted that Mommaerts et al., (2010) did report that there was 100% mortality at 0.5 and 1 ppm after 1 and 3 weeks exposure, respectively.

No suitable data demonstrating the oral toxicity to bumble bee larvae were available.

2.4. Toxicity to solitary bees

No suitable data demonstrating the acute oral, acute contact, chronic oral toxicity to adult solitary bees or oral toxicity to solitary bee larvae were available. In accordance with EFSA, 2013b, a screening assessment can be performed by using the available endpoints for honeybees divided by 10. Therefore, the acute risk assessment for solitary bees can be performed using a surrogate contact LD₅₀ of 0.0024 µg a.s./bee and a surrogate oral LD₅₀ of 0.0005 µg a.s./bee (Table 3). Owing to the lack of honeybee data, no chronic adult or larvae screening assessment could be performed.

2.5. Summary of the endpoints to be used in risk assessment

Table 6 summarises the toxicity endpoints, which were selected for use in the tier 1 risk assessments for honeybees, bumble bees and solitary bees. The previous EU agreed acute (oral and contact) endpoints for honeybees were maintained.

Table 6: Toxicity endpoints selected for tier 1 risk assessments

Risk assessment type	Endpoint	Honeybee	Bumble bee	Solitary bee
Acute contact	48-hour LD ₅₀ (µg a.s./bee)	0.024	0.0275	0.0024 ¹
Acute oral	48-hour LD ₅₀ (µg a.s./bee)	0.005	0.005	0.0005 ¹
Chronic (oral)	LDD ₅₀ (µg a.s./bee/day)	No endpoint available	No endpoint available	No endpoint available
Larvae	NOEL _{mortality} (µg a.s./larva per development period)	No endpoint available	No endpoint available	No endpoint available
Development of hypopharyngeal glands	NOEL (µg a.s./bee/day)	No endpoint available	Not relevant	Not relevant

¹ Surrogate endpoint by using the honeybee toxicity endpoint divided by a factor of 10.

3. Risk assessments for products applied as a foliar spray

3.1. Tier 1: Risk assessments for honeybees, bumble bees and solitary bees

For contact exposure, Hazard Quotients (HQs) are calculated for the treated crop (during flowering growth stages only), weeds within the treated field and also for the field margin (which covers exposure from residues on the adjacent crop also). The HQ values are calculated by the deposition, depending on the application rate and the scenario, divided by the acute contact LD₅₀ value for honeybees, bumble bees and solitary bees. The HQ values are then compared to the trigger values given in EFSA, 2013b. These 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 (e.g. 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 (including flowering permanent crops in the successive year). ETRs are calculated for the acute risk to adult bees, chronic risk to adult bees and chronic risk to bee larvae for honeybees, bumble bees and solitary bees. ETRs represent the estimated exposure divided by the toxicity endpoint (acute adult LD₅₀, chronic adult LDD₅₀ and NOEC mortality for larvae). The exposure is calculated by the application rate multiplied by the exposure factors (ef values) 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. Degradation of the residues is accounted for in the chronic assessments using a time-weighted average factor (TWA).

The shortcut values used in the risk assessment depend on whether the crop produces pollen and nectar and whether it is attractive to honeybees, bumble bees and solitary bees (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 honeybees, bumble bees and solitary bees for pollen and/or nectar (i.e. alfalfa, barley, buckwheat¹², cow peas¹², aubergines, grapes, kiwi fruit, lentils¹², maize, melon, oats¹², olives, potatoes, quinces, rye, cotton, tobacco, tomatoes and triticale). Therefore, in the first instance, in accordance with EFSA, 2013b, in the following 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 likely of low attractiveness for pollen and/or nectar collection (for either honeybee, bumble bee, or solitary bee) but it could not be fully excluded, therefore it may be possible to provide further information regarding the attractiveness of these crops which could change the risk assessment presented below. For further details, please see Appendix D of EFSA, 2013b. Regarding the attractiveness of potatoes to honeybees, data were provided by Denmark during the experts' meeting indicating that honeybees collect pollen from potatoes (see study evaluation notes, EFSA, 2015a).

In order to perform a first-tier risk assessment according to the recommendations of EFSA, 2013b, the authorised uses have been grouped into crop categories as presented in Table 7. A distinction has been made for the authorised uses which are applied post-flowering of the treated crop only. 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, it has been assumed that the authorised use is for all growth stages after BBCH 10. The same process was repeated for the uses made in open-protected structures and is summarised in Table 8.

The soil DT₅₀ of thiamethoxam ranges from 34 to 276 days under laboratory conditions (European Commission, 2006). These values are greater than the triggers for DegT₅₀ 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.

As only acute endpoints are available for honeybees and bumble bees, and a surrogate acute endpoint for solitary bees, only an acute risk assessment could be performed.

¹² Crop not specified in authorised uses (in the GAP tables) but may be covered by crop groups (cereals, peas, beans).

Table 7: Summary of the authorised **foliar spray outdoor field** uses of thiamethoxam grouped, where possible, according to the categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2)

Crop grouping ¹	Can exposure to nectar and/or pollen on the treated crop/plant be excluded?	Authorised uses	Spray drift category ²	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Banana	Yes, not foraged by bees for nectar and pollen ³	Banana	Orchard (group 1 and 3)	125	125
Bulb vegetable	Yes, harvested prior to flowering or post flowering	Onions	Arable field crop	40	250
	No, not harvested prior to flowering	Onions	Arable field crop	40	250
Cereals	No	Spring barley, cereal group, winter barley, rye, triticale, spring wheat, winter wheat	Arable field crop	15	25
Clovers	No ⁴	Alfalfa	Arable field crop	12	12
Cotton	No	Cotton	Arable field crop	50	75
	Yes, post-flowering	Cotton	Arable field crop	30	37.5
Fruiting vegetables group 1	No	Cucumber, cucurbit group, melon, watermelon, bell pepper, chilli pepper, pepper group, courgette (zucchini), vegetable group	Arable field crop	30	112.5
	Yes, post-flowering	Cucumber, melon, watermelon, bell pepper, courgette (zucchini), vegetable group	Arable field crop	30	192
Fruiting vegetables group 2	No	Aubergine (eggplant), tomato, tobacco ⁵	Arable field crop	15	112.5
	Yes, post-flowering	Aubergine (eggplant), tomato, tobacco ⁵	Arable field crop	50	192
Grapes	No	Grapes	Grapes	40	75
	Yes, post-flowering	Grapes	Grapes	48	50
Hops	No	Hops	Hops	50	50
Leafy vegetables	Yes, harvested prior to flowering	Artichoke, broccoli, sprouts, baby leafs, cabbage, cauliflower	Arable field crop	30	300

Crop grouping ¹	Can exposure to nectar and/or pollen on the treated crop/plant be excluded?	Authorised uses	Spray drift category ²	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
	No, not harvested prior to flowering	Artichoke, broccoli, sprouts, baby leafs, cabbage, cauliflower	Arable field crop	30	300
Lettuce	Yes, harvested prior to flowering	Lettuce group, rocket, salad	Arable field crop	30	100
	No, not harvested prior to flowering	Lettuce group, rocket, salad	Arable field crop	30	100
Maize	No	Maize	Arable field crop	25	32.5
Oilseed rape	No	Rape	Arable field crop	17.5	20
Olives	Yes, post-flowering	Olives	Orchard (group 2)	30	30
Orchards group 1	No	Almond, apple, apricot, cherry, nectarine, peach, pear, plum, stone fruit group	Orchard (group 1 and 3)	25	112.5
	Yes, post-flowering	Almond, apple, pear, apricot, cherry, fruit group, nectarine, peach, plum, quince	Orchard (group 1 and 3)	25	112.5
Orchards group 2	No	Citrus fruit group, clementine, lemon, mandarin, orange	Orchard (group 2)	72	192
	Yes, post-flowering	Citrus fruit group	Orchard (group 2)	60	150
Orchards group 3	No	Kiwi fruit ⁷	Orchard (group 1 and 3)	75	112.5
Ornamentals and ornamental trees	No	Ornamental group, plants and nursery stock, rose, palm trees	Orchard (group 1 and 3)	37.5	100
	Yes, post-flowering, not foraged or harvested before flowering	Non edible medicinal/aromatic or fragrant plants, ornamental group (floriculture, tree nursery) and shrubs	Orchard (group 1 and 3)	25	192
Non-orchard trees	No	Forest nursery	Orchard (group 1 and 3)	37.5	37.5
	Yes, post-flowering or not foraged by bees for nectar and pollen	Medlar tree, coniferous trees ⁶ , pine trees ⁶ , spruce trees ⁶	Orchard (group 1 and 3)	50	100
Potatoes	No	Potatoes	Arable field crop	15	50
	Yes, post-flowering	Potatoes	Arable field crop	19.2	20
Pulses	No	Peas, beans	Arable field crop	100	125

Crop grouping ¹	Can exposure to nectar and/or pollen on the treated crop/plant be excluded?	Authorised uses	Spray drift category ²	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Root vegetables	Yes, harvested prior to flowering	Carrots	Arable field crop	30	30
	No, not harvested prior to flowering	Carrots	Arable field crop	30	30
Sunflower	No	Sunflower	Arable field crop	15	32.5

¹ Crop grouping has been performed according to the categories in the Appendix Y of EFSA, (2013b) (Bee tool v.2) 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 and tobacco), the grouping was identified and agreed by the experts at the Pesticides Peer Review Experts' Meeting 129.

² Spray drift category used for risk assessment for field margin and adjacent crop scenarios. Arable field crops applied with downward spray. Orchards and grapes applied with side or upward spray. See also Table 10.

³ Commercial banana fruits typically develop by vegetative parthenocarpy (i.e. with neither fertilisation nor pollination required), and are completely seedless and sterile (OECD, 2009). Therefore, no risk assessment for the treated crop scenario is required.

⁴ It is assumed that alfalfa will flower again after cutting.

⁵ Tobacco was considered to be similar to tomato by the experts' meeting and therefore included in the crop category 'fruiting vegetables 2'.

⁶ Conifers, spruce trees and pine trees are not foraged by bees for pollen.

⁷ Kiwi fruit only authorised for growth stages BBCH 63 – 81.

Table 8: Summary of the authorised **foliar spray uses** of thiamethoxam **made in open-protected structures** grouped where possible, according to the categories given in Appendix Y of EFSA, 2013b (Bee tool v.2)

Crop grouping ¹	Can exposure to nectar and or pollen on the treated crop/plant be excluded?	Authorised uses	Spray drift category ²	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Fruiting vegetables group 1	No	Cucumber, cucurbit group, melon, watermelon, bell pepper, pepper group, courgette (zucchini), vegetable group	Arable field crop	48	200
	Yes, post-flowering	Cucumber, melon, watermelon, bell pepper, courgette (zucchini), vegetable group	Arable field crop	192	192
Fruiting vegetables group 2	No	Aubergine (eggplant), tomato, vegetable group	Arable field crop	48	200
	Yes, post-flowering	Aubergine (eggplant), tomato, vegetable group	Arable field crop	192	192
Leafy vegetables	Yes, harvested prior to flowering	Broccoli, sprouts, baby leaves	Arable field crop	100	300
	No, not harvested prior to flowering	Broccoli, sprouts, baby leaves	Arable field crop	100	300
Lettuce	Yes, harvested prior to flowering	Lettuce group	Arable field crop	48	100
	No, not harvested prior to flowering	Lettuce group	Arable field crop	48	100
Ornamentals and ornamental trees	No	Ornamental group, Non edible medicinal/aromatic or fragrant plant shrubs	Orchard (group 1 and 3)	5	100
	Yes, post-flowering	Ornamental group	Orchard (group 1 and 3)	50	192
Pulses	No	Beans	Arable field crop	100	100
	Yes, post-flowering	Beans	Arable field crop	77	77
Strawberries	Yes, post-flowering	Strawberries	Arable field crop	96	96

¹ Crop grouping has been performed according to the categories in the Appendix Y of EFSA, (2013b) (Bee tool v.2) 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), the grouping was identified and agreed by the experts at the Pesticides Peer Review Experts' Meeting 129.

