TECHNICAL REPORT

APPROVED: 27 July 2018

doi:10.2903/sp.efsa.2018.EN-1474

Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for sulfoxaflor 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 sulfoxaflor are presented. The current report summarises the outcome of the consultation process organised by the co-rapporteur Member State Czech Republic and presents EFSA's scientific views and conclusions on the individual comments received.

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

Requestor: European Commission

Question number: EFSA-Q-2018-00534

Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for sulfoxaflor in light of confirmatory data. EFSA supporting publication 2018:EN-1474. 73 pp. doi:10.2903/sp.efsa.2018.EN-1474

ISSN: 2397-8325

Summary

Sulfoxaflor was approved in accordance with Regulation (EU) No 1107/2009 on 29 July 2015 by Commission Implementing Regulation (EU) No 2015/1295, amending the Annex to Commission Implementing Regulation (EU) No 540/2011. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on:

(a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;

(b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;

(c) the risk to pollinators other than honey bees;

(d) the risk to bee brood.

by 18 August 2017.

In accordance with the specific provision, the applicant, Dow AgroSciences, submitted an updated dossier to the rapporteur Member State (RMS) Ireland, in August 2017. The updated dossier was evaluated by the designated co-rapporteur Member State (co-RMS), Czech Republic, on behalf of Ireland, in the form of an addendum to the draft assessment report. In compliance with guidance document SANCO 5634/2009-rev.6.1, the co-RMS distributed the addendum to Member States, the applicant and EFSA for comments on 12 March 2018. The co-RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 July 2018. 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 co-RMS, Czech Republic, and presents EFSA's scientific views and conclusions on the individual comments received.

The risk assessment for bees has been amended considering the newly available laboratory and higher tier studies. Following the recommendations of the Pesticide Peer Review Meeting 133 (EFSA 2015), the co-RMS evaluated the higher tier studies in light of the issues raised in EFSA PPR Panel (2012) and EFSA (2013). It is noted that the tier 1 risk assessment according to the SANCO guidance remains unchanged compared to the previous conclusions reached during the peer review of the risk assessment of sulfoxaflor in 2014. The assessment of the higher tier studies made use of the latest state of the knowledge on the topic, without diverging from the SANCO guidance recommendations. The risk assessment included some novel refinement steps on which divergent views were expressed by Member States during the commenting phase. Different opinions were also expressed in relation to the interpretation and the use of the available higher tier studies and as regards the consideration of risk mitigation measures for the use of sulfoxaflor. Based on the data assessed, a low risk could not be demonstrated for honeybees and non-Aphis bees as a result of the current assessments (points a – d).

Several issues were identified which would need further consideration and Member States experts' consultation.

Table of contents

1. Introduction

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

Sulfoxaflor was approved in accordance with Regulation (EC) No 1107/2009[1], on 29 July 2015 by Commission Implementing Regulation (EU) No 2015/1295[2], amending the Annex to Commission Implementing Regulation (EU) No 540/2011[3]. It was a specific provision of the approval that the applicant was required to submit to the European Commission further studies on:

(a) the risk to honey bees via the different routes of exposure, in particular nectar, pollen, guttation fluid and dust;

(b) risk to honey bees foraging in nectar or pollen in succeeding crops and flowering weeds;

(c) the risk to pollinators other than honey bees;

(d) the risk to bee brood.

by 18 August 2017.

In accordance with the specific provision, the applicant, Dow AgroSciences, submitted an updated dossier to the rapporteur Member State (RMS) Ireland, in August 2017. The updated dossier was evaluated by the designated co-rapporteur Member State (co-RMS), Czech Republic, on behalf of Ireland, in the form of an addendum to the draft assessment report (Czech Republic, 2018a). In compliance with guidance document SANCO 5634/2009-rev.6.1 (European Commission, 2013), the co-RMS distributed the addendum to Member States, the applicant and the EFSA for comments on 12 March 2018. The co-RMS collated all comments in the format of a reporting table, which was submitted to EFSA on 2 July 2018 (Czech Republic, 2018b). 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 co-RMS, Czech Republic, 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 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 sulfoxaflor 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 30 July 2018.

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.

[1] 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.

[2] Commission Implementing Regulation (EU) 2015/1295 of 27 July 2015 approving the active substance sulfoxaflor, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.OJ L 199, 29.7.2015, p. 8–11.

[3] 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.

2. Assessment

The comments received on the pesticide risk assessment for the active substance sulfoxaflor 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 co-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. Czech Republic, 2018a. Addendum to the assessment report on sulfoxaflor, confirmatory data, March 2018, as revised in July 2018. Available online: www.efsa.europa.eu.

2. Czech Republic, 2018b. Reporting table, comments on the pesticide risk assessment for sulfoxaflor in light of confirmatory data, July 2018.

References

European Commission, 2002. Guidance Document on terrestrial ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final. 17 October 2002.

