

Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thiamethoxam in light of confirmatory data

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the risk assessment for an active substance in light of confirmatory data requested following approval in accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the confirmatory data and their use in the risk assessment for thiamethoxam are presented. The current report summarises the outcome of the consultation process organised by the rapporteur Member State Spain and presents EFSA's scientific views and conclusions on the individual comments received.

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

Requestor: European Commission

Question number: EFSA-Q-2016-00193

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Suggested citation: EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thiamethoxam in light of confirmatory data. EFSA supporting publication 2016:EN-1020. 27 pp.

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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 Implementing Regulation (EU) No 485/2013 following the EFSA conclusion on the risk assessment for bees as regards the authorised uses applied as seed treatments and granules (EFSA, 2013a). EFSA finalised another conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules on 31 July 2015 (EFSA, 2015a).

It was a specific provision of the amended approval that the applicant was required to submit to the European Commission further ecotoxicological studies by 31 December 2014.

In accordance with the specific provision, the applicant Syngenta submitted an updated dossier, which was evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev.6.1, the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 12 November 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 4 March 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the RMS Spain and presents EFSA's scientific views and conclusions on the individual comments received.

Overall, the information provided within the confirmatory data set was considered not sufficient to address the confirmatory data requirements:

- (a) the risk to pollinators other than honey bees: confirmatory data considered insufficient for foliar spray and seed treatment uses;
- (b) the risk to honey bees foraging in nectar or pollen in succeeding crops: confirmatory data considered insufficient for foliar spray and seed treatment uses;
- (c) the potential uptake via roots to flowering weeds: confirmatory data considered insufficient for foliar spray uses but sufficient for seed treatment uses;
- (d) the risk to honey bees foraging on insect honey dew: confirmatory data considered insufficient for foliar spray and seed treatment uses;
- (e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure: confirmatory data considered insufficient for foliar spray and seed treatment uses;
- (f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure: confirmatory data considered sufficient for seed treatment uses on sugar beet, carrot, indoor uses on brassica but insufficient for potato use;
- (g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen: confirmatory data considered insufficient for seed treatment uses on potato. No specific confirmatory data were provided for the post-flowering applications.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Thiamethoxam was included in Annex I to Directive 91/414/EEC¹ on 1 February 2007 by Commission Directive 2007/6/EC², and has been deemed to be approved under Regulation (EC) No 1107/2009³, in accordance with Commission Implementing Regulation (EU) No 540/2011⁴, as amended by Commission Implementing Regulation (EU) No 541/2011⁵. The peer review leading to the approval of this active substance was finalised in 2006, however EFSA was not involved in that evaluation. Following a request of the European Commission, a specific conclusion was issued by EFSA on 19 December 2012 on the risk assessment for bees as regards the authorised uses applied as seed treatments and granules (EFSA, 2013a).

The specific provisions of the approval were amended by Commission Implementing Regulation (EU) No 485/2013⁶, to restrict the uses of thiamethoxam, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing these active substances to professional users. In particular, the uses as seed treatment and soil treatment of plant protection products containing thiamethoxam have been prohibited for crops attractive to bees and for cereals except for uses in permanent greenhouses and for winter cereals. Foliar treatments with plant protection products containing thiamethoxam have been prohibited for crops attractive to bees and for cereals with the exception of uses in permanent greenhouses and uses after flowering. Furthermore, the European Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees for thiamethoxam, taking into account all uses other than seed treatments and granules, including foliar spray uses as mentioned in recital 7 of Commission Implementing Regulation (EU) No 485/2013. EFSA finalised its conclusion on the risk assessment for bees as regards all uses other than seed treatments and granules on 31 July 2015 (EFSA, 2015a).

It was a specific provision of the amended approval that the applicant was required to submit to the European Commission further ecotoxicological studies by 31 December 2014.

In accordance with the specific provision, the applicant Syngenta submitted an updated dossier, which was evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an addendum to the draft assessment report (Spain, 2015). In compliance with guidance document SANCO 5634/2009-rev.6.1 (European Commission, 2013), the RMS distributed the addendum to Member States, the applicant and EFSA for comments on 12 November 2015. The RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 4 March 2016. EFSA added its scientific views on the specific points raised during the commenting phase in column 4 of the reporting table.

The current report summarises the outcome of the consultation process organised by the RMS, Spain, and presents EFSA's scientific views and conclusions on the individual comments received.

1.2. Interpretation of the Terms of Reference

On 22 December 2014 the European Commission requested EFSA to provide scientific assistance with respect to the risk assessment of confirmatory data following approval of an active substance in

¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p.1-32.

² 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.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

⁴ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.1-186.

⁵ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p.187-188.

⁶ Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances. OJ L 139, 25.5.2013, p 12-26.

accordance with Article 6(1) of Directive 91/414/EEC and Article 6(f) of Regulation (EC) No 1107/2009. EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States, the applicant and EFSA on the risk assessment of confirmatory data for thiamethoxam are presented.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The deadline for providing the finalised report is 2 April 2016.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focused peer review and to provide its conclusions on certain specific points.

2. Assessment

The comments received on the pesticide risk assessment for the active substance thiamethoxam in light of confirmatory data and the conclusions drawn by the EFSA are presented in the format of a reporting table.

The comments received are summarised in column 2 of the reporting table. The RMS' considerations of the comments are provided in column 3, while EFSA's scientific views and conclusions are outlined in column 4 of the table.

The finalised reporting table is provided in Appendix A of this report.

Documentation provided to EFSA

1. Spain, 2015. Addendum to the assessment report on thiamethoxam, confirmatory data, October 2015, revised in March 2016. Available online: www.efsa.europa.eu.
2. Spain, 2016. Reporting table, comments on the pesticide risk assessment for thiamethoxam in light of confirmatory data, March 2016.