² Spray drift category used for risk assessment for field margin and adjacent crop scenarios. Arable field crops applied with downward spray. Orchards and grapes applied with side or upward spray. See also Table 10.

3.1.1. First-tier acute 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 acute oral ETR values and acute contact HQ values, for the treated crop scenario, are presented in a separate spreadsheet 'Appendix B_Thiamethoxam-Risk assessment spreadsheet' accompanying this Conclusion.

For the **authorised use to bananas**, a **low risk to honeybees, bumble bees and solitary bees** (acute contact, acute oral chronic, larvae and HPG) for the treated crop scenario was concluded as commercial banana trees only produce sterile flowers which are not foraged by bees for pollen and/or nectar.

On the basis of the first-tier risk assessment, a **high acute oral 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 (except bananas) when applications are made either **before or during flowering**. Furthermore, a **high acute oral risk to solitary bees** could not be excluded on the basis of the **screening assessment**, using the honeybee endpoints divided by ten, for any of the authorised uses (except bananas) when applications are made either **before or during flowering**. For all of the authorised uses a **low acute 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 (except bananas) 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 any of the authorised uses (except bananas) when applications are made **during flowering**. A **low contact risk to all bee species** can be concluded for the situations when the applications are performed **before or after the flowering period**.

For the authorised uses on **bulb vegetables, leafy vegetables, lettuce and carrot**, it was not always 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 contact exposure and foraging for pollen and nectar directly from the treated crop. Bees do not forage for nectar or pollen on **coniferous, pine or spruce trees** (non-orchard trees, Table 7), therefore there is a **low risk to bees** from foraging for pollen and nectar directly from the treated crop. The authorised outdoor field use to '**non edible medicinal/aromatic or fragrance plants**' was indicated to be either post-flowering or to plants which are harvested before flowering. Therefore there is a **low risk to bees** from contact exposure and foraging for pollen and nectar directly from the treated crop.

A summary of the risk assessment for the treated crop scenario is presented in Table 9.

Table 9: Summary of the first-tier oral and contact risk assessment for the treated crop scenario 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)	High acute risk to honeybees and bumble bees except if the crop is harvested before flowering. Screening assessment did not exclude a high acute risk to solitary bees.	Low risk to honeybees, bumble bees and solitary bees.
During flowering (BBCH 60- 69)	High acute risk to honeybees and bumble bees. Screening assessment did not exclude a high acute risk to solitary bees.	High acute risk to honeybees and bumble bees. Screening assessment did not exclude a high acute risk to solitary bees.
After flowering (BBCH \geq 70)	Low risk to honeybees, bumble bees and solitary bees.	Low risk to honeybees, bumble bees and solitary bees.
Crops harvested before flowering or crops which only produce sterile flowers (i.e. bananas)	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 ETR values and the acute contact HQ values, for the scenario covering weeds within the treated field, are presented in a separate spreadsheet ‘Appendix B_Thiamethoxam-Risk assessment spreadsheet’ accompanying this Conclusion. On the basis of the assessment, **a high acute oral and contact risk to honeybees and bumble bees is indicated for all authorised uses and for all growth stages**. Furthermore, a **high risk to solitary bees** could not be excluded on the basis of the screening assessment using the honeybee endpoints divided by ten. 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 remainder of the season to prevent residues in pollen and nectar in newly emerged weeds. 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 has been performed by calculation of the application rate which results in a low risk to bees (rounded down to the nearest whole gram a.s. per hectare). These ‘limit rates’ can then be compared with the authorised foliar spray uses of thiamethoxam. The calculation of the ‘limit rates’ has been performed for six relevant spray-drift scenarios according to the risk assessment scheme in EFSA, 2013b, e.g. all arable field crops have been grouped together as the spray drift values for field crops are identical (see Tables 7 and 8). The ‘limit rates’ have been determined for both the acute oral and acute contact risk assessment for honeybees, bumble bees and solitary bees. The resulting ‘limit rates’ are presented in Table 10 and in a separate spreadsheet ‘Appendix B_Thiamethoxam-Risk assessment spreadsheet’ accompanying this Conclusion. The acute oral ‘limit rates’ were lower than those for the contact assessment and therefore only the acute oral ‘limit rates’ have been summarised in Table 10. Furthermore, only the lower ‘limit rate’ for either the field margin or adjacent crop was reported in Table 10. It should be noted that the solitary bee ‘limit rates’ have been calculated using the honeybee toxicity endpoint divided by 10 as a surrogate, given that no suitable endpoints were available.

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 10: Thiamethoxam: ‘Limit rates’, assuming 0% and 95% spray drift mitigation, which indicate a low acute risk to honeybees, bumble bees and solitary bees from exposure in the field margin and adjacent crop

Crop group and application type	Authorised uses		‘Limit rate’ for acute risk assessment (g a.s./ha)						
	Crops/plants		Range of authorised application rates (g a.s./ha)	Honeybee (oral LD ₅₀ = 0.005 µg a.s./bee)		Bumble bee (oral LD ₅₀ = 0.005 µg a.s./bee)		Solitary bee (surrogate oral LD ₅₀ = 0.0005 µg a.s./bee)	
				0 % mitigation	95 % mitigation	0 % mitigation	95 % mitigation	0 % mitigation	95 % mitigation
Arable field crop, downward spray	Outdoor-field	Alfalfa, artichoke, aubergine (eggplant (oriental)), baby leaves, barley, bean (garden), bell pepper, chili pepper, broccoli, Brussels sprouts, cabbage group, carrot, cauliflower, cereal group, cotton, cucumber, lettuce and/or salad, maize, melon/watermelon/cucurbit, onion, pea (non specified), pepper, potato, rocket (rucola), rye, sunflower (common), tobacco, tomato, triticale, vegetable group, wheat, courgette (zucchini).	12 – 300	29	587	3	60	<1	18
	Open-protected	Aubergine, baby leaves, bean (garden), bell pepper, broccoli, Brussels sprouts, cucumber, lettuce group, melon/watermelon/cucurbit, pepper, strawberry, tomato, vegetable group, courgette (zucchini).	48 - 300						
Orchards group 1 and 3 early ¹ Side/upward spray	Outdoor-field	Almond, apple, apricot, banana, cherry, kiwi, nectarine, peach, pear, plum, quince, stone fruit group. Non edible medicinal/aromatic or fragrance plants, ornamentals, palm tree, plants, nursery stock, shrubs. Coniferous tree, forest (nursery), medlar tree, pine, spruce.	25 – 125	1	39	<1	4	<1	1
	Open-protected	Non edible medicinal/aromatic or fragrance plant, ornamentals, shrubs.	5 - 192						
Orchards group 1 and 3 late ² Side/upward spray	Outdoor-field	Almond, apple, apricot, banana, cherry, kiwi, nectarine, peach, pear, plum, quince, stone fruit group. Non edible medicinal/aromatic or fragrance plants, ornamentals, palm tree, plants, nursery stock, shrubs. Coniferous tree, forest (nursery), medlar tree, pine, spruce.	25 – 125	4	84	<1	10	<1	2
	Open-protected	Non edible medicinal/aromatic or fragrance plant, ornamentals, shrubs.	5 - 192						
Orchards group 2 late Side/upward spray	Outdoor-field	Citrus fruit group, clementine, lemon, mandarin, olives, orange.	72 - 192	4	84	<1	10	<1	2

Crop group and application type	Authorised uses			'Limit rate' for acute risk assessment (g a.s./ha)					
	Crops/plants		Range of authorised application rates (g a.s./ha)	Honeybee (oral LD ₅₀ = 0.005 µg a.s./bee)		Bumble bee (oral LD ₅₀ = 0.005 µg a.s./bee)		Solitary bee (surrogate oral LD ₅₀ = 0.0005 µg a.s./bee)	
				0 % mitigation	95 % mitigation	0 % mitigation	95 % mitigation	0 % mitigation	95 % mitigation
Hops Side/upward spray	Outdoor-field	Hops.	50	3	64	<1	7	<1	1
Grapes early (BBCH <20) Side/upward spray	Outdoor-field	Grapes.	40 - 75	27	559	3	61	<1	14
Grapes late (BBCH ≥20) Side/upward spray	Outdoor-field	Grapes.	40 - 75	9	184	1	20	<1	4

¹ Includes bananas up to BBCH >20

² Includes bananas at BBCH < 20

In summary, for the field margin/adjacent crop scenario for foliar spray uses:

- It is possible to **mitigate the acute risk to honeybees for all arable field crops, hops and grapes** by spray drift reduction.
- It is also possible to **mitigate the acute risk to honeybees for orchard uses** at or below the application rate of 39 g a.s./ha for orchard groups 1 and 3, and at or below 84 g a.s./ha for orchard group 2. However, for **some orchard uses, a high acute risk to honeybees is indicated even with 95% spray drift mitigation.**
- It is possible to mitigate the **acute risk to bumble bees for arable field crop** uses at or below 60 g a.s./ha. However, for **some arable field crop uses, a high acute risk to bumble bees is indicated even with 95% spray drift mitigation.**
- For **all uses to orchards** (with the exception of some uses to late ornamentals) and **hops, a high acute risk to bumble bees is indicated for the field margin/adjacent crop scenario even with 95% spray drift mitigation.**
- For some uses to **early grapes**, it is possible to mitigate the acute risk to bumble bees. However, none of the authorised uses to grapes were restricted to early growth stages only.
- The screening assessment indicated that a **high acute risk** could not be excluded for **solitary bees for any of the authorised uses on orchards, hops or grapes**, and for the **authorised uses on arable field crops**, except a few uses at or below 18 g a.s./ha.

It is important to note that the 'limit rates' have only been calculated using the available acute adult endpoints as no chronic adult or larvae endpoints were available for risk assessment (see Sections 3.1.2 and 3.1.3) and therefore the 'limit rates' should not be regarded as conclusive of the level of mitigation required to protect honeybees, bumble bees and solitary bees.

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

The acute oral ETR values, for the succeeding crop scenario, are presented in a separate spreadsheet 'Appendix B_Thiamethoxam-Risk assessment spreadsheet' accompanying this Conclusion.

