CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam[1]

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ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including thiamethoxam, as regards the risk to bees. 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 the uses of thiamethoxam applied as a seed treatment on a variety of crops currently authorised in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as the available EU evaluations and monitoring data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

KEY WORDS

Thiamethoxam, peer review, risk assessment, pesticide, insecticide

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[1] On request from the European Commission, Question No EFSA-Q-2012-00553, approved on 19 December 2012.

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[3] Following corrections reported by Sweden and Greece in relation to some of the authorised uses of thiamethoxam as a seed treatment on sunflower, oilseed rape and sugar beet, the risk assessment for these uses, where relevant, have been revised to take into account the appropriate maximum application rates. As a consequence, the Conclusion has been amended as follows:

- **Section 2.1**, *Risk from contamination of adjacent vegetation via dust drift (field uses)*: the HQ values were recalculated for oilseed rape and sunflower and the corresponding text in the section has been amended accordingly.
- **Section 2.2**, *Risk via systemic translocation in plants – residues in nectar and pollen (including sublethal effects)*: the ETR values were recalculated for oilseed rape and sunflower and the related text in the section has been amended accordingly.
- **Section 7,** *Overview of the concerns identified for the authorised uses of thiamethoxam*: the relevant rows in the table reflecting the outcome of the risk assessment for the products CRUISER OSR in Sweden for oilseed rape (both application rates) and CRUISER 600 FS for sugar beet were removed; the outcome of the risk assessment for the product CRUISER 600 FS in Greece for sunflower has been amended to reflect the correct application rate and, as a consequence, the outcome of the acute risk assessment from dust exposure has been changed from "risk identified" (*i.e.* 'R' in the overview table) to an "issue that could not be finalised" (*i.e.* 'X' in the overview table). The outcome of the risk assessment for the other uses on sunflower and the uses of treated oilseed rape and sugar beet seeds remained unchanged.
- **Appendix A**, *Summary of authorised uses for seed treatment and granules,* the rows referring to the products CRUISER OSR in Sweden for oilseed rape (both application rates) and CRUISER 600 FS for sugar beet were removed; the entry for the product CRUISER 600 FS in Greece for sunflower has been amended to reflect the correct application rate.

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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.

The specific provisions of the approval were amended by Commission Directive 2010/21/EU, to permit use as a seed treatment only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In January 2010 the European Commission received new studies on honey bees from the notifier, Syngenta, which were evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an Addendum to the Draft Assessment Report. The European Commission distributed the Addendum to Member States and the EFSA for comments on 1 July 2011. The RMS collated all comments in the format of a Reporting Table, which was submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH) in September 2011. Following consideration of the comments received, and the further discussions in the SCFCAH, the Commission requested the EFSA to organise a peer review of the RMS's evaluation of the new data and to deliver its conclusions on the risk assessment for honey bees. The conclusions arising from the peer review were subsequently laid down in the EFSA Conclusion approved on 20 February 2012 (EFSA Journal 2012;10(3):2601).

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 April 2012 the European Commission requested the EFSA to provide conclusions as regards the risk of neonicotinoid active substances for bees, 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. Following discussions at the SCFCAH in June / July 2012, and taking into account the outcome of the EFSA statement on the findings in recent studies investigating sublethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe (EFSA Journal 2012;10(6):2752), the EFSA received an updated request from the European Commission to prioritise the review of 3 neonicotinoid substances, including thiamethoxam, and to perform an evaluation of the currently authorised uses of these substances as seed treatment and granules. It is noted that the information provided by Member States (see Appendix A) did not indicate any granular use of thiamethoxam.

The conclusions laid down in this report were reached on the basis of the evaluation of the studies 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, for the uses as seed treatments on a variety of crops in Europe. In addition, the EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA Journal 2012;10(5):2668), some relevant literature data, as well as monitoring data available at national level were also considered in the current evaluation.

Several data gaps were identified with regard to the risk to honey bees from exposure via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid for the authorised uses of thiamethoxam as a seed treatment. Furthermore, the risk assessment for pollinators other than honey bees, the risk assessment following exposure to insect honey dew and the risk assessment from exposure to succeeding crops could not be finalised on the basis of the available information.

A high risk was indicated or could not be excluded in relation to certain aspects of the risk assessment for honey bees for some of the authorised uses. For some exposure routes it was possible to identify a low risk for some of the authorised uses.

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BACKGROUND

Thiamethoxam was included in Annex I to Directive 91/414/EEC[4] on 1 February 2007 by Commission Directive 2007/6/EC[5], and has been deemed to be approved under Regulation (EC) No 1107/2009[6], in accordance with Commission Implementing Regulation (EU) No 540/2011[7], as amended by Commission Implementing Regulation (EU) No 541/2011[8]. The peer review leading to the approval of this active substance was finalised in 2006, however, EFSA was not involved in this evaluation.

The specific provisions of the approval were amended by Commission Directive 2010/21/EU[9], to permit use as a seed treatment only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In January 2010 the European Commission received new studies on honey bees from the notifier, Syngenta, which were evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an Addendum to the Draft Assessment Report (Spain, 2011). Following consideration of the comments received on the RMS's evaluation, and the further discussions in the Standing Committee on the Food Chain and Animal Health (SCFCAH), in November 2011 the European Commission requested the EFSA to organise a peer review of the RMS's assessment of the new data, and to deliver its conclusions on the risk assessment for honey bees. The conclusions following the peer review of the risk assessment of the post-approval data are laid down in the EFSA Conclusion approved on 20 February 2012 (EFSA, 2012d).

In view of the various studies and research activities carried out in recent years, the European Commission decided to consult the EFSA in accordance with Article 21 of Regulation (EC) No 1107/2009. By written request, received by the EFSA on 25 April 2012, the European Commission requested the EFSA to provide conclusions as regards the risk of neonicotinoid active substances for bees, 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.

Following discussions at the SCFCAH in June / July 2012, and taking into account the outcome of the EFSA statement on the findings in recent studies investigating sublethal effects in bees of some neonicotinoids in consideration of the uses currently authorised in Europe (EFSA, 2012b), the EFSA received an updated request from the European Commission on 30 July 2012. With this new mandate, EFSA was asked to prioritise the review of 3 neonicotinoid substances, including thiamethoxam, and to perform an evaluation of the authorised uses as seed treatments and granules, focusing on:

- dust from seeds and granules;

[4] 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.

[5] 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.

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

[7] 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.

[8] 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.

[9] Commission Directive 2010/21/EU of 12 March 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to clothianidin, thiamethoxam, fipronil and imidacloprid OJ L 65, 13.3.2010, p.27-30.

- residues in nectar and pollen and sublethal effects on bees and bee colonies survival;
- guttation.

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 October 2012. 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 97 on ecotoxicology in November 2012. 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 December 2012.

The conclusions laid down in this report were reached on the basis of the evaluation of the existing data in relation to the risk assessment for bees submitted for the approval of the active substance at EU level and in support of the product authorisations at Member State level, with regard to the uses of thiamethoxam authorised as seed treatments on a variety of crops in Europe. In addition to the available EU evaluations including EFSA Conclusions, the EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (EFSA, 2012a) was also taken into account. Furthermore, some relevant literature data as well as monitoring data made available by Member States during the peer review were also considered in the current evaluation.

A key background document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised during the peer review. The Peer Review Report (EFSA, 2012e) comprises the following documents, in which all views expressed during the course of the peer review, including minority views where applicable, can be found:

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

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

CONCLUSIONS OF THE EVALUATION

The risk assessment was performed taking into consideration the recommendations in EFSA 2012a.

The experts at the Pesticides Peer Review Experts' Meeting 97 (November 2012) expressed concern over the scope of the risk assessments performed. Some experts highlighted that some Member States had made considerable progress in improving the quality of seed treatment processes or have specific agronomic practices in place which could reduce the potential risk to pollinators. The Member State experts were concerned that, due to consideration of all authorised uses in the EU, it was not possible to adequately account for these specific Member State practices and authorised GAPs. It was also noted that some of the studies were conducted specifically to address a concern raised by the Member State during national registration; therefore, the data were not designed or intended to cover all of the authorised uses in the EU. Although the concerns raised by the Member States are acknowledged, it was noted that specific information on Member State agronomic practices (e.g. seed treatment quality criteria, drilling machine criteria) was not available and therefore could not be accounted for in the risk assessments.

Limited information was available for pollinators other than honey bees. The biology, behaviour and ecology of bumble bees and other pollinators differ from honey bees and therefore special consideration in a risk assessment is necessary. For example, exposure via soil or plant materials used for nesting materials might be a potential route of contact exposure for some bumble bee or solitary bee species. Oral exposure may also differ since the nectar, pollen or water requirement for other pollinators is different to that of honey bees. Currently it is unclear whether these routes of exposure are covered by other risk assessment, such as via dust drift. The risk to pollinators other than honey bees should be further considered. A data gap is therefore concluded for further information to address the risk to pollinators (other than honey bees).

Exposure to succeeding crop residues in nectar and pollen or guttation fluid could represent a concern and should be further considered. A number of residue studies in succeeding crops were available for thiamethoxam and confirmed that this route of exposure is possible (e.g. Knäbe (2010), S08-01284, S08-01279, S08-01285, see Study evaluation notes; EFSA 2012e). The risk to bees from residues in succeeding crops could be considered to be covered by an assessment for in-field risk (via residues in nectar, pollen and guttation fluid) for the crops representing potentially high risk (perhaps oilseed rape or maize). However, for an absolute risk assessment it would be necessary to take account of the application rate in the preceding crop, consequent residues in nectar, pollen and guttation fluid, and the type of succeeding crop (i.e. attractiveness, production of guttation fluid). A data gap is therefore concluded for further assessment of the risk to honey bees foraging in nectar and/or pollen in succeeding crops.

Theoretically, residues in weeds in the treated field could also be a route of exposure to honey bees. However, the risk via this route of exposure was considered to be negligible as weeds will not be present in the field when the crop is sown and considerable uptake via the roots is unlikely as the substance is concentrated around the treated seed.

Considering the available information in this conclusion, the risk assessments focused on the risk to honey bees via systemic contamination of the treated crop and contamination of other crops via dust drift. The risk assessments presented follow a tiered step-wise approach, and data gaps have been identified in the overall conclusion for each section (i.e. risk via dust exposure: section 2.1.5, risk via residues in nectar and pollen: section 2.2.6, and risk via exposure to guttation fluid: section 2.3.3).

Thiamethoxam is known to degrade to metabolite clothianidin (CGA322704) in various matrices, for example in soil (European Commission, 2006). Residues have also been detected in nectar, pollen and guttation fluid (see Study evaluation notes; EFSA 2012e). Clothianidin is also a systemic neonicotinoid active substance authorised in plant protection products in the EU (Commission

Directive 2006/41/EC[11]). Metabolite clothianidin (CGA322704) is of comparable toxicity to honey bees in laboratory studies (see Table 1, below) and literature information has also highlighted a concern to bees. For a comprehensive assessment of the risk to bees from the use of thiamethoxam treated seed it is also necessary to consider the risk from the metabolite clothianidin (CGA322704). For the following reasons the risk assessments presented in this conclusion are considered to also cover the risk posed by the metabolite clothianidin (CGA322704) and therefore a separate risk assessment was not presented.

Exposure via dust:

It is considered that the dust generated during sowing of treated seed is likely to primarily contain residues of the parent substance, thiamethoxam. Therefore, for the acute risk assessments performed in section 2.1, the exposure estimates have been determined for thiamethoxam only. The exposure studies used in the tier 2 assessment did not include residue analysis for the metabolite clothianidin (CGA322704) and therefore it is not possible to confirm no residues of the metabolite clothianidin (CGA322704). However, the field study (Knäbe (2012), study reference: S11-01639, see Study evaluation notes; EFSA 2012e) included residue analysis of both thiamethoxam and the metabolite clothianidin (CGA322704) in oilseed rape flower heads, which had been present in the adjacent vegetation during the drilling. Residues of thiamethoxam were detected, however, the residues for the metabolite clothianidin (CGA322704) were always less than the LOQ (< 0.0005 mg/kg). It is therefore considered that this supports the assumption that, for an acute risk assessment, exposure will be primarily to the parent substance only. This assumption should not be extrapolated to a chronic risk assessment or a risk assessment for bee brood. However, for the reasons discussed under sections 2.1.2 and 2.1.3, tier 1 and tier 2 risk assessments could not be performed for the chronic risk to adult honey bees and for honey bee brood from exposure via dust drift.

Exposure via residues in nectar and pollen:

The first-tier risk assessments presented for residues in nectar and pollen used RUD values (Residue per Unit Dose, expressed and calculated for an application rate in terms of 1 kg a.s./ha). The RUD values were taken from Appendix I of the draft EFSA guidance document[12] and were calculated from studies where residues of both thiamethoxam and the metabolite clothianidin (CGA322704) were measured. As described in Appendix I of the draft EFSA guidance document, the RUD values were calculated using the sum of the residues of thiamethoxam and the metabolite clothianidin (CGA322704). As the toxicity of thiamethoxam and the metabolite clothianidin (CGA322704) is comparable, the presented first-tier risk assessments are considered to cover exposure from both the parent substance and the metabolite clothianidin (CGA322704).

Exposure via guttation fluid:

No first-tier risk assessment scheme is available to assess the risk to honey bees from exposure via guttation fluid. Therefore, only a screening step was presented using residues of the parent thiamethoxam measured in the guttation fluid. Residues of the metabolite clothianidin (CGA322704) were also detected in guttation fluid, however, for the purposes of a screening step assessment the residues were not combined.

Risk assessment using data from higher tier effects studies (semi-field and field studies, relevant for all routes of exposure):

Risk assessments using higher tier effect studies are also relevant for the metabolite clothianidin (CGA322704) as the bees are also exposed to the metabolite under the field conditions; this is

[11] Commission Directive 2006/41/EC of 7 July 2006 amending Council Directive 91/414/EEC to include clothianidin and pethoxamid as active substances. OJ L 187, 8.7.2006, p. 24-27.

[12] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

confirmed by residue analysis which was performed in the available higher tier studies (see sections 2.1.4, 2.2.5, 2.3.2, and the Study evaluation notes; EFSA 2012e).

It is important to note than any data gaps concluded for the parent, thiamethoxam, are also relevant for the metabolite clothianidin (CGA322704) and should account for the combined exposure.

1. Toxicity endpoints

1.1. Acute toxicity

Table 1 summarises the available acute laboratory toxicity data for thiamethoxam and the metabolite clothianidin (CGA322704).

Table 1 Available laboratory toxicity data for thiamethoxam and the metabolite clothianidin (CGA322704)

Test substance	Toxicity endpoint	Species	Value[3]	Reference
thiamethoxam	Acute oral LD_{50}	*Apis mellifera*	**0.005 µg a.s./bee**	European Commission (2006)
thiamethoxam	Acute contact LD_{50}	*Apis mellifera*	**0.024 µg a.s./bee**	European Commission (2006)
Dust from formulation A9700B (dust contained 7.24 % thiamethoxam)	Acute oral LD_{50}	*Apis mellifera*	**0.00936 µg a.s./bee**	EFSA (2012d)
Dust from formulation A9700B (dust contained 7.24 % thiamethoxam)	Acute contact LR_{50}[2]	*Apis mellifera*	13.26 g a.s./ha	EFSA (2012d)
Dust from A9700B treated maize seed containing 7.24 % w/w thiamethoxam	Oral toxicity	*Apis mellifera*	No mortality of bees which had a target treatment of 1 ng thiamethoxam/bee (actual dose consumed was variable). Maximum of 63.3% (after 3 days) mortality observed in the bees which had a target treatment of 5 ng thiamethoxam/bee (actual dose consumed was variable).	Kling (2010) S09-02846 (see Study evaluation notes; EFSA 2012e)
Dust from A9700B treated maize seed containing 7.24 % w/w thiamethoxam	Contact toxicity[2]	*Apis mellifera*	Maximum of 13.3% (after 3 days) mortality observed in the bees which had a target treatment of 4 g thiamethoxam/ha. Maximum of 73.3% (after 3 days) mortality observed in the bees which had a target treatment of 20 g thiamethoxam/ha.	Kling (2010) S09-02846 (see Study evaluation notes; EFSA 2012e)
metabolite clothianidin (CGA322704)	Acute oral LD_{50}	*Apis mellifera*	**0.00379 µg/bee[1]**	European Commission (2005)

Test substance	Toxicity endpoint	Species	Value[3]	Reference
metabolite clothianidin (CGA322704)	Acute contact LD_{50}	*Apis mellifera*	0.0275 µg/bee	European Commission (2006)

[1] An acute oral LD_{50} 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 LD_{50} reported in the Review Report (European Commission, 2005) for the active substance clothianidin, the latter value has been reported in Table 1.

[2] The contact toxicity studies used dust from A9700B treated maize seed which was then applied to leaves and placed in the cage with bees. The study authors expressed the endpoints as an application rate per hectare (g thiamethoxam/ha).

[3] Values highlighted in **bold** were used for risk assessment.

1.2. Chronic toxicity

A subchronic feeding study with thiamethoxam and metabolite clothianidin (CGA322704) was available (Belzunces (2002), see Study evaluation notes; EFSA 2012e). After 10 days of exposure (10 hours per day) a mortality of less than 7 % was observed. The cumulative dose ingested over a 10-day period was approximately 2 ng/bee. For the purposes of risk assessment a 10-day **LC_{50} > 0.2 ng a.s./bee per day** is assumed.

1.3. Sublethal effects

In the data submitted for the purpose of this assessment, there were two studies which specifically considered the sublethal effects of thiamethoxam or the metabolite clothianidin (CGA322704) to bees. The two return-flight ability studies conducted by Werner von der Ohe (2001) (see Study evaluation notes; EFSA 2012e) were of reasonable scientific quality but 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 recent studies by Henry *et al* (2012a) 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 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.

In the study of Henry *et al.*, (2012a) (considered in EFSA, 2012b) sublethal effects on return-flight ability were observed at 1.34 ng/bee.

It is interesting to see that the results of the two studies, although conducted using different methodologies, both indicate an adverse effect on the return-flight ability of honey bees. For the purposes of risk assessment a sublethal dose of **1.34 ng a.s./bee** will be considered.

1.4. Toxicity endpoints on brood

Table 2 summarises the available acute laboratory toxicity data for thiamethoxam.