References

- EFSA (European Food Safety Authority), 2013a. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. EFSA Journal 2013;11(1):3067, 68 pp. doi:10.2903/j.efsa.2013.3067
- EFSA (European Food Safety Authority), 2013b. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp. doi:10.2903/j.efsa.2013.3295
- EFSA (European Food Safety Authority), 2015a. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam considering all uses other than seed treatments and granules. EFSA Journal 2015;13(8):4212, 70 pp. doi:10.2903/j.efsa.2015.4212
- EFSA (European Food Safety Authority), 2015b. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam, considering all uses other than seed treatments and granules. Available online: www.efsa.europa.eu
- European Commission, 2013. Guidance document on the procedures for submission and assessment of confirmatory information following approval of an active substance in accordance with Regulation (EC) No 1107/2009. SANCO 5634/2009-rev. 6.1

Abbreviations

a.s.	active substance
BBCH	Biologische Bundesanstalt, Bundessortenamt und CHemische Industrie
DAR	draft assessment report
GAP	good agricultural practice
MS	Member State
RMM	risk mitigation measure
RMS	Rapporteur Member State
SPG	specific protection goals
TMX	thiamethoxam

Appendix A – Collation of comments from Member States, applicant and EFSA on the pesticide risk assessment for the active substance thiamethoxam in light of confirmatory data and the conclusions drawn by EFSA on the specific points raised

General comments on overall document and assessment

General				
No.	Column 1 Reference to addendum to assessment report	Column 2 Comments from Member States / applicant / EFSA	Column 3 Evaluation by rapporteur Member State	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data
0 (1)	Confirmatory data addendum, Appendix 1, GAP tables	EFSA: For the representative uses to sugar beet, carrot, onion, broccoli, cabbage, cauliflower, Brussels sprouts, Japanese mustard, mustard, spinach, kale, Tatsoi, endive and lettuce, it would be more complete to indicate whether these crops are harvested before flowering and do not include situations where they are grown for seed production (i.e. when they would flower).	ES: Noted. A footnote is included by RMS in the GAP Table of Appendix 1 and 2 indicating "the crop should be harvested before flowering avoiding situations where they are grown for seed production (i.e. when they would flower)."	Noted. The RMS has updated the GAP table in the revised addendum. However, this should be confirmed by the applicant and Member States where the use of thiamethoxam is authorised for these crops. In the case it is confirmed that the authorised uses are restricted to the listed crops which are harvested before flowering then a low risk to bees can be concluded for the treated crop scenario.
0 (2)	Confirmatory data addendum, Appendix 1, GAP tables	EFSA: Where it is stated that sowing will occur indoors, please can it be confirmed what is meant by indoors? Does it mean a closed building, permanent greenhouse or other type of (semi) protected structure?	ES: In the appendix 2 of the addendum, which corresponds to the GAP included in the doc M of confirmatory data It corresponds to a closed building.	Addressed.
0 (3)		Syngenta: Regulation 485/2013 required submission of confirmatory data for existing uses. However the EFSA Bee Guidance document to rely on to address these data gaps is unadopted. An implementation roadmap has already highlighted some delays in development of detailed guidelines related to large number of the	ES understands the methodological and conceptual difficulties found by Syngenta for addressing the confirmatory data requested by EU Regulation 485/2013. Nevertheless, RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further	Noted.

		confirmatory data request.	information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	
0 (4)	Vol. 3, 9.3. General comment	DE: As no new information was submitted by the applicant, RMS could not evaluate further confirmatory data. Therefore, no detailed commenting is possible.	ES noted.	Noted. However, it should also be noted that some data and argumentation was provided.

Ecotoxicology (B.9)

General

No.	Column 1 Reference to addendum to assessment report	Column 2 Comments from Member States / applicant / EFSA	Column 3 Evaluation by rapporteur Member State	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data
5 (1)	Confirmatory data addendum, Foliar uses, B.9.3.1.1, and Seed treatment uses, B.9.3.1.1, Risk to pollinators other than honey bees	EFSA: No data has been submitted to address the risk to bumble bees and solitary bees.	ES: Due to an editing mistake, the final conclusion regarding the risk to bees other than honey bees was not included in the Addendum. The final Addendum is updated including "as new information is not submitted by applicant, <i>RMS cannot evaluate it and this point remains open</i> "	Point open for foliar spray and seed treatment uses. No information was included in the confirmatory data assessment to address the risk to bumble bees and solitary bees. For situations where exposure cannot be excluded (e.g. via dust drift for crops sown outdoors), the risk assessment remains open.
5 (2)	Confirmatory data addendum, Foliar uses and seed treatment uses, B.9.3.1.2, B.9.3.2.2, Risk to honeybees foraging in nectar and/or pollen in succeeding crops	EFSA: The applicant proposed using the available 4 year studies performed on oilseed rape and maize seed treatments discussed in Pilling et al. (2013) to exclude a risk to honeybees from residues in succeeding crops. However, a number of concerns were identified with these studies in EFSA (2013a): <i>Conclusion on the peer review of the pesticide risk assessment for</i>	ES: The applicant only submitted the paper of the open literature (Pilling et al , 2013) and the EFSA conclusion, 2013 (Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. EFSA Journal 2013; 11(1):3067 [68 pp.]). RMS does not have more information.	Point open for foliar spray and seed treatment uses. No new data were submitted. The risk assessment for the succeeding crop scenario (both foliar spray uses and seed treatments uses) remains open as the study that was submitted is a summary of studies which were considered in the EFSA

bees for the active substance thiamethoxam. EFSA Journal 2013;11(1):3067 [68 pp.].