For the **authorised use to bananas, a low risk to honeybees, bumble bees and solitary bees** (acute, chronic, larvae and HPG) was concluded as commercial banana trees only produce sterile flowers which are not foraged by bees for pollen and/or nectar. A **low acute oral risk to honeybees** was indicated for the authorised use on **kiwi fruit** (lowest 'maximum application rate'), **hops** (lowest and highest 'maximum application rate') and **olives** (lowest and highest 'maximum application rate'). For **all other authorised uses a high acute oral risk was indicated for honeybees. A high acute oral risk to bumble bees** was indicated for **all of the authorised uses** (except bananas). Furthermore, a **high acute oral risk to solitary bees** could not be excluded for **any authorised uses** (except bananas) based on the screening assessment using the honeybee endpoints divided by ten.

It 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.

3.1.2. First-tier chronic oral risk assessment for honeybees (including HPG), bumble bees and solitary bees

No first-tier chronic risk assessment for honeybees (including an assessment of the HPG), bumble bees or solitary bees could be performed as no suitable chronic toxicity endpoints were available (see Sections 2.1, 2.3 and 2.4). Nevertheless, a low chronic risk to honeybees, bumble bees and solitary bees can be concluded for the treated crop scenario for post-flowering and those uses harvested prior to flowering (see Section 3.1.1.1). Furthermore, risk mitigation measures to prevent the weeds within the treated crop from flowering would result in a low chronic risk to bees for the in-field weed scenario (see Section 3.1.1.2).

3.1.3. First-tier larvae risk assessment for honeybees, bumble bees and solitary bees

No first-tier risk assessment for honeybee, bumble bee or solitary bee larvae could be performed as no suitable toxicity endpoints were available (see Sections 2.1, 2.3 and 2.4). Nevertheless, a low risk to bee larvae can be concluded for the treated crop scenario for post-flowering and those uses harvested prior to flowering (see Section 3.1.1.1). Furthermore, risk mitigation measures to prevent the weeds within the treated crop from flowering would result in a low risk to bee larvae (see Section 3.1.1.2).

3.2. Tier 2: risk assessment (oral) for honeybees, bumble bees and solitary bees

EFSA, 2013b suggests a number of options to refine the 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 thiamethoxam regulatory dossiers included three studies reporting residue data on the active substance (i.e. thiamethoxam) and/or its metabolites. All three studies reported some residue measurements for bee-relevant matrices (nectar and pollen). Residue data for matrices not relevant for bee risk assessment (flowers, tomato fruit) were disregarded. The relevant measurements are summarised in Table 11. The available residue data are reported in full in Appendix E.

Table 11: Available thiamethoxam residue data on bee-relevant matrices

Crop/ location	BBCH at application	Type ¹	Application technique	Matrix	Max RUD (mg/kg) ²	Min RUD (mg/kg) ²	DAT ³
Honeydew melon Italy	61-64	SF	Foliar spray	Pollen from forager bees	0.39	-	15
Honeydew melon Italy	61-64	SF	Foliar spray	Nectar from forager bees	0.16	-	16
Peach Italy	55-57	F	Foliar spray	Pollen from forager bees	< LOQ (0.08)	-	9
Peach Italy	55-57	F	Foliar spray	Nectar from forager bees	< LOQ (0.08)	-	9
Apple Switzerland	57-59	F	Unknown	Pollen from plants	0.85	0.61	15-18

¹ Field (F) / Semi-Field (SF)

² Maximum and minimum RUD refer to the same sampling date (usually the first available sampling)

³ Days After Treatment: interval (days) between treatment and sample collection

Some analysed samples were collected during field studies (EFSA, 2015a). It should be considered that pollen and nectar transported by foragers to the hives may have partially been collected outside the treated area. However, the influence of dilution on the residue measurements is difficult to be quantified.

No dissipation rate could be derived for any matrix. The only available time series was for nectar in the semi-field study on honeydew melon; however, no decline curve could be fitted. All measurements in the field study on peach were below the LOQ.

Other studies reporting measurements of thiamethoxam residues were present 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 certain bee-relevant matrices (i.e. guttation fluid, nectar, pollen, water). Residues in other bee-relevant matrices (e.g. beebread, dew, honey, propolis, etc.) were not evaluated as these matrices are not considered in the risk assessment methodology described in EFSA, 2013b. The availability of information on the application rate, in order to express residues as RUD, was also a selection criterion. No relevant studies were found at the end of the screening process.

In comparison to the variety of crops and geographic location of the authorised uses, the available residue data are very limited (Appendix E). Furthermore, the representativeness of the studies in relation to worst-case or 90th percentile exposure is very uncertain (see study evaluation notes; EFSA, 2015a).

According to Appendix G of EFSA, 2013b, to perform an exposure 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 need to be available for each of the authorised uses of thiamethoxam, taking account of the growth stage of the crop when applications are made. In the Pesticides Peer Review Experts' 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 thiamethoxam are therefore not considered sufficient to perform a robust tier 2 assessment for any of the authorised uses.

3.3. Tier 3: higher tier risk assessment using effects studies for honeybees, bumble bees and solitary bees

3.3.1. Higher tier effects studies performed with honeybees (foliar sprays)

The available higher tier effects studies from the dossiers and/or made available by Member States have been evaluated according to the criteria given in EFSA, 2013b. A full evaluation of each study was reported in the study evaluation notes; EFSA, 2015a. A brief summary of the observations is given in Appendix B (Tables 17 and 19).

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 (90th percentile worst case for the hives at the edge of the 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 90th percentile exposure, EFSA, 2013b suggests that an exposure assessment is undertaken by performing residue studies in areas representative of where the active substance will be applied. The level of exposure achieved in the effect field study can then be demonstrated to be representative across a wider area (i.e. if it equates to the 90th percentile exposure level). As discussed in Section 3.2, insufficient residue data were available to perform an exposure assessment (hence a tier 2 risk assessment) for any of the authorised uses of thiamethoxam. 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 thiamethoxam 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 (7% reduction in colony strength). 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. to increase the size of field, to increase the distance between the test fields and the control, to include overwintering success or improvements to the measurements of mortality and colony strength.

None of the available studies fulfilled the criteria of EFSA, 2013b. It is acknowledged that the studies were performed prior to the publication of EFSA, 2013b. In evaluating these studies, any deficiency in the study design, beyond those identified on the basis of the new elements introduced by EFSA, 2013b, was also highlighted. Several studies had severe limitations which question their reliability for any form of risk assessment (e.g. lack of untreated control).

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

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

3.3.2. Higher tier effects studies performed with bumble bees (foliar sprays)

The available higher tier effects studies have been evaluated according to the criteria given in EFSA, 2013b. Similarly to that described for honeybees, according to EFSA, 2013b, higher tier effects studies for bumble bees should be designed to be able to address the specific protection goals (SPG) for worst case exposure (90th percentile worst case at the edge of the treated fields in the area of use) and to ensure that the studies are sufficiently sensitive in order to detect biological effects to meet the SPG for the level of effect. Therefore, in order to demonstrate that the studies have achieved the 90th percentile exposure it is first necessary to undertake 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 90th percentile exposure level).

Only one semi-field study investigating the effects on bumble bees from exposure to thiamethoxam following a foliar spray application was available (see study evaluation notes; EFSA, 2015a). The study was not considered sufficient for risk assessment in accordance with EFSA, 2013b. A brief summary of the observations is given in Table 18 in Appendix B.

3.4. Uncertainty analysis

As it is not possible to perform tier 2 or tier 3 refined risk assessments, no uncertainty analysis is required.

4. Risk assessments for products applied as dips, 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 or granules (i.e. no exposure factors and shortcut values are available). Therefore, the exposure to bees for the authorised uses applied as seedling dumping¹³, drenches, drip

¹³ Seedling dumping: 'seedlings dipped in the product (or a solution of the product) before planting in the field', see Appendix D.

irrigation, dips, soil incorporation, etc. was discussed at the experts' meeting. A summary is provided in Appendix D and full details of the discussions can be found in Appendix 3 of the meeting report (EFSA, 2015a).

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 crop scenario has therefore been performed (see Section 4.1). In the absence of specific shortcut values for drenches, drip irrigation and dips, the shortcut values for 'incorporated granules' were used as a surrogate (i.e. granules with the growth stage restricted to BBCH < 10). For the authorised uses, such as for seedling dumping, drenches, drip irrigation and dips, to 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. drenches, drip and irrigation). In these cases, it is considered that the use of shortcut values for 'incorporated granules' is likely to underestimate the risk to bees, given the possibility for foliar contamination of the liquid and the shorter time between the application and the flowering of the crop/plant.

For the authorised uses as 'soil incorporation' (an application of liquid formulations together with the seed along the line drawn by the plough), the risk assessment was performed using the same parameters as for foliar sprays but limiting the growth stage to before BBCH 10.

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 presented in Table 12 (which correspond to the crop categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2) for oral risk assessment). A distinction has been made for the authorised uses which are applied post-flowering of the treated crop only.

Table 12: Summary of the authorised **outdoor field uses** of thiamethoxam applied using other application techniques grouped, where possible, according to the categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2) and the surrogate tier 1 parameters used in the risk assessment

Crop grouping ¹	Can exposure to nectar and or pollen on the treated crop/plant be excluded?	Authorised uses	Application methods	Surrogate tier 1 risk assessment parameters	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Fruiting vegetables group 1	No	Bell pepper, cucumber, melon, watermelon, pepper, courgette (zucchini)	Dip, drench, irrigation, nursery drip	Incorporated granules (BBCH < 10)	48	200
Fruiting vegetables group 1, BBCH <10 ²	No	Vegetable group	Soil incorporated	Foliar spray (BBCH < 10)	200	200
Fruiting vegetables group 2	No	Aubergine (eggplant), tomato,	Dip, drench, drip, irrigation, nursery drips	Incorporated granules (BBCH < 10)	48	200
Leafy vegetables	Yes, harvested prior to flowering	Broccoli, Brussels sprouts, cabbage group, Chinese cabbage, head cabbage, cauliflower, kale, kohlrabi	Dip, irrigation, nursery drips	Incorporated granules (BBCH < 10)	50	200
	No, not harvested prior to flowering	Broccoli, Brussels sprouts, cabbage group, Chinese cabbage, head cabbage, cauliflower, kale, kohlrabi	Dip, irrigation, nursery drips	Incorporated granules (BBCH < 10)	50	200
Lettuce	Yes, harvested prior to flowering	Lettuce group	Dip, drench, drip, irrigation, nursery drips	Incorporated granules (BBCH < 10)	48	200
	No, not harvested prior to flowering	Lettuce group	Dip, drench, drip, irrigation, nursery drips	Incorporated granules (BBCH < 10)	48	200
Orchards group 2	No	Citrus fruit group	Drench	Incorporated granules (BBCH < 10)	200	200
Ornamentals and ornamental trees	No	Ornamental group and palm trees	Drench, drip	Incorporated granules (BBCH < 10)	100	200

Crop grouping ¹	Can exposure to nectar and or pollen on the treated crop/plant be excluded?	Authorised uses	Application methods	Surrogate tier 1 risk assessment parameters	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Potato, BBCH <10	No	Potato	Soil incorporated, ground application, pre-plant incorporated	Foliar spray (BBCH < 10)	25	150
Pulses	No	Garden bean	Drip	Incorporated granules (BBCH < 10)	100	100
Strawberries	No	Strawberries	Drip	Incorporated granules (BBCH < 10)	50	200

¹ Crop grouping has been performed according to the categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2)

² Fruiting vegetables 1 for growth stages BBCH <10 are worst case for all vegetable groups.