Table 2 Available laboratory toxicity data for thiamethoxam

Test substance	Study	Species	Endpoint	Reference
thiamethoxam	5-day dietary toxicity	Larval honey bees *Apis mellifera*	LC_{50} >113 µg a.s./g diet No mortality level = 6.25 µg a.s./g diet No NOEL could be concluded due to a delay in defecation[1]	Overmyer and Huang (2012) (GLP) TK0029906 (see Study evaluation notes; EFSA 2012e)
thiamethoxam	Bee brood feeding study	Larval honey bees *Apis mellifera*	Mortality NOEL 0.0125 µg a.s./g diet	Giffard (2009) (non-GLP) 105-2007 (see Study evaluation notes; EFSA 2012e)

[1] After defecation larvae stops feeding and starts spinning a cocoon

Two larvae feeding studies were available for thiamethoxam. As summarised in Table 2, the resulting toxicity endpoint (no mortality level) was found to be substantially different in the two studies (a factor of 500). This is considered surprising as the studies followed similar methodology where the larvae were fed contaminated food for 5 days. The selection of the endpoint was discussed at the Pesticides Peer Review Experts' Meeting 97. The experts noted several uncertainties with each of the studies, however, no absolute reasoning for the difference in toxicity endpoints was identified. Due to the extreme difference in toxicity observed it is considered that a risk assessment using either of the endpoints could be potentially misleading.

2. Risk assessments for seed dressing products

2.1. Risk from contamination of adjacent vegetation via dust drift (field uses)

2.1.1. First-tier acute risk assessment

Screening step

A quantitative risk assessment was not available and currently no agreed guidance or trigger value is available to assess the risk to honey bees from dust drift. However, Appendix J of EFSA, 2012a suggests to use the full dose (active substance application rate in terms of g a.s./ha) as a very worst case screening step. The use of the full dose is on the basis of 10 % dust deposition in the neighbouring areas (a conservative value on the basis of experience gathered by Petri dish measurements in the last few years) multiplied by a factor of 10 to account for the interception by the three-dimensional structured plants. The screening assessments considering the whole in-field application rate for the highest and lowest 'maximum application rates' authorised in the EU are illustrated in Table 3, below. The acute oral LD_{50} value used in the following risk assessment is taken from the laboratory study, which investigated the toxicity of thiamethoxam seed-dust to honey bees (LD_{50} = 0.00936 µg a.s./bee, Table 1). The available acute contact toxicity endpoint from the laboratory study conducted with dust from formulation A9700B was calculated in terms of g a.s./ha, and therefore, it is not suitable to calculate a screening HQ. The standard acute contact toxicity value for thiamethoxam will therefore be used (LD_{50} = 0.024 µg a.s./bee, see Table 1).

Table 3 HQ values calculated using the in-field application rate for the lowest and highest 'maximum application rates' authorised in the EU, and laboratory LD_{50} values

		Acute oral	Acute contact
LD_{50} (µg a.s./bee)		0.00936	0.024
Hazard Quotient for lowest 'maximum application rate'[1] (poppy)	7 g a.s./ha	747.9	291.7
Hazard Quotient highest 'maximum application rate' (potato)	280 g a.s./ha	29915	11667

[1] Where a range of application rates were provided by the Member States for a product, the highest application rate of the range was used for risk assessment. Therefore, the lowest application rate refers to the lowest 'maximum application rate' (see Appendix A).

The resulting HQ values are high and therefore the screening risk assessment is not sufficient to indicate a low risk.

Tier 1 risk assessment using the default deposition values proposed in draft guidance documents

The risk assessment for honey bees exposed to dust drift was discussed at the Pesticides Peer Review Experts' Meeting 97. The experts proposed that a risk assessment using the default deposition values for dust drift in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012[13]' would be useful. It is important to note that these values are taken from a draft guidance document and therefore may be subject to change at a later date; therefore, care should be taken with the interpretation of the following risk assessments. Furthermore, the default values in the 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' are based on pneumatic drillers which are fitted with a deflector.

The following risk assessments for maize, oilseed rape, cereals and sugar beet use the proposed default deposition values to adjacent vegetation given in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012'. The assessment is based on the highest and lowest 'maximum application rates' authorised in the EU for each of these uses. The same acute oral and acute contact LD_{50} values which were used in the screening assessment (Table 3) were used. Table 4 presents the resulting acute HQ values for honey bees foraging in adjacent vegetation following dust emission during the drilling of maize, oilseed rape, cereals and sugar beet.

Table 4 Tier 1 HQ values calculated using the proposed default deposition values in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' for the highest and lowest 'maximum application rates' authorised in the EU for maize, oilseed rape, cereals and sugar beet

Crop	Parameter	Lowest 'maximum application rate' authorised in the EU	Highest 'maximum application rate' authorised in the EU
Maize	Application rate (g a.s./ha)	63	101
	% deposition (adjacent vegetation)	7	7
	Predicted off-field deposition rate (g a.s./ha)	4.41	7.07
	Acute oral HQ[2]	471.2	755.3
	Acute contact HQ[3]	183.8	294.6

[13] European Commission; Draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012; DRAFT, 8 March 2012

Crop	Parameter	Lowest 'maximum application rate' authorised in the EU	Highest 'maximum application rate' authorised in the EU
Oilseed rape	Application rate (g a.s./ha)	8	33.6
	% deposition (adjacent vegetation)	2.7	2.7
	Predicted off-field deposition rate (g a.s./ha)	0.216	0.907
	Acute oral HQ[2]	23.1	96.9
	Acute contact HQ[3]	9.0	37.8
Cereals	Application rate (g a.s./ha)	70	105
	% deposition (adjacent vegetation)	4.1	4.1
	Predicted off-field deposition rate (g a.s./ha)	2.87	4.305
	Acute oral HQ[2]	306.6	459.9
	Acute contact HQ[3]	119.6	179.4
Sugar beet	Application rate (g a.s./ha)	15.05	90
	% deposition (adjacent vegetation)	0.01	0.01
	Predicted off-field deposition rate (g a.s./ha)	0.0015	0.009
	Acute oral HQ[2]	0.16	0.96
	Acute contact HQ[3]	0.06	0.38

[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see Table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see Table 1)

No agreed trigger value is available for the interpretation of the tier 1 HQ values. EFSA 2012a proposed a trigger value of 50, which is in line with the current trigger for a first-tier risk assessment for foliar sprays. However, currently this value has not been agreed for use in honey bee risk assessment from dust exposure.

As indicated in Table 4, above, the resulting tier 1 HQ values for maize and cereals are clearly not sufficient to exclude an acute risk to honey bees foraging in adjacent vegetation following dust emission during drilling, and therefore a higher tier risk assessment is required (see section 2.1.4). The resulting tier 1 HQ values for oilseed rape may be considered to indicate a low risk to honey bees for the lowest 'maximum application rate' (8 g a.s./ha); however, in the absence of an agreed trigger value a definitive conclusion cannot be reached. However, the acute oral HQ value for the highest 'maximum application rate' authorised for oilseed rape (33.6 g a.s./ha) is clearly not sufficient to exclude an acute risk to honey bees foraging in adjacent vegetation following dust emission during drilling. The resulting tier 1 HQ values for sugar beet for both oral and contact exposure are low and less than the currently proposed trigger value of 50. Although the trigger value has not yet been agreed, it is considered that the margin of safety obtained in the risk assessment is sufficient to demonstrate a low acute risk to honey bees for sugar beet.

The deposition values used to calculate the above HQ values (Table 4) were considered within the draft EFSA guidance document for bees[14] (under development at the time of this evaluation) and were amended by taking into account landscape factors when contamination of nectar and pollen is estimated (i.e. by considering the oral exposure). The default deposition values for adjacent crops proposed are approximately 50 % of those used in the risk assessments presented Table 4. Consequently, the resulting HQ values would be 50 % lower.

[14] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

2.1.2. First-tier chronic risk assessment

In addition to the HQ calculations to cover acute effects, EFSA, 2012a suggests to calculate a chronic ETR_{adult} (exposure to toxicity ratio) between the amount of residues that may be ingested by an adult bee in 1 day and the 10-day LC_{50} value. This assessment would cover the potential chronic effects. To conduct such calculations, the uptake rate of a bee should be estimated after foraging on crops exposed to dust drift. Currently no official guidance is available for these estimations, however, if the residues in nectar and pollen, and the daily consumption of bees were known, then the daily uptake of thiamethoxam could be estimated. However, information on the residue levels in nectar and pollen occurring after dust drift to adjacent vegetation is not available, and therefore the first-tier chronic risk assessment for situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed.

It is noted that the acute risk assessment for dust drift during the drilling of sugar beet seeds was sufficient to conclude a low acute risk to honey bees. This conclusion was reached based on a risk assessment performed using the default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012', where it is suggested that only 0.01 % of the in-field application rate will deposit on adjacent vegetation following the drilling of treated sugar beet seeds; this value is noted to be several orders of magnitude less than for other crops such as maize. Although as indicated above, parameters needed to conduct a chronic risk assessment for honey bees foraging on adjacent vegetation are not available, it may be considered reasonable to conclude a low chronic risk to bees from dust emission during the drilling of sugar beet due to the likelihood of very low exposure.

2.1.3. First-tier risk assessment for bee brood

EFSA, 2012a also suggests calculating an ETR_{larvae} between the amount of residues that may be ingested by a larva in 1 day and the no observed effect level (NOEL) for larvae. Currently no official guidance is available for these estimations, however, if the residues in nectar and pollen, and the daily consumption of bees were known, then the daily uptake of thiamethoxam could be estimated. However, information on the residue levels in nectar and pollen occurring after dust drift to adjacent vegetation is not available, and therefore the first-tier risk assessment for bee brood for the situations when bees forage on a crop exposed to dust drift emitted during the drilling procedure cannot be performed.

It is noted that the acute risk assessment for dust drift during the drilling of sugar beet seeds was sufficient to conclude a low acute risk to honey bees. This conclusion was reached based on a risk assessment performed using the default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment, SANCO/10553/2012' document, where it is suggested that only 0.01 % of the in-field application rate will deposit on adjacent vegetation following the drilling of treated sugar beet seeds; this value is noted to be several orders of magnitude less than for other crops such as maize. Although as indicated above, parameters needed to conduct a risk assessment for honey bee larvae are not available, it may be considered reasonable to conclude a low risk to bee larvae from dust emission during the drilling of sugar beet due to the likelihood of very low exposure.

2.1.4. Risk assessment using higher tier studies

Tier 2 - higher tier acute risk assessment using refined exposure estimates in adjacent vegetation

In March 2012 EFSA published a conclusion on the peer review of the pesticide risk assessment of post-approval data submitted for thiamethoxam (EFSA, 2012d). The post-approval data were in relation to dust generated during the drilling of maize seeds which had been treated with thiamethoxam. In particular, the assessment considered the effectiveness of the use of sowing machines fitted with deflectors as risk mitigation to protect bees foraging in the off-crop area. As part of this assessment there were six studies which investigated residues of thiamethoxam in the off-crop area. In addition to the above mentioned data, three further field studies are available which included an assessment of dust-drift (see Study evaluation notes; EFSA 2012e); one residue study conducted in Greece using cotton, one residue study conducted in Germany using treated sunflower, and an effects study which included exposure estimates conducted in France.

Several experiments on dust drift were conducted also in Germany (Heimbach, U., *et al.*, 2012; Georgiadis *et al*., 2012a, 2012b; Pistorius, J. *et al*., 2012), and a publication of Forster *et al.*, 2012 on data obtained from different research facilities, which were considered during the Pesticides Peer Review Experts' Meeting 97.

In Marzaro *et al.*, 2011 (considered in the APENET project, EFSA 2012c), it is reported that aerial contamination is likely to be the most relevant route of exposure rather than contact with the adjacent vegetation. However, it was noted that in this paper the exposure to ground dust deposition was not investigated. In the experiments performed in Germany it was concluded that the relevant route of exposure is foraging in contaminated areas. Marzaro *et al*., 2011, also concluded that it is important to investigate the mechanism through which honey bees come into contact with the dust to enable effective mitigation measures to be applied. In APENET (EFSA, 2012c), it was also concluded that forager bees are at risk when they fly through the dust clouds emitted by conventional seeders sowing maize seeds coated with thiamethoxam. In another experiment within the APENET project (Pochi *et al.,* 2012), the application of an innovative air recycling/filtering system resulted in a substantial reduction in the active substance concentration in air.

Several experiments within the APENET project (Pochi *et al*., 2011, Biocca *et al.,* 2011) showed that the application of air deflectors on pneumatic drilling machines results in a reduction of dust drift deposition. The same findings were observed in the experiments from Germany, where it was concluded that the use of deflectors and high seed quality were considered to reduce dust emission. However, the experts noted that it was difficult to indicate standard mitigation measures which may cover different Member State situations. Furthermore, acute effects on mortality were observed even with such reduced dust emission, while effects on colony were not observed.

Maize

There are seven available studies investigating the deposition of dust generated during the drilling of maize treated with thiamethoxam. Six of these studies were already peer reviewed (Pesticides Peer Review Experts' Meeting 89) and considered in the EFSA Conclusion (EFSA, 2012d). A number of the studies employed deflectors to reduce the emission of the dust. All of the studies used Petri dishes to trap the dust deposited on bare soil at various distances from the drilled field (a number of the studies also included additional assessments). The study authors calculated the resulting residues deposited in the Petri dishes and the percentage of the applied dose per hectare. When the driller did not have a deflector, the highest mean deposition was found at 5 m and was 1.12 % of the applied dose (i.e. 'maximum of the means'). When the driller had a deflector attached, the highest mean deposition was found at 3 m and was 0.22 % of the applied dose (i.e. 'maximum of the means'). It should be noted that the values do not account for other influential factors such as type of deflector, seed dressing quality (e.g. Heubach-AI value) and environmental conditions during drilling. Care must be taken in the interpretation of the above values, as the 'maximum of the means' does not account for the range of deposition that can occur.

As presented in Appendix A, the highest application rate for maize authorised in the EU is 101 g a.s./ha and the lowest of the 'maximum application rates' authorised is 63 g a.s./ha. Using the above maximum of mean value for the percentage of the applied dose (with and without deflectors) and the highest and lowest 'maximum application rate' authorised for maize in the EU, the following HQ values are obtained for the acute oral and contact risk.

Table 5 Tier 2 refined acute oral and acute contact HQ values for the highest and lowest 'maximum application rates' authorised in the EU for maize

Application rate	63 g a.s./ha		101 g a.s./ha	
	Without deflector	**With deflector**	**Without deflector**	**With deflector**
% of applied rate in Petri dish	1.12	0.22	1.12	0.22
Predicted off-field deposition rate (g a.s./ha)	0.71	0.14	1.13	0.22
Predicted off-field deposition rate with factor of 10[1] (g a.s./ha)	7.06	1.39	11.31	2.22
Acute oral HQ[2]	753.8	148.1	1208.5	237.4
Acute contact HQ[3]	294.0	57.8	471.3	92.6

[1] A factor of 10 was applied to the exposure estimate to account for extrapolation of residues on 2-D Petri dishes to 3-D plant structures taking account of interception (EFSA 2012a).
[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see Table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see Table 1)

Sunflower

Only a single study (consisting of two trials) is available investigating the dust deposition following the drilling of thiamethoxam treated sunflower seeds (Knäbe (2012) S11-02903, see Study evaluation notes; EFSA 2012e). The study only considered residues deposited in Petri dishes following the drilling of sunflower seeds using a driller equipped with a deflector. The study author calculated the resulting residues deposited in the Petri dishes and the percentage of the applied dose per hectare. The study author also calculated a 90th percentile value, however, this value is a 90th percentile Petri dish residue using the mean values at specific distances. As such, the value is not considered to be suitable for risk assessment. In line with the above risk assessment for maize, the following risk assessment has used the maximum of the mean value (= 0.106 % of the applied dose). It should be noted that the values do not account for influential factors such as the type of the deflector, seed dressing quality (e.g. Heubach-AI value) and environmental conditions during the drilling.

As presented in Appendix A, the highest application rate for sunflower authorised in the EU is 20.8 g a.s./ha and the lowest 'maximum application rate' authorised is 16.4 g a.s./ha. Using the above maximum of mean value for the percentage of the applied dose and the highest and lowest 'maximum application rate' authorised for sunflower in the EU, the following HQ values are obtained for the acute oral and contact risk.

Table 6 Tier 2 refined acute oral and acute contact HQ values for the highest and lowest 'maximum application rate' authorised in the EU for sunflower

Application rate	16.4 g a.s./ha		20.8 g a.s./ha	
	Without deflector	**With deflector**	**Without deflector**	**With deflector**
% of applied rate in Petri dish	-	0.106	-	0.106
Predicted off-field deposition rate (g a.s./ha)	-	0.02	-	0.02
Predicted off-field deposition rate with factor of 10[1] (g a.s./ha)		0.17		0.22

Application rate	16.4 g a.s./ha		20.8 g a.s./ha	
	Without deflector	With deflector	Without deflector	With deflector
Acute oral HQ[2]	-	18.6	-	23.56
Acute contact HQ[3]	-	7.2	-	9.19

[1] A factor of 10 was applied to the exposure estimate to account for extrapolation of residues on 2-D Petri dishes to 3-D plant structures taking account of interception (EFSA 2012a).
[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see Table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see Table 1)

Cotton

Only a single study (consisting of two trials) is available investigating the dust deposition following the drilling of thiamethoxam treated cotton seeds (Knäbe (2012) S11-01916, see Study evaluation notes; EFSA 2012e). The study only considered residues deposited in Petri dishes following the drilling of cotton seeds using a driller equipped with a deflector. The study author calculated the resulting residues deposited in the Petri dishes and the percentage of the applied dose per hectare. The study author also calculated a 90th percentile value, however, this value is a 90th percentile Petri dish residue using the mean values at specific distances. As such, the value is not considered to be suitable for risk assessment. In line with the above risk assessment for maize, the following risk assessment has used the maximum of the mean values (= 0.122 % of the applied dose). It should be noted that the values do not account for influential factors such as the type of the deflector, seed dressing quality (e.g. Heubach-AI value) and environmental conditions during the drilling.

As presented in Appendix A, the highest application rate for cotton authorised in the EU is 63 g a.s./ha and the lowest 'maximum application rate' is 52.5 g a.s./ha. Using the above maximum of mean value for the percentage of the applied dose and the highest and lowest 'maximum application rate' authorised for cotton in the EU, the following HQ (hazard quotient) values are obtained for the acute oral and contact risk.