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

EFSA (European Food Safety Authority), 2013. 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. https://doi.org/10.2903/j.efsa.2013.3295

EFSA (European Food Safety Authority), 2014a. Conclusion on the peer review of the pesticide risk assessment of the active substance sulfoxaflor. EFSA Journal 2014;12(5):3692, 170 pp. doi: 10.2903/j.efsa.2014.3692

EFSA (European Food Safety Authority), 2014b. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance sulfoxaflor. Available at www.efsa.europa.eu

EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA Supporting Publication 2015; 12(12):EN-924. 62 pp. doi: 10.2903/sp.efsa.2015.EN-924

EFSA (European Food Safety Authority), 2016a. Conclusion on the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted. EFSA Journal 2016;14(11):4606, 34 pp. doi: 10.2903/j.efsa.2016.4606

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted. EFSA Journal 2016;14(11):4607, 39 pp. doi: 10.2903/j.efsa.2016.4607.

EPPO (2010) EPPO Standards PP 3/10 (3) Environmental risk assessment for plant protection products. Chapter 10: honey bees. Bulletin OEPP/EPPO Bulletin40, 323–331

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2006. Guidance document on estimating persistence and degradation kinetics from environmental fate studies. Sanco/10058/2005, version 2.0, June 2006.

FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use), 2014. Generic Guidance for estimating persistence and degradation kinetics from environmental fate studies. Referring to Sanco/10058/2005, 18 December 2014.

OECD, 2007. Guidance Document on the honey bee (*Apis mellifera*) brood test under semi-field conditions. ENV/JM/MONO(2007)22. 31 August 2007

OECD, 2016. Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure Series on Testing & Assessment No. 239. ENV/JM/MONO(2016)34.

Abbreviations

a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
DAR	draft assessment report
GAP	good agricultural practice
DT50	period required for 50% dissipation (define method of estimation)
ETR	exposure toxicity ratio
EU	European Union
HQ	hazard quotient
MS	Member State
NOEC	no observed effect concentration
OSR	oilseed rape
PEC	predicted environmental concentration
PEC_{sw}	predicted environmental concentration in surface water
RMS	rapporteur Member State
RUD	residue per unit dose
SV	shortcut value
TMDI	theoretical maximum daily intake
TWA	time-weighted average

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

1. Ecotoxicology

Confirmatory Information (bees) Addendum to B.9

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
(1)	Addendum to B.9, Confirmatory data (bees), LoEP	EFSA: Two of the toxicity values for the chronic test are accompanied with a '*' with no explanation. Could you please add or remove the '*' marks?	Co-RMS CZ: The marks will be removed.	Addressed
(2)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, larval test	EFSA: Uneaten food was recorded for some of the test concentrations. Was there some estimation for what were the proportions of the uneaten food?	Co-RMS CZ: Only the presence of uneaten food was qualitatively recorded on day 8 and number of alive larvae with uneaten food is given for each replicate in the study report. But no information on proportion of uneaten food is available.	Addressed Explanation provided under column 3
(3)	3	EFSA: A number of residue trials on 4 different crops were available. These tests provided information on residue levels in pollen and nectar and residue decline in these matrixes. After some assessments, co-RMS has decided that the initial residue levels will not be used, but the residue decline data can be used in exposure	Co-RMS CZ: Assessment using the residue decline data in qualitative way can be included into addendum by Co-RMS.	The approach used to refine the exposure assessment by using measured residue decline data endpoints to be used for risk assessment should be further discussed and agreed in an experts' meeting

Confirmatory Information (bees) Addendum to B.9				
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**
		refinements (which approach is agreed) and Tier 2 risk assessments were conducted accordingly. The residue decline data had been checked and several cases, e.g. were only 3 data points were available or the fit was regarded as too poor, had been excluded. For the remaining cases, DT50 values were derived and considering of the uncertainties of the available data set, worst case values were considered in the refined assessments for the representative uses (i.e. DT50 of 1.487 d for pollen from a strawberry trial and 1.337 d for nectar from a pumpkin trial). It is further noted that in the case of those trials where DT50 values were derived, only 4 data points were available and in many cases there were some rain events during the trial. In other cases there was no proper information on the weather. Using the residue decline data in qualitative rather than quantitative way may be considered as an option (e.g. considering the sampling time of the samples where the residue levels were clearly below the half of		Considering that the use of residue decline in pollen and nectar is a novel way of refinement (i.e. Tier 2), divergent considerations were raised during the written consultation with Member States regarding this approach. Due to the considerable uncertainties, an experts' discussion is therefore proposed. Nevertheless, it is also noted that the available data and information indicate that the refinement step will unlikely result in a low risk conclusion under these cases. See also comments (47), (48), (66), (67), (68), (69), (78) and (91).