Table 13: Summary of the authorised uses made in **open-protected structures** of thiamethoxam applied using other application techniques grouped, where possible, according to the categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2) and the surrogate tier 1 parameters used in the risk assessment

Crop grouping ¹	Can exposure to nectar and or pollen on the treated crop/plant be excluded?	Authorised uses	Application methods	Surrogate tier 1 risk assessment parameters	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
Fruiting vegetables group 1	Yes, harvested prior to flowering	Vegetable group	Dip, drench, drip, irrigation, nursery drips, seedling dumping	Incorporated granules (BBCH < 10)	100	200
	No, not harvested prior to flowering	Bell pepper, cucumber, melon, watermelon, pepper, pepper group, courgette (zucchini), vegetable group		Incorporated granules (BBCH < 10)	48	200
Fruiting vegetables group 2	Yes, harvested prior to flowering	Vegetable group	Drench, drip, irrigation, dip, seedling dumping	Incorporated granules (BBCH < 10)	100	200

Crop grouping ¹	Can exposure to nectar and or pollen on the treated crop/plant be excluded?	Authorised uses	Application methods	Surrogate tier 1 risk assessment parameters	Lowest 'maximum application rate' g a.s./ha	Highest 'maximum application rate' g a.s./ha
	No, not harvested prior to flowering	Aubergine (eggplant), tomato, tobacco, vegetable group		Incorporated granules (BBCH < 10)	48	200
Leafy vegetables	Yes, harvested prior to flowering	Broccoli, Brussels sprouts, cabbage group, Chinese cabbage, head cabbage, cauliflower, kale, kohlrabi	Drip, irrigation, seedling dumping	Incorporated granules (BBCH < 10)	50	200
	No, not harvested prior to flowering	Broccoli, Brussels sprouts, cabbage group, Chinese cabbage, head cabbage, cauliflower, kale, kohlrabi	Drip, irrigation, seedling dumping	Incorporated granules (BBCH < 10)	50	200
Lettuce	Yes, harvested prior to flowering	Lettuce group, lettuce and/or salad	Drench, drip, irrigation, dip, seedling dumping	Incorporated granules (BBCH < 10)	48	200
	No, not harvested prior to flowering	Lettuce group, lettuce and/or salad	Drench, drip, irrigation, dip, seedling dumping	Incorporated granules (BBCH < 10)	48	200
Ornamentals and ornamental trees	No	Ornamental group, ornamentals, palm trees	Drip, drench	Incorporated granules (BBCH < 10)	100	200
Non-orchard trees	Yes, not foraged by bees for nectar and pollen	Pine trees ² , fir trees ²	Drip before planting	Incorporated granules (BBCH < 10)	75	125
Pulses	No	Bean, garden bean	Drip	Incorporated granules (BBCH < 10)	100	200
Strawberries	No	Strawberries	Drip, drench	Incorporated granules (BBCH < 10)	50	200

¹ Crop grouping has been performed according to the categories given in the Appendix Y of EFSA, 2013b (Bee tool v.2)

² Pine and fir trees are not foraged by bees for pollen.

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

Treated crop scenario

The resulting acute oral ETR values for the treated crop scenario are presented in a separate spreadsheet 'Appendix B_Thiamethoxam-Risk assessment spreadsheet' accompanying this Conclusion. A **low acute oral risk to honeybees** from the **soil incorporation use on potatoes** was indicated (lowest 'maximum application rate' only); however, a **high acute risk to bumble bees** was indicated. A **high acute oral risk to honeybees and bumble bees** was indicated for the soil incorporation use on vegetables.

For the **authorised uses as seedling dumping, drenches, drip irrigation and dips**, a **low acute oral risk to honeybees** was indicated for the authorised uses on **fruiting vegetables 2** and **lettuce** (lowest 'maximum application rate' only); however, a **high acute risk to bumble bees** was indicated. A **high acute oral risk to honeybees and bumble bees** was indicated for all other authorised uses **as seedling dumping, drenches, drip irrigation and dips** (unless the crop is harvested before flowering or not foraged by bees).

A **high acute oral risk to solitary bees** could not be excluded for any **of the authorised uses applied as soil incorporation, seedling dumping, drenches, drip irrigation and dips** (unless the crop is harvested before flowering or not foraged by bees), on the basis of the screening assessment using the honeybee endpoints divided by ten.

Bees do not forage for nectar or pollen on **pine and fir trees** (non-orchard trees, Table 13) therefore there is a **low risk to bees** from foraging for pollen and nectar directly from the treated crop.

For the authorised uses on **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 for pollen and nectar directly from the treated crop. For some of the authorised uses **to 'vegetable group'** the GAP indicated that the **crop is harvested before flowering** and therefore there is a **low risk to bees** from foraging for pollen and nectar directly from the treated crop.

Weed, field margin, adjacent crop and succeeding crop scenarios

The experts at the meeting agreed that, for the authorised uses as soil incorporation, seedling dumping, drenches (including to pots/containers/nursery trays), irrigation, drip irrigation and dips, exposure to bees from **weeds** in the treated field and **succeeding crop** is possible (see Table 23, Appendix D). 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 as seedling dumping, drenches to pots/containers/nursery trays, drip irrigation and dips, for the **field margin** and the **adjacent crop** scenarios it was agreed at the experts' meeting that exposure to bees via drift is unlikely (see Table 23, Appendix D) and therefore a low risk was concluded. For the authorised uses as soil incorporation, drenches (excluding to pots/containers/nursery trays) 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 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) for honeybees, bumble bees and solitary bees

No studies were available which provide residue measurements in nectar and pollen following applications of thiamethoxam applied via drench, drip irrigation and other application methods. Therefore no tier 2 risk assessment could be performed.

4.3. Tier 3: higher tier risk assessment using effects studies for honeybees, bumble bees and solitary bees

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

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

There were two field studies performed with honeybees; one performed using a drip irrigation application method to honeydew melons in Spain (Schur, 2003) and the second using an in-furrow application to cucumbers in the USA (Mayer, 2000). Neither of the studies were considered sufficient for risk assessment in accordance with EFSA, 2013b. A brief summary of the observations is given in Table 19 in Appendix B.

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

There were three semi-field studies which investigated the effects on bumble bees following drench or drip irrigation application of thiamethoxam to tomatoes (Aldershof (2000), Reber (1999a) and Balluf (2001)). The studies have been evaluated and are summarised in the study evaluations notes (EFSA, 2015a). None of the studies were considered sufficient for risk assessment in accordance with EFSA, 2013b. A brief summary of the observations is given in Table 20 in Appendix B.

4.4. Uncertainty analysis

As it is not possible to perform tier 2 or tier 3 refined risk assessments, no uncertainty analysis is required.

5. Risk assessment for 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 a higher tier risk assessment is required. No toxicity data investigating accumulative effects were 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, i.e. via guttation fluid, surface water and puddles should be considered. It is noted that other potential routes of exposure (e.g. exposure via drinking 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. According to the risk assessment scheme a risk assessment for bumble bees and solitary bees is not needed.

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 assessment for the authorised uses applied as foliar spray and other application techniques is presented in Table 14.

Table 14: Screening risk assessment for honeybees via guttation fluid on the treated crop

	Step	Assessment	
1	Check whether exposure is negligible.	<ul style="list-style-type: none"> • Permanent greenhouse uses are considered to result in negligible exposure to honeybees from exposure to guttation fluid. • 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 thiamethoxam = 4.1 g/L (= 4.1 µg/µL) at 25°C (European Commission, 2006).	
a	$ETR_{acute} \text{ adult honeybees} = W \times PEC/LD_{50}$ $LD_{50} = \text{acute oral } LD_{50} \text{ (}\mu\text{g a.s./bee)}$ $W = \text{water uptake of adult honeybees} = 11.4 \mu\text{L/bee}$ $PEC = \text{concentration in guttation fluid in } \mu\text{g}/\mu\text{L and is assumed to be:}$ 100% of the water solubility for acute assessment.	$Acute \text{ oral } LD_{50} = 0.005 \mu\text{g a.s./bee}$ $PEC = 4.1 \mu\text{g}/\mu\text{L}$ $W = 11.4 \mu\text{L/bee}$	Screening ETR = 9348 Which is greater than the trigger of 0.2
b	$ETR_{chronic} \text{ honeybees} = W \times PEC/LDD_{50}$ $LDD_{50} = \text{chronic lethal dietary dose (}\mu\text{g a.s./bee per day)}$ $W = \text{water uptake of adult honeybees} = 11.4 \mu\text{L/bee}$ $PEC = \text{concentration in guttation fluid in } \mu\text{g}/\mu\text{L and is assumed to be:}$ 54% of the water solubility for chronic assessment	No suitable endpoint available for assessment.	
c	$ETR_{HPG} \text{ honeybees} = W \times PEC/NOEL_{HPG}$ $NOEL_{HPG} = \text{NOEL based on HPG dose (}\mu\text{g a.s./bee per day)}$ $W = \text{water uptake of adult honeybees} = 11.4 \mu\text{L/bee}$ $PEC = \text{concentration in guttation fluid in } \mu\text{g}/\mu\text{L and is assumed to be:}$ 54% of the water solubility	No suitable endpoint available for assessment.	
d	$ETR_{larvae} \text{ honeybees} = W \times PEC/NOEL_{larvae}$ $NOEL_{larvae} = \text{NOEL for larvae } \mu\text{g a.s./larvae per developmental period}$ $W = \text{water uptake of larvae over 5 days} = 111 \mu\text{L/larvae per 5 days}$ $PEC = \text{concentration in guttation fluid in } \mu\text{g}/\mu\text{L and is assumed to be:}$ 72% of the water solubility	No suitable endpoint available for assessment.	
4 and 5	Refine exposure calculation 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 were available for the assessment for the authorised uses of thiamethoxam.	

As indicated in Table 14, the acute screening step was not sufficient to demonstrate a low acute risk to honeybees for the authorised uses made outdoors and in open-protected structures.

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 database in the available systematic literature review did not reveal any literature data giving measurements of concentrations of thiamethoxam, clothianidin or imidacloprid occurring in guttation fluid following foliar spray applications or drenches. However, residues of clothianidin in guttation fluid occurring in potatoes have been detected following application of a product containing clothianidin (for further details refer to study 10_THW-0337 in EFSA, 2015b, study evaluation notes for clothianidin).

With the information available, the risk assessment for honeybees exposed to residues of thiamethoxam 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 a low risk to bees via this route of exposure.

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

In the absence of an agreed aquatic exposure assessment for the authorised uses, the risk to honeybees consuming residues in surface water could not be assessed.

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

In the absence of an agreed aquatic exposure assessment 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 puddles of treatment solution is expected to be present and therefore there is a low risk to bees via this route of exposure.

6.4. Uncertainty analysis and conclusions

As no refined risk assessments were available no uncertainty analysis is required.