Table 7 Tier 2 refined acute oral and acute contact HQ values for the highest and lowest 'maximum application rate' authorised in the EU for cotton

Application rate	52.5 g a.s./ha		63 g a.s./ha	
	Without deflector	With deflector	Without deflector	With deflector
% of applied rate in Petri dish	-	0.122	-	0.122
Predicted off-field deposition rate (g a.s./ha)	-	0.06	-	0.08
Predicted off-field deposition rate with factor of 10[1] (g a.s./ha)		0.64		0.77
Acute oral HQ[2]	-	68.4	-	82.1
Acute contact HQ[3]	-	26.7	-	32.0

[1] A factor of 10 was applied to the exposure estimate to account for extrapolation of residues on 2-D Petri dishes to 3-D plant structures taking account of interception (EFSA 2012a).
[2] Calculated using an acute oral LD_{50} of 0.00936 µg a.s./bee for dust from formulation A9700B (see Table 1)
[3] Calculated using an acute contact LD_{50} of 0.024 µg a.s./bee from a standard laboratory study (see Table 1)

Interpretation of the risk assessment using refined exposure estimates with Petri dish residues

No agreed trigger value is available for the interpretation of the tier 2 HQ values. EFSA 2012a proposed a trigger value of 50, which is in line with the current trigger for a first-tier risk assessment for foliar sprays. However, currently this value has not been agreed for use in honey bee risk assessment from dust exposure.

As indicated in Tables 5 and 7, the tier 2 refined HQ values for oral exposure for maize and cotton, even when a deflector is used to mitigate the risk, are clearly not sufficient to demonstrate a low acute oral risk to honey bees (HQ > 50).

The acute oral and contact HQ values for sunflower are < 50 for the highest and lowest application rates. However, as the trigger value of 50 has not been agreed, the risk assessment cannot be finalised.

As indicated in Table 5, the tier 2 refined HQ values for contact exposure for maize, even when a deflector is used to mitigate the risk, are clearly not sufficient to demonstrate a low acute contact risk to honey bees (HQ > 50). The refined tier 2 HQ values for contact exposure when a deflector is applied to the driller machine during the drilling of cotton and sunflower are < 50, and could potentially be considered to demonstrate a low acute contact risk when risk mitigation measures are employed (driller deflectors). However, it is important to note that there is uncertainty regarding the above calculated HQ values. The exposure estimates used to calculate the HQ values have been calculated using the 'maximum of the mean values'. Furthermore, only seven studies are available investigating dust deposition following the drilling of maize, and only a single study is available for sunflower and for cotton. As limited exposure data are available it is not known whether the conditions of the studies were suitable to generate worst case exposure estimates (e.g. 90^{th} percentile values). The HQ values calculated following the use of a driller equipped with deflectors are only considered relevant for the specific type of deflector used in the study. Although, it should be noted that, for maize, Petri dish estimates have been calculated for various types of deflectors and the highest value was used for the risk assessment. Furthermore, other influential factors, such as seed dressing quality (e.g. Heubach-AI value) and environmental conditions during the drilling, will affect the relevance of the risk assessment for other situations in the EU.

Overall, the tier 2 acute risk assessment using refined exposure estimates is not considered sufficient to demonstrate a low acute risk to adult bees from dust exposure in maize and cotton. The risk assessment for sunflowers cannot be finalised due to the lack of an agreed trigger value for the interpretation of the risk assessment.

Tier 3 - higher tier risk assessment using effects data from semi-field and field studies

In March 2012 EFSA published a conclusion on the peer review of the pesticide risk assessment of post-approval data submitted for thiamethoxam (EFSA 2012d). As part of this assessment there was a semi-field study which considered the potential effects on bees foraging on *Phacelia tanacetifolia*, which was contaminated with dust from thiamethoxam treated seed. In addition to the above mentioned data, four further relevant field studies were available (see Study evaluation notes; EFSA 2012e).

Semi-field studies

A semi-field study where bees foraged on flowering *Phacelia tanacetifolia* is available (Bocksch (2010), (S09-02400), see EFSA 2012d). The study considered two different application rates and used dust generated from thiamethoxam treated maize seeds: T1 was treated with an equivalent application rate of 1 g a.s./ha and T2 was equivalent to an application rate of 5 g a.s./ha. A statistically significant increase in bee mortality was noted in both T1 and T2 over days 0 - 21. Furthermore, precipitation was noted to have occurred during the study, which may have reduced the potential exposure to bees (i.e. potentially washed the dust from the plants). Therefore, for these reasons, the study is not sufficient to demonstrate a low risk to foraging bees at the tested application rates.

Field studies

Four field studies are available which investigated the effects on bees from the drilling of maize seed treated with thiamethoxam. Three of the studies (Kriszan (2012), S10-01857, S10-01859 and S10-01860, see Study evaluation notes; EFSA 2012e) followed the same methodology and assessed the mortality of bees during drilling, during the early stages of the crop when guttation could occur, and during flowering. All three studies were conducted with maize seed treated with the formulated product ‘A9700B’, which contains 350 g/L thiamethoxam. The application rates of thiamethoxam were 69.15, 74.7 and 76.61 g a.s./ha. The studies included an assessment of the Heubach value for the treated seed and the values were 2 g dust/100 kg seed in two of the studies, and 2.2 g dust/100 kg seed in the third study. The studies benefited from long-term assessments of the bee brood and colony strength including overwintering success. The studies did not specifically include an adjacent flowering crop and therefore are only useful for the dust drift exposure assessment in the field boundaries. The studies did not include Petri dish deposition values. An important point to note is that the pneumatic drillers used in all three studies included a deflector attached to the driller and the outlet air was directed towards the ground.

The fourth field study (Knäbe (2012) S11-01639, see Study evaluation notes; EFSA 2012e) was also conducted with the formulated product ‘A9700B’. The application rate of thiamethoxam was 78.87 g a.s./ha. Again the driller used was fitted with a deflector. The study design did include an adjacent attractive flowering crop (oilseed rape). Assessments were also made of the deposition in Petri dishes, and the residues in the flowers in the adjacent oilseed rape were determined. The study included assessment of the bee brood and colony strength but did not include overwintering success of the hives. Similarly to the other three studies, the study also considered the potential effects of exposure to bees from residues in guttation fluid. The study did not include Heubach values for the treated seed.

The four available studies were carefully designed to account for the potential exposure to bees from dust drift (and guttation fluid). Although, as noted in the Study evaluation notes (EFSA 2012e), each of the studies is considered to have a number of limitations (e.g. lack of statistical analysis, survey of surrounding crops was only performed for a 2 km radius). In addition, in Kriszan (2012, S10-01860), there was evidence to suggest that the control hives were exposed to residues of thiamethoxam during the study (residues were detected in dead bees and pollen from the control field). This was considered to be surprising since the control and treated field were 12 km distance apart. It was noted, however, that a flowering apple orchard was in the (2 km radius) vicinity of the control fields, and it is possible that the apple orchard had been treated with a foliar spray application of thiamethoxam. However, information on the pesticide applications in the apple orchard was not included in the study report. The results from this study should therefore be interpreted with care. Similarly, in the study by Knäbe (2012, S11-01639), it was noted that both the bee pollen load and the bee honey stomach analysis for ‘non-oilseed rape’ in the control hives on day 7 after drilling detected levels of thiamethoxam. It was therefore considered that exposure of the control hives cannot be excluded. Again, care must be taken with the interpretation of the results from this study. Due to contamination of the controls in Kriszan (2012, S10-01860) and Knäbe (2012, S11-01639), the studies are not considered to be totally reliable. However, it is useful to consider the results as part of the available data set as a whole (i.e. as supportive information). The contamination of the control hives in Kriszan (2012, S10-01860) and Knäbe (2012, S11-01639) was discussed at the Pesticides Peer Review Experts’ Meeting 97. The experts confirmed that due to contamination of the controls, the studies cannot be relied upon but the results should be considered as supportive information.

<u>Mortality effects (acute risk) after drilling (pre-emergence)</u>

The four studies were discussed in the Pesticides Peer Review Experts’ Meeting 97. It was noted that there was an increase in mortality in the treatment hives compared to the control hives (Kriszan (2012), S10-01859), which is considered to be due to exposure via dust following the drilling of seed (application rate = 74.70 g a.s./ha). No statistical analysis of the mortality results is available but it is noted that the mortality in the treatment hives was consistently greater than that in the control hives between the drilling of the seed and the emergence of the crop. The greatest level of mortality was observed 4 days after drilling and was a mean of 75.8 dead bees/hive/day (range = 30 to 124 dead bees/hive/day). Residues of thiamethoxam and metabolite clothianidin (CGA322704) were detected in the dead bee samples collected between the drilling and the emergence of the crop. The experts at the Pesticides Peer Review Experts’ Meeting 97 considered that it would be useful to express the increase in mortality compared with the control in terms of percentage in order that the observed effects can be compared with the protection goals outlined in the draft EFSA guidance document[15] when agreed. It is important to note that the driller used in the study (Monosem/Nodet Gougin) was equipped with a deflector (the type was not specified in the study report). It is proposed that the mortality was likely to be due to dust exposure and was of a sufficient level to be a concern.

In Kriszan (2012), S10-01857, there was also an increase in mortality in the treatment hives compared to the control hives. However, this increase was only evident 9 days after drilling. Residue analysis of dead bees, except for 2 samples, indicated no residues of thiamethoxam and metabolite clothianidin (CGA322704) up until 28th May (11 days after drilling or 1 day before emergence). However, all the dead bee samples from 28th May – 4th June contained residues of thiamethoxam and metabolite clothianidin (CGA322704). It is therefore considered unlikely that the mortality was due to exposure of dust and may be due to exposure via guttation fluid (refer to section 2.3 regarding the risk assessment for guttation fluid). In Kriszan (2012) S10-01860 and Knäbe (2012) S11-01639 the results are less clear and the evidence of exposure of the control hives means that interpretation of the results is difficult.

Overall, it appears that under certain conditions, <u>even with the use of a deflector</u>, the drilling of thiamethoxam treated maize seed can lead to exposure of honey bee hives, which results in a noticeable and relevant increase in mortality. The biological relevance of the level of mortality observed should be further considered. It must also be borne in mind that it is not known whether the conditions of the study are worst case (i.e. in terms of parameters which affect dust drift/deposition and in terms of study design and maximising the exposure to bees). Moreover, the application rate used in Kriszan (2012), S10-01859 was 74.70 g a.s./ha, while the authorised uses of thiamethoxam treated maize in the EU include rates up to 101 g a.s./ha.

<u>Long-term effects and colony survival (chronic risk and bee brood)</u>

All of the four available higher tier field studies investigating long-term effects on bee hives also included potential exposure to the hive from guttation fluid and foraging on the treated crop. Therefore, the long-term effects on colony survival and bee brood assessments are discussed in the risk assessment for guttation fluid below (section 2.3).

2.1.5. Conclusion on the risk via dust drift

Maize: An acute risk to honey bees from dust drift from thiamethoxam treated maize is identified. When deflectors are attached to the drilling machinery, the risk is reduced but this mitigation has not been demonstrated to be sufficient to indicate a low acute risk to honey bees. The biological relevance of the level of mortality observed in the field studies should be further considered. Furthermore, there is uncertainty as to whether the deflectors used in the study are representative of drilling equipment used in all areas of the EU where thiamethoxam treated maize seed is sown. A data gap is therefore concluded to address the acute risk to honey bees from dust drift following the drilling of treated maize seeds. It is considered that further analysis of the available long-term data is required to reach a definitive conclusion. Therefore, long-term effects on colony development and survival cannot be excluded. A data gap is concluded for additional information to address the long-term risk to colony survival and development, and the risk to bee brood from exposure via dust drift following the drilling of treated maize seed.

Beet crops: On the basis of a tier 1 risk assessment a low risk to honey bees from dust deposition from drilling may be concluded for the authorised uses of thiamethoxam as sugar beet seed treatment. It should be noted that this conclusion is based on default deposition values proposed in the draft 'Guidance document on the authorisation of plant protection products for seed treatment,

[15] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

SANCO/10553/2012'. Assuming the same technology for seed pelleting and drilling, this conclusion was extrapolated to beet and fodder beet.

Cereals and oilseed rape: The tier 1 risk assessments for dust deposition from drilling of cereal seeds were not sufficient to conclude a low risk to honey bees. The tier 1 risk assessments for oilseed rape, at the lowest 'maximum application rate' authorised in the EU, could potentially be considered to present a low acute risk to adult honey bees, however, in the absence of an agreed trigger value, a definitive conclusion cannot be reached. For the highest 'maximum application rate' authorised for oilseed rape the tier 1 risk assessment indicated a high acute risk to honey bees. Furthermore, no risk assessment for chronic exposure or for honey bee larvae could be performed. A data gap is concluded to address the acute risk to honey bees from dust drift during the drilling of cereals and oilseed rape. A data gap is also concluded to perform an assessment considering the long-term risk to colony survival and development, and the risk to bee brood from exposure via dust drift during the drilling of cereals and oilseed rape.

Sunflowers and cotton: The tier 2 risk assessments on sunflower, at the lowest and highest 'maximum application rate' authorised in the EU, when deflectors are used, could potentially be considered to demonstrate a low acute risk to adult honey bees. However, in the absence of an agreed trigger value for such an assessment a definite conclusion cannot be reached. Moreover, currently there are a number of uncertainties in the exposure data used in the tier 2 risk assessment. The HQ values for cotton were not considered sufficient to demonstrate a low risk to honey bees from exposure via dust drift. A data gap is concluded for further information to address the acute risk to honey bees from dust drift during the drilling of sunflowers and cotton. A data gap is also concluded to perform an assessment considering the long-term risk to colony survival and development, and the risk to bee brood from exposure via dust drift during the drilling of sunflowers and cotton.

It should be noted that the risk assessments performed for cereals, oilseed rape, sunflower and cotton have all used exposure estimates based on drilling machines which were equipped with dust deflectors. There is uncertainty as to whether the deflectors, and hence the exposure estimates, are representative of drilling equipment used in all areas of the EU where thiamethoxam treated seed is sown. It should also be noted, that the screening step, first-tier assessments and tier 2 Petri dish assessments have focused on a relatively narrow strip downwind at the edge of the treated field. In practice, this assessment indicates that forager honey bees or other pollinators occurring in this strip are at high risk (e.g. via direct contact to dust) and may be able to carry considerable residues back to the hive (for social bees). Bees present beyond this strip or foraging upwind during the sowing have considerably less exposure. The deposition values used to calculate the tier 1 HQ values (section 2.1.1, above) were considered within the draft EFSA guidance document for bees[16] and were amended by taking into account landscape factors when contamination of nectar and pollen is estimated (i.e. by considering the oral exposure). The default deposition values for adjacent crops proposed are approximately 50 % of those used in the risk assessments presented in section 2.1.1, above. Consequently, the resulting HQ values would be 50 % lower.

Other crops: No higher tier effects studies are available for crops other than maize. Therefore, currently, it is not possible to conclude a low risk to honey bees for any of the other authorised crops. A data gap is concluded to address the potential exposure, and hence the acute and the long-term risk to colony survival and development, and the risk to bee brood from dust drift.

The GAP tables did not specify whether any crops would be sown in glasshouses and subsequently transplanted to the field (as may be the practice for some vegetables in some Member States). If seeds are sown indoors then, due to negligible exposure, the risk to bees via dust drift exposure is negligible.

[16] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

It should be noted that the above assessments do not specifically consider the potential risk to honey bees from relevant sublethal effects following exposure via dust drift. Currently, there is no agreed testing strategy for assessment of sublethal effects. Furthermore, it is not fully understood what type of sublethal effect could potentially lead to adverse effects on honey bee colonies. A consideration of the sublethal dose (see section 1.3) could not be performed as data on the residues in nectar in the adjacent vegetation following dust drift are not available.

2.2. Risk via systemic translocation in plants – residues in nectar and pollen (including sublethal effects)

The risk to pollinators is dependent on many factors (e.g. landscape factors). The most important of these, in relation to the risk via residues in pollen and nectar, is the attractiveness of the crop, including whether agronomic practices will allow the crop to flower. Some of the crops on which thiamethoxam is authorised as a seed-dressing do not flower, are harvested before flowering, or do not produce nectar or pollen. Therefore these crops will not pose any risk to bees via this route of exposure. In Table 8, below, the crops on which thiamethoxam is authorised, are separated based on their attractiveness to honey bees. This allocation is based on the list compiled in the Netherlands for the same purposes (Ctgb, 2011). The list of non-attractive crops should not be extrapolated to crops which are grown for seed-production as in these circumstances the plants will be allowed to flower and therefore can be attractive to bees (e.g. cabbage in the second year). It should be noted that the attractiveness of a crop to honey bees is not necessarily the same for other pollinators. Potato flowers for example are indicated as non-attractive to honey bees, but it is known that some bumble bee species collect pollen from potato flowers.

Table 8 Attractiveness of crops (for which thiamethoxam seed treatments are authorised) to honey bees for collection of nectar and/or pollen

Attractive crops to honey bees	Non-attractive crops to honey bees	
Maize (corn)	Head cabbage	Wheat
Oilseed rape	Kale	Barley
Sunflower	Broccoli	Oat
Peas	Cauliflower	Rye
Poppy	Carrot	Triticale
Flax (linseed)	Chinese Cabbage	Potato
Cotton	Brussels Sprouts	Lettuce
Sorghum	Fodder beet	Endive
Fodder rape	Sugar beet	Radicchio rosso
Mustard	Beets	Sugar loaf
-	Scarole frisée	-

A low risk to honey bees from foraging on nectar and pollen from the treated crop is concluded for the non-attractive crops listed in Table 8, above.

Potentially honey bees could forage on insect honey dew present in treated crops. It may be argued that insect honey dew will not be present in crops grown from thiamethoxam treated seed as the purpose of the seed treatment is to prevent crop pests such as aphids. However, no information was available to demonstrate that the seed treatment will prevent the formation of insect honey dew. Therefore, with the information available, it cannot be excluded that there is a potential risk to bees from foraging on insect honey dew. A data gap is therefore concluded for further information to address the risk to honey bees foraging on insect honey dew.