Confirmatory Information (bees) Addendum to B.9				
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**
		the initial level).		
(4)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, ix), Cage test by Renz, D.; 2017	EFSA: A semi-field study on phacelia was undertaken with the application rate of 24 and 48 g/ha (±10%). The application was in the evening, after bee flight. There was evidence for a reasonable exposure of the bees (flight intensity, weather conditions, residues, results of the reference group). There were 6 replicates, the sizes of the cages were cca. 100m2 and an intensive observation regime was undertaken with novel parameters (i.e. the study design was more robust than a classical EPPO 170 study). The exposure period was a week followed by a post observation in a monitoring site. It is however noted that the hives were supplied with sucrose solutions 3 times, first on day 14 after the application. It is also noted that the nutrition status of T2 was considered as better than of the control (page 113). It is also noted that equalisation for pollen stores was done before the exposure. Please clarify if the residues from the phacelia plant as reported on page 130 are referring to pollen or nectar.	Co-RMS CZ: It is stated in the study report that some individual hives had very low levels of nectar after installation at the monitoring site and were at risk of starving, therefore moderate feeding of all hives was done on 14DAA2. The second feeding was done on 35DAA2 in preparation of the first treatment against *Varroa* mites and to prevent the risk of starving in some hives. The third feeding was done on 63DAA2 to prepare the colonies for overwintering according to good beekeeping practice. All these feeding were done to prevent starvation and they are considered justifiable. Regarding the residues from the Phacelia plants, the whole Phacelia plants were used for analysis of residues of sulfoxaflor.	Addressed Explanation provided under Column 3. See also comment (28).

Confirmatory Information (bees) Addendum to B.9				
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)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, ix), Cage test by Renz, D.; 2017	EFSA: According to the co-RMS, the worker mortality was slightly increased when compared with the initial colony size. However, the mortality in the treated groups should be compared with the mortality in the control. This indicates a very clear initial effect on that parameter. Sublethal effects were also observed on a considerable number of bees. It is agreed that there was an effect on the flight activity. As regards colony strengths, it is agreed that large, apparent (or statistically significant) effect had not happened, however some small effects cannot be excluded (according to the figure on page 111, T1 and T2 on average had smaller population till 14 days after application of the control; that difference is larger than the difference before the application). An unexpected high termination rate was observed for eggs and young larvae (page 113, and figures on page 115 and 118) for C and T groups (1rst brood cycle). This high brood mortality indicates some (unknown?) condition which impacted a normal development for these	Co-RMS CZ: In the first place, mortality in the treatment and reference groups was compared to control. If necessary, the sentence on comparison to the initial colony size will be removed. As regards colony strength, the variance in control is quite large and it overlaps with variances of treatment groups (even though only partly in 3DAA2). Therefore, the differences can be considered as variability of the test. The other comments are noted.	Addressed It is noted that the study indicated that colony level adverse effects cannot be excluded. See also comments (25) and (97)

Confirmatory Information (bees) Addendum to B.9				
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**
		stages. This brings a high uncertainty on the validity of this parameter. It is also strange that dimethoate had clear effects on brood index and brood termination rates for young larvae while insegar (active substance: fenoxycarb) had not (graphs on page 117 and 118).		
(6)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, x), Colony feeder test by Szczesniak, B.; 2017	EFSA: A colony feeder study was undertaken with 5 test concentrations (up to 4 mg/kg) with 5 repetitions in Germany. The feeding solutions were offered to the colonies over a period of 10 consecutive days. An intensive observation regime was conducted including overwintering assessments and analytics for several matrixes. As regards the methodology, it is noted that sugar supply was offered to the colonies several times during the post exposure period staring already in June. The study was running in a wet/rainy period. Could you please give more details on the colonies (origin, size, health status at the beginning of the test) and about the consumption rate of the spiked food? Moreover, please clarify whether all the samples for analytics were taken	Co-RMS CZ: More details on the colonies will be included in the addendum. Information on remaining feeding solution in the test groups is available in the study report and will be added into the addendum. All the samples for analytics were taken from the combs.	Addressed The required information was added to the Confirmatory data addendum (Czech Republic, 2018a). Further explanations are also provided under Column 3. See also comment (51).

Confirmatory Information (bees) Addendum to B.9				
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**
		from the combs (i.e. the pollen contamination is a result of some in-hive processes by the bees?).		
(7)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, x), Colony feeder test by Szczesniak, B.; 2017	EFSA: The conclusions on the worker mortality for T4, and T5 is agreed and it is noted that the effects were more severe than for the reference substances and some effects appeared quite after the exposure period. In addition it is noted that between 30 June and 6 July, the mortality was continuously higher in the T3 group than in the control (on average). Statistically not significant difference was reported for the brood assessments (1st cycle) with some indications for potential effects at T4 (brood termination rate 22.7 vs 13.45) and T5 and T5 (brood termination rate 52.64 vs 13.45). However, clear effects were observed on brood mortality in T4 and T5. It is noted that the brood termination rate for the 2nd brood cycle is very uncertain due to high brood mortality in the control. The conclusions of the co-RMS on the colony size is not fully agreed. In the summer 2016, the control colonies	Co-RMS CZ: Noted.	Addressed It is noted that the study indicated that colony level adverse effects cannot be excluded. See also comments (32), (53), (51), (55), (84), (85) and (92).