7. Risk posed by metabolites

According to EFSA, 2013b each metabolite which exceeds 10% TRR or 0.01 mg/kg identified in the plant metabolism studies should be considered. It is noted that several plant metabolism studies are reported in the previous EU evaluation of thiamethoxam (Spain, 2001; European Commission, 2006). These studies together with plant metabolism studies available for the authorised uses in Member States should be considered according to the recommendations of EFSA, 2013b, to identify all metabolites which exceed 10% TRR or 0.01 mg/kg. Nevertheless, thiamethoxam is known to degrade to metabolite clothianidin (CGA322704) in various matrices, for example in soil (European Commission, 2006). Residues of metabolite clothianidin (CGA322704) have also been detected in nectar, pollen and guttation fluid (EFSA, 2013a). Clothianidin is also a systemic neonicotinoid active substance authorised in plant protection products in the EU. Metabolite clothianidin (CGA322704) is of comparable toxicity to honeybees in laboratory studies (see Table 3). Therefore the risk to bees from metabolite clothianidin (CGA322704) was considered in Table 15 below.

Table 15: Consideration of the risk posed by metabolite clothianidin (CGA322704)

Section of risk assessment	Consideration of risk posed by metabolite clothianidin (CGA322704)
First-tier risk assessment for honeybees (oral)	Honeybees are of comparable sensitivity to metabolite clothianidin (CGA322704) and thiamethoxam (<u>acute</u> oral, see Table 3). However, for first-tier exposure estimates the exposure will always be less than that for the parent. Therefore, the first-tier <u>acute</u> risk assessment for thiamethoxam is considered to cover the risk from the metabolite clothianidin (CGA322704) and no separate risk assessment has been presented. No honeybee chronic adult (including HPG and accumulative effects) or larvae toxicity data were available for comparison.
First-tier risk assessment for bumble bees (oral)	No bumble bee acute adult, chronic adult or larvae toxicity data were available for comparison.
First-tier risk assessment for solitary bees (oral)	No solitary bee acute adult, chronic adult or larvae toxicity data were available for comparison.
Tier 2 risk assessment using refined exposure estimates (oral)	A tier 2 risk assessment using refined exposure estimates must also consider exposure to metabolite clothianidin (CGA322704) (i.e. via exposure to the treated crop, weeds, field margin, adjacent crop and succeeding crops). No suitable data were available to perform a tier 2 risk assessment for metabolite clothianidin (CGA322704) or the parent substance.
Tier 3 risk assessment using higher tier effect studies (oral)	Theoretically metabolite clothianidin (CGA322704) should also be covered by higher tier effect studies performed with the parent substance and residue measurements for metabolite clothianidin (CGA322704) should have been performed. Some of the available higher tier effect studies included residue analysis of metabolite clothianidin (CGA322704) (study evaluation notes, EFSA, 2015a). However, the available higher tier effect studies were not considered sufficient to reliably conclude on the risk posed by either thiamethoxam or metabolite clothianidin (CGA322704).
Risk to honeybees from exposure via contaminated water (guttation fluid, surface water and puddles)	According to EFSA, 2013b there is no need to consider the risk to honeybees from metabolites forming in guttation fluid, surface water and puddles. However, given the fact that metabolite clothianidin (CGA322704) is a known active substance, in this instance, it is considered appropriate to assess the risk to bees from exposure via contaminated water. Exposure estimates used in the risk assessment should consider metabolite clothianidin (CGA322704) in addition to thiamethoxam. Only a screening step assessment of exposure from residues of thiamethoxam in guttation fluid could be performed, which indicated that further consideration was necessary. Therefore, the refined assessment should also consider potential exposure from metabolite clothianidin (CGA322704). This is also the case for the assessment of exposure via residues in surface water and puddles.

As summarised in Table 15, the risk assessment for bees from exposure to metabolite clothianidin (CGA322704) could not be finalised for the authorised uses of thiamethoxam with the available information.

8. Overall conclusions 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.

More specifically, for all authorised uses **outdoor** or **in open-protected structures**, the following is concluded:

- A low acute risk to honeybees for the **treated crop** scenario from the soil incorporation use on potatoes (lowest ‘maximum application rate’) was indicated. A low acute risk to honeybees for the **treated crop** scenario was indicated for the authorised uses on **fruiting vegetables 2** and **lettuce** (drench application, lowest ‘maximum application rate’). For uses on post-flowering crops/plants, crops/plants harvested before flowering or trees not foraged by honeybees, bumble bees and solitary bees for pollen and/or nectar a low risk for the treated crop scenario was concluded. For all other authorised uses before flowering, or on flowering crops/plants, a high acute risk to honeybees and bumble bees foraging on the treated crop was indicated.
- Where a risk assessment could be performed, a high acute risk to honeybees and bumble bees from foraging on **weeds** in the treated field was indicated, unless risk mitigation measures are applied to prevent the weeds within the treated crop from flowering.
- For several authorised uses, it is possible to mitigate the **acute** risk to honeybees and bumble bees from foraging in the **field margin and adjacent crop** by use of spray drift reduction (see Table 10 in Section 3.1.1.3). For a number of authorised uses a high acute risk to honeybees and bumble bees was indicated even with 95% spray drift mitigation. Moreover, owing to the lack of toxicity data, the field margin and adjacent crop risk assessment for honeybees, bumble bees and solitary bees could not be finalised (see details under bullet point 5, below), and therefore the identified mitigation should not be regarded as conclusive of the level of mitigation required to protect honeybees, bumble bees and solitary bees. For the authorised uses as seedling dumping, drenches to pots/containers/nursery trays, drip irrigation 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/containers/nursery trays) 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 on permanent crops (kiwi, olives, hops and bananas), a high acute risk to honeybees and bumble bees was indicated for the **succeeding crop/plant** scenario for the foliar spray uses. For the authorised uses as soil incorporation, drenches, drip irrigation, seedling dumping and dips, the risk assessment was not finalised except for trees which are not foraged by honeybees, bumble bees and solitary bees for pollen and/or nectar.
- Numerous aspects of the risk assessment could not be finalised due to lack of data (risk to solitary bees, chronic risk to honeybees, chronic risk to bumble bees, risk to honeybee larvae, risk to bumble bee larvae, risk to honeybee HPG (a sublethal effect), accumulative effects, risk to honeybees from contaminated water (via guttation fluid, puddles, surface water), risk assessment from the metabolite clothianidin and an assessment of toxicity for a number of the authorised formulated products).
- 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 (e.g. application rate) on the authorised uses provided by the Member States.
- 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.

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).

Results spring/summer season 2012: 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 four substances was detected. This is related to 51% of the apiaries where residue analyses were positive (totally around 600 hives). All four 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 or 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 beebread 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 or other). The samples were also analysed for other pesticides and in several samples pesticide active substances were detected.

Hungary reported that cropped fields, 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 competent 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 (max. values): < 1 – 4.7 µg/kg flower; clothianidin as metabolite of thiamethoxam: < 1 – 3.2 µg/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 (max. 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 on the level of risk or provide feedback on risk assessment methodologies 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 outdoor 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 outdoor field uses, uses in open-protected structures and uses in permanent greenhouses).
- Information to address the risk to honeybees, bumble bees and solitary bees from exposure to the metabolite clothianidin (relevant for all outdoor field uses, uses in open-protected structures and, for honeybees, also for uses in permanent greenhouses).

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 for all outdoor 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 10 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. chronic, larvae and HPG (for honeybees only)).

12. Concerns

12.1. Issues that could not be finalised

The assessments are considered not finalised when there were no data or when only a screening level assessment could be performed (i.e. honeybee: chronic oral adult, oral larvae, HPG, accumulative effects, consumption of contaminated water; bumble bee: chronic oral adult, oral larvae; solitary bee: acute oral adult, acute contact adult, chronic oral adult, oral larvae).

The issues that could not be finalised are marked with an 'X' in the overview table in Section 13. See Table 16.

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. Bumble bees: acute oral adult, acute contact adult). See Table 16.

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

Table 16: Summary of concerns for each scenario according to the risk assessment scheme in EFSA, 2013b, accounting for particular conditions proposed to be taken into account to manage the risks identified

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 (i.e. **honeybee**: acute oral adult, acute contact adult. **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 (i.e. **honeybee**: acute oral adult, acute contact adult. **Bumble bees**: acute oral adult, acute contact adult)]. A low acute risk can be concluded for some of the uses provided that 95% risk mitigation of spray drift is applied. Refer to Table 10.

R(2): A high acute risk was indicated with some exceptions: a) lowest authorised 'maximum application rate' to kiwi fruit and the authorised uses on olives; b) lowest authorised 'maximum application rate' to potatoes (soil incorporation); c) lowest authorised 'maximum application rate' to fruiting vegetables 2 (dip application) and lettuce (dip and drench application); d) commercial banana trees are not foraged by bees for pollen and/or nectar as they only produce sterile flowers.

X = Risk assessment not finalised due to the lack of data or when only a screening level assessment could be performed (i.e. **honeybee**: chronic oral adult, oral larvae, HPG, accumulative effects, consumption of contaminated water; **bumble bee**: chronic oral adult, oral larvae; **solitary bee**: acute oral adult, acute contact adult, chronic oral adult, oral larvae).

X(1) = Risk assessment not finalised with the exception of the treated crop and succeeding crop scenario for the authorised use on commercial banana trees which only produce sterile flowers and therefore are not foraged by bees for pollen and/or nectar.

The table does not reflect authorised 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. In addition, the table does not reflect authorised uses indicated as home garden only (see Section 1.1, Section 1.1.3 and the separate Excel spreadsheet 'Appendix A_Thiamethoxam_GAP Table' accompanying this Conclusion, refer to supporting worksheets No. 1 and 2, column L).

Refer to Tables 7 and 8 (Section 3.1), 12 and 13 (Section 4) and to Appendix F (Tables 25 and 26) for the crops/plants covered by the categories in the following table.

Categories				Honeybee							Bumble bee					Solitary bee						
Crop/plant	Outdoor, open-protected or permanent greenhouse use	Flowering stage		Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Guttation fluid	Surface water	puddles	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	
Foliar spray uses																						
Orchards	Outdoor	Pre-flowering and Flowering	Risk identified	R(2d)		R(1)	R(1)	R(2ad)				R(2d)		R	R	R(2d)						
			Assessment not finalised	X(1)		X	X	X(1)	X	X	X	X(1)		X	X	X(1)	X(1)			X	X	X(1)
		Post-flowering	Risk identified			R(1)	R(1)	R(2ad)							R	R	R(2d)					
			Assessment not finalised			X	X	X(1)	X	X	X				X	X	X(1)			X	X	X(1)
Arable field crops	Outdoor and open-protected uses	Pre-flowering and Flowering	Risk identified	R				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							R(1)	R(1)	R					
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X			X	X	X
		Crops harvested before flowering	Risk identified					R							R(1)	R(1)	R					
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X			X	X	X
Hops	Outdoor	Pre-flowering and Flowering	Risk identified	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					
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X			X	X	X

Categories				Honeybee							Bumble bee					Solitary bee						
Crop/plant	Outdoor, open-protected or permanent greenhouse use	Flowering stage		Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Guttation fluid	Surface water	puddles	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	
Grapes	Outdoor	Pre-flowering and Flowering	Risk identified	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						
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X				X	X
Ornamentals	Outdoor and open-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 or plants 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
Non-orchard trees	Outdoor	Pre-flowering and Flowering	Risk identified	R		R(1)	R(1)	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(1)	R(1)	R						R	R	R						
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X				X	X
		Not foraged by bees for pollen and nectar	Risk identified			R(1)	R(1)								R	R						
			Assessment not finalised			X	X			X	X	X			X	X					X	X
All crops/plants	Permanent greenhouse	All	Risk identified																			
			Assessment not finalised							X												