Information on the residue levels occurring in nectar and pollen was collected and reported in EFSA, 2012b and EFSA, 2012a. The database was amended and further improved (derivation of residue unit doses) for the draft EFSA guidance document on bee risk assessment[16] and for the current mandate for neonicotinoids. Regarding thiamethoxam, information from sixteen outdoor studies on three crops, (oilseed rape, sunflower and maize) were available in the database. To ease the risk assessment, these residue values were expressed as RUD (residue unit dose) to make them independent from the application rate used in the studies. Only a few studies allowed RUD calculations, i.e. those where residues were detected > LOD (limit of detection) and detailed information on the application rate was available. These values are reported in Appendix I of the draft EFSA guidance document[17] on bee risk assessment and are summarised in Table 9, below. It was noted that in the majority of the residue studies, thiamethoxam was measured < LOD or < LOQ, however it is also noted that in most of these cases a relatively high LOQ was used.

No RUD value for residue in sunflower nectar was reported in Appendix I of the draft EFSA guidance document as the residues were < LOQ. However, for the purposes of a worst-case risk assessment an RUD value has been determined by taking the LOQ value for thiamethoxam as a measured residue (in this case 0.001 mg a.s./kg). It would have been preferable to take the LOD value, however, the LOD was not provided in the analytical report (Balluf (2001) 99332/S1-BFEU and Mair (2000) 104/00, see Study evaluation notes; EFSA 2012e). Using the LOQ, the resulting RUD value for thiamethoxam in nectar is estimated to be 0.036 mg a.s./kg (calculated using an application rate of 28 g a.s./ha used in the study. Taking the LOQ value as a measured residue in sunflower nectar could be considered to be worst case. However, it should also be noted that this was calculated from data on a single study and the residue was determined in nectar in the bee honey stomach rather than in plant nectar (Balluf (2001) 99332/S1-BFEU and Mair (2000) 104/00, see Study evaluation notes; EFSA 2012e); consequently, there is a significant amount of uncertainty related to this value.

Table 9 RUD values of thiamethoxam for pollen and nectar referring to application rate of 1 kg/ha

	RUD value for thiamethoxam in nectar	**RUD value for thiamethoxam in pollen**
Oilseed rape	0.032 - **0.081** mg a.s./kg based on application rate of 1 kg a.s./ha	0.033 - **0.574** mg a.s./kg based on application rate of 1 kg a.s./ha
Sunflower	**0.036 mg a.s./kg** based on application rate of 1 kg a.s./ha	0.039 - **0.145** mg a.s./kg based on application rate of 1 kg a.s./ha
Maize	Not applicable.	0.045 - **0.213** mg a.s./kg based on application rate of 1 kg a.s./ha

Values in **bold** were used to estimate the residue intakes

The level of residues that are expected to be present in nectar and pollen via root uptake and systemic distribution in the plant is crop dependent. Therefore, extrapolation from one crop to another is highly uncertain, and a risk assessment can only be performed for those crops for which residue data are available. As residue data were not available for all of the authorised crops in the EU, no first-tier risk assessment could be performed for crops other than maize, sunflower and oilseed rape. Moreover, in order to achieve a worst case risk assessment it should be demonstrated that the conditions of the study are worst case in terms of residue formation. As information is not available to support the severity of the conditions in the studies there is uncertainty as to whether the RUD values are suitably worst case. It is also important to note that the RUD values in Table 9, above, have been derived from studies conducted in France and Germany. There are uncertainties with the extrapolation of this residue information to other situations in the EU, for example, due to climatic and environmental influences.

2.2.1. First-tier acute risk assessment

EFSA, 2012a suggests calculating an ETR_{acute} (acute exposure to toxicity ratio) taking into account the amount of residues that may be ingested by a honey bee in 1 day via contaminated pollen and/or nectar and the oral LD_{50}. Currently no practical guidance is formally available regarding the estimation of the ingestion rate of residues or regarding the comparison of this estimation with the toxicological endpoint. However, if the residues in nectar and pollen and the daily consumption of bees are known,

[17] European Food Safety Authority; EFSA Draft Guidance Document on the Risk Assessment of Plant Protection Products on bees (*Apis mellifera, Bombus* spp. and solitary bees). DRAFT (published for public consultation on 20th September 2012).

the daily uptake of thiamethoxam can be estimated. Residue information (in the form of RUD values) is available and presented in Table 9, above.

Regarding the feed consumption, EFSA, 2012a reported data for different castes of bees. As a worst case for adult honey bee, the following scenarios were considered:

- 32 - 128 mg sugar/day for a forager bee;
- 34 - 50 mg sugar/day and 6.5 - 12 mg pollen/day for a nurse bee.

Since instead of nectar consumption, the energy needs of the bees are reported (sugar/day), the daily nectar consumption needs first to be estimated. For this estimation the sugar content of nectar needs to be considered. The sugar content of nectar is crop-specific and highly dependent on several biotic and abiotic factors. For example, Nicolson concluded (Nicolson, 2008) that honey bees prefer sugar concentrations of 30 – 50 %, but in practice they collect from a much wider range of nectars, which was measured by Seeley (1986) to be 15 – 65 % in nectar loads being brought into a single colony.

When the nectar consumption is estimated, the residue intake (RI) of a forager honey bee and a nurse honey bee can be calculated by using the following formulae:

$$RI_{forager} = \frac{Rn \ x \ Cn}{1000}$$

$$RI_{nurse} = \frac{(Rn \ x \ Cn) + (Rp \ x \ Cp)}{1000}$$

Where: $RI_{forager}$ is the residue intake by a forager bee expressed in µg a.s./bee/day
RI_{nurse} is the residue intake by a nurse bee expressed in µg a.s./bee/day
Rn is the residue level in nectar in mg a.s./kg
Rp is the residue level in pollen in mg a.s./kg
Cn is the consumption of nectar in mg (mg/bee/day)
Cp is the consumption of pollen in mg (mg/bee/day)

Oilseed rape

Based on the data submitted by the Member States, thiamethoxam is authorised in 11 EU countries as a seed-dressing under the product name ‘Cruiser OSR’. The authorised rates are between 8 and 33.6 g a.s./ha[18]. Considering these doses and the highest available RUD values from Table 9, the calculated residue levels (expressed in µg/kg) in nectar are between 0.648 and 2.72 µg a.s./kg and for pollen they are between 4.592 and 19.29 µg a.s./kg.

Assuming 15 % as a realistic worst case estimation for sugar content of oilseed rape nectar to be relevant for risk assessment, the nectar consumption was estimated to be 213 - 853 mg nectar/bee/day for a forager and 227 - 333 mg nectar/bee/day for a nurse bee. Using the calculated residues and the higher value for consumption, the residue intake (RI) (expressed in ng/bee/day) was calculated to be between 0.553 – 2.32 ng a.s./bee/day for a forager and between 0.2714 – 1.139 ng a.s./bee/day for a nurse bee, for the lowest and the highest ‘maximum application rate’, respectively. Considering these ingestion rates the ETR values as reported in Table 10, below were derived.

[18] considering the highest and lowest ‘maximum application rates’, see Appendix A

Table 10 Calculation of ETR_{acute} values for the authorised uses on oilseed rape

	Lowest 'maximum application rate' authorised for oilseed rape in the EU	**Highest 'maximum application rate' authorised for oilseed rape in the EU**
Application rate g a.s./ha	8	33.6
RUD nectar mg a.s./kg	0.081	0.081
Residue level in nectar for application rate	0.000648 mg a.s./kg (=0.648 µg a.s./kg)	0.00272 mg a.s./kg (=2.72 µg a.s./kg)
RUD pollen mg a.s./kg	0.574	0.574
Residue level in pollen for application rate	0.004592 mg a.s./kg (=4.592 µg a.s./kg)	0.019286 mg a.s./kg (=19.29 µg a.s./kg)
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	0.553	2.322
RI for nurse bee ng a.s./bee/day	0.271	1.139
Acute oral LD_{50} ng a.s./bee	5	5
ETR_{acute} forager bee	**0.11**	**0.464**
ETR_{acute} nurse bee	**0.05**	**0.228**

Sunflower

Based on the data submitted by the Member States, thiamethoxam is authorised in 3 EU countries as a seed-dressing under the product names 'Cruiser 600 FS' and 'Cruiser 350 FS'. The authorised rates are between 16.4 and 20.8 g a.s./ha[19]. Considering these doses and the highest available RUD values from Table 9, the calculated residue levels (expressed in µg/kg) in pollen are between 2.378 and 3.02 µg a.s./kg, and for nectar residue levels are between 0.59 and 0.75 µg a.s./kg.

Using the calculated residues and the higher value for consumption, the residue intake (RI) (expressed in ng/bee/day) was calculated to be between 0.504 – 0.639 ng a.s./bee/day for a forager, and between 0.225 – 0.286 ng a.s./bee/day for a nurse bee for the lowest and the highest 'maximum application rate', respectively. Considering these ingestion rates the ETR values as reported in Table 11, below were derived.

Table 11 Calculation of ETR_{acute} values for the authorised uses on sunflower

	Lowest 'maximum application rate' authorised for sunflower in the EU	**Highest 'maximum application rate' authorised for sunflower in the EU**
Application rate g a.s./ha	16.4	20.8
RUD nectar mg a.s./kg	0.036	0.036
Residue level in nectar for application rate	0.0005904 mg a.s./kg (= 0.59 µg a.s./kg)	0.00075 mg a.s./kg (=0.75 µg a.s./kg)
RUD pollen mg a.s./kg	0.145	0.145
Residue level in pollen for application rate	0.002378 mg a.s./kg (=2.378 µg a.s./kg)	0.003016 mg a.s./kg (=3.02 µg a.s./kg)

[19] considering the highest and lowest 'maximum application rates', see Appendix A

	Lowest 'maximum application rate' authorised for sunflower in the EU	Highest 'maximum application rate' authorised for sunflower in the EU
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	0.504	0.639
RI for nurse bee ng a.s./bee/day	0.225	0.286
Acute oral LD_{50} ng a.s./bee	5	5
ETR_{acute} forager bee	**0.101**	**0.128**
ETR_{acute} nurse bee	**0.045**	**0.057**

Maize

Based on the data submitted by the Member States, thiamethoxam is authorised in 9 EU countries as a seed-dressing under the product names 'Cruiser 70 WS', 'Cruiser 350 FS' and 'Cruiser 600 FS'. The authorised rates are between 63 and 101 g a.s./ha[20]. Considering these doses and the highest available RUD values from Table 9, the calculated residue levels (expressed in µg/kg) in pollen are between 13.419 and 21.513 µg a.s./kg.

Using the calculated residues and the higher value for consumption, the residue intake (RI) (expressed in ng/bee/day) was calculated to be between 0.161 – 0.258 ng a.s./bee/day for a nurse bee for the lowest and the highest 'maximum application rate', respectively. Considering these ingestion rates the ETR values as reported in Table 12, below were derived.

Table 12 Calculation of ETR_{acute} values for the authorised uses on maize

	Lowest 'maximum application rate' authorised for maize in the EU	Highest 'maximum application rate' authorised for maize in the EU
Application rate g a.s./ha	63	101
RUD pollen mg a.s./kg	0.213	0.213
Residue level in pollen for application rate	0.013419 mg a.s./kg (=13.419 µg a.s./kg)	0.021513 mg a.s./kg (=21.513 µg a.s./kg
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	-	-
RI for nurse bee ng a.s./bee/day	0.161	0.258
Acute oral LD_{50} ng a.s./bee	5	5
ETR_{acute} forager bee	**-**	**-**
ETR_{acute} nurse bee	**0.03**	**0.05**

[20] considering the highest and lowest 'maximum application rates', see Appendix A

Interpretation of the first-tier acute risk assessment for adult honey bees following exposure via residues in nectar and pollen

Tables 10 - 12 present acute ETR values for adult bees for oilseed rape, sunflower and maize. There is no agreed trigger value for the interpretation of the risk assessment and therefore it is not possible to conclude on the basis of the first-tier ETR values. Moreover, there are a number of uncertainties with the data used to derive the exposure estimates. Sixteen studies, conducted in France and Germany, were used to generate the RUD values which were used in the risk assessment. Although there is a reasonably large data set, the relevance and severity of the conditions of the studies to other situations in the EU is not known. Only a single residue study was available for sunflower and the LOQ was taken as a surrogate value for residues in nectar. Therefore, the risk assessment should only be considered for illustrative purposes only. More reliable residue data would be necessary to calculate definitive ETR values for sunflowers.

2.2.2. First-tier chronic risk assessment

Using the same risk assessment methodology and input parameters as described above for the acute risk assessment in oilseed rape, sunflower and maize, and the chronic adult 10-day LC_{50} > 0.2 ng a.s./bee/day, chronic ETR_{adult} values are calculated and presented in Tables 13, 14 and 15.

Table 13 Calculation of chronic ETR_{adult} values for the authorised uses on oilseed rape

	Lowest 'maximum application rate' authorised for oilseed rape in the EU	**Highest 'maximum application rate' authorised for oilseed rape in the EU**
Application rate g a.s./ha	8	33.6
RUD nectar mg a.s./kg	0.081	0.081
Residue level in nectar for application rate	0.000648 mg a.s./kg (=0.648 µg a.s./kg)	0.00272 mg a.s./kg (=2.72 µg a.s./kg)
RUD pollen mg a.s./kg	0.574	0.574
Residue level in pollen for application rate	0.004592 mg a.s./kg (=4.592 µg a.s./kg)	0.019286 mg a.s./kg (=19.29 µg a.s./kg)
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	0.553	2.322
RI for nurse bee ng a.s./bee/day	0.271	1.139
Chronic 10-day LC_{50} for adult ng a.s./bee/day	>0.2	>0.2
Chronic ETR_{adult} forager bee	**<2.765**	**<11.612**
Chronic ETR_{adult} nurse bee	**<1.355**	**<5.693**

Table 14 Calculation of chronic ETR_{adult} values for the authorised uses on sunflower

	Lowest 'maximum application rate' authorised for sunflower in the EU	**Highest 'maximum application rate' authorised for sunflower in the EU**
Application rate g a.s./ha	16.4	20.8
RUD nectar mg a.s./kg	0.036	0.036
Residue level in nectar for application rate	0.0005904 mg a.s./kg	0.00075 mg a.s./kg

	Lowest 'maximum application rate' authorised for sunflower in the EU	**Highest 'maximum application rate' authorised for sunflower in the EU**
	(= 0.59 μg a.s./kg)	(=0.75 μg a.s./kg)
RUD pollen mg a.s./kg	0.145	0.145
Residue level in pollen for application rate	0.002378 mg a.s./kg (=2.378 μg a.s./kg)	0.003016 mg a.s./kg (=3.02 μg a.s./kg)
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	0.504	0.639
RI for nurse bee ng a.s./bee/day	0.225	0.286
Chronic 10 day LC_{50} for adult ng a.s./bee/day	>0.2	>0.2
Chronic ETR_{adult} forager bee	**<2.520**	**<3.195**
Chronic ETR_{adult} nurse bee	**<1.125**	**<1.429**

Table 15 Calculation of chronic ETR_{adult} values for the authorised uses on maize

	Lowest 'maximum application rate' authorised for maize in the EU	**Highest 'maximum application rate' authorised for maize in the EU**
Application rate g a.s./ha	63	101
RUD pollen mg a.s./kg	0.213	0.213
Residue level in pollen for application rate	0.013419 mg a.s./kg (=13.419 μg a.s./kg)	0.021513 mg a.s./kg (=21.513 μg a.s./kg
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
Maximum nectar consumption nurse bee Cn (mg/bee)	333.3	333.3
RI for forager bee ng a.s./bee/day	-	-
RI for nurse bee ng a.s./bee/day	0.161	0.258
Chronic 10-day LC_{50} for adult ng a.s./bee/day	>0.2	>0.2
Chronic ETR_{adult} forager bee	**-**	**-**
Chronic ETR_{adult} nurse bee	**<0.805**	**<1.290**

<u>Interpretation of the first-tier chronic risk assessment for adult honey bees following exposure via residues in nectar and pollen</u>

Tables 13 - 15 present chronic ETR values for adult bees for oilseed rape, sunflower and maize. Currently there is no agreed trigger value for the interpretation of the risk assessment. For oilseed rape and sunflower the ETR values for both the nurse and forager bee are > 1, indicating that the exposure exceeds the toxicity value. For maize, at the highest application rate, the ETR for the nurse bee is also > 1. In these cases, the first-tier risk assessment is clearly not sufficient to demonstrate a low chronic risk to adult honey bees. In the risk assessment for lowest 'maximum application rate' assessed for maize, the ETR value for a nurse bee was < 1. However, in the absence of an agreed trigger value it is not possible to reach a conclusion on the basis of the first-tier ETR values. Moreover, there are a number of uncertainties with the data used to derive the exposure estimates. Sixteen studies, conducted in France and Germany, were used to generate the RUD values which were used in the risk assessment. Although there is a reasonably large data set, the relevance and severity of the conditions of the studies to other situations in the EU is not known. Furthermore, there are no standardised test guidelines for chronic adult toxicity studies and therefore there is some uncertainty with the toxicity value used in the assessment. Only a single residue study was available for sunflower and the LOQ was taken as a surrogate value for residues in nectar. Therefore, the risk assessment should only be considered for illustrative purposes only. More reliable residue data would be necessary to calculate definitive ETR values for sunflowers.

2.2.3. First-tier risk assessment for brood

As discussed in section 1.4, currently no reliable bee brood endpoint is available for use in a first-tier risk assessment. Therefore, no risk assessment can be performed.

2.2.4. Risk assessment for sublethal effects using first-tier exposure estimates

Currently, there is no agreed testing strategy for assessment of sublethal effects. Furthermore, it is not known what type of sublethal effect could potentially lead to adverse effects on honey bee colonies. Nevertheless, using the available information for thiamethoxam and the same approach as for the acute risk assessment, a ratio between the sublethal dose of 1.34 ng/bee (Henry *et al*., (2012a) considered in EFSA 2012b) and the residue intake (RI) was calculated. These calculations were only performed for foragers because the dose tested by Henry *et al*., (2012a) was administered as sucrose solution which is comparable with the consumption of nectar (main route of exposure for foragers, EFSA 2012a). Since residue data in nectar were available only for oilseed rape, it was not possible to perform a risk assessment for the other authorised uses in Europe.