Confirmatory Information (bees) Addendum to B.9				
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**
		performed continuously better than any of the treated group (on average) which might be considered as an indication to some effects, even if in many case it was statistically not different from control. Nevertheless the apparent effect on T4 and T5 is agreed. As regards overwintering, again, the control group (on average) performed better than any of the treated group (except R3). The argumentation for no treatment relation of this phenomena may be better elaborated. The pattern for the brood development (photographic assessment) is similar to the pattern for colony size. Also, the data on pupa weight do not suggest that test item related effects can be excluded.		
(8)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, xi), Field test on guttation by Dittbrenner, N. Dr.; 2017	EFSA: It is noted that this is an interim report and additional data are awaited (e.g. overwintering). The test was done on oilseed rape, guttation were relatively frequently observed, but practically no bees were observed collecting guttation liquid. It is noted that all hives at the treated fields had lower colony size than the controls, which was	Co-RMS CZ: Noted. See also comment (60).	Addressed See also comments (35), (60), (86) and (96).

Confirmatory Information (bees) Addendum to B.9				
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**
		explained as likely due to an artefact. It is noted that the results of some chemical analysis indicated <LOQ for pollen and <LOD for nectar taken from flowers (i.e. early post spray application resulted in residues in traces, < 1 ug/kg), while residues were detected earlier in plant samples and guttation samples.		
(9)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, xii), Residues in succeeding crop by Appeltauer A.; 2017e	EFSA: A succeeding crop situation was simulated by this semi-field test using OSR at 4 sites in Germany. Could you please confirm that at each site there was 1 treated and 1 control tunnel? It is noted that with initial (fresh) soil residues of 0.0169-0.033 mg/kg (dry weight) (48 g/ha was sprayed), no residues (i.e. < LOD of 0.0003 mg/kg) were detected in pollen and nectar from bees foraging on flowering OSR. According to the summary, the sugar content of OSR was also measured. Are the results available?	Co-RMS CZ: Yes, each trial consisted of two treatment groups: the test item group (1 replicate/tunnel) and an untreated control C (1 replicate/tunnel). Information on measured sugar content is available in the study report and will be added into the addendum.	Addressed Information on the sugar content was added to the Addendum (Czech Republic, 2018a).
(10)	Addendum to B.9, Confirmatory data (bees), B.9.4.1, xiii), BB greenhouse study by Tänzler, V., Dr. Eichler,	EFSA: In this study 4 bumblebee hives were studied in a greenhouse with treated tomato in flowering. It is not entirely clear whether the spray application was done during the night or during the day but the hives were	Co-RMS CZ: The test treatment replicates were treated during full flowering of the tomato plantation (BBCH 63) and without bumble bees actively foraging on the crop.	Addressed Additional information was added to the addendum (Czech Republic, 2018a) and explained in Column 3. It is noted that the number of bees

Confirmatory Information (bees) Addendum to B.9				
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**
	M.; 2016	closed/removed. Could you please clarify this? From the results section, it is described that the colonies were continuously supplied with sugar water of which weight was included in the colony weight data. Pollen from bees contained residues of sulfloxaflor. Could you provide some details how these samples were taken (number of bees, time after the application)?	The reference item replicates were treated during full flowering of the tomato plantation and with bumble bees actively foraging on the crop. In the evening after bee flight, before the day of application, the flight holes of the bumble bee hives in the control and test item treatment group were closed. On the following day (= DAT0), the application of the test item and reference item in the corresponding compartments was performed. The flight holes of the bumble bee hives in the control and test item treatment compartments remained closed until the morning of the following day (DAT1). In the morning of DAT1, the flight holes of the hives were re-opened in order to start/continue the exposure. By this it was ensured that no bumble bees were actively flying or foraging on the tomato plantation during the time of spraying of the test	involved in the sampling is still not clear, but overall the sampling regime is sufficiently described.

Confirmatory Information (bees) Addendum to B.9				
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**
			item and at least until the morning after the day of application. The bumble bee hives in the reference item group compartments were not closed at any time during the application procedure. The reference item was sprayed during foraging activity of the bumble bees on DAT0. The tomato plants of the control group were left untreated. Regarding pollen residue analysis, the sampling of foraging bumble bees was performed from the hive entrance when the bumble bees were returning back to the hive or directly from the field site (exhauster, tweezers) and collected in a container with dry ice. Afterwards, the pollen attached to each bumble bee was removed (tweezers) and collected in a sampling vial. In total there was 1 sampling day in the control compartment and 1 sampling day in the test item treated compartment. The	