Furthermore, according to EFSA (2013) it should be checked that the exposure in the studies cover the SPG for exposure. Without an exposure assessment for the succeeding crop scenario this step is not possible.

Please also note that care must be taken to ensure that exposure to metabolite clothianidin in the studies is sufficient to cover exposure to residues in succeeding crops (unless a separate risk assessment addressing the risk from metabolite clothianidin in succeeding crops is available).

RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.

Regarding the confirmatory data to be addressed by Piling et al, (2013) study, under expert`s opinion, the context of evaluating the risk in succeeding crop is to assess the potential exposure of bees through consumption of pollen/nectar and guttation in a crop sown in a field previously cultivated with a crop treated with TMX

Under expert`s opinion the design of Pilling 2013, considering treated maize during 4 consecutive years is a worst **case for exposure** for TMX and its metabolite because of the attractiveness of bees to this crop See comment 5(4) for more information .

With respect to address the point (b) of confirmatory data (*the risk to honey bees foraging in nectar or pollen in succeeding crop*), the experts thinks through more confidential results with a stronger statistical confirmation should be need to assure this risk is considered acceptable.

Consequently, this point remains open

RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be

(2013a) conclusion. The underlying studies that were referred to were not considered sufficient to demonstrate a low risk to honeybees. See also 5(4), 5(5), 5(7), 5(8).

			considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	
5 (3)	Vol. 3, 9.3.1.2	<p>DE: The applicant statement refers to data which were already evaluated. Therefore, the RMS comment may be misleading, that RMS cannot confirm the applicant's statement, as these data have been evaluated in detail before.</p> <p>The RMS comment statement could be considered sufficient as: "no new information submitted".</p>	ES noted The addendum was updated.	<p>Addressed.</p> <p>The RMS included a correction in the updated addendum.</p>
5 (4)	B.9.3.2.2. Risk to honey bees foraging in nectar and/or pollen in succeeding crops	<p>NL: The RMS states that the study is well-designed and conducted as regards long-term effects, but goes on to say that the general weaknesses as put forth by both the study authors and EFSA apply – adequate statistical analysis is not performed, adequate background/control data are not available, etc. Taking that into account, the RMS states that "further information that allow investigating the power of the experiment for identifying differences among treated and control trials would be suitable for assuring lack of adverse effects among them." However, the RMS then concludes that the study represents a worst-case for assessing the succeeding crop scenario. Does this mean that the RMS considers the point addressed?</p>	<p>ES considers the design of the study could be used for assessing the risk in succeeding crops because represents the potential natural aging process in the soil from multi-year uses of maize seeds treated with thiamethoxam.</p> <p>However, the way to treat the results for reaching a conclusion of no-effects could entail uncertainties because of lack of strong statistical analysis.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	Refer to point 5(2).
5 (5)	B.9.3.2.2. Risk to honey bees foraging in nectar and/or pollen in succeeding crops	<p>NL: The study by Pilling showed shorter exposure times than may be expected in reality, due to exposure to multiple fields (exposure for the length of flowering of</p>	<p>ES: Maize is a highly bee attractive crops and hence it can be considered acceptable to cover succeeding crop scenario.</p> <p>Does NL have information on the length of</p>	<p>Refer to point 5(2).</p> <p>It should be noted that maize does not produce nectar. Therefore, whilst it cannot</p>

		one field only – thus ~19 days).	<p>flowering period of different bee attractive crops?</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	be excluded that honeybees forage on maize pollen it is not regarded as a highly attractive crop covering all possible succeeding crops. However, the study (Pilling, 2013) submitted is a summary paper of studies which were previously assessed in the EFSA Conclusion of 2013 (EFSA, 2013a). It was previously concluded that the underlying studies were not sufficient to demonstrate a low risk to honeybees.
5 (6)	Reference list, B.9.3/03	NL: The Pilling study was published in PLoS one in October of 2013 (rather than 2014), as the RMS correctly states in the conclusions.	ES noted. The addendum and RT has been revised	Addressed The RMS updated the addendum.
5 (7)	B.9.3.2.2. Risk to honey bees foraging in nectar and/or pollen in succeeding crops	<p>NL: Isn't the published study by Pilling et. al. a summary of several studies performed for regulatory purposes (we believe that at least the interim reports from which were included in the EFSA conclusion on thiamethoxam)?</p> <p>It seems more appropriate to evaluate/use the EU evaluation(s) of the more complete studies (reports) submitted for regulatory purposes, rather than basing a conclusion on a version created for the public literature and lacking in raw data...</p> <p>Is no final report for all of the studies summarized in this paper available/submitted?</p>	<p>ES: The applicant only submitted the paper of the open literature (Pilling et al, 2013) and the EFSA conclusion (2013). Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. EFSA Journal 2013;11(1):3067 [68 pp.].</p> <p>The RMS has not more information</p> <p>Please refer to comment 5(2) and 5(4)</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	Refer to point 5(2).
5 (8)	Confirmatory data, B.9.3.2.2 and B.9.3.3 b)	FR: Considering the risk to honeybees foraging in nectar/pollen in succeeding crop for foliar uses, FR agrees with RMS conclusion considering that the study (Pilling et al 2013) represents a worst-case for assessing the "succeeding crops"	<p>ES: noted. See point 5(2), 5(4), 5(7)</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information,</p>	Refer to point 5(2).