Table 16 Ratio between sublethal dose and residue intake (RI) for the authorised uses on oilseed rape

	Lowest 'maximum application rate' authorised for oilseed rape in the EU	**Highest 'maximum application rate' authorised for oilseed rape in the EU**
Application rate g a.s./ha	8	33.6
RUD nectar mg a.s./kg	0.081	0.081
Residue level in nectar for application rate mg a.s./kg	0.000648	0.00272
Maximum nectar consumption forager bee Cn (mg/bee)	853.3	853.3
RI for forager bee ng a.s./bee/day	0.553	2.322
Sublethal dose = 1.34 ng a.s./bee	1.34	1.34
Ratio between RI and sublethal dose	0.41	1.733

As indicated in Table 16, the ratio between the residue intake (RI) and the sublethal dose, for the maximum authorised application rate on oilseed rape in the EU, is > 1 and therefore the RI exceeding the sublethal dose indicated to have an adverse effect on the homing behaviour of honey bees (under the conditions of the study). The ratio between the RI and the sublethal dose, for the lowest authorised 'maximum application rate' on oilseed rape in the EU, is < 1, indicating that the likely exposure does not exceed the sublethal dose. However, it should be noted that the toxicity value used in the above risk assessment is not a NOEL but a sublethal dose, which has been demonstrated to have an adverse effect on the return-flight ability of honey bees. Currently there are no agreed trigger values (or a risk assessment scheme) for sublethal effects. A low risk to honey bees from exposure to sublethal doses cannot be concluded on the basis of the above risk assessment.

2.2.5. Risk assessment using higher tier studies

Numerous higher tier semi-field and field studies were available for oilseed rape, maize and sunflower. Each crop will be considered individually.

Oilseed rape

There are several higher tier effect studies and residue studies which were conducted on oilseed rape. Of the available studies two were semi-field studies and five were standard field studies. In addition, there were two multi-year field studies which investigated the effects of exposure to thiamethoxam on honey bee colonies over a four-year period.

Due to the age of the semi-field and the standard field studies a number of deficiencies with the methodology used were noted. For this reason the studies were considered to be of limited use for risk assessment but may be used as supportive information. However, the two multi-year studies (Hecht-Rost (2009) 20050141/F1-BFEU and 20050141/F2-BFEU, see Study evaluation notes; EFSA 2012e) were well performed and included detailed assessments, which allow for a better understanding of the potential for exposure of the honey bees. The study design is also useful to try to understand potential long-term effects on the colony. Although the studies are considered to address many of the concerns raised by EFSA (2012a), it is noted that there were a number of aspects of the study design which were not ideal. In particular, the lack of statistical analysis and methodology used to assess bee brood makes the interpretation of the effect results difficult. These studies were discussed at the Pesticides Peer Review Experts' Meeting 97. The experts agreed that the studies were comprehensive and detailed.

The application rates tested were between 12.23 g a.s./ha and 16.5 g a.s./ha (except in 2004 in Hecht-Rost (2009) 20050141/F1-BFEU where 30 g a.s./ha was applied). The seed loading of thiamethoxam ranged between 4.19 and 4.6 g thiamethoxam/kg seed. The authorised application rates for thiamethoxam treated oilseed rape range from 8 g a.s./ha to 33.6 g a.s./ha, and in general the seed loading has been reported to be 4.2 mg thiamethoxam/kg seed (information regarding seed loading from the Member State GAP tables was incomplete and not presented in a harmonised manner). Both of the studies included several useful assessments (flight intensity, pollen load analysis, honey stomach analysis, residue analysis and surveys of surrounding area), which can be used to interpret the severity of the exposure.

EFSA (2012a) recommends that information to demonstrate residues (in hive) under very worst case conditions (e.g. in a carefully designed semi-field study) should be used to support the severity of the conditions achieved in the field studies. Three semi-field studies are available which were specifically designed to measure residues in bee matrices (hive wax, hive nectar, hive honey, hive pollen, bee pollen, bee nectar and royal jelly) (Hecht-Rost (2007) 20051041/F1-BZEU, 20051041/F2-BZEU and 20051041/F3-BZEU, see Study evaluation notes; EFSA 2012e). The studies were conducted under semi-field (tunnel) conditions, and hence the bees did not have an alternative foraging area. As such, the conditions to transfer residues from plant pollen and nectar to bees and the bee hive are considered to be reasonably worst case. It is noted that all of the studies were conducted in France and the relevance to the rest of the EU is unknown. Nevertheless, the data set is considered to be useful and provides measured residues under real conditions, albeit in a limited area with limited conditions. The application rates used in the semi-field studies were 13.2 g a.s./ha, 14.39 g a.s./ha and 30 g a.s./ha, with a seed loading of 4.4 g thiamethoxam/kg seed. The residues of thiamethoxam ranged from <LOQ to 0.003 mg/kg in comb pollen, < LOQ to 0.004 mg/kg in bee pollen, < LOQ in comb nectar, < LOQ in comb honey, < LOQ to 0.004 mg/kg in bee nectar, < LOQ in comb wax, and < LOQ to 0.007 mg/kg in whole plant.

In the two multi-year field studies, residue analysis was also performed in bee pollen and bee nectar. When compared to the maximum values obtained in the semi-field studies for all of the years tested, the residues were noticeably lower (between < LOQ and a factor of 4 lower in bee pollen, and between < LOQ and a factor of 1.3 less for nectar). However, comparison of maximum values may not provide a realistic comparison of exposure as it does not account for the distribution of residues in both studies (i.e. overall exposure), and it must be acknowledged that many of the samples indicated residues which were less than the LOQ. The experts at the Pesticides Peer Review Experts' Meeting 97 expressed a concern over the comparison of the very worst case residue found in all semi-field studies performed (in the EU). The experts considered that such a comparison would be better performed for individual Member States, taking into account the authorised GAP in the Member State and accounting for environmental and climatic conditions. Whilst this approach is agreed in principle, it is noted that limited data are available and the risk assessment is for all of the authorised uses in the EU. It also highlights the uncertainty in the extrapolation of data from where the studies were performed to other areas in the EU. Some experts also considered that, due to dilution from other available sources of pollen and nectar, it was expected that residues in standard field studies would be less than those found in semi-field studies, where honey bees have no alternative foraging area. Nevertheless, EFSA (2012a) suggests that the conditions of field studies should be ensured to replicate very worst case (e.g. 90^{th} percentile) conditions, and residue data collected from semi-field conditions can be used as evidence. Overall, it is considered that further assessment of the available residue data could be performed which may support the severity of the conditions in the multi-year studies.

In addition to residue analysis, a number of additional assessments were also performed in the multi-year field studies, which provide information to understand the level of exposure: assessments of the percentage of oilseed rape pollen in bee pollen loads; percentage of oilseed rape nectar in bee honey stomachs; surveys of surrounding crops (2 km); and flight intensity assessments. There is limited experience in the interpretation of such assessments but the results do suggest that the exposure was not worst case. In particular, some flowering crops were noted to be in the vicinity of the treated field during a number of the tested years (e.g. oilseed rape was in the vicinity of the treated field in 2006 in Hecht-Rost (2009) 20050141/F2-BFEU). Currently there are no standard values for comparison of the percentage of bee pollen loads and honey stomach assessments containing oilseed rape pollen and nectar. Although the assessments in the multi-year studies confirmed exposure to honey bees, it is considered that the assessments did not indicate high levels of oilseed rape pollen and nectar in bees. Further evidence should be provided to support the level of exposure during the studies.

Currently, the information available suggests that the exposure in the multi-year field studies is not worst case and therefore is not considered to cover all of the conditions in the EU where thiamethoxam treated oilseed rape is used. Furthermore, except for one year, the tested application rate was around 15 g a.s./ha, which is less than the majority of the EU authorised application rates (range 8 g a.s./ha to 33.6 g a.s./ha), although it may be argued that the seed loading is a more useful comparison in such studies. Incomplete and not harmonised information is available regarding the seed loading for some of the authorised uses in the EU.

Acute effects (mortality)

Statistical analysis of the mortality results was not performed in the two multi-year studies (Hecht-Rost (2009) 20050141/F1-BFEU and 20050141/F2-BFEU). In consideration of the mortality results it seems that in seven of the scenarios the mortality in the treatment hives was not noticeably different to that of the control. However, in 2005 of Hecht-Rost (2009) 20050141/F2-BFEU the mortality in the treatment hives was noticeably greater than that of the control and this was evident for the entire assessment period. It is acknowledged that the control mortality was very low (dead bee trap mortality during days 0 – 21 was a mean of 5.6 dead bees/day) and the treatment mortality could also be considered as low in relation to the size of the colony (dead bee trap mortality during days 0 – 21 was a mean of 12.3 dead bees/day). Although it cannot be excluded that the test item contributed to the increase in mortality, the biological relevance of the level of mortality observed in the treated field should be further considered. Exposure assessments (residue, bee pollen loads and bee honey stomach assessments) were not performed in 2005 and therefore it is not possible to determine whether there was a specific reason for the difference in mortality in relation to the other scenarios.

Effects on bee brood, colony development and survival

Bee brood assessments were performed in the two multi-year studies. A number of potential adverse effects were noted in a number of the treatment colonies. However, the assessments were only performed in a qualitative manner and no quantitative interpretation was available. For this reason, further assessment of the results is required to deduce whether there were effects on the bee brood.

In consideration of the colony strength assessments in the multi-year studies, it is noted that there is no noticeable difference in the mean colony strength between the treatment and the control hives. However, it is considered that it is more appropriate to follow the colony strength assessments for individual hives. It is noted that some potential adverse effects on a number of the treatment hives were observed. However, adverse effects were also observed on a number of the control hives. The experts at the Pesticides Peer Review Experts' Meeting 97 discussed the bee brood and colony strength results in the two multi-year studies (Hecht-Rost (2010) 20061138/F1-BFEU, 20061138/F2-BFEU and 20061138/F3-BFEU). The experts acknowledged that there was no statistical analysis performed and the way in which the results had been presented meant that definitive conclusions could not be reached. However, the experts noted that the majority of the potential adverse observations could be explained (such as brood separation, presence of disease, damage caused by brood assessments). The experts considered that no clear adverse trend of long-term effects caused by thiamethoxam was evident in the studies. However, the experts acknowledged that there was uncertainty with this conclusion and that further analysis is required to reach definite conclusions. Guidance is not available for the interpretation of multi-year studies; it must be acknowledged that the multi-year studies are of novel design and there is little experience in the interpretation of these studies, hence knowledge of natural background effects in such studies is scarce. Whilst it is agreed that other influential parameters such as a brood assessment or presence of disease will affect the colony strength (as demonstrated by the effects observed in the control colonies), it is considered that further analysis would be required to ensure that potential treatment-related effects are not missed. With the analysis available it is not possible to ascertain whether the effects in the treatment hives can be attributed to exposure to thiamethoxam or were due to chance or other influential parameters such as disease presence. Furthermore, although the studies included an equal number of control hives and treatment hives, it is not considered rational to dismiss the potential treatment-related effects on the basis of adverse effects also observed in the control, i.e. the controls in the studies are not considered sufficient to understand the natural background effects on colony strength. Overall, on the basis of the available analysis of the results of the multi-year field studies, a low long-term risk to honey bee colonies cannot be concluded, and further analysis of the results is required for a definitive conclusion to be reached.

Sublethal

The available field studies, discussed above, include an assessment of long-term effects on the colony. The studies are considered useful to cover some potential effects to honey bees, and consequent effects on the colony, from sublethal exposure to thiamethoxam and the metabolite clothianidin (CGA322704). The study authors included assessments of flight intensity and also made observations of bee behaviour. However, due to the study design (hives were placed adjacent to the treated crop), the studies cannot be considered to cover all potential adverse effects which could occur following sublethal exposure, e.g. effect on homing failure of forager honey bees in situations where hives are at some distance from the treated crop.

Maize

There are several higher tier bee studies and residue studies which were conducted on maize. The available effects studies include three multi-year field studies, which investigated the effects of exposure to thiamethoxam on honey bee colonies over a four-year period (Hecht-Rost (2010) 20061138/F1-BFEU, 20061138/F2-BFEU and 20061138/F3-BFEU, see Study evaluation notes; EFSA

2012e). The studies were of well performed and followed similar methodology to the multi-year studies conducted on oilseed rape.

In addition, four studies are available which investigated the potential effects to bees and bee colonies following exposure to dust generated during drilling, guttation fluid and foraging on the treated crop (Kriszan (2012), S10-01857, S10-01859 and S10-01860 and Knäbe (2012), S11-01639). Although the studies were well designed and were well performed, it was not demonstrated that there was exposure to the bees during the maize flowering exposure phase. These studies are therefore considered more relevant for the dust exposure and guttation fluid risk assessments in sections 2.1 and 2.3.

The multi-year studies were also well performed and are considered to be potentially useful for risk assessment. However, although the studies are considered to address many of the concerns raised by EFSA (2012a), it is noted that there were a number of aspects of the study design which were not ideal. In particular, the lack of statistical analysis and methodology used to assess bee brood makes the interpretation of the effect results difficult.

The application rates tested were between 80.26 g a.s./ha and 105.9 g a.s./ha. The seed loading of thiamethoxam ranged was 315 g thiamethoxam 100/kg seed. The authorised application rates for thiamethoxam treated maize range from 63 g a.s./ha to 101 g a.s./ha, and in general the seed loading has been reported to be 315 g thiamethoxam/100 kg seed (information regarding seed loading from the Member State GAP tables was incomplete and not presented in a harmonised manner). All of the studies included several useful assessments (flight intensity, pollen load analysis, honey stomach analysis, residues analysis and surveys of surrounding area), which can be used to interpret the severity of the exposure.

Three reliable semi-field studies (each covering two years) are available which were specifically designed to measure residues in bee matrices (Hecht-Rost (2007) 20051149/F1-BZEU and 20051149/F2-BZEU and Hargreaves (2007), T003256-05-REG, see Study evaluation notes; EFSA 2012e). The studies were conducted under semi-field (tunnel) conditions hence the bees did not have an alternative foraging area. As such, the conditions to transfer residues from plant pollen and nectar to bees and the bee hive are considered to be reasonably worst case. The data set is considered to be useful and provides measured residues under real conditions, albeit in a limited area with limited conditions. The application rates used in the semi-field studies were between 85 g a.s./ha and 90 g a.s./ha, with a seed loading of around 320 g thiamethoxam/100 kg seed. The residues of thiamethoxam ranged from < LOQ to 0.004 mg/kg in comb pollen, < LOQ to 0.012 mg/kg in bee pollen, < LOQ to 0.0009 mg/kg in comb wax, and 0.002 mg/kg to 0.05 mg/kg in whole plant.

In the three multi-year field studies residue analysis was also performed in bee pollen and bee nectar. In many cases, insufficient pollen attached to bee pollen loads was collected for analysis. When compared to the maximum values obtained in the semi-field studies for all of the years tested, the residues were noticeably lower (between < LOQ and a factor of 12 lower in bee pollen). As discussed above (for the multi-year oilseed rape studies), the experts at the Pesticides Peer Review Experts' Meeting 97 expressed a concern over the comparison of the very worse case residue found in all semi-field studies performed (in the EU). The experts considered that such a comparison would be better performed for individual Member States, taking into account the authorised GAP in the Member State and accounting for environmental and climatic conditions. Whilst this approach is agreed in principle, it is noted that limited data are available and the requested risk assessment was to cover all of the authorised uses in the EU. It also highlights the uncertainty in the extrapolation of data from where the studies were performed to other areas in the EU. Some experts also considered that, due to dilution from other available sources of pollen, it was expected that residues in standard field studies would be less than those found in semi-field studies where honey bees have no alternative foraging area. Nevertheless, EFSA (2012a) suggests that the conditions of the field studies should be ensured to replicate very worst case (or 90th percentile) conditions and residue data collected from semi-field conditions can be used as evidence. Overall, it is considered that further assessment of the available residue data should be performed which may support the severity of the conditions in the multi-year studies.

In addition to residue analysis a number of additional assessments were also performed in the multi-year field studies, which provide information to understand the level of exposure: assessments of the percentage of maize pollen in bee pollen loads; surveys of surrounding crops (2 km); and flight intensity assessments. The percentage of bees carrying maize pollen in their pollen loads and the percentage of maize pollen found in pollen traps was variable but generally low. This taken together with the low residues detected in bee pollen suggests that exposure during the studies was low, and therefore the conditions of the studies cannot be considered to be sufficiently worst case to cover all of the conditions in the EU where thiamethoxam treated maize seed is sown. The exposure in the three multi-year field studies conducted with maize was discussed during the Pesticides Peer Review Experts' Meeting 97. The experts noted that the evidence suggested low exposure to the honey bee colonies.

On the other hand it is acknowledged that there are seven well-designed field studies covering sixteen different scenarios (scenario being trial and year). The study authors took steps to ensure reasonable exposure in the studies and it seems that there is clear trend of low exposure. Maize is not highly attractive to honey bees, which may have been a contributory factor for the low exposure during the field studies. It is therefore considered that further information or research could be performed to investigate whether the conditions of the available studies are in fact representative of worst case conditions.

<u>Acute effects (mortality)</u>

Statistical analysis of the mortality results was not performed in the available field studies. The mortality results in the available studies are very variable for both the treatment and the control hives. It is therefore difficult to conclude based on the available data, however, the results do not indicate any strong effects on honey bee mortality.

<u>Effects on bee brood, colony development and survival</u>

Bee brood assessments were performed in the available studies. A number of potential adverse effects were noted in a number of the treatment colonies. However, the assessments were only performed in a qualitative manner and no quantitative interpretation was available. For this reason, further assessment of the results is required to deduce whether there were effects on the bee brood. In consideration of the colony strength assessments in the multi-year studies, it is noted that there is no noticeable difference in the <u>mean</u> colony strength between the treatment and the control hives. However, it is considered that it is more appropriate to follow the colony strength assessments for individual hives. It is noted that some potential adverse effects on a number of the treatment hives were observed. However, adverse effects were also observed on a number of the control hives. The experts at the Pesticides Peer Review Experts' Meeting 97 discussed the bee brood and colony strength results in the two multi-year studies (Hecht-Rost (2010) 20061138/F1-BFEU, 20061138/F2-BFEU and 20061138/F3-BFEU). The experts acknowledged that there was no statistical analysis performed and the way in which the results had been presented meant that definitive conclusions could not be reached. However, the experts noted that the majority of the potential adverse observations could be explained (such as brood separation, presence of disease, damage caused by brood assessments). The experts considered that no clear adverse trend of long-term effects caused by thiamethoxam was evident in the studies. However, the experts acknowledged that there was uncertainty with this conclusion and that further analysis is required to reach definite conclusions. Guidance is not available for the interpretation of multi-year studies; it must be acknowledged that the multi-year studies are of novel design and there is little experience in the interpretation of these studies, hence knowledge of natural background effects in such studies is scarce. Whilst it is agreed that other influential parameters such as a brood assessment or presence of disease will affect the colony strength (as demonstrated by the effects observed in the control colonies), it is considered that further analysis would be required to ensure that potential treatment-related effects are not missed. With the analysis available, it is not possible to ascertain whether the effects in the treatment hives can be attributed to exposure to thiamethoxam or were due to chance or other influential parameters such as disease presence. Furthermore, although the studies included an equal number of control hives and treatment hives, it is not considered rational to dismiss the potential treatment-related effects on the basis of adverse effects also observed in the control, i.e. the controls in the studies are not considered sufficient to understand the natural background effects on colony strength. Overall, on the basis of the available analysis of the results of the multi-year field studies, a low long-term risk to honey bee colonies cannot be concluded, and further analysis of the results is required for a definitive conclusion to be reached.