Confirmatory Information (bees) Addendum to B.9

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
			sampling was done on DAT1. All these information will be added into the addendum.	
(11)	Addendum to B.9, Confirmatory data (bees), B.9.4.2, RA for bees, Tier 1	EFSA: It is noted that EFSA, (2013) was used. Please note that all uses includes the flowering period, therefore the treated crop scenario for the contact route of exposure should be considered. This will lead to high risk at tier 1 for the situations when the application is done during the flowering (as for weeds). As regards the tier 1 oral assessment for fruiting vegetables it is noted that crops such as tomato and eggplant has lower SV for the treated crop (they have only pollen) than have other fruiting vegetables. As regards the assessment for the puddle water, the PECsw is not an appropriate input according to EFSA, (2013).	Co-RMS CZ: The treated crop scenario for the contact route of exposure was considered for all uses, however, excel tool provided HQ values 0.0. It is not clear which PEC should be used in calculation for the puddle water. According to the EFSA 2013 GD, the highest peak concentration in the runoff water from the four FOCUS runoff scenarios should be used. Is this the correct approach?	Addressed Some elements of the Tier 1 risk assessment as they are currently included in the addendum would require further amendments. However, the overall prediction (high risk) for the Tier 1 risk assessment would not change. It is noted that the excel tool (Bee Tool; EFSA, 2013) has some 'multiple choice green boxes' – next to the filter options - which should also be treated appropriately. The Tier 1 calculations for the oral route of exposure for some vegetables seem to be too worst case. Concentration in the runoff water is not equal to the PECsw.
(12)	Addendum to B.9, Confirmatory data (bees), B.9.4.2, RA for bees, Higher tiers	EFSA: It is noted that some Tier 2 assessments were conducted considering residue decline data and refining twa factor, which still indicated a high risk for many of the	Co-RMS CZ: Noted.	Addressed As regards to the risk mitigation options, see comments (21), (41), (54), (56), (57), (58), (74), (77), (83),

Confirmatory Information (bees) Addendum to B.9				
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**
		cases. Higher tier effect studies are available for further refinement (see related EFSA's comments above). It is noted that co-RMS suggests risk mitigation considering the results of some studies. It is noted that risk mitigation options for the treated crop scenario had already been discussed at the Pesticides Peer Review expert meeting 107 (EFSA, 201) on the basis of the same studies. Additional risk mitigation options are discussed for the weed scenario.		(92) and (98).
(13)	Vol. 3 Annex B.9 page 3 Introduction	UK: Please can it be clarified if the "other formulation" GF-2372 is to be considered in this assessment or whether just the representative formulation GF-2626 is relevant.	Co-RMS CZ: There are two representative formulations, GF-2626 and GF-2372.	Addressed
(14)	Vol. 3 Annex B.9 page 16 (iii) Chronic oral toxicity to adult honey bee	UK: It is noted that data on the test concentrations are missing.	Co-RMS CZ: It is a typo, test concentrations will be added in the text.	Addressed The text for the chronic oral toxicity study was amended with information on the test concentrations.
(15)	Vol. 3 Annex B.9 page 16 (iii) Larval toxicity laboratory test	UK: It is noted that the RMS has compared the study to the draft OECD guidance document, however this has been finalised and hence it	Co-RMS CZ: Agreed, the finalized OECD guidance document will be included in the evaluation. It is stated in the addendum that	Addressed The addendum was amended by assessing the study against the

Confirmatory Information (bees) Addendum to B.9				
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**
		would have been useful if OECD Guidance Document on Honey Bee Larval Toxicity Test following Repeated Exposure Series on Testing & Assessment (OECD, 2016) had been used. Details of the diets used should have been included.	the diets were based on 50% fresh royal jelly and 50% aqueous solution containing variable amounts of yeast extract, glucose and fructose. If necessary, more details on the diets will be added.	finalised OECD guidance document (OECD, 2016). Details on the diets had already been included in the addendum.
(16)	Vol. 3 Annex B.9 page 18 (iv) Apple pollen and nectar residue trial	UK: How were the 300 bees collected? How was the pollen collected?	Co-RMS CZ: Sampling of forager bees for preparation of nectar: The hive entrances were sealed before the sampling and the forager bees were subsequently collected as they returned to the hive using modified hoovers. Sampling of pollen from pollen traps: forager bees were collected by using pollen traps - The hives in each tunnel were equipped with pollen traps. The grid was either inserted one day before sampling (after bee flight) or on the sampling days. Bees were stripped of pollen when passing the grid and the pollen was collected from the pollen trap installed below. The grid was removed after each	Addressed Further details, as explained under Column 3, were added to the addendum.

Confirmatory Information (bees) Addendum to B.9				
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**
			sampling. This information will be included in the addendum.	
(17)	Vol. 3 Annex B.9 page 25 (v) Strawberry pollen and nectar residue trial	UK: How were the bees collected? How was the pollen collected?	Co-RMS CZ: Sampling of forager bumblebees for preparation of nectar: The hive entrances were sealed before the sampling and the forager bumblebees were either collected as they returned to the hive or directly from flowers from strawberry plants using modified hoovers. After sampling, the hives were re-opened. On each sampling day an A sample of at least 30 bumblebees was collected, with exception of sampling S5 in trial -03, when only 18 bumblebees were collected Sampling of Pollen: Forager bumble bees were collected directly from strawberry flowers and pollen loads were detached using tweezers. This information will be included in the addendum.	Addressed Further details, as explained under Column 3, were added to the addendum.
(18)	Vol. 3 Annex B.9 page 31 (vi) Pumpkin pollen and nectar residue trial	UK: How were the 300 bees collected? How was the pollen collected?	Co-RMS CZ: The method was the same as in apples (see comment (16)).	Addressed