Categories				Honeybee							Bumble bee					Solitary bee							
Crop/plant	Outdoor, open-protected or permanent greenhouse use	Flowering stage		Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Guttation fluid	Surface water	puddles	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹		
Other application techniques																							
Soil incorporation use to potatoes	Outdoor	Pre-flowering	Risk identified	R(2b)								R											
			Assessment not finalised	X		X	X	X	X	X	X	X	X		X	X	X	X			X	X	X
Soil incorporation use to vegetables	Outdoor	Pre-flowering	Risk identified	R								R											
			Assessment not finalised	X		X	X	X	X	X	X	X		X	X	X	X			X	X	X	
		Crops harvested before flowering	Risk identified																				
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X				X	X	X
All authorised uses as drip-irrigation, dips, seedling dumping, drenches to seedling trays and nursery drips	Outdoor and open-protected uses	Pre-flowering and Flowering	Risk identified	R(2c)								R											
			Assessment not finalised	X					X	X	X	X	X				X	X				X	
		Crops harvested before flowering	Risk identified																				
			Assessment not finalised						X	X	X	X					X						X
		Not foraged by bees for pollen and nectar	Risk identified																				
			Assessment not finalised							X	X	X											

Categories				Honeybee							Bumble bee					Solitary bee						
Crop/plant	Outdoor, open-protected or permanent greenhouse use	Flowering stage		Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Guttation fluid	Surface water	puddles	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	Treated crop scenario	Weed scenario with mitigation	Field margin with 95% mitigation	Adjacent crop with 95% mitigation	Succeeding crop ¹	
All authorised uses as drenches and irrigation	Outdoor and open-protected uses	Pre-flowering and Flowering	Risk identified	R(2c)								R										
			Assessment not finalised	X		X	X	X	X	X	X	X		X	X	X	X		X	X	X	X
		Crops harvested before flowering	Risk identified																			
			Assessment not finalised			X	X	X	X	X	X	X			X	X	X			X	X	X
All crops / plants	Permanent greenhouse	All	Risk identified																			
			Assessment not finalised							X												

¹The 'succeeding crop' scenario includes an assessment from the risk to bees from residues occurring in flowering permanent crops in the successive year.

REFERENCES

- Aliouane Y, El Hassani A, Gary V, Armengaud C, Lambin M and Gauthier M, 2009. Subchronic exposure of honeybees to sublethal doses of pesticides: effects on behaviour. *Environmental Toxicology and Chemistry*, (28)1: 113–122.
- Aufauvre J, Misme-Aucouturier B, Viguès B, Texier C, Delbac F and Blot N, 2014. Transcriptome analyses of the honeybee response to *Nosema ceranae* and insecticides. *PLoS ONE* 9(3): e91686. doi:10.1371/journal.pone.0091686
- Badiou-Beneteau A, Carvalho SM, Brunet J-L, Carvalho GA, Bulete A, Giroud B and Belzunces LP, 2012. Development of biomarkers of exposure to xenobiotics in the honey bee *Apis mellifera*: Application to the systemic insecticide thiamethoxam. *Ecotoxicology and Environmental Safety*, 82: 22-31.
- Bekele AZ, Mor SK, Phelps NBD, Goyal SM and Armién AG, 2015. A case report of *Nosema ceranae* infection in honey bees in Minnesota, USA. *Veterinary Quarterly*, doi:10.1080/01652176.2014.981766
- Betti MI, Wahl LM and Zamir M, 2014. Effects of infection on honey bee population dynamics: a Model. *PLoS ONE* 9(10): e110237. doi:10.1371/journal.pone.0110237
- EFSA (European Food Safety Authority), 2012a. Conclusion on the peer review of the pesticide risk assessment of post-approval data submitted for the active substance thiamethoxam. *EFSA Journal* 2012;10(3):2601, 12 pp. doi:10.2903/j.efsa.2012.2601
- EFSA (European Food Safety Authority), 2012b. Statement on the findings in recent studies investigating sub-lethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe. *EFSA Journal* 2012;10(6):2752, 27 pp. doi:10.2903/j.efsa.2012.2752.
- EFSA (European Food Safety Authority), 2013a. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. *EFSA Journal* 2013;11(1):3067, 68 pp. doi:10.2903/j.efsa.2013.3067
- EFSA (European Food Safety Authority), 2013b. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). *EFSA Journal* 2013;11(7):3295, 268 pp. doi:10.2903/j.efsa.2013.3295
- EFSA, (European Food Safety Authority), 2014a. EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. *EFSA Journal* 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615
- EFSA (European Food Safety Authority), 2014b. Towards an integrated environmental risk assessment of multiple stressors on bees: review of research projects in Europe, knowledge gaps and recommendations. *EFSA Journal* 2014;12(3):3594, 102 pp., doi:10.2903/j.efsa.2014.3594
- EFSA (European Food Safety Authority), 2015a. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam, considering all uses other than seed treatments and granules. Available online: www.efsa.europa.eu
- EFSA (European Food Safety Authority), 2015b. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment for bees for the active substance clothianidin, considering all uses other than seed treatments and granules. Available online: www.efsa.europa.eu
- EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2012. Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees). *EFSA Journal* 2012;10(5) 2668, 275 pp. doi:10.2903/j.efsa.2012.2668

- European Commission, 2005. Review report for the active substance clothianidin. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of clothianidin in Annex I of Directive 91/414/EEC. SANCO/10533/05 – Final, 18 January 2005.
- European Commission, 2006. Review report for the active substance thiamethoxam. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 July 2006 in view of the inclusion of thiamethoxam in Annex I of Directive 91/414/EEC. SANCO/10390/2002-rev.final, 14 July 2006.
- FOCUS, 2007. “Landscape and Mitigation Factors in Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations”. Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.
- Fryday S, Tiede K and Stein J, 2015. Scientific services to support EFSA systematic reviews: Lot 5 Systematic literature review on the neonicotinoids (namely active substances clothianidin, thiamethoxam and imidacloprid) and the risks to bees. EFSA supporting publication 2015:EN-756, 656 pp. Available online: www.efsa.europa.eu/publications
- El Hassani AK, Dacher M, Gary V, Lambin M, Gauthier M and Armengaud C, (2008). Effects of sublethal doses of acetamiprid and thiamethoxam on the behavior of the honeybee (*Apis mellifera*). Archives of Environmental Contamination and Toxicology, 54(4): 653-661.
- Girsch and Moosbeckhofer, 2012. Investigations to identify a possible exposure of honeybees to clothianidin, thiamethoxam, imidacloprid and fipronil in areas used for apiculture. Report in German: http://www.ages.at/fileadmin/AGES2015/Themen/Bienen/Monitoringprojekt_Bienen_Abschlussbericht_2012.pdf
- Gisder S and Genersch E, 2015. Identification of candidate agents active against *N. ceranae* infection in honey bees: establishment of a medium throughput screening assay based on *N. ceranae* infected cultured cells. PLoS ONE 10(2): e0117200. doi:10.1371/journal.pone.0117200
- Goblirsch M, Huang ZY and Spivak M, 2013. Physiological and behavioral changes in honey bees (*Apis mellifera*) induced by *Nosema ceranae* infection. PLoS ONE 8(3): e58165. doi:10.1371/journal.pone.0058165
- Graystock P, Goulson D and Hughes OH, 2014. The relationship between managed bees and the prevalence of parasites in bumblebees. PeerJ 2:e522; DOI 10.7717/peerj.522
- Henry M, Beguin M, Requier F, Rollin O, Odoux J-F, Aupinel P, Aptel J, Tchamitchian S and Decourtye A, 2012. A common pesticide decreases for-aging success and survival in honey bees. Scienceexpress 1215039.
- Illarionov AI and Derkach AA, 2008. Toxicity and Hazard of Neonicotinoids for Honeybees. Agrokhimiya, 10: 74-81.
- Iwasa T, Motoyama N, Ambrose JT and Roe RM, 2004. Mechanism for the differential toxicity of neonicotinoid insecticides in the honey bee, *Apis mellifera*. Crop Protection, 23(5): 371-378.
- Jordán László, 2014. Jelentés a 2013. évben virágzó növénykultúrákban végzett rovarölő szermaradék-analitikai vizsgálatokról. Nemzeti Élelmiszerlánc-biztonsági Hivatal Növény-, Talaj- és Agrárkörnyezet-védelmi Igazgatóság (NÉBIH NTAI), 20 March 2014.
- Khoury DS, Barron AB and Myerscough MR, 2013. Modelling food and population dynamics in honey bee colonies. PLoS ONE 8(5): e59084. doi:10.1371/journal.pone.0059084.
- Kumar S, Regupathy CM and Regupathy A, 2005. Risk assessment of neonicotinoids applied to coffee ecosystem. International Pest Control, 47(2): 82-87.
- Laurino D, Porporato M, Patetta A and Manino A, 2011. Toxicity of neonicotinoid insecticides to honey bees: laboratory tests. Bulletin of Insectology, 64(1): 107-113.

- Laurino D, Manino A, Patetta A and Porporato M, 2013. Toxicity of neonicotinoid insecticides on different honey bee genotypes. *Bulletin of Insectology*, 66(1): 119-126.
- Mommaerts V, Reynders S, Boulet J, Besard L, Sterk G and Smagghe G, 2010. Risk assessment for side-effects of neonicotinoids against bumblebees with and without impairing foraging behavior. *Ecotoxicology*, 19(1): 207-215.
- Moosbeckhofer and Mayr, 2013. Investigations to identify a possible exposure of honeybees to clothianidin, thiamethoxam, imidacloprid and fipronil in the field. Report in German: http://www.ages.at/fileadmin/migrated/content/uploads/v2-final_Abschlussbericht_Bienenexposition-Ueberwachungsprogramm_2013_Bienexpo_13_.pdf
- Natsopoulou ME, McMahon DP, Doublet V, Bryden J and Paxton RJ, 2015. Interspecific competition in honeybee intracellular gut parasites is asymmetric and favours the spread of an emerging infectious disease. *Proc. R. Soc. B* 282: 20141896. <http://dx.doi.org/10.1098/rspb.2014.1896>.
- Naug D, 2014. Infected honeybee foragers incur a higher loss in efficiency than in the rate of energetic gain. *Biol. Lett.* 10: 20140731. <http://dx.doi.org/10.1098/rsbl.2014.0731>.
- OECD (Organisation for Economic Co-operation and Development), 2009. Consensus document on the biology of bananas and plantains (*Musa* spp.). ENV/JM/MONO(2009)43, 24 November 2009.
- Perry CJ, Søvika E, Myerscough MR and Barron AB, 2014. Rapid behavioral maturation accelerates failure of stressed honey bee colonies. *PNAS* 112(11): 3427–3432, doi: 10.1073/pnas.1422089112
- Pettis JS, van Engelsdorp D, Johnson J and Dively G, 2012. Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*. *Naturwissenschaften* (2012) 99:153–158 DOI 10.1007/s00114-011-0881-1
- Sandrock C, Tanadini M, Tanadini LG, Fauser-Misslin A and Potts SG, et al., 2014. Impact of chronic neonicotinoid exposure on honeybee colony performance and queen supersedure. *PLoS ONE* 9(8): e103592. doi:10.1371/journal.pone.0103592
- Simeunovic P, Stevanovic J, Cirkovic D, Radojicic S, Lakic N, Stanisic L and Stanimirovic Z, 2014. *Nosema ceranae* and queen age influence the reproduction and productivity of the honey bee. *Journal of Apicultural Research* 53(5): 545-554.
- Spain, 2001. Draft Assessment Report (DAR) prepared by the rapporteur Member State Spain on the active substance thiamethoxam in the framework of Directive 91/414/EEC. November 2001.
- Wolf S, McMahon DP, Lim KS, Pull CD, Clark SJ, Paxton RJ and Osborne JL, 2014. So near and yet so far: harmonic radar reveals reduced homing ability of *Nosema* infected Honeybees. *PLoS ONE* 9(8): e103989. doi:10.1371/journal.pone.0103989

APPENDICES

APPENDIX A – THIAMETHOXAM: 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_Thiamethoxam_GAP Table**’ accompanying this Conclusion.