		scenario even if further information that allow investigating the power of the experiment would be necessary.	submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	
5 (9)	Confirmatory data addendum, Foliar uses, B.9.3.1.3, risk to bees from foraging on weeds in the field. Percentage of weed coverage	EFSA: A SETAC poster (Maynard et al. 2015) is not considered to be suitable scientific evidence to be used in a risk assessment. It is considered that the underlying data and analyses are required to draw conclusions. It is noted that results of the poster included in the addendum (once confirmed) look promising to refine the risk for annual crops .	ES See comment 5(10). Experts inform background doc is also included in the confirmatory data of imidacloprid and clothianidin. RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	Point open for foliar spray uses. The SETAC poster (Maynard et al. 2015) is not considered to be suitable scientific evidence to be used in a risk assessment. See also 5(9), 5(10), 5(11), 5(12)
5 (10)	B.9.3.1.3 Potential uptake via roots to flowering weeds (foliar uses)	Syngenta: The presented poster didn't assessed the amount of thiamethoxam that is taken up by roots of flowering weeds. However, the idea of this overview was to demonstrate that in worst case scenarios (i.e. high weed pressure plots with no other weed control practice) that weeds are not relevant to the 90th%ile exposure scenarios. Methodology followed to produce poster is publicly available at: http://pub.jki.bund.de/index.php/JKA/article/viewFile/5381/5517 A more detailed analysis of the 67000 individual efficacy trial recordings is planned to be published before the end of 2016. This analysis will contain trial site locations, seasons. In such way it can be compared to thiamethoxam GAP.	ES understands completely the meaning of the submitted information by Syngenta which intends to address the point (d) included in the EU Regulation 485/2013 as confirmatory data " <i>the potential uptake via roots to flowering weeds</i> " by demonstrating this scenario is not relevant. The new information submitted by notifier during commenting period corresponds to a proceedings presented at the "12th International Symposium of the ICP-PR Bee Protection Group". As it was already included in the Addendum, for permanent crops , RMS considers that the future analysis mentioned by notifier should include parameters such as the specific crop (not only orchards), trial location, name of weeds species (attractiveness), EU zone, climatic condition, crop BBCH stage, pre-	Refer to 5(9).

			<p>application information....All these data gathered together could be very usefull for refining the risk or for assessing the risk of bees by exposure through flowering weeds in permanent crops.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	
5 (11)	Confirmatory data, B.9.3.1.3	FR: Considering the potential exposure via flowering weeds for foliar uses, applicant refers to a poster presented at SETAC conference in March 2015. Raw data could be provided to RMS to cover uncertainties reported by RMS (description of experimental conditions, details on the permanent crops considered, ect ...)	<p>ES: RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p> <p>please refer to comment 5(10)</p>	Refer to 5(9).
5 (12)	Confirmatory data, B.9.3.1.3 and B.9.3.3 c)	FR: Considering the potential exposure via flowering weeds for foliar uses for permanent crops, risk mitigation to prevent flowering of weeds within the treated crop (i.e., Do not apply when flowering weeds are present/Remove weeds before flowering) could be considered to conclude to an acceptable risk for this route of exposure.	<p>ES noted. However , taking into account EFSA (2015) EFSA Journal 2015;13(8):4212:</p> <p><i>It is important to note that the removal of the flowering weeds would need to be continued for the whole season to prevent residues in pollen and nectar in newly emerged flowers. It has also to be noted that the recommendation 'remove weeds before flowering' is likely to have undesired side effects such as removing a source of nectar and pollen, which in turn may impact on honeybees, solitary bees and bumble bees.</i></p>	<p>Noted</p> <p>Risk mitigation to remove all flowering weeds is a possibility and was discussed in the previous conclusions EFSA (2013a) and EFSA (2015a).</p>

5 (13)	Confirmatory data addendum, Foliar uses, B.9.3.1.4, and Seed treatment uses, B.9.3.2.4, Risk to bees from foraging on insect honeydew	EFSA: It is noted that the EFSA Guidance Document (EFSA, 2013b) could not propose a risk assessment scheme to cover the risk from bees foraging in insect honeydew as there are too many uncertainties regarding exposure via this route. Although no risk assessment scheme is available, for substances which show high toxicity to bees, it is considered that it should be checked that the risk assessment for other exposure routes are likely to cover the risk from insect honeydew (e.g. in the case that exposure from pollen/nectar is totally excluded).	ES Noted . Experts have not found further information with respect this. RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation. Please refer to comment 5(14)	Refer to 5(14).
5 (14)	Vol. 3, 9.3.1.4.	DE: Several crops are known to produce honey dew, which are relevant to bees given that high numbers of aphids develop. In our conditions, these are namely potato and winter cereals. So far, no relevant honey dew production -in spite of high numbers (but a different species of) aphids- have been reported in sugar beets, and also leafy vegetables. We consider honey dew as a relevant route, especially if already relevant amounts of aphids (higher numbers of aphids which produce considerable amounts of honey dew) and honey dew are present, which is confirmed by incident reports. Without any doubt, any thiamethoxam-containing formulations can be considered to pose a risk. On the other hand, risk assessment cannot be performed without link to risk management. For other highly toxic substances, (including Clothianidin, Metamidophos) the use of risk mitigation measures has proven to be an applicable measure. Furthermore, e.g. in seed potatoes (high number of insecticide	ES appreciates the comments of Germany. No information was submitted by the notifier with respect the relevance of honey dew in these crops. Therefore RMS cannot evaluate it and conclude. On the other hand, the experts have concerns on its effectiveness considering that the proposal is increasing the use of other insecticides. RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	Point open Further information is needed to address the risk to bees from foraging on insect honeydew. It is noted that the EFSA Guidance Document (EFSA, 2013b) could not propose a risk assessment scheme to cover the risk from bees foraging in insect honeydew as there are too many uncertainties regarding exposure via this route. Although no risk assessment scheme is available, for substances which show high toxicity to bees, it is considered that it should be checked that the risk assessment for other exposure routes are likely to cover the risk from insect honeydew (e.g. in the case that exposure from pollen/nectar is totally excluded).