Sunflower

Seven higher tier bee studies with treated sunflower seeds were available. Although the available studies were of reasonable quality, due to the age of the studies there were a number of deficiencies, which meant that the results are of limited use for risk assessment. None of the available field and tunnel studies are considered to have replicated absolute worst case conditions for forager bees. It is noted that the studies did not indicate any strong effects on honey bee mortality and bee brood. However, the assessments performed cannot be considered to be conclusive evidence for risk assessment. As such, further data and risk assessment are required to address the potential risk to honey bees from the authorised uses of thiamethoxam as a seed treatment for sunflowers.

2.2.6. Conclusion on the risk via systemic translocation in plants – residues in nectar and pollen (including sublethal effects)

First-tier risk assessments for the EU authorised uses of thiamethoxam treated oilseed rape, maize and sunflower indicate a potential risk to honey bees. Furthermore, the RUD values used in the exposure estimates would need to be further supported for the risk assessment to be considered conclusive.

It is highlighted that the residue intake estimations (i.e. the consumption value and the sugar content) represent worst case scenarios. Further higher tier refinements might be performed. For example, data on metabolism in bees, dilution factors, or specific sugar content in the crops could be considered in these calculations, but no agreed approaches are currently available. It has also to be noted that the highest residue levels were used for the intake estimation. The experts at Pesticides Peer Review Experts' Meeting 97 expressed a concern over the comparison of the very worst case residue found in all studies performed (in the EU). The experts considered that such a comparison would be better performed for individual Member States, taking into account the authorised GAP in the Member State and accounting for environmental and climatic conditions. Whilst this approach is agreed in principle, it is noted that limited data are available and the requested risk assessment is for all of the authorised uses in the EU. A larger residue data set might be useful for a better definition and representativeness of the residue levels.

Sublethal effects: A consideration of a sublethal dose, indicated to have adverse effects on the homing success of forager honey bees, was presented. On the basis of the first-tier assessment (for oilseed rape), the residue intake (RI) exceeded the sublethal dose for the maximum application rate authorised, indicating that further consideration should be given. Henry *et al.,* (2012a) used the sublethal dose (1.34 ng/bee) in modelling to try and understand the potential impact on the hive. The modelling predicted a potential effect on the colony under certain circumstances. However, the modelling used by Henry *et al.*, (2012a) has not been validated and the parameters are still under scientific debate (Cresswell and Thompson, 2012 and Henry *et al.*, 2012b). Some experts at the Pesticides Peer Review Experts' Meeting 97 indicated some concerns over the conclusions of Henry *et al.*, (2012a). Acknowledging the uncertainties with the field study methodology, the experts noted an apparent disparity between the predictions of Henry *et al.,* (2012a) and the evidence from the available field studies. It was considered that some impact from homing failure would have been evident if the modelling was accurate. Equally, as the studies were not designed to investigate the potential impact of homing failure over larger distances, the studies cannot be considered as sufficient to fully address this concern. Overall, with the available information a conclusion cannot be reached regarding the impact on the hive of the homing failure of forager bees. Furthermore, it is highlighted that currently there is no agreed testing strategy for the assessment of sublethal effects. It is also not fully understood what type of sublethal effect could potentially lead to adverse effects on honey bee survival and behaviour. Therefore, a data gap to further address the risk to honey bees from sublethal exposure is concluded.

Overall, the following conclusions were drawn:

Maize and oilseed rape: Comprehensive multi-year higher tier effects studies were available for oilseed rape and maize. The conditions of the studies do not appear to have been conducted under worst case conditions and hence cannot be considered as representative for all of the conditions across the EU, where thiamethoxam treated maize and oilseed rape seeds are used. However, further analysis may be useful to demonstrate the severity of the conditions in the studies. A data gap is therefore concluded for further information to support the use of the available higher-tier effects studies in maize and oilseed rape (e.g. information to demonstrate the severity of exposure and the relevance of the conditions to elsewhere in the EU).

Lack of statistical analysis creates uncertainty with the interpretation of the results and therefore only strong effects are likely to have been evident. The acute risk to honey bees foraging in maize was indicated to be low under the conductions of the available field studies; however, as discussed above, a data gap has been identified for further information to support the use of the field studies and therefore, currently, the assessment cannot be finalised. A potential acute effect was noted in one year (out of 8 potential year and trial scenarios) in the oilseed rape studies; the biological relevance of the level of mortality observed should be further considered. A data gap is therefore concluded to further address the acute risk to bees foraging in oilseed rape. With regard to the long-term effects, no absolute conclusion could be reached owing to the lack of analysis of the bee brood and colony strength results. A number of potential effects were noted and therefore, in the absence of robust analysis of the data, long-term effects on the colony cannot be excluded. The experts at the Pesticides Peer Review Experts' Meeting 97 proposed that no clear adverse trend of long-term effects caused by thiamethoxam was evident in the studies; nevertheless it is considered that further analysis of the available long-term data is required to reach a definitive conclusion. A data gap is concluded for further information to address the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees from residues in nectar and/or pollen in maize and oilseed rape.

Sunflower and other crops: The available higher tier data conducted using treated sunflower seeds were not considered suitable for risk assessment. No higher tier studies, investigating the potential effects on honey bees from foraging on the treated crop, were available for other crops (other than maize, oilseed rape and sunflowers). Therefore, the honey bee risk assessment for treated sunflowers and other crops is unresolved. A data gap is concluded to address the acute and the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees foraging in nectar and/or pollen for sunflower and other honey bee-attractive crops (**sunflower, peas, poppy, linseed (flax), cotton, sorghum, fodder rape and mustard**). A low risk to honey bees from residues in nectar and pollen is concluded for non-attractive crops (see Table 8). However, further information is required to exclude the potential risk to honey bees foraging on insect honey dew (see data gap concluded in section 2.2, above).

2.3. Risk via systemic translocation in plants – guttation

2.3.1. First-tier risk assessment

A number of field studies investigating guttation fluid in maize are available. High residues of both thiamethoxam and the metabolite clothianidin (CGA322704) have been measured in the guttation fluid from maize plants grown from thiamethoxam treated seed (see Study evaluation notes; EFSA 2012e). However, it is noted that no guttation fluid was observed in a field study conducted with cotton plants in Greece.

In all of the available studies conducted using treated maize seeds, there was frequent occurrence of guttation fluid from the time of emergence and throughout the sampling period (49 days after emergence). Chemical analysis indicated high residues of both thiamethoxam and the metabolite clothianidin (CGA322704). The highest residues occurred at the time of emergence with a subsequent decline in the concentration.

EFSA 2012a indicates that ETR_{acute}, $ETR_{chronic}$ and ETR_{larvae} should be calculated for potential exposure via guttation fluid. However, insufficient information is available regarding the water consumption of forager bees, in-nest bees and bee brood, and therefore it was not possible to calculate first-tier ETR values. As a form of screening step, to understand the potential risk to bees, a comparison of the acute toxicity of thiamethoxam with the concentrations found in the guttation fluid is made. It is important to note that this screening step does not consider the actual consumption of water by honey bees and therefore should not be considered as a true reflection of the risk. It should be noted that residues of thiamethoxam and metabolite clothianidin (CGA322704) simultaneously occurred in guttation fluid and therefore there may be combined exposure to honey bees. However, for the purposes of the following screening step assessment, the residue values have not been combined.

The acute oral LD_{50} of thiamethoxam to honey bees is 0.005 µg a.s./bee and the acute oral LD_{50} of the metabolite clothianidin (CGA322704) to honey bees is 0.00379 µg/bee (European Commission 2006). The highest residue of thiamethoxam and the metabolite clothianidin (CGA322704) in guttation fluid was reported in the study of Kriszan (2012, S10-01860) and was a mean of 46990.12 µg/L for thiamethoxam and 5585.38 µg/L for the metabolite clothianidin (CGA322704), measured 1 day after emergence. It can be estimated:

- For thiamethoxam: a honey bee would have to consume 0.106 µL of guttation fluid to reach the acute oral LD_{50}.
- For the metabolite clothianidin (CGA322704): a honey bee would have to consume 0.68 µL of guttation fluid to reach the acute oral LD_{50}.

To provide a consideration of the duration of the potential risk, using the residue values in the guttation fluid from maize 40 days after emergence measured in Knäbe (2012) (S11-01639) (28.4 µg/L for thiamethoxam and 12.2 µg/L for the metabolite clothianidin (CGA322704)), it can be estimated:

- For thiamethoxam: a honey bee would have to consume 176 µL of guttation fluid to reach the acute oral LD_{50}.
- For the metabolite clothianidin (CGA322704): a honey bee would have to consume 313 µL of guttation fluid to reach the acute oral LD_{50}.

An average of 46 trips per day for water foragers was estimated by Seeley (1995). If bees carry 30 µl up to a maximum of 58 µl of water in their crop (Visscher *et al.,* 1996), they will carry a total of 1.4 – 2.7 ml of water per day (EFSA, 2012a).

On the basis of these calculations, it is clear that the concentrations found in the guttation fluid in maize seedlings could potentially pose a concern to bees if there is exposure to guttation fluid.

2.3.2. Risk assessment using higher tier studies

There are four available field studies which investigated the effects of potential exposure of honey bees to guttation fluid. Three of the studies (Kriszan (2012), S10-01857, S10-01859 and S10-01860, see Study evaluation notes; EFSA 2012e) followed the same methodology and assessed the mortality of bees during drilling, during the early stages of the crop (when guttation may occur), and during flowering of the maize. All three studies were conducted with maize seed treated with the formulated product ‘A9700B’, which contains 350 g/L thiamethoxam. The studies included a survey of alternative water sources in the surrounding area of 300 m from the hives. The application rates of thiamethoxam were 69.15, 74.7 and 76.61 g a.s./ha. The studies benefited from long-term assessments of the bee brood and colony strength including overwintering success.

The fourth field study (Knäbe (2012) S11-01639, see Study evaluation notes; EFSA 2012e) was also conducted with the formulated product 'A9700B'. The application rate of thiamethoxam was 78.87 g a.s./ha. Use on maize is authorised in the EU at application rates between 63 g a.s./ha and 101 g a.s./ha. The study included an assessment of the bee brood and colony strength but did not include an assessment of the overwintering success of the hives. Similarly to the other three studies, the study also considered the potential effects of exposure to bees from dust emission.

The four available studies were carefully designed to account for the potential exposure to bees from guttation fluid. Although the studies were well performed, each of the studies is considered to have a number of limitations (e.g. lack of statistical analysis). As discussed previously, in Kriszan (2012, S10-01860) there was evidence to suggest that the control hives were exposed to residues of thiamethoxam during the study (residues were detected in dead bees and pollen from the control field). Similarly, in the study by Knäbe (2012, S11-01639) it was noted that both the bee pollen load and the bee honey stomach analysis for 'non-oilseed rape' in the control hives 7 days after drilling detected levels of thiamethoxam. Furthermore, low levels of thiamethoxam and metabolite clothianidin (CGA322704) were detected in the guttation fluid in one of the control fields. It was therefore considered that exposure to control hives cannot be excluded. Again, care must be taken in the interpretation of the results from this study. Due to contamination of the controls in Kriszan (2012, S10-01860) and Knäbe (2012, S11-01639), the studies are not considered to be totally reliable. However, it is useful to consider the results as part of the available data set as a whole (i.e. as supportive information).

The experts at the Pesticides Peer Review Experts' Meeting 97 raised a concern over the suitability of effect field studies to address the potential risk to bees from exposure via guttation fluid. The experts considered that there are many influential parameters which are not yet fully understood (e.g. under what conditions bees are most likely to collect guttation fluid). Due to the fact that the studies are relatively new to regulatory risk assessment, there are no agreed study guidelines and there is only limited experience in their use for risk assessment. The experts therefore considered that there is some uncertainty as to the results of the available studies, and the relevance of the studies to all conditions in the EU.

<u>Acute risk</u>

When considering the mortality results during the guttation phase in the four available studies, it appears that a peak of mortality occurred at the time of emergence. In Kriszan (2012) S10-01857, S10-01859 and S10-01860, analytical assessments of dead bees were performed. During the guttation period residues of thiamethoxam and the metabolite clothianidin (CGA322704) were detected in dead bees in all three studies. This therefore suggests that the mortality was due to exposure of the bees to thiamethoxam and/or the metabolite clothianidin (CGA322704). It must be borne in mind that the bee hives in all four studies also had the potential to be exposed to dust drift during the studies. However, as discussed above (section 2.1.4), in Kriszan (2012), S10-01857, there was no evidence of an acute effect following the drilling of the seed, whereas in Kriszan (2012), S10-01859, there was evidence of mortality at the time of drilling. Furthermore, as the peak of mortality coincides with the emergence of the crop (hence potential for occurrence of guttation fluid), it is considered reasonable to assume that the mortality is linked to the exposure via guttation fluid. The peak of mortality in the Knäbe (2012, S11-01639) study was not attributed to exposure from guttation fluid, however, there was some uncertainty with this conclusion (see Study evaluation notes; EFSA 2012e).

Overall, mortality results from three of the studies indicate that there is an acute risk to bees from guttation fluid at the time of emergence. It is noted that in Kriszan (2012) S10-01859, the difference in mortality between the control and treatment hives was only noticeable for a few days. In contrast, in Kriszan (2012) S10-01857, the peak mortality was lower but appears to persist for a longer period of time. It is difficult to draw conclusions using the results of Kriszan (2012) S10-01860 and Knäbe (2012) S11-01639, due to contamination of the control hives.

The four studies were discussed in the Pesticides Peer Review Experts' Meeting 97. The experts agreed that the mortality in the Kriszan (2012) (S10-01857, S10-01859 and S10-01860) studies around the time of crop emergence was attributable to exposure via guttation fluid. The experts noted that this conclusion was not consistent with some data in the literature (e.g. Reetz *et al*. 2011), which could be considered to indicate a low risk to bees from guttation fluid as it was questioned whether bees use guttation fluid as a source of water. The experts discussed whether there was a reason for the mortality observed in these studies (e.g. climatic conditions and other sources of water available to the bees). No clear reasoning could be identified. The Kriszan (2012) studies included a survey of alternative water sources in the surrounding 300 m radius. In study S10-01860 it was reported that there were two ponds and a marshy meadow whereas no water sources were reported in the studies S10-01857 and S10-01859.

Chronic risk, risk to bee brood and risk to the survival of the colony

As discussed previously, as the four available higher tier field studies investigating the effects of exposure via guttation fluid also included potential exposure via dust drift, the long-term effects on colony survival and bee brood are relevant for both types of risk assessment.

Bee brood assessments were performed in the available studies. A number of potential adverse effects were noted in a number of the treatment and control colonies. However, the assessments were only performed in a qualitative manner and no quantitative interpretation was available. For this reason, further assessment of the results is required to deduce whether there were effects on the bee brood.

In consideration of the colony strength assessments in the multi-year studies, it is noted that there is no noticeable difference in the mean colony strength between the treatment and the control hives. However, it is considered that it is more appropriate to follow the colony strength assessments for individual hives. It is noted that some potential adverse effects on a number of the treatment hives were observed. However, adverse effects were also observed on a number of the control hives. The experts at the Pesticides Peer Review Experts' Meeting 97 discussed the bee brood and colony strength results in the two multi-year studies (Hecht-Rost (2010) 20061138/F1-BFEU, 20061138/F2-BFEU and 20061138/F3-BFEU). The experts acknowledged that there was no statistical analysis performed and the way in which the results had been presented meant that definitive conclusions could not be reached. However, the experts noted that the majority of the potential adverse observations could be explained (such as brood separation, presence of disease, damage caused by brood assessments). The experts considered that no clear adverse trend of long-term effects caused by thiamethoxam was evident in the studies. However, the experts acknowledged that there was uncertainty with this conclusion and that further analysis is required to reach definite conclusions. Guidance is not available for the interpretation of multi-year studies; it must be acknowledged that the multi-year studies are of novel design and there is little experience in the interpretation of these studies, hence knowledge of natural background effects in such studies is scarce. Whilst it is agreed that other influential parameters such as a brood assessment or presence of disease will affect the colony strength (as demonstrated by the effects observed in the control colonies), it is considered that further analysis would be required to ensure that potential treatment-related effects are not missed. With the analysis available it is not possible to ascertain whether the effects in the treatment hives can be attributed to exposure to thiamethoxam or were due to chance or other influential parameters such as disease presence. Furthermore, although the studies included an equal number of control hives and treatment hives, it is not considered rational to dismiss the potential treatment-related effects on the basis of adverse effects also observed in the control, i.e. the controls in the studies are not considered sufficient to understand the natural background effects on colony strength. Overall, on the basis of the available analysis of the results of the multi-year field studies, a low long-term risk to honey bee colonies cannot be concluded, and further analysis of the results is required for a definitive conclusion to be reached.

Additional information

During the Pesticides Peer Review Experts' Meeting 97 the German expert provided feedback on several experiments conducted in Germany investigating the potential effects to honey bees from exposure to guttation fluid (Frommberger, M. *et al*., 2012; Pistorius, J. *et al*., 2012; Joachimsmeier *et al*., 2012). The experiments were all conducted with plant protection products containing clothianidin and therefore were not directly relevant to the risk assessment for plant protection products containing thiamethoxam. Nevertheless, the general conclusions may be useful. The German expert reported that different crops varied in terms of frequency and intensity of guttation events. Peak residues were reported in early growth stages. In the experiments conducted in Germany, it was reported that there were several other water sources in the area surrounding the colony and the guttation droplets were only present for a limited time. It was noted that the potential collection of guttation fluid poses a different risk than foraging on nectar and pollen, where the bees will be attracted to the crop. With regard to the effects observed, it was noted that in a few situations in maize a peak of mortality was observed. However, mortality was not observed in the majority of studies. No long-term effects on the colony were reported. Although the German studies were conducted using plant protection products containing clothianidin, it is interesting that, under some circumstances, acute effects are observed. This is in line with the results of the available field studies conducted with thiamethoxam (see section 2.3.2, above).