APPENDIX B – SUMMARY OF THE HAZARD QUOTIENTS, EXPOSURE TOXICITY RATIOS, LIMIT RATES AND HIGHER TIER DATA

1) **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_Thiamethoxam-Risk assessment spreadsheet**’ accompanying this Conclusion.

Table of contents:

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 than foliar spray	outdoor field	Flowering crops/plants; post flowerings crop/plants; non-flowering or crops/plants not foraged by bees
14	Oral	Other application than foliar spray	open-protected	Flowering crops/plants; post flowerings crop/plants; non-flowering or crops/plants not foraged by bees
15	Oral/ Contact	Foliar spray		Limit rate field margin adjacent crop

2) Summary of observations in the available tier 3 effects studies from the dossiers

It is important to note that only clear observations in the studies were included in Tables 17-20. Moreover, the level of exposure achieved has not been considered and only the tested application rate has been included in the tables.

Furthermore, a number of the studies were considered to have severe limitations such as lack of untreated control (see study evaluation notes for details; EFSA, 2015a).

Table 17: Summary of observations in the available higher tier effects studies with **honeybees** using **foliar spray applications** (ranked in accordance with the application rate but not accounting for the actual exposure)

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
1 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field During bee flight.	Decrease in foraging activity.	Nengel, 1998a	Study does not meet the requirements of EFSA 2013b.
1 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field After bee flight.	Decrease in foraging activity.	Nengel, 1998a	Study does not meet the requirements of EFSA 2013b.
5 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field During bee flight.	Decrease in foraging activity. Increase in forager mortality.	Nengel, 1998a	Study does not meet the requirements of EFSA 2013b.
5 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field After bee flight.	Decrease in foraging activity. Increase in forager mortality.	Nengel, 1998a	Study does not meet the requirements of EFSA 2013b.
50 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field	Decrease in foraging activity. Increase in forager mortality. Bees showed trouble, irritation and aggressiveness.	Kleiner (1997)	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
62.5 g a.s./ha	Peach (just before flowering)	Field Bees introduced 16 days after application	Slight increase in forager mortality. Decrease in foraging activity.	Bocksch, 2011b	Study does not meet the requirements of EFSA 2013b.
62.5 g a.s./ha	Peach (just before flowering)	Field Bees introduced 7 days after application	Increased forager mortality. Decrease in foraging activity.	Bocksch, 2011b	Study does not meet the requirements of EFSA 2013b.

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
75 g a.s./ha	Apple (after flowering)	Field	No clear differences between pre-application mortality and post-application mortality.	Nengel, 1998b	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
100 g a.s./ha	Apple (flowering)	Field Bees introduced 8 days after application	No clear differences in foraging activity between the control and treatment hives. Possible increase in forager mortality.	Schur, 2002	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
100 g a.s./ha	Broad bean (flowering)	Field	Possible, slight increase compared to pre-application mortality.	Nengel, 1998c	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
100 g a.s./ha	Melon (flowering)	Semi-field Bees introduced after 5 days of aging	Increased forager mortality (statistically significant) No statistically significant differences in flight intensity.	Bocksch, 2011a	Study does not meet the requirements of EFSA 2013b.
100 g a.s./ha	Melon (flowering)	Semi-field Bees introduced after 10 days of aging	Increased forager mortality (statistically significant). Decrease in flight intensity (statistically significant).	Bocksch, 2011a	Study does not meet the requirements of EFSA 2013b.
100 g a.s./ha	Apple (flowering)	Field	Increased forager mortality compared to pre-application mortality (no untreated control).	Nengel, 1997a	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
100 g a.s./ha	Apple (after flowering)	Field	Potential slight increased forager mortality compared to pre-application mortality (no untreated control).	Nengel, 1997b	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
100 g a.s./ha (2 applications)	Apple post flowering	Field	No obvious effects on mortality.	Barth (2000)	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)
200 g a.s./ha	<i>Phacelia tanacetifolia</i> (flowering)	Semi-field	Decrease in foraging activity. Increase in forager mortality. Bees showed trouble, irritation and aggressiveness.	Kleiner (1997)	Study does not meet the requirements of EFSA 2013b. Severe limitations (see study evaluation notes ¹)

¹ Study evaluation notes (EFSA, 2015a)

Table 18: Summary of observations in the available higher tier effects studies with **bumble bees** using **foliar spray applications**

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
100 g a.s./ha	Potted flowering tomato plants	Semi-field	<p>i) Hives placed in the tunnel immediately after application and the</p> <p>ii) Hives placed two weeks after application.</p> <p>In both scenarios there was a large reduction in the bumble bee population compared to the untreated control (79 % for the hives placed in the tunnel immediately after application and 85.2 % reduction for the hives placed in the tunnel two weeks after application).</p>	Reber, 1999b	Study does not meet the requirements of EFSA 2013b.

Table 19: Summary of observations in the available higher tier effects studies with **honeybees** using **other application techniques**

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
200 g a.s./ha	Honeydew melons in Spain	field study Application made via drip irrigation at BBCH 103 (leaf development) in test field 1 and BBCH 69 (flowering) in test field 2	The study author noted an increase in forager mortality following the application made during flowering but not for the application made during leaf development.	Schur, 2003	Study does not meet the requirements of EFSA 2013b.
	Cucumbers in the USA	An in-furrow application of thiamethoxam was made when the cucumbers were being planted in the field. In addition, an assessment was also made following foliar spray applications made in the evening and morning when the cucumbers were flowering.	It is noted that the foliar spray applications resulted in a statistically significant effect on the number of dead forager bees, whereas no statistically significant effect was detected following the in-furrow application.	Mayer, 2000	Study does not meet the requirements of EFSA 2013b.

Table 20: Summary of observations in the available higher tier effects studies with **bumble bees** using **other application techniques**

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
207 – 215 g a.s./ha Drench application	Tomatoes grown on a rockwool substrate	Glasshouse study, Netherlands.	<p>The effects on bumble bees introduced to the glasshouse 1, 8 and 24 days after a drench application were investigated.</p> <p>It is noted that the study author concluded an increase in mortality for all three application timings but with the highest increase for the bees introduced 8 days after the drip irrigation. The effect on mortality for the bees introduced 24 days after application was only a slight (4 %) increase compared to the untreated control. The effects on brood was only assessed for the bees introduced 1 day after irrigation but a statistically significant decrease in the number of pupae and larvae was observed. The foraging activity was also reduced in the treatment groups compared to the untreated control.</p>	Aldershof (2000)	Study does not meet the requirements of EFSA 2013b.
100 g a.s./ha Single application via drip irrigation	Potted tomato plants	Glasshouse study, Switzerland.	Statistical analysis of the number of dead bees was not performed but it is noted that there was an increase in mortality of the bumble bees in the test item compared to the untreated control.	Reber (1999a)	Study does not meet the requirements of EFSA 2013b.

Application rate (g a.s./ha)	Crop	Field/semi-field; study design	Key observations	Reference (EFSA, 2015a)	Remark
Two applications of thiamethoxam at 100 g a.s./ha via drip irrigation	Tomato plants	Glasshouse study, Spain	<p>Two scenarios were investigated. The first scenario considered the effects when bumble bees were introduced to the tunnel 21 and 14 days after the first and second application, respectively. The bumble bees in the second scenario were introduced to the tunnel 9 and 2 days after the first and second application, respectively. Assessments were made on bee mortality, hive weight, forager activity, sugar consumption and effects on the brood.</p> <p>It is noted that the study author concluded that there were no detectable effects on the bumble bee parameters assessed. However, due to the limitations of the study this conclusion cannot be agreed.</p>	Balluf (2001)	Study does not meet the requirements of EFSA 2013b.

APPENDIX C – 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	<p>Exposure depends on whether the plants or trees are attractive and applications are made pre- or during the flowering period.</p> <p>If the type of ornamental plant or tree is not stated then it should be assumed that they are attractive to bees for pollen and nectar collection.</p> <p>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).</p> <p>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).</p> <p>For attractive trees, the use of early orchard scenario can be used.</p> <p>For the assessment of thiamethoxam, 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.</p>
Weeds within the treated field	<p>Exposure depends on the amount of interception by the ornamental plant or tree.</p> <p>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.</p> <p>If the growth stage for trees is not specified then it should be assumed that applications can be early orchards.</p> <p>For the assessment of thiamethoxam, 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.</p>
Field margin	<p>Exposure depends on the application method and the size of the plants or trees.</p>
Adjacent crop	<p><u>Ornamentals:</u></p> <p>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.</p> <p>For ornamental plants greater than 50 cm in height the spray drift values late vines should be used.</p> <p>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.</p> <p><u>Non-orchard trees</u></p> <p>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 is assumed that applications can be made to large trees.</p> <p>For the assessment of thiamethoxam, 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.</p>

Succeeding crop/plants	Exposure to bees from residues in nectar and pollen in succeeding ornamental plants may occur. For trees exposure in the succeeding year depends on whether the tree is attractive to bees (in line with the treated crop scenario). For the assessment of thiamethoxam, 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 D – SUMMARY OF THE APPROACH TO THE RISK ASSESSMENT FOR APPLICATION TECHNIQUES OTHER THAN FOLIAR SPRAYS

Many of the authorised uses of thiamethoxam 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 summarised in Table 23.