		applications to avoid aphid-induced plant viruses) no such build-up of aphids occurs. Therefore, in the argumentation the potential differences in exposure between seed treatments and spray applications could be considered.		
5 (15)	Confirmatory data addendum, Foliar uses, B.9.3.1.7, Risk to bees from exposure to residues in pollen and nectar	<p>EFSA:</p> <p>i) Please see EFSA comment in the GAP table requesting confirmation that a number of the representative uses are to plants which will be harvested before flowering.</p> <p>ii) It is noted that according to the EFSA (2013) guidance document, it cannot be totally excluded that bees may forage on potatoes, tomatoes and aubergines for pollen. It is also noted that data were provided by Denmark during the Pesticides Peer Review Expert Meeting 129 (March, 2015) indicating that honeybees collect pollen from potatoes (Thiamethoxam Peer Review Report, EFSA, 2015). .</p> <p>iii) EFSA (2013) guidance document indicates that peppers are attractive to bees for both pollen and nectar.</p> <p>iv) EFSA (2013) guidance document indicates that tobacco plants are attractive to honeybees for pollen and could not be excluded to be attractive for bumble bees and solitary bees.</p>	<p>ES:</p> <p>i) Addendum updated</p> <p>ii) to iv) Noted . However, The current confirmatory data were generated based on the EU implementing Regulation 485/2013, in which all these crops were not considered as attractive crop to bees.</p> <p>EFSA GD has not been adopted already by the Standing Committee</p> <p>Further RMM could be considered at MS level</p>	<p>Point open</p> <p>Further information is needed to address the risk to bees foraging on pollen/nectar for the representative uses on potatoes, tomatoes, aubergines, peppers and tobacco.</p> <p>The EFSA Guidance Document (EFSA, 2013b) indicates that it cannot be totally excluded that bees may forage on potatoes, tomatoes and aubergines for pollen. It is also noted that data were provided by Denmark during the Pesticides Peer Review Expert Meeting 129 (March, 2015) indicating that honeybees collect pollen from potatoes (Thiamethoxam Peer Review Report, EFSA, 2015b).</p> <p>EFSA Guidance Document (EFSA, 2013b) indicates that peppers are attractive to bees for both pollen and nectar.</p> <p>EFSA Guidance Document (EFSA, 2013b) indicates that tobacco plants are attractive to honeybees for pollen and could not be excluded to be attractive for bumble bees and solitary bees.</p>
5 (16)	B.9.3.2.1 Risk to pollinators other than honey bees (seed treatment uses)	<p>Syngenta:</p> <p>Syngenta submitted at EFSA Data Call-In in September 2015, new data on effects on Osmia in field from oilseed rape seed</p>	<p>ES Noted RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further</p>	<p>Noted.</p> <p>Only data submitted as confirmatory data package can be considered within this procedure.</p>

		<p>treated with thiamethoxam.CEH submitted at EFSA Data Call-In in September 2015 an interim report of 3 field studies conducted in 2015 in Germany:</p> <ul style="list-style-type: none"> - <i>Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) - A Field Study to Evaluate Side Effects on Red Mason Bees (Osmia bicornis L.) in Winter Oil Seed Rape in Germany (Tübingen – S15-01803) - interim report</i> - <i>Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) - A Field Study to Evaluate Side Effects on Red Mason Bees (Osmia bicornis L.) in Winter Oil Seed Rape in Germany (Niefern – S15-01802) - interim report</i> - <i>Thiamethoxam/Metalaxyl-M/Fludioxonil FS (A9807F) - A Field Study to Evaluate Side Effects on Red Mason Bees (Osmia bicornis L.) in Winter Oil Seed Rape in Germany (Celle – S15-01804) - interim report</i> 	<p>information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	
5 (17)	Confirmatory data addendum, Seed treatment uses, B.9.3.2.3, risk to bees from foraging on weeds in the field.	<p>EFSA: It is noted that the EFSA Guidance Document (EFSA, 2013b) indicates that a risk assessment for weeds within the field is not necessary for seed treatment uses. As such, it is agreed that no further data and risk assessment are considered necessary for this scenario.</p>	ES noted	<p>Point closed for the seed treatments</p> <p>EFSA Guidance Document (EFSA, 2013b) indicates that a risk assessment for weeds within the field is not necessary for seed treatment uses.</p>
5 (18)	Vol. 3, 9.3.2.4	<p>DE: RMS concludes that it cannot support the assumption and argumentation of the applicant that the residues in guttation liquid are comparable to xylem sap or concentrations in leaf homogenates.</p> <p>If such comparability was demonstrated, what would be the conclusion of the RMS on susceptibility of aphids compared to bees?</p>	<p>ES: The comparability was not demonstrated in the confirmatory data dossier. Therefore, RMS cannot conclude.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	<p>Addressed</p> <p>The risk to bees from foraging on insect honeydew and guttation fluid is not considered comparable.</p>