Confirmatory Information (bees) Addendum to B.9

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
				Details, as explained under Column 3, were added to the addendum.
(19)	Vol. 3 Annex B.9 page 38 (vii) Oilseed rape pollen and nectar residue trial	UK: How were the bees collected? How was the pollen collected?	Co-RMS CZ: Co-RMS CZ: The method was the same as in apples (see comment (16)).	Addressed Details, as explained under Column 3, were added to the addendum.
(20)	Vol 3 Annex B.9 residue trials	UK: Has the RMS assessed the methods of analysis associated with the 4 residue studies?	Co-RMS CZ: No, the methods of analysis will be assessed in the revised addendum.	Addressed Some further details and the co-RMS's assessment of the methods of analysis were added to each study description.
(21)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix) (Renz (2017))	UK: It is noted that according to Table 9.4.1-32 application of the test material GF2626 was made in the evening after bee flight, whereas the application of the control (i.e. water), dimethoate and fenoxycarb were made during bee flight. The different treatment of the GF2626 plots with the controls (both positive and negative controls) fundamentally questions the robustness of the study. Furthermore, by applying the test product after bee flight a risk mitigation measure is automatically applied which may not be relevant or appropriate to all MS.	Co-RMS CZ: This issue should be further discussed.	The reliability and use of the study (Renz (2017)) should be further discussed in an experts' meeting. See also comment (92) EFSA is of the opinion that the different spraying time of the controls does not question the reliability of the study. Nevertheless the different view of UK is noted. Regarding the applicability of mitigation measures, please see the expert consultation recommended under point (58).

Confirmatory Information (bees) Addendum to B.9

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
(22)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: The text at the bottom of page 85 and subsequent text and tables, e.g. Table 9.4.1-33, state that certain activities were made before or after the second application, however the preceding text on page 85 makes no mention of two applications being made. It is assumed that this refers to applications to the controls. Please can it be clarified as to how many applications were made and if more than one application was made what the application interval was.	Co-RMS CZ: Application 1 is related to treatment groups (evening application) while application 2 is related to control and reference items (during bee flight) (see the Table 9.4.1-32). Thus, only one application was done in each test group.	Addressed It was clarified that only one application was made for each test group.
(23)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: There does not appear to be any information regarding the additional replicate T1s and T2s and how they were treated. Please could this be clarified?	Co-RMS CZ: The comment is unclear. There were six replicates per T1 group and six replicates per T2 group. All relevant information is included in the study summary.	Addressed As reported in Table 9.4.1-32, T1s and T2s were used for sampling. There were 's' repetitions for the controls, as well, which were used only to get analytical samples (but logically were not used for biological observations). According to the tables, these repetitions were treated the same way as the other tunnels.
(24)	Vol 3 Annex B.9 Cage tests/field tests GF2626	UK: Due to the concentration on reporting weather details after A2,	Co-RMS CZ: Application A1 was done on 7 July 2016 and	Some information on the weather conditions during the days of

Confirmatory Information (bees) Addendum to B.9

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
	(ix)	there is a lack of information regarding what the weather was at the time of application for A1. If this is available, please can this be added?	application A2 on 8 July 2016. Weather conditions during these days are given in Table 9.4.1-38.	application was included in the addendum. Information on the exact weather at the time of applications was not provided. Such information would be appreciated in order to ensure that there was no anomaly during application (e.g. windy condition). Further clarification may be provided if a revised addendum is required by a mandate at a later stage. However, the information is currently considered not essential.
(25)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: According to Table 9.4.1-40 there was a significant increase in mortality compared to the control despite GF2626 being applied after bee flight. This effect was observed in both application rates. Similarly when dimethoate is applied during bee flight there is a statistically significant increase in mortality.	Co-RMS CZ: Noted.	Addressed It is noted that this parameter indicated a short (2 days), but rather clear effect. See also comments (5) and (97).
(26)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: The relevance of the data on dead drones and male pupae is questioned given the statement that the dead drones and male pupae were found very infrequently.	Co-RMS CZ: Noted.	Noted. The high uncertainty of this parameter is agreed.
(27)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: It is stated that the mean daily foraging activity per treatment group was statistically reduced, i.e. 16.9 bees/m2/1 min compared to 20.5	Co-RMS CZ: It can be confirmed that the mean daily foraging activity per treatment group T1 was statistically reduced, i.e.	Addressed Table 9.4.1-45 includes information