Table 22: Details of application techniques used for the authorised uses of thiamethoxam (other than foliar sprays)

Method of application	Crops	Member State	Details of application technique
Drench and irrigation	Aubergine Citrus fruit Cucumber Lettuce Melon Ornamentals Bell pepper Tomato Courgette	CY DE IT EL MT	<i>Application of the product together with water. The target of the application is the soil rather than the canopy of the plant.</i>
Drip irrigation	Aubergine Bell pepper Beans Bracken Broccoli Brussels sprouts Cabbages Cauliflower Cucumber Kale Kohlrabi Lettuce Melon Ornamentals Palm tree Pepper Strawberry Tomato Courgette	ES PT HU	<i>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.</i>
Dip	Aubergine Bell pepper Broccoli Brussels sprouts Cabbage Cucumber Lettuce Melon Tomato Courgette	HU IT LV	<i>Plants roots of seedlings or bulbs dipped in the product (or a solution of the product) before planting in the field.</i>
Soil incorporation	Potato Vegetable group	NL BG	<i>Application of liquid formulations together with the seed along the line drawn by the plough.</i>

Method of application	Crops	Member State	Details of application technique
Seedling dumping	Aubergine Broccoli Cucumber Lettuce Melon Pepper Tomato courgette (zucchini)	HR	<i>Similar as a dip, except that the entire seedling is dipped.</i>

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
Dip	N	N	N	Y	Y	N	N	Y	Y	Y	Y
Drench+irrigation	N if it is just above the ground Y if the crop is touched ⁽⁶⁾	Y if it is above the weeds height N otherwise	N ⁽¹⁾	Y	Y	Y ⁽²⁾	Y ⁽²⁾	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 ⁽³⁾	N	N	Y ⁽³⁾	Y	Y ⁽³⁾	Y ⁽³⁾
Drip irrigation	N	N	N	Y	Y ⁽⁴⁾	N	N	Y	Y	Y	Y
Immersion and drip (nursery trays)	N	N	N	Y	Y	N	N	Y	Y	Y	Y
In-furrow spray and soil incorporated	N	N	N	Y	Y	Y ⁽²⁾	Y ⁽²⁾	Y	Y	Y ⁽²⁾	Y
Seedling dumping (before outdoor transplanting)	N ⁽⁵⁾	N	N	Y	Y	N	N	Y	Y	Y	Y

N: No/low exposure

Y: Exposure likely to occur

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

(2) Route of exposure might be possible via runoff

(3) Only if transplanted to the field

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

(5) The seedlings have no flowers at the time of application nor do they have them shortly after.

(6) 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 E – RESIDUE DATA

Table 24: Available residue data on thiamethoxam from the dossiers

Formulation	Rate [g a.s./ha]	Application type	Crop	Country	Matrix	Application/Collection interval [days]	RUD (mg/kg)	Residue value [mg a.s./kg]	Authors	Study year	Ref/Study ID
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	11	0.080	0.008	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	14	0.010	<0.001	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	15	0.030	0.003	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	6	0.160	0.016	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	9	0.080	0.008	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Nectar (from foragers)	10	0.080	0.008	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	100	Foliar spray	Honeydew melon	Italy	Pollen (from foragers)	15	0.390	0.039	Bocksch S	2011a	EFSA, 2015a A9584C_10176
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Nectar (from foragers)	20	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Nectar (from foragers)	9	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Nectar (from foragers)	11	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	18	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	20	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	22	0.080	<0.005	Bocksch S	201b1	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	9	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	11	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara 25 WG	62.5	Foliar spray	Peach	Italy	Pollen (from foragers)	13	0.080	<0.005	Bocksch S	2011b	EFSA, 2015a A9584C_10173
Actara	100 ¹	na	Apple	Switzerland	Pollen (from plants)	18	0.850	0.085	Kühne-Thu H	2002	501/01
Actara	100 ¹	na	Apple	Switzerland	Pollen (from plants)	15	0.610	0.061	Kühne-Thu H	2002	501/01

¹ The application rate is not fully clear in the study report

APPENDIX F – AUTHORISED USES COVERED BY THE CATEGORIES IN SECTION 13

Table 25: Crop/plants covered by the categories in Section 13 (Table 16) for the authorised foliar spray uses

Categories		Crops/plants	
Orchards	Outdoor	Pre-flowering and Flowering	Almond, apple, apple and pear, apple (non specified), apricot, banana, cherry, kiwi, nectarine, peach, peach/nectarine, pear, pear (common), pear (non specified), plum, stone fruit group orange, mandarin and lemon, citrus fruit group, citrus (non specified), clementine, lemon, mandarin, orange
		Post-flowering	Almond, apple, apple and pear, apple (non specified), apricot, cherry, cherry (sweet, sour), cherry tree (dwarf), fruit group (plums, apples, pears, cherry), nectarine, olives, peach, peach tree group, pear, pear tree group, pear (common), pear (non specified), plum, quince citrus fruit group, citrus fruit group (young trees), citrus group, citrus (non specified)
Arable field crops	Outdoor	Pre-flowering and Flowering	Alfalfa, artichoke, aubergine, aubergine & tomato, baby leafs (all cabbages, komatsuna, mizuna, tatsoi), barley, barley (spring), barley (winter), bean (garden), bell pepper, bell pepper, chili pepper, broccoli, Brussels sprouts, cabbage group, cabbage, head, carrot, cauliflower, cereal group, cotton, cotton group, cucumber, eggplant (oriental), lettuce, lettuce and/or salad, lettuce group, lettuce & chicory & scarole & lamb's lettuce, rucola, maize, melon, watermelon, cucurbit, onion, pea (non specified), pepper, pepper group, potato, rocket (rucola), rye, sunflower (common), tobacco, tobacco group, tomato, triticale, triticale (winter), vegetable group, wheat, wheat group, wheat (spring), wheat (winter), courgette (zucchini)
		Post flowering	Aubergine, bell pepper, cotton, cucumber, melon, watermelon, onion, potato, tobacco, tomato, vegetable group, watermelon, courgette (zucchini)
		Crops harvested before flowering	Not specified in any GAP but it is possibly relevant for: baby leafs (all cabbages, komatsuna, mizuna, tatsoi), broccoli, Brussels sprouts, cabbage group, cabbage, head, carrot, cauliflower), lettuce, lettuce and/or salad, lettuce group, lettuce & chicory & scarole & lamb's lettuce, rocket (rucola), onion, rocket (rucola)
	Open-protected uses	Pre-flowering and Flowering	Aubergine, baby leafs (all cabbages, komatsuna, mizuna, tatsoi), bean, garden, bell pepper, broccoli, Brussels sprouts, cucumber, lettuce, lettuce group, melon, watermelon, cucurbit, pepper, pepper group, tomato, vegetable group, courgette (zucchini)
		Post flowering	Aubergine, bean (garden), bell pepper, cucumber, melon, watermelon, strawberry, tomato, courgette (zucchini)
		Crops harvested before flowering	Not specified in any GAP but it is possibly relevant: baby leafs (all cabbages, komatsuna, mizuna, tatsoi), broccoli, Brussels sprouts, lettuce, lettuce group
Ornamentals	Outdoor	Pre-flowering and Flowering	Ornamental group, ornamentals, palm tree, plants, nursery stock
		Post flowering	Non edible medicinal/aromatic or fragrance plants, ornamental group, ornamental group (floriculture, tree nursery and perennials), shrubby
		Crops harvested before flowering	Non edible medicinal/aromatic or fragrance plants.
	Open-protected uses	Pre-flowering and Flowering	Non edible medicinal/aromatic or fragrance plants, ornamental group, ornamentals, shrubby
		Post flowering	Ornamental group, ornamentals
Non-orchard trees	Outdoor	Pre-flowering and Flowering	Forest: nursery
		Post flowering	Medlar tree, common
		Not foraged by bees for pollen and nectar	Coniferous tree, pine, spruce (non specified)
All crops / plants	Permanent greenhouse	All	Cucumber, ornamental group, ornamental group (floriculture, flower bulbs and bulb flowers, tree nursery and perennials), tomato

Table 26: Crop/plants and application techniques covered by the categories in Section 13 (Table 16) for the authorised uses other than foliar sprays

Categories			Application technique	Crops/ plants
All authorised uses as drip irrigation, dips, seedling dumping, drenches to seedling trays and nursery drips	Outdoor and open-protected uses	Pre-flowering and Flowering	Dip	Aubergine, bell pepper, broccoli, Brussels sprouts, cabbage group, cucumber, lettuce group, melon, watermelon, tomato, courgette (zucchini)
			Drip irrigation ¹	Ornamentals
			Drench (seedling trays)	Aubergine, tomato
			Drench or application through the drip irrigation system	Aubergine, cucumber, melon, watermelon, pepper group, tobacco, tomato, courgette (zucchini)
			Drip	Aubergine, bean, bean (garden), broccoli, cucumber, lettuce and/or salad, melon, watermelon, ornamental group, palm tree, pepper, strawberry, tomato, watermelon, courgette (zucchini)
			Nursery drip application over the top of plants	Melon, watermelon
			Seedling dumping	Aubergine, broccoli, cucumber, lettuce group, melon, watermelon, pepper, tomato, courgette (zucchini)
		Crops harvested before flowering	Dip irrigation	Vegetables
		-	-	It is also possibly relevant for: broccoli, Brussels sprouts, cabbage group, lettuce group, lettuce and/or salad.
		Not foraged by bees for pollen and nectar	Drip	Fir trees, pine trees
All authorised uses drenches and irrigation	Outdoor and open-protected uses	Pre-flowering and Flowering	Drench	Aubergine, bell pepper, citrus fruit group, cucumber, lettuce group, melon, watermelon, ornamental group, ornamentals, pepper group, strawberry, tobacco, tomato, courgette (zucchini)
			Irrigation	Aubergine, bell pepper, broccoli, Brussels sprouts, cabbage group, cabbage, Chinese, cabbage (head), cauliflower, cucumber, kale, kohlrabi, lettuce, lettuce group, melon, watermelon, pepper, tomato, vegetable group, courgette (zucchini)
		Crops harvested before flowering	-	Not specified in any GAP but it is possibly relevant for: lettuce group, broccoli, Brussels sprouts, cabbage group, cabbage, Chinese, cabbage (head), cauliflower, kale, kohlrabi, lettuce, lettuce group.
All crops / plants	Permanent greenhouse	All	Drench	Ornamentals (potted), aubergine, bell pepper, cucumber, lettuce group, melon, watermelon, ornamental group, tomato, courgette (zucchini)
			Dip	Aubergine, bell pepper, broccoli, cucumber, lettuce group, melon, watermelon, tomato, courgette (zucchini)
			Nursery drip application over the top of plants	Aubergine, bell pepper, broccoli, cucumber, lettuce group, melon, watermelon, tomato, courgette (zucchini)

¹ Reported as 'dip irrigation' in the GAP, presumed to be a typographic error

ABBREVIATIONS

µg	microgram
a.s.	active substance
AF	assessment factor
AV	avoidance factor
BBCH	Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
CI	confidence interval
COM	European Commission
d	day
DAT	day after treatment
DM	dry matter
DT ₅₀	period required for 50 per cent disappearance (define method of estimation)
DT ₉₀	period required for 90 per cent 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 factors
ER ₅₀	emergence rate/effective rate, median
ErC ₅₀	effective concentration (growth rate)
ETR	exposure to toxicity ratio
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FERA	Food and Environmental Research Agency
FIR	Food intake rate
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
g	gram
GAP	good agricultural practice
GLP	good laboratory practice
GM	geometric mean
GS	growth stage
h	hour(s)
ha	hectare
HPG	hypopharyngeal glands
IPM	Integrated Pest Management practice
HQ	hazard quotient
L	litre
LC ₅₀	lethal concentration, median
LD ₅₀	lethal dose, median; dosis letalis media
LDD ₅₀	lethal dietary dose
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
PER	proboscis extension reflex
pH	pH-value
PHI	pre-harvest interval
pK _a	negative logarithm (to the base 10) of the dissociation constant
P _{ow}	partition coefficient between <i>n</i> -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
RFID	radio-frequency identification
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SPG	specific protection goals
SSD	species sensitivity distribution
SV	shortcut value
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