<p>5 (19)</p>	<p>Confirmatory data addendum, seed treatment uses, B.9.3.2.5, Risk to honey bees via guttation fluid, Kriszan (2012) (S10-01275)</p>	<p>EFSA: The level of detail in the study summary is not sufficient to transparently evaluate the study and the proposed conclusions. However, on the basis of what is presented the following points/questions are noted:</p> <ul style="list-style-type: none"> i) Distance between treatment and control fields? ii) Where the conclusions reached on the basis of consideration of individual hives or were the results combined? iii) Was a survey of surrounding crops and water sources performed? Over what distance? What were the results? iv) It would be very helpful if the results were presented in a manner which allows for comparison to the effect SPG in the EFSA Bee Guidance Document (i.e. for forager mortality and effects on the colony). vi) Was there statistical analysis performed on the effects data? If so, what is the statistical power of the study? v) Residue analysis results were mentioned but the details are not provided. It would be very helpful if they were presented in sufficient detail to compare/assess against the exposure SPG in the EFSA bee GD. It is noted that the RMS has stated that the accompanying residue analysis study was not submitted. vi) Please include sufficient detail of the analytical methods to ensure that the methods are appropriate. vii) The study summary has missed indicating whether the study was performed to GLP. 	<p>ES has amended the Addendum including a widespread summary of the study (Kriszan, 2012).</p> <ul style="list-style-type: none"> i) Regarding to the distance among treatment and control, no specific information was not found in the original study. ii) The conclusion of mortalities was reached based on both, individual and combined hives. iii) The major abundant flowering weeds and open water sources were recorded in the surrounding of a 300 m distance from field trials (controls and treatments). iv) No statistical analysis was performed v) the detailed results of the residue analysis are reported in a separate study (S11-03046). RMS does not have access to this study vi) It is a non-GLP report. <p>RMS informs that in the interim report No summary tables and figures were included and no further information was given in doc M of CD package.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of</p>	<p>Addressed</p> <p>The RMS has included additional information in the study summary in the revised addendum. It is noted that the accompanying residue analysis report has not been provided as part of the confirmatory data assessment.</p> <p>It has to be noted that in this study guttation of maize seedlings is assessed. Therefore any results from this study cannot be extrapolated to other crops (i.e. to the current approved uses). Furthermore, the design, methodology and results of this study should be considered further together with the results of the other available field studies investigating the potential effects of exposure to honeybees to residues in maize guttation fluid which were already considered in the EFSA (2013a) conclusion.</p> <p>See point 5(21)</p>
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5 (20)	Confirmatory data addendum, seed treatment uses, B.9.3.2.5, Risk to honey bees via guttation fluid, Kriszan (20112) (S10-01275)	EFSA: It is noted that additional studies regarding the effects of exposure to guttation fluid in maize were considered in EFSA (2013). Ideally the results of all the available data should be considered together.	ES: Please refer to comment 5(22)	Refer to 5(19).
5 (21)	Confirmatory data addendum, seed treatment uses, B.9.3.2.5, Risk to honey bees via guttation fluid, conclusion of the RMS	EFSA: It is agreed that the risk assessment for bees from exposure to guttation fluid cannot be finalised with the available information.	ES Noted. Please refer to comment 5(22)	<p>Point open</p> <p>It is agreed that the risk assessment for bees from exposure to guttation fluid cannot be finalised with the available information for the approved uses.</p>
5 (22)	B.9.3.2.5 Risk to honey bee from exposure via guttation fluid	<p>Syngenta:</p> <p>The monitoring of potential effects on honeybees of drilling thiamethoxam treated maize seeds is a complementary study to 3 studies assessed during first EFSA review (EFSA Journal 2013;11(1):3067). (Kriszan (2012) S10-01857, S10-01859 and S10-01860). The monitoring study was conducted at the same time period and in the same region as the 3 studies already reviewed by EFSA in 2013.</p> <p>Commercial seed lots were used for the monitoring on 19 treatment sites with total planted surface of 65.6 ha. The amount of seeds required was closed to 2 metric tons.</p>	<p>ES would indicate that this information was not included in the dossier and data package that Syngenta submitted to ES and consequently was not taking into account.</p> <p>RMS informs that according to article 13(3) of Regulation 1107/2009 no further data will be evaluated in the framework of confirmatory data.</p> <p>ES: remembers this study was submitted by addressing the point <i>(e) the potential guttation exposure and the acute and long-term risk to colony survival and development, and the risk to bee brood</i></p>	Refer to 5(19).

		<p>It was impossible to arrange GLP certification for all seed lots used on 19 treatment sites. Registered rate in France was 0.63 mg TMX/seed.</p> <p>The detailed results of the residue analysis in dead bees can be submitted anytime.</p>	<p><i>resulting from such exposure.</i> The potential effects on honeybees produced by the exposure to dust drift by sowing maize seeds treated with thiamethoxam, is not in the scope of current confirmatory data evaluation because the use of treated maize seeds with thiamethoxam are currently forbidden by EU Implementing Regulation 485/2013. Consequently, confirmatory data for this use were not required by the European Commission and it was not submitted by Syngenta.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	
5 (23)	Vol. 3, 9.3.2.5	<p>DE: It is concluded: RMS considers that the number of honey bees observed in this study collecting guttation is low. However, the presence of other natural water sources within the foraging radius of the honey bees could be an explanation of this.</p> <p>From our point of view and on the basis of own research data, it can be rarely observed that single bees will visit plants for collection of guttation droplets. If bees use them (e.g. in forced conditions), high mortality will occur (see Frommberger et al., 2012), which would be a detectable incident. To our knowledge, no incidents with a suspected or obvious link to higher mortalities were ever observed (at least none ever proven in DE).</p> <p>Regardless of the evaluation of the</p>	ES: please refer to commnet 5(22)	Refer to 5(19) and 5(21).