Bees were not observed to collect guttation fluid from triticale and maize (Reetz *et al*., 2011). In addition, Schneider *et al.*, 2012 reported that the relevance of guttation exposure is still unclear. Girolami *et al.,* 2009, in a paper investigating the residue levels of imidacloprid, clothianidin and thiamethoxam, and their toxicity by offering contaminated guttation droplets to honey bees, concluded that the likelihood that bees could drink from maize or other crops' guttation drops is not yet quantified, and therefore it is not possible to make a judgment on a possible correlation between neonicotinoid translocation in guttation drops and Colony Collapse Disorder. This conclusion was also supported by further experiments within the APENET project (EFSA 2012c). For example Tapparo *et al*, 2011 concluded that guttation is affected by several factors that cause a high variability both in intensity and in the residue levels, and therefore further experiments would be needed to understand the phenomenon and its consequence in the risk assessment.

2.3.3. Conclusion on the risk via systemic translocation – guttation

Maize: Lack of statistical analysis creates uncertainty with the interpretation of the results and therefore only strong effects are likely to have been evident. An acute effect at around the time of emergence of the crop was noted in three of the studies conducted in maize, and this was attributed to exposure via guttation fluid. With regard to the long-term effects no absolute conclusion could be reached owing to the lack of analysis of the bee brood and colony strength results. A number of potential effects were noted and therefore, in the absence of robust analysis of the data, long-term effects on the colony cannot be excluded. The experts at the Pesticides Peer Review Experts' Meeting 97 proposed that no clear adverse trend of long-term effects caused by thiamethoxam was evident in the studies. Furthermore, the experts considered that there is some uncertainty with the use of effect field studies to address the risk to bees from exposure via guttation fluid. The relevance of the conditions of the studies to all conditions in the EU, where maize seed treated with thiamethoxam is authorised, is uncertain. A data gap is concluded to address the acute risk to honey bees from exposure via guttation fluid in maize. A data gap is also concluded for further information to address the long-term risk to colony survival and development, and the risk to bee brood for honey bees from exposure via guttation fluid in maize.

Cotton: No guttation was observed in the available study conducted in cotton suggesting a low risk to bees. However, further information on the potential guttation occurrence in cotton is needed to support this conclusion. A data gap is concluded for further information to address the likelihood of cotton plants producing guttation fluid or information to address the risk (i.e. the acute and long-term risk on colony survival, development, and the risk for bee brood) to honey bees from exposure via guttation fluid in cotton.

Other crops: It was acknowledged that there is evidence to suggest that crops will vary in the intensity and frequency of occurrence of guttation events (e.g. sugar beet and carrot are thought to infrequently guttate). However, no quantified data were available regarding the occurrence of guttation fluid in crops other than maize, and therefore it was not possible to conclude on the risk to honey bees. A data gap is concluded for information to address the exposure, and hence risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood) to honey bees from exposure via guttation fluid.

The experts at the Pesticides Peer Review Experts' Meeting 97 discussed the feasibility of risk mitigation measures to reduce the risk to bees from exposure via guttation fluid. The experts considered that it could be problematic to recommend that other water sources should be made available to bees as it may increase disease transmission. Furthermore, it is not known whether offering an alternative water source would result in the bees no longer using guttation fluid, and hence would be effective in mitigating the risk. The experts were also concerned with the practicalities of compliance.

3. Monitoring data

During the Pesticides Peer Review Experts' Meeting 97 monitoring data from Austria, Slovenia, Italy and France were presented.

3.1. Austrian monitoring project – MELISSA

MELISSA ("Investigations in the incidence of bee losses in corn and oilseed rape growing areas of Austria and possible correlations with bee diseases and the use of insecticidal plant protection products") (Austria, 2012) was a monitoring project conducted in Austria during 2009, 2010 and 2011. The objectives of the MELISSA project were: to document the incidences of honey bee losses in production areas of maize and oilseed rape; to analyse possible causes (honey bee pathogens and parasites, plant protection products); to evaluate the results with respect to measures taken to prevent honey bee losses; and to develop decision guidance for authorities, beekeepers and farmers for the implementation of measures to prevent honey bee losses by pathogens, parasites and plant protection products.

Diagnosis was performed for pathogens and parasites like *Varroa destructor*, *Nosema* spp., and several bee viruses. In addition, pesticide residue analyses in different bee matrices were performed for a variety of active substances including neonicotinoid seed treatments.

The results of the MELISSA project provided evidence that, in Austria, regional clustered bee damage had occurred in the years 2009 – 2011, which were frequently associated with the use of maize and oilseed pumpkin seeds coated with insecticides. It was noted that in some cases there was severe bee damage/colony losses yet no residues of the neonicotinoid pesticide active substances were detected. It was also noted that the presence of disease and combined stresses could have contributed or caused the colony damage. It was acknowledged that the residue analysis results would be diluted by samples from dead bees which had died from natural causes, therefore it is not surprising that residues greater than the LOQ were not detected. However, it was noted that monitoring data from Germany indicated detectable residue levels of neonicotinoids in dead bees where colony damage was observed.

The AT expert reported that regulatory measures (e.g. use of deflectors) to prevent honey bee losses possibly due to the exposure of bees to insecticidal seed dressing substances have significantly improved the situation. However, incidences of honey bee mortality observed repeatedly in defined regions suggest a systematic correlation with local factors contributing to the increased exposure of bees. The AT expert also noted that seed dressing quality and seed drilling equipment still need further improvement, and sowing of treated seed with pneumatic seed drillers should be avoided under windy conditions.

3.2. Incidences reported in Slovenia (2011)

The data presented at the meeting summarised reports on bee poisoning incidents in spring 2011 in the region of Pomurje (Slovenia, 2012). The incidents concerned more than 2500 hives, representing nearly 10 % of the beekeepers in that region. Loss of worker bees and bee brood was reported by 41 beekeepers, and the majority of the beekeepers had bees foraging on flowering oilseed rape. The flowering oilseed rape had coincided with maize sowing.

A total of 42 samples were taken from dead bees, pollen, nectar, honey combs, flowering oilseed rape and maize seeds collected in the field, which were subsequently analysed for pesticide residues. A total of 19 samples of maize seeds treated with either ‘Poncho’ or ‘Cruiser’ from different commercial suppliers were analysed for dust abrasion (Heubach test). Furthermore, the following investigations were undertaken at farms within 3 km of the affected bee hives: land use, register and legitimacy of plant protection product use, accuracy of maize sowing equipment and spraying equipment, and declarations on maize seed. Further samples from other regions, where no bee poisoning incidents were reported, were taken from dead bees, pollen, oilseed rape and vegetables, and were subsequently analysed for pesticide residues. The active substance clothianidin was most frequently found and was detected in 24 out of 51 samples, of which 12 were dead bee samples. The seed fulfilled prescribed national quality standards for dust abrasion that were introduced following bee poisoning incidents in 2008. Further records of bee poisoning in May and subsequent findings of clothianidin and thiamethoxam in dead bees can not be attributed to the sowing of maize as a route of exposure. Thiamethoxam was found in 4 samples, of which 2 were dead bee samples, but only after withdrawal of authorisation of ‘Cruiser’ for seed treatment. Several other active substances were detected in the samples of dead bees, pollen, nectar, fruit, oilseed rape and maize seeds. Although it was hypothesized that bees could have been exposed to dust generated during the maize sowing, further scientific investigations were envisaged by the Slovenian Authorities.

3.3. Monitoring in Italy

APENET monitoring network

Within the APENET project, a national monitoring network was established in 2009 - 2011, in order to gather information on the health status of the honey bee colonies. Hives situated in different geographic areas were monitored by means of periodic sampling and laboratory analysis on dead bees, live bees, brood, honey, wax and pollen. Monitoring data from the APENET network were considered in EFSA 2012c.

BEENET monitoring network

The project named "BeeNet-Beekeeping and networked environment" is a monitoring network and alert system to investigate Italian beekeeping problems, as well as to monitor abnormal events. This project is a follow-up of APENET and represents the institutional monitoring activities for beekeeping need (Italy, 2012). The project started in 2011 and will end in June 2013. No further data are available.

3.4. Monitoring data from France

Targeted monitoring data for thiamethoxam (product ‘Cruiser’) from 2008 to 2010 in different regions of France were presented during the meeting. The monitoring program included fields treated with thiamethoxam and control fields. Investigations for pathogens and parasites such as *Varroa* and *Nosema* spp., and residue analysis of thiamethoxam and clothianidin were performed.

The hives were maintained on-site so that they could potentially be exposed to dust, guttation fluid and foraging on the flowering crop. Deflectors were introduced as mitigation measures in France in recent years. There were no effects which had been linked to exposure to thiamethoxam seed treatments. Some samples indicated detectable residues but these were not linked to adverse effects on the hive. It was noted to be problematic to conduct such dedicated and targeted monitoring. Some samples of thiamethoxam were detected in bee bread but this was prior to sowing and therefore could not be explained. Overall, there were no treatment-related bee losses over the 3-year monitoring period. It is acknowledged that this type of trial is difficult to conduct, nevertheless the FR expert believed that the results are useful to indicate no treatment-related effects on bee hives.

3.5. Overall conclusion on the monitoring data

During the Pesticides Peer Review Experts' Meeting 97 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). It was also noted that the monitoring data are only relevant to the specific Member State (and to the GAPs approved in that Member State) and not to all authorised uses, environmental and agronomic conditions in the EU. 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.

4. List of data gaps identified during the assessment

The following data gaps are relevant for both the parent, thiamethoxam, and the metabolite clothianidin (CGA322704) and when addressing the data gaps the assessments should account for the combined exposure.

- Further information to address the risk to pollinators other than honey bees (relevant for all outdoor authorised uses; see section on 'Conclusions of the evaluation').

- Further assessment of the risk to honey bees foraging in nectar and/or pollen in succeeding crops (relevant for all outdoor authorised uses; see section on 'Conclusions of the evaluation').

- Further information to address the risk to honey bees foraging on insect honey dew (relevant for all outdoor authorised uses; see section 2.2).

- Further information to address the acute risk to honey bees from dust drift following the drilling of treated maize seeds. Additional information is also required to support the use of the available data to address the long-term risk to colony survival and development, and the risk to bee brood from dust drift following the drilling of treated maize seed (relevant for all authorised uses on maize; see sections 2.1.1, 2.1.2, 2.1.3, 2.1.4 and 2.1.5).

- Further information to address the acute and the long-term risk to colony survival and development, and the risk to bee brood for honey bees from dust drift following the drilling of treated cereals, oilseed rape, sunflower and cotton seeds (relevant for all authorised uses on cereals, oilseed rape, sunflower and cotton; see sections 2.1.1, 2.1.2, 2.1.3, 2.1.4 and 2.1.5).

- Information to address the potential exposure, and hence the acute and the long-term risk to colony survival and development, and the risk to bee brood for honey bees from dust drift (relevant for all authorised outdoor uses on broccoli, Brussels sprouts, cabbage, kale, cauliflower, carrots, flax (linseed), endive/ lettuce/ radicchio rosso/ sugar loaf/ scarole frisée, mustard, peas, poppy, potato, sorghum, and fodder rape; see section 2.1.5).

- Further information to address the acute risk to honey bees foraging in oilseed rape following exposure via residues in nectar and/or pollen. Additional information is also required to support the use of the available data to address the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees foraging in nectar and/or pollen for oilseed rape (relevant for all authorised uses on oilseed rape; see sections 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5 and 2.2.6).

- Additional information to support the use of the available data to address the acute and the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees foraging in nectar and/or pollen for maize (relevant for all authorised uses on maize; see sections 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5 and 2.2.6).

- Information to address the acute and the long-term risk to colony survival and development, the risk to bee brood, and the risk following exposure to sublethal doses for honey bees foraging in nectar and/or pollen for sunflower and other honey bee-attractive crops (relevant for the authorised uses on sunflower, peas, poppy, linseed (flax), cotton, sorghum, fodder rape and mustard; see section 2.2.6).

- Further information to address the acute risk to honey bees from exposure via guttation fluid in maize. Additional information is also required to support the use of the available data to address the long-term risk to colony survival and development, and the risk to bee brood for honey bees from exposure via guttation fluid (relevant for all authorised uses in maize; see sections 2.3.1, 2.3.2 and 2.3.3).

- Further information to address the likelihood of cotton plants producing guttation fluid or information to address the risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood) to honey bees from exposure via guttation fluid in cotton (relevant for all authorised uses on cotton; see sections 2.3.1, 2.3.2 and 2.3.3).

- Information to address the exposure, and hence risk (i.e. the acute and the long-term risk to colony survival and development, and the risk to bee brood) to honey bees from exposure via guttation fluid (relevant for all authorised uses on broccoli, Brussels sprouts, cabbage, kale, cauliflower, carrots, cereals, flax (linseed), endive/ lettuce/ radicchio rosso/ sugar loaf/ scarole frisée, mustard, oilseed rape, peas, poppy, potato, sorghum, beets, fodder rape and sunflower; see section 2.3.3).

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

- None

6. Concerns

6.1. Issues that could not be finalised

Several issues that could not be finalised were identified in relation to the exposure of honey bees via dust, from consumption of contaminated nectar and pollen, and from exposure via guttation fluid. In addition, the risk to pollinators other than honey bees, the risk from residues in insect honey dew, and the risk from exposure to residues in succeeding crops could not be finalised.

The assessments are considered not finalised where there were no data, or insufficient data available to reach a conclusion, or where there are no agreed risk assessment schemes available. The issues that could not be finalised are marked with an 'X' in the overview table in section 7.

6.2. Critical areas of concern

A high acute risk to honey bees was identified from exposure via dust drift for the authorised uses in cereals, cotton, oilseed rape (except for uses with the lowest application rate authorised in the EU) and maize. A high acute risk was also identified for exposure via guttation fluid for the authorised uses in maize.

The risks identified are marked with an 'R' in the overview table in section 7. Risks have been identified where either a 1st tier risk assessment indicated a high risk (not including the screening step assessment for exposure via dust and guttation), or a higher tier study indicated a high risk.

7. Overview of the concerns identified for the authorised uses of thiamethoxam

X **Assessment not finalised** – where there were no data, or insufficient data available to reach a conclusion / where there are no agreed risk assessment schemes available.

R **Risk identified** – where either a first tier assessment indicated a high risk (not including the screening step assessment for exposure via dust and guttation) or higher tier study indicated a high risk.