Confirmatory Information (bees) Addendum to B.9

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
		bees/m2/1 min, however Table 9.4.1-45 does not indicate that this is statistically significant. Please can this be clarified? It is noted that foraging in the higher rate was statistically reduced on several occasions and overall 0DBA2 to 7DAA2.	16.9 bees/m^2/1 min compared to 20.5 bees/m^2/1 min. This will be corrected in Table 9.4.1-45.	on the mentioned statistical differences.
(28)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: The moderate feeding of all hives 14 DAA2 as well as feeding prior to treatment against Varroa is noted. Whilst it is appreciated why the hives were fed, this has the consequence that any data on overwintering survival will be potentially compromised and difficult to interpret and read across to the field situation.	Co-RMS CZ: See comment (4).	Noted. EFSA agrees with UK comment. See also comment (4).
(29)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (ix)	UK: Has the method of analysis used for the residue analysis been assessed?	Co-RMS CZ: No, the methods of analysis will be assessed in the revised addendum.	Addressed Some further details and the co-RMS's assessment about the methods of analysis were added to the study description.
(30)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (x) (Szczesniak (2017))	UK: On page 134 it is stated that the "colonies were free-flying, with access to natural nectar sources" however no details have been provided regarding what the surrounding habitat was and hence what the bees may have been	Co-RMS CZ: More information on surrounding habitat will be provided. Regarding weather conditions, the temperatures down to -12°C were measured during overwintering which is not	Addressed Some further details on the surrounding habitat were provided. This information confirms that likely, the bees continuously had at least some sources of nectar/pollen in the

Confirmatory Information (bees) Addendum to B.9

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
		foraging on. It is noted that the weather conditions included some potentially extreme events, e.g. no rainfall for two months and temperatures down to -12°C. Theses should be considered in the risk assessment.	such an unusual event in winter in Central and Northern Europe.	vicinity. Information from longer distance is apparently not available. See also comment (51) and (52).
(31)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (x)	UK: Whilst there is a statistically significant effect on the level of mortality in T4 and T5, the variability these treatment levels (see Table 9.4.1-58) is noted. Please note that the heading is confusing in that the column refers to dead work bees whereas the title of the table refers to larvae and pupae. (Considering Table 9.4.1-59 it is assumed that Table 9.4.1-58 refers to pupae and not adults?)	Co-RMS CZ: The heading is correct but the column should refer to mortality of larvae and pupae. This will be revised.	The mentioned correction (typo) on the addendum might be added in a revised addendum, if this is required by a mandate at a later stage.
(32)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (x)	UK: The mean colony size of all the treatments was lower than the control towards the end of the study, similarly the amount of brood. Whilst the text states that this is not treatment related due to changing foraging conditions and a lack of a dose response, this is still of potential concern and warrants closer examination.	Co-RMS CZ: Further discussion on this issue will be included in the addendum.	Based on the available higher tier studies, the potential effects of GF-2626 on the honeybee and honeybee brood should be further considered in an experts' meeting. It is further noted that the co-RMS added some considerations to the addendum, suggesting for further examination of the issues mentioned by UK.

Confirmatory Information (bees) Addendum to B.9

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
				See also comment (7) where similar concerns were raised,(53), (55), (84) and (92).
(33)	Vol 3 Annex B.9 Cage tests/field tests GF2626 (x)	UK: Has the method of analysis been assessed?	Co-RMS CZ: No, the methods of analysis will be assessed in the revised addendum.	Addressed Further details and the co-RMS's assessment about the methods of analysis were added to the study description.
(34)	Vol 3 Annex B.9 Cage tests/field tests GF2372 (xi) (Dittbrenner (2017))	UK: It is noted that this study is not conducted on the representative formulation. On page 162 it is stated that the colonies were placed at the field site after honeybee flight and after application, however it then goes on to say that the mortality and behaviour of the honeybees was assessed over 3 consecutive days before exposure. It is unclear as to when colonies were exposed and for how long, can this be clarified? It would be useful if further details were provided as to how guttation was determined. Further details regarding the sampling of plants would be useful, i.e. which plants, which part of the plant etc.	Co-RMS CZ: GF- 2372 is the other representative formulation. Before installation of the colonies at the field sites, mortality of the honeybees was recorded by counting the number of dead honeybees in the dead bee traps attached to the hives. After installation of the colonies at the field sites, mortality of the honeybees was recorded by counting the number of dead honeybees in the dead bee traps attached to the hives and on the linen sheets which were spread out in front of the hives as well as in the fields. Additional information requested will be provided in the addendum.	Addressed Further details were added to the revised addendum.

Confirmatory Information (bees) Addendum to B.9

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
(35)	Vol 3 Annex B.9 Cage tests/field tests GF2372 (xi) (Dittbrenner (2017))	UK: On page 173 there is reference to re-analysis of plant samples – please can it be clarified as to why this was carried out? As regards the residues in guttation fluid, it would be useful to indicate in the text how this was sampled (plants sampled at random?); it would also be useful to consider these data in light of the effects data, i.e. comparing when exposure occurs to possible effects. Were there any visual assessments carried out regarding bees foraging on guttation fluid?	Co-RMS CZ: The requested details will be added in the addendum, based on the final report.	Not all of the requested details were added to the revised addendum. It is noted that since this study had only an interim report, further details may be available at a later stage. See also comments (8), (60), (86) and (96).
(36)	Vol 3 Annex B.9 Cage tests/field tests GF2372 (xi) (Dittbrenner (2017))	UK: It is noted that this study is not yet finalised, i.e. the overwintering work still needs to be reported.	Co-RMS CZ: Agreed.	See also comments (8), (35) and (60).
(37)	Vol 3 Annex B.9 Cage tests/field tests GF2372 (xii) Appeltauer (2017e))	UK: It is noted that this study was not conducted with the representative formulation. It would be useful to include details regarding how the bees were collected. Has the method of analysis used in this study been assessed?	Co-RMS CZ: GF- 2372 is the other representative formulation. For sampling of bees see comment (16), the method was the same. This information will be included in the addendum. The method of analysis will be assessed in the revised addendum.	The requested details were not added to the revised addendum However, it is noted similar residue studies conducted by the same facility, same author and in the same year, are summarised in the addendum. It may be assumed that the methodology followed in this study was the same. See also comments (16) and (20).
(38)	Vol 3 Annex B.9 Cage tests/field tests GF2626	UK: The rate of application is noted, is it possible to convert this to a more	Co-RMS CZ: 24 g a.s.ha/mCH was erroneously considered	The method to convert the application rate was not added to the revised

Confirmatory Information (bees) Addendum to B.9

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
	(xiii)	conventional application rate? The RMS comment states that the rate is 24 g/ha, is 24 g a.s.ha/mCH equivalent to 24 g a.s./ha?	equivalent to 24 g a.s./ha. Converted application rate will be included in the addendum.	addendum. Co-RMS might consider checking the height of the treated tomato in this test in a revised addendum, if this is required by a mandate at a later stage.
(39)	Vol 3 Annex B.9.4.2.2	UK: It is noted that the yet to be noted EFSA bee guidance document has been used to assess the risk.	Co-RMS CZ: Based on the "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology" (EFSA, 2015), the risk assessment for bees should be carried out according to EFSA (2013).	Noted.
(40)	Vol 3 Annex B.9.4.2.2	UK: As regards the risk assessment, it is assumed that the default assumptions have been used as per the guidance document? It is noted that in several places the HQ or ETR is 0 – would it more appropriate to state that the calculation is not relevant, i.e. the risk to bees foraging the crop at BBCH <50 and >70 is not considered to be appropriate as this is prior to/after flowering. Should there be a consideration of systemic properties of sulfoxaflor and in particular whether there would be residues in flowers following treatment prior to flowering?	Co-RMS CZ: The calculations resulting in 0 should be consulted with EFSA.	Addressed An ETR of 0 may be interpreted that the scenario is not relevant; however the result is the same. Tier 1 risk assessments consider residues appearing in pollen and nectar from pre-flowering applications. See also comment (11).
(41)	Vol 3 Annex B.9.4.2.2	UK: Given the systemic properties of	Co-RMS CZ: This consideration will	Addressed

Confirmatory Information (bees) Addendum to B.9

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
		sulfoxaflor and the concern raised during the zonal assessment of GF 2626 and GF 2372, shouldn't there be a consideration of systemic properties of sulfoxaflor and in particular whether there would be residues in flowers following treatment prior to flowering?	be provided in the addendum.	A consideration to this issue was included in the addendum. As regards to the risk mitigation options, see comments (12), (21), (54), (56), (57), (58), (74), (77), (83), (92) and (98).
(42)	Vol 3 Annex B.9.4.2.2	UK: It is unclear as to why the HQ/ETR for fruiting vegetables growth stage BBCH > 50 is 0 for contact exposure, is this related to the attractiveness of all fruiting vegetables? Further justification/explanation would be useful.	Co-RMS CZ: This should be consulted with EFSA.	Addressed No further justification is needed; the calculations should simply be repeated with appropriate settings. See comment (11).
(43)	Vol 3 Annex B.9.4.2.2	UK: Why has the risk been determined for BBCH<50 and BBCH>50 when there is only one application that can be made anytime between BBCH 20-89?	Co-RMS CZ: The comment is unclear.	Addressed According to the guidance EFSA (2013), these two BBCH categories have to be chosen in order to cover the range of BBCH 20-89.
(44)	Vol 3 Annex B.9.4.2.2	UK: Please can it be clarified how the concentration in guttation fluid was determined; was it using the default values in the guidance document?	Co-RMS CZ: PECsw value was used but it was disagreed by EFSA (see comment (11)).	Addressed For guttation, the water solubility was used, as requested by the guidance EFSA (2013).
(45)	Vol 3 Annex B.9.4.2.2	UK: At the end of the tables related to the honey bee risk assessment, it	Co-RMS CZ: This will be included in the addendum.	The co-RMS might consider adding further summary tables to a revised

Confirmatory Information (bees) Addendum to B.9

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
		would be useful to conclude regarding which scenarios require further consideration.		addendum if peer-review process is required by mandate at a later stage.
(46)	Vol 3 Annex B.9.4.2.2	UK: It is noted that the assessment of non-*Apis* bees only considers the acute risk to bumble bees as the view of the RMS is that the risk will fail once the additional assessment factor of 10 is incorporated.	Co-RMS CZ: Noted. The risk assessment for non-*Apis* bees will be re-considered in the addendum.	The co-RMS might consider adding further quantitative assessments to non-*Apis* bees in a revised addendum if peer-review process is required by mandate at a later stage. It is noted however that this would not change the conclusion. See also comment (76).
(47)	Vol 3 Annex B