		<p>substance thiamethoxam, we would like to mention that also in our trials with very dry conditions and no other water sources nearby, the number of honey bees that could be observed was always very low. We suggest not using counts of individuals as a quantitative measure in determining exposure of bees.</p> <p>The applicant's conclusion may therefore be also an over-interpretation, as it seems honey bees just do not use guttation droplets frequently, even if guttation is there and bees are active.</p>		
5 (24)	Vol. 3, 9.3.2.5, p. 30	DE: Please check the citation of Joachimsmeier et al. for typos.	ES: Checked and addendum updated	Addressed. The RMS updated the citation in the revised addendum.
5 (25)	Confirmatory data addendum, seed treatment uses, B.9.3.2.6, Risk to honeybees from exposure to dust , Interim report – Investigating the dust deposition during the sowing of seed treated sugar beet seeds.....	EFSA: It is noted that only an interim report of this study is available. Furthermore, more details of the chemical analysis are needed.	<p>ES: No information available in the confirmatory data dossier. Details cannot be included. Please see comment 5(30)</p> <p>The samples were analysed for residues of COMPOUND-SB at SGS INSTITUT FRESENIUS GmbH in Taunusstein, Germany in compliance with the OECD principles of Good Laboratory Practice.</p> <p>The interim report includes the following statement "<i>Details of the analysis, such as reference items, used equipment and chemicals are documented in the raw data and will be described in the final analytical phase report</i>".</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of</p>	Please refer to 5(26).

			confirmatory data evaluation.	
5 (26)	Confirmatory data addendum, seed treatment uses, B.9.3.2.6, Risk to honeybees from exposure to dust , RMS conclusion for sugar beet	EFSA: It is correct that it was previously concluded a low risk to honeybees from exposure via dust drift generated during the sowing of sugar beet. This conclusion is also in line with appendix C of the EFSA Guidance Document (EFSA, 2013b).	ES Noted.	Point closed for seed treatment uses to sugar beet. A low risk to bees from exposure via dust drift during the sowing of sugar beet can be concluded.
5 (27)	Confirmatory data addendum, seed treatment uses, B.9.3.2.6, Risk to honeybees from exposure to dust , RMS conclusion for carrot	EFSA: It is noted that appendix C of the EFSA Guidance Document (EFSA, 2013b) indicates that a risk assessment for dust drift during the sowing of carrots is not relevant. However, if the applicant wishes to provide the underlying reports mentioned in their statement regarding the quality of the seed coating, this would help provide additional certainty in reaching the conclusion of low risk.	ES noted. RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	Point closed for seed treatment uses to carrots. A low risk to bees from exposure via dust drift during the sowing of carrots can be concluded providing that the seed coating is of high quality.
5 (28)	Confirmatory data addendum, seed treatment uses, B.9.3.2.6, Risk to honeybees from exposure to dust , RMS conclusion for brassicas	EFSA: Please refer to the EFSA comment regarding the 'glasshouse uses' in the GAP table. If it is confirmed that sowing will occur only in permanent greenhouses or indoors (i.e. closed systems), then it would be agreed that no risk assessment for dust drift during the sowing of the seed is needed.	ES agrees. The addendum is updated considering this comment.	Point closed for indoor seed treatment uses to broccoli, Brussels sprouts, head cabbage, kale, cauliflower, endive and lettuce. A low risk to bees from exposure via dust drift for crops which are sown indoors can be concluded.
5 (29)	Confirmatory data addendum, seed treatment uses, B.9.3.2.6, Risk to honeybees from exposure to dust , RMS conclusion for potatoes	EFSA: EFSA agree with the RMS that evidence is needed to support the applicants statement that there is no dust drift during the sowing of potatoes. It is noted that the sowing of potatoes is different to other seed types.	ES: Please see comment 5(32) RMS informs that according to article 13(3) of Regulation 1107/2009 no further data will be evaluated in the framework of confirmatory data.	Point open for the seed treatment use to potatoes. No evidence was provided to support the applicant's statement that there is no dust drift during the sowing of potatoes. It is noted that the sowing of potatoes is different to other crop types.
5 (30)	B.9.3.2.6 Risk to honey bee from exposure to dust Sugar beet	Syngenta: Final report of dust deposition during sowing of sugar beet treated seeds has been released in December 2015 (Reference: <i>COMPOUND-SB - Investigating</i>	ES Noted In the interim report submitted by Syngenta is highlighted:	Noted. Please refer to 5(26).

		<p><i>the dust deposition during sowing of seed-treated sugar beet seeds with mechanical and pneumatic sowing machinery during 2014 and 2015.</i></p> <p><i>CGA173506_11884).</i></p> <p>The final report includes 4 trials conducted with mechanical drillers and 2 trials with pneumatic drillers. This report has been submitted to UBA on December 23rd, 2015. UBA will assess this report in the light of revised dust risk assessment for seed treatment.</p>	<p><i>SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, 65232 Taunusstein, Germany will archive the following documents under GLP conditions:</i></p> <ul style="list-style-type: none"> <i>• the original of the study plan and all amendments to the study plan;</i> <i>• the original raw data of field phase;</i> <i>• the original raw data of the analytical phase;</i> <i>• the original raw data of soil characterisation phase;</i> <i>• the original of the report(s) of the soil characterisation phase;</i> <i>• the original of the interim report; and</i> <i>• the original of the final report including the original of the final analytical phase report as appendix</i> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	
5 (31)	B.9.3.2.6 Risk to honey bee from exposure to dust carrot	<p>Syngenta:</p> <p>Syngenta collected quality control results from the only carrot seed processing company for Belgian market. All batches for 2014-2015 campaign have monitored for dustiness. The results are only presented as a spreadsheet with batch references, Heubach values and thousand grain weight. This processing company is certified according to ESTA. ESTA certification includes a validation of Heubach measurement. Reported values should be considered even if supporting</p>	<p>ES considers it is need a convincing argumentation to support the dustiness of carrots seeds. In the opinion of the evaluators, an excel sheet without further explanation is not the way to address a confirmatory data required by EU Implementing Regulation 485/2013.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be</p>	<p>Refer to 5(27).</p> <p>Whilst the comment of the RMS is agreed a low risk to bees from exposure via dust drift during the sowing of carrot seeds can be concluded on the basis of the EFSA Guidance Document (EFSA, 2013b) (for high quality seed coating). Therefore, this information is not needed.</p>