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
broccoli	Cruiser 70 WS 12852	NL	53	X	X				X	X	X	X	X
Brussels sprouts	Cruiser 70 WS 12852	NL	49	X	X				X	X	X	X	X
(head) cabbage / chinese cabbage	Cruiser	BE	Not available	X	X				X	X	X	X	X
	Cruiser 70 WS 12852	NL	88	X	X				X	X	X	X	X
	Cruiser 70 WS 12852	NL	80	X	X				X	X	X	X	X
kale	Cruiser 70 WS 12852	NL	74	X	X				X	X	X	X	X
cauliflower	Cruiser 70 WS 12852	NL	36	X	X				X	X	X	X	X
carrots	Cruiser	BE	12.2	X	X				X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
cereals: barley/ wheat/ rye/ oat/ triticale	Celest Top	HU	102.3	R	X				X	X	X	X	X
	CRUISER 350 FS	FIN	105	R	X				X	X	X	X	X
	CRUISER 350 FS	FIN	70	R	X				X	X	X	X	X
	CRUISER 350 FS	CZ, FIN	105	R	X				X	X	X	X	X
cotton	CRUISER 350 FS	EL	63	R	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	ES	52.5	R	X	X	X	X	X	X	X	X	X
	Cruiser 70 WS	ES	63	R	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS, Cruiser 70 WS	IT	52.5	R	X	X	X	X	X	X	X	X	X
flax falseflax, Camelina sativa	Cruiser 350 FS	BE	77.35	X	X	X	X	X	X	X	X	X	X
	CRUISER OSR (A9807F)	FIN	44.8	X	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Endive/ lettuce/ radicchio rosso/ sugar loaf/ scarole frisée	Cruiser	BE	Not available data	X	X				X	X	X	X	X
	CRUISER 70 WS (024874-00)	DE	80	X	X				X	X	X	X	X
	CRUISER 70 WS (024874-00)	DE	80	X	X				X	X	X	X	X
	Cruiser 70 WS	ES	Not available data	X	X				X	X	X	X	X
	Cruiser 600 FS	FR	60	X	X				X	X	X	X	X
	Cruiser 70 WS 12852	NL	74	X	X				X	X	X	X	X
	Cruiser 70 WS 12852	NL	80	X	X				X	X	X	X	X
maize /sweet corn	Cruiser 350 FS	AT	63	R	X	X	X	X	R	X	X	X	X
	Cruiser 350	CZ	94.5	R	X	X	X	X	R	X	X	X	X
	CRUISER 600 FS	EL	63	R	X	X	X	X	R	X	X	X	X
	CRUISER 350 FS	EL	63	R	X	X	X	X	R	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees from dust exposure	Long term risk to honey bees from dust exposure	Acute risk to honey bees from residues in nectar and/or pollen	Long term risk to honey bees from residues in nectar and/or pollen	Risk to honey bees from sublethal exposure from residues in nectar and/or pollen	Acute risk to honey bees from exposure via guttation fluid	Long term risk to honey bees from exposure via guttation fluid	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
maize /sweet corn	Cruiser 70 WS	ES	73	R	X	X	X	X	R	X	X	X	X
	Cruiser 350 FS	ES	101	R	X	X	X	X	R	X	X	X	X
	Cruiser 350	FR	69.3	R	X	X	X	X	R	X	X	X	X
	Cruiser 350 FS	HU	63	R	X	X	X	X	R	X	X	X	X
	Cruiser 350 FS, Cruiser 70 WS	IT	63	R	X	X	X	X	R	X	X	X	X
	Cruiser 350 FS 12913	NL	63	R	X	X	X	X	R	X	X	X	X
	Cruiser 350 FS	SK	70	R	X	X	X	X	R	X	X	X	X
mustard	Cruiser OSR	CZ, UK	33.6	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	CZ	33.6	X	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
oilseed rape (winter/ spring)	CRUISER OSR	CZ	33.6	R	X	X	X	X	X	X	X	X	X
	CRUISER OSR (024922-00)	DE	33.6	R	X	X	X	X	X	X	X	X	X
	CRUISER OSR	DK	8	X	X	X	X	X	X	X	X	X	X
	Cruiser Raps	DK	8	X	X	X	X	X	X	X	X	X	X
	Cruiser OSR	EE	25.2	R	X	X	X	X	X	X	X	X	X
	CRUISER OSR	EL	33.6	R	X	X	X	X	X	X	X	X	X
	CRUISER OSR (A9807F)	FIN	33.6	R	X	X	X	X	X	X	X	X	X
	Cruiser OSR 322 FS	HU	33.6	R	X	X	X	X	X	X	X	X	X
	Cruiser OSR	LT	18.9	R	X	X	X	X	X	X	X	X	X
	Cruiser OSR	LV	21	R	X	X	X	X	X	X	X	X	X
	Cruiser OSR	SK	21	R	X	X	X	X	X	X	X	X	X
	Cruiser OSR	UK	33.6	R	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
Peas /canned peas/ combining peas/vining peas	Cruiser 350 FS	BE	131.25	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	CZ	131.25	X	X	X	X	X	X	X	X	X	X
	CRUISER 350 FS	FIN	102.9	X	X	X	X	X	X	X	X	X	X
	Cruiser FS	FR	121	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	HU	100	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS 12913	NL	105	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS 12913	NL	110	X	X	X	X	X	X	X	X	X	X
poppy	Cruiser OSR	CZ, SK	7	X	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
potato	CRUISER 350 FS	EL	105	X	X				X	X	X	X	X
	Cruiser 70 WS	ES	100	X	X				X	X	X	X	X
	Cruiser 350 FS	ES	97.5	X	X				X	X	X	X	X
	CRUISER 350 FS	FIN	107.8	X	X				X	X	X	X	X
	Cruiser 350 FS, Cruiser 70 WS	IT	150	X	X				X	X	X	X	X
	Actara 25 d.g.	LV	150	X	X				X	X	X	X	X
	Cruiser OSR	LV	126	X	X				X	X	X	X	X
	Cruiser 350 FS	SK	280	X	X				X	X	X	X	X
sorghum	Cruiser 350	FR	69.3	X	X	X	X	X	X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
sugar beet/ fodder beat / beet	Cruiser 350 FS	AT	78						X	X	X	X	X
	Cruiser	BE	72						X	X	X	X	X
	Cruiser 600 FS	BE	72						X	X	X	X	X
	CRUISER 600 FS (006034-00)	DE	78						X	X	X	X	X
	CRUISER 70 WS (024874-00)	DE	78.4						X	X	X	X	X
	CRUISER SB 600 FS	EL	72						X	X	X	X	X
	Cruiser 70 WS	CZ, ES	78						X	X	X	X	X
	CRUISER SB	FIN	58.5						X	X	X	X	X
	Cruiser 600 FS	FR	78						X	X	X	X	X
	Cruiser 70 WS	HU	60.2						X	X	X	X	X
	Cruiser 600 FS SB	IT	Not available data						X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
sugar beet/ fodder beat / beet	Cruiser 70 WS, Cruiser 70 WS BN	IT	90						X	X	X	X	X
	Cruiser SB 12863	NL	60						X	X	X	X	X
	Cruiser 70 WS	PL	55.5						X	X	X	X	X
	Cruiser OSR 322 FS	PL	33.6						X	X	X	X	X
	CRUISER SB (A9765K)	SE	58.5						X	X	X	X	X
	Cruiser 70 WS	SK	59.99						X	X	X	X	X
	Cruiser 70 WS	SK	15.05						X	X	X	X	X
	Cruiser SB	UK	78						X	X	X	X	X
	Cruiser SB (M12958)	UK	Not available data						X	X	X	X	X
	Cruiser SB (M15012)	UK	78						X	X	X	X	X
	Cruiser SB (M12958)	UK	Not available data						X	X	X	X	X

Crop/Situation	Product Name	Member State	'Maximum application rate' g a.s./ha	Acute risk to honey bees	Long term risk to honey bees	Acute risk to honey bees	Long term risk to honey bees	Risk to honey bees from sublethal exposure	Acute risk to honey bees	Long term risk to honey bees	Risk to pollinators other than honey bees	Risk from insect honey dew	Risk from exposure to residues in succeeding crops
				from dust exposure		from residues in nectar and/or pollen			from exposure via guttation fluid				
fodder rape	Cruiser OSR	UK	33.6	X	X	X	X	X	X	X	X	X	X
sunflower	CRUISER 600 FS	EL	20.8	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	HU	16.4	X	X	X	X	X	X	X	X	X	X
	Cruiser 350 FS	SK	16.8	X	X	X	X	X	X	X	X	X	X

Table compiled on the basis of Appendix A.

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APPENDICES

APPENDIX A – THIAMETHOXAM: SUMMARY OF AUTHORIZED USES FOR SEED TREATMENT AND GRANULES

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
broccoli	Cruiser 70 WS 12852	NL		53	1.4 mg a.s./seed	n/a (seeds sown indoors) 38000 plants/ha
brussels sprouts	Cruiser 70 WS 12852	NL	42	49	1.4 mg a.s./seed	n/a (seeds sown indoors) 35000 plants/ha
(head) cabbage / chinese cabbage	Cruiser	BE		Not available data	140 g/100 000 seeds	
	Cruiser 70 WS 12852	NL	70	88	1.4 mg a.s./seed	n/a (seeds sown indoors) 63000 plants/ha
	Cruiser 70 WS 12852	NL	34	80	1.4 mg a.s./seed	n/a (seeds sown indoors) 57000 plants/ha
kale	Cruiser 70 WS 12852	NL	42	74	1.4 mg a.s./seed	n/a (seeds sown indoors) 33000 plants/ha
cauliflower	Cruiser 70 WS 12852	NL	30	36	1.4 mg a.s./seed	n/a (seeds sown indoors) 26000 plants/ha
carrots	Cruiser	BE		12.2	6.1 g/100 000 seeds	max. 200 000 seeds/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
cereals: barley/ wheat/ rye/ oat/ triticale	Cruiser	COM review report		105		150 kg seeds/ha
	Cruiser	COM review report		91		175 kg seeds/ha
	Celest Top	HU	47.3	102.3	31.5-34.1 g/100 kg seed	150-300 kg seed/ha
	CRUISER 350 FS	FIN	70	105	0.035-0.0525 kg a.s./100 kg seed	200 kg seed/ha
	CRUISER 350 FS	FIN	35	70	0.035-0.070 kg a.s./100 kg seed	100 kg seed/ha
	CRUISER 350 FS	CZ, FIN	70	105	0.035-0.0525 kg a.s./100 kg seed	200 kg seed/ha
cotton	CRUISER 350 FS	EL	21	63	105-315 g/100 kg seed	20 kg seed/ha
	Cruiser 350 FS	ES		52.5	210 g a.s./100 kg seed	25 kg seed/ha
	Cruiser 70 WS	ES		63	210 g a.s./100 kg seed	30 kg seed/ha
	Cruiser 350 FS, Cruiser 70 WS	IT		52.5	0.210 kg a.s./100 kg seeds	25 kg seed /ha
	Cruiser	COM review report		63		30 kg seed/ha
flax falseflax, Camelina sativa	Cruiser 350 FS	BE		77.35	59.5 g/100 kg seeds	
	CRUISER OSR (A9807F)	FIN	33.6	44.8		

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
Endive/ lettuce/ radicchio rosso/ sugar loaf/ scarole frisée	Cruiser	BE		Not available data	80.5 g/100 000 seeds	
	CRUISER 70 WS (024874-00)	DE		80	114.3 ml/ seedunit*	max. 1 seedunit*/ha
	CRUISER 70 WS (024874-00)	DE		80	114.3 ml/ seedunit*	max. 1 seedunit*/ha
	Cruiser 70 WS	ES		Not available data	60-81 g a.s./100 000 seeds	
	Cruiser 600 FS	FR		60	60 g a.s./100 000 seeds	100 000 seeds/ha
	Cruiser 70 WS 12852	NL	48	74	0.805 mg a.s./seed	n/a (seeds sown indoors) 92500 plants/ha
	Cruiser 70 WS 12852	NL	59	80	0.805 mg a.s./seed	n/a (seeds sown indoors) 99000 plants/ha
Maize / sweet corn	Cruiser 350 FS	AT		63		
	Cruiser 350	CZ		94.5	3.15 kg a.s./t	30 kg seed/ha
	CRUISER 600 FS	EL	63	63	315 g/100 kg seed	20 kg seed/ha
	CRUISER 350 FS	EL	21	63	105-315 g/100 kg seed	20 kg seed/ha
	Cruiser 70 WS	ES		73	315 g a.s./100 kg seed	115 000 seeds/ha
	Cruiser 350 FS	ES		101	315 g a.s./100 kg seed	32 kg seed/ha
	Cruiser 350	FR		69.3	31.5 g as/unit (50 000 seeds per unit)	2.2 unit/ha (50 000 seeds per unit)
	Cruiser 350 FS	HU	31.5	63	315-630 g/100 kg	50 000 seed/ha
	Cruiser 350 FS, Cruiser 70 WS	IT		63		20 kg/ha
	Cruiser 350 FS 12913	NL		63	0.63 mg a.s./seed	100 000 seeds/ha
	Cruiser 350 FS	SK		70	350 g/100 kg	20 kg seed/ha
	Cruiser	COM review report		73		115.000 grains/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
mustard	Cruiser OSR	CZ, UK		33.6	4.2 kg a.s. / t seed	8 kg seeds/ha
	Cruiser 350 FS	CZ		33.6	4.2 kg a.s. / t seed	8 kg seeds/ha
oilseed rape (winter/ spring)	CRUISER OSR	CZ	33.6	33.6	420 g /100 kg seed	6 kg seed/ha
	CRUISER OSR (024922-00)	DE		33.6	15 ml/kg	max. 8 kg seeds/ha
	CRUISER OSR	DK		8		
	Cruiser Raps	DK		8		
	Cruiser OSR	EE	18.9	25.2	315 - 420 g a.s./100 kg seed	
	CRUISER OSR	EL	33.6	33.6	420 g /100 kg seed	8 kg seed/ha
	CRUISER OSR (A9807F)	FIN	33.6	33.6	1.5 l/100 kg seed (420 g a.s./100 kg seed)	8 kg/ha
	Cruiser OSR 322 FS	HU	25.2	33.6	420 g/100 kg seed	6-8 kg seed/ha
	Cruiser OSR	LT	12.6	18.9	3.15 kg/t seeds	4-6 kg rape seed per ha
	Cruiser OSR	LV	16.8	21	336- 420 g a.s./100 kg seeds	5 kg seeds/ha
	Cruiser OSR	SK		21	420 g/100 kg	5 kg seed/ha
	Cruiser OSR	UK		33.6	4.2 kg a.s. / t seed	8 kg seeds/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
Peas /canned peas/ combining peas/vining peas	Cruiser 350 FS	BE		131.25	52.5 g/100 kg seeds	
	Cruiser 350 FS	CZ		131.25	52.5 g a.s./100 kg seed	max. 250 kg seeds/ha
	CRUISER 350 FS	FIN	102.9	102.9	0.049 kg a.s./100 kg seed	210 kg seed/ha
	Cruiser FS	FR		121	52.5 g a.s./100 kg seed	230 kg seeds/ha
	Cruiser 350 FS	HU	35	100	50 g/ 100 kg seed	70-200 kg seed /ha
	Cruiser 350 FS 12913	NL		105	0.18 mg a.s./seed	600000
	Cruiser 350 FS 12913	NL		110	0.18 mg a.s./seed	270000 - 630000
	Cruiser	COM review report		105		200 kg seed /ha
poppy	Cruiser OSR	CZ, SK		7	700 g/100 kg	1 kg seed/ha
potato	CRUISER 350 FS	EL	105	105	5-7 g/100 kg tubers	2100 kg tubers/ha
	Cruiser 70 WS	ES		100	7.5 g a.s./100 kg seed	1300 kg seed/ha
	Cruiser 350 FS	ES		97.5	7.5 g a.s./100 kg seed	1300 kg seed/ha
	CRUISER 350 FS	FIN	107.9	107.8	0.0049 kg as/100 kg seed	2200 kg seed /ha
	Cruiser 350 FS, Cruiser 70 WS	IT	100	150		2000 kg/ha
	Actara 25 d.g.	LV	150	150	15 g a.s./100 kg tuber	3 t tubers/ha
	Cruiser OSR	LV	126	126	4.2 g a.s./100 kg tuber	3 t tubers/ha
	Cruiser 350 FS	SK		280	7 g/100 kg	4t seed/ha
	Cruiser	COM review report		135		1800 kg tubers/ha
sorghum	Cruiser 350	FR		69.3	315 g a.s./100 kg seeds	22 kg seeds/ha

Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
sugar beet/ fodder beat / beet	Cruiser 350 FS	AT		78		
	Cruiser	BE		72	72 g/100 000 seeds	
	Cruiser 600 FS	BE		72	60 g/100 000 seeds	
	CRUISER 600 FS (006034-00)	DE		78	100 ml/ seedunit*	max. 1.3 seed units*/ha
	CRUISER 70 WS (024874-00)	DE		78,4	86 ml/ seedunit*	max. 1.3 seed units*/ha
	CRUISER SB 600 FS	EL	48	72	30-45 g/unit*	1.6 units* seed/ha
	Cruiser 70 WS	CZ, ES		78	60 g a.s./100 000 seeds	130 000 seeds/ha
	CRUISER SB	FIN	45	58.5	45 g a.s./unit seed (1 unit = 100 000 seeds)	1.3 units/ha (1 unit = 100000 seeds)
	Cruiser 600 FS	FR		78	60 g a.s./unit (100 000 seeds/unit)	1.3 unit/ha (100 000 seeds/unit)
	Cruiser 70 WS	HU		60.2	60.2 g/100 000 seeds	100 000 seeds/ha
	Cruiser 600 FS SB	IT		Not available data		
	Cruiser 70 WS, Cruiser 70 WS BN	IT	67.5	90	0.045-0.06 kg a.s./seedunit (100 000 seeds)	1.5 unit/ha (100 000 seeds)
	Cruiser SB 12863	NL		60	0.6 mg a.s./seed	100 000 seeds/ha
	Cruiser 70 WS	PL		55.5	44.8 g/seedunit*	1.24 seed unit*/ha
	Cruiser OSR 322 FS	PL	18.9	33.6	4.2 g/kg seeds	4.5 - 8 kg seeds/ha
	CRUISER SB (A9765K)	SE		58.5	45 g a.s./unit*	Max 1.3 units*/ha
	Cruiser 70 WS	SK		59.99	59.99 g /unit*	
	Cruiser 70 WS	SK		15.05	15.05 g/unit*	
	Cruiser SB	UK		78	60 g a.s. / 100 000 seeds	130 000 seeds / ha

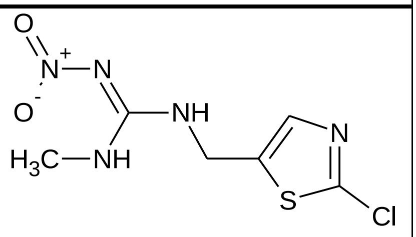
Crop/Situation	Product Name	Member State	Application rate per treatment			
			g a.s./ha min.	'Maximum application rate' g a.s./ha	Seed dressing rate	Seed drilling rate
sugar beet/ fodder beat / beet	Cruiser SB (M12958)	UK		Not available data	60 g a.s. / 100 000 seeds	-
	Cruiser SB (M15012)	UK		78	60 g a.s. / 100 000 seeds	130 000 seeds / ha
	Cruiser SB (M12958)	UK		Not available data	60 g a.s. / 100 000 seeds	-
	Cruiser	COM review report		78	30-60 g/unit*	1.3 unit*/ha
fodder rape	Cruiser OSR	UK		33.6	4.2 kg a.s. / t seed	8 kg seeds/ha
sunflower	CRUISER 600 FS	EL		20.8		
	Cruiser 350 FS	HU	9.6	16.4	350-437.5 g/100 kg seed	50 000 seed/ha
	Cruiser 350 FS	SK		16.8	280 g/100 kg	6 kg seed/ha
	Cruiser	COM review report		24.5		7 kg seeds /ha

Table compiled based on Member States` feedback provided during a consultation via a written procedure in September 2012. Note: not all the 27 Member States provided feedback

* The amount of seeds in the unit is not available

COM= European Commission

APPENDIX B – USED COMPOUND CODE(S)

Code/Trivial name	Chemical name*	Structural formula*
Clothianidin (CGA322704)	(*E*)-1-[(2-chloro-1,3-thiazol-5-yl)methyl]-3-methyl-2-nitroguanidine	

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

ABBREVIATIONS

µg	microgram
a.s.	active substance
AF	assessment factor
AV	avoidance factor
BCF	bioconcentration factor
bw	body weight
CAS	Chemical Abstract Service
D	day
DAE	days after emergence
DAF	days after (the start of) flowering
DAS	days after sowing
DM	dry matter
DT_{50}	period required for 50 percent disappearance (define method of estimation)
DT_{90}	period required for 90 percent disappearance (define method of estimation)
dw	dry weight
EAC	environmentally acceptable concentration
EbC_{50}	effective concentration (biomass)
EC_{50}	effective concentration
EEC	European Economic Community
ER_{50}	emergence rate/effective rate, median
ErC_{50}	effective concentration (growth rate)
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
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
L	litre
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
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
OM	organic matter content
Pa	Pascal
PD	proportion of different food types
PEC	predicted environmental concentration

PEC_{air}	predicted environmental concentration in air
PEC_{gw}	predicted environmental concentration in ground water
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
pH	pH-value
PHI	pre-harvest interval
pK_a	negative logarithm (to the base 10) of the dissociation constant
P_{ow}	partition coefficient between *n*-octanol and water
ppm	parts per million (10^{-6})
ppp	plant protection product
PT	proportion of diet obtained in the treated area
r^2	coefficient of determination
RFID	Radiofrequency identification
RUD	residue per unit dose
SD	standard deviation
SFO	single first-order
SSD	species sensitivity distribution
$t_{1/2}$	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
WHC	water holding capacity
WHO	World Health Organisation
wk	week
yr	year