		documentation is light.	considered by RMS in the context of confirmatory data evaluation.	
5 (32)	B.9.3.2.6 Risk to honey bee from exposure to dust Brassica and lettuce	Syngenta: Annex I to Appendix VI in Draft guidance on seed treatment SANCO10553_2012rev0(mar2012) quotes Representative coating practice and conditions of use of coated seeds within the EU. Lettuce and brassica: All these crops are only sown and raised to young plants indoors, later transplanted indoors or outdoors. Therefore exposure to dust is not relevant for these crops.	ES: please see comment 5(25)	Refer to 5(28). The GAP has indicated that these crops are sown indoors and therefore exposure to bees via dust drift can be excluded.
5 (33)	Vol. 3, 9.3.2.6	DE: We agree with the conclusions of the RMS. However, is it possible to give Heubach g as/100.000 seeds in addition to the nominal loading of e.g. 90 g as/100.000 seeds? In our point of view, only the Heubach as/ha allows comparability between different seed batches and to compare the seeds used in individual trials to qualities available on the market, which is in our opinion an essential prerequisite for the evaluation of side effects of dusts. However, our comment seems to be more of general relevance. For the seed treatment and route of exposure evaluated here we agree with the RMS conclusion, who considers the risk to honey bees from exposure to dust produced during drilling of treated sugar beet as acceptable.	ES Noted Please refer to comment 5(31) RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.	Refer to 5(26).
5 (34)	Vol. 3, 9.3.2.6	DE: For Brassica and Lettuce no new data were submitted, but applicant's statement considered valid and acceptable regarding formation of dust drift and risk as the crops are raised in greenhouse.	ES: please see comment 5(25)	Refer to 5(28). The GAP has indicated that these crops are sown indoors and therefore exposure to bees via dust drift can be excluded.

5 (35)	Vol. 3, 9.3.2.6	DE: For potato seed treatment, the issue is unlikely to be reflected by dust drift at all, as the treatment is a liquid, which is sprayed on tubers. If considered relevant, drift should be evaluated accordingly to spray drift but not to dust drift.	ES believes the exposure by drift when potatoes treated with PPPs containing thiamethoxam are sown should be considered. The exposure to bees during the sown may be not by dust, but a exposure by drift produced during the sowing of treated seeds (potatoes) is likely to happen. This kind of exposure should be evaluated. In the opinion of RMS, this evaluation can be included in this point (dust drift) attending to similarities among exposures since both are exposures by drift during sowing (by dust or not by dust)	Refer to 5(29).
5 (36)	Confirmatory data, B.9.3.2.6	FR: Considering the risk to honeybees from exposure to dust for brassicas and lettuce, FR considered that if brassica and lettuce seeds are raised to plantes in greenhouses and then transplanted in field there is no dust formation at transplanting of such crops. Therefore, risk could be considered acceptable for this route of exposure for these crops.	ES: please see comment 5(25)	Refer to 5(28).
5 (37)	Confirmatory data addendum, Seed treatment uses, B.9.3.2.7 Conclusion of the RMS for the risk to honeybees from residues in pollen and nectar – carrots and sugar beet	EFSA: It is agreed that there is a low risk to bees from residues in pollen and nectar from the treated crop for those crops which are harvested before flowering. However, it should be confirmed that the authorised uses are restricted to seeds where the plants are harvested before flowering and not when the crop is grown for seed production (i.e. when they allowed to flower).	Please see comment 0(1)	Refer to 0(1).
5 (38)	Confirmatory data addendum, Seed treatment uses, B.9.3.2.7 Conclusion of the RMS for the risk to honeybees from residues in pollen and	EFSA: It should be noted that in the EFSA Bee guidance document it is indicated that it could not be excluded that honeybees will take pollen from potatoes. Furthermore, data were provided by Denmark during the Pesticides Peer Review	ES Noted. However, the current confirmatory data were generated based on the EU implementing Regulation 485/2013, in which potatoes are not considered as attractive crop to bees. ES understands Syngenta has used this	Point open for seed treatment uses to potatoes Further information is needed to address the risk to bees foraging on pollen/ for the representative uses to potatoes.

	nectar - potatoes	Expert Meeting 129 (March, 2015) indicating that honeybees collect pollen from potatoes (Thiamethoxam Peer Review Report, EFSA, 2015).	<p>rationale for addressing the confirmatory data.</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	<p>The EFSA Guidance Document (EFSA, 2013b) indicates that it cannot be totally excluded that bees may forage on potatoes for pollen. It is also noted that data were provided by Denmark during the Pesticides Peer Review Expert Meeting 129 (March, 2015) indicating that honeybees collect pollen from potatoes (Thiamethoxam Peer Review Report, EFSA, 2015b).</p> <p>It has also to be noted that in the EFSA conclusion on thiamethoxam (EFSA, 2013a), on the basis of the information available, potato crop was considered not attractive to for pollen and nectar for honeybees.</p>
5 (39)	B.9.3.2.7 Risk to honey bee from exposure to contaminated nectar and pollen	NL: The NL considers potatoes to be attractive to honey bees, as well, based on data from Denmark indicating the relatively high percentage of potato pollen in hives in locations where (known) highly bee attractive crops were also available for foraging, as well as upon a literature analysis from WUR.	<p>Please see comment 5(38)</p> <p>RMS is of the opinion that the information submitted in framework of article 13(3) of the Regulation 1107/2009 shall be considered and no further information, submitted under other procedures, will be considered by RMS in the context of confirmatory data evaluation.</p>	Refer to 5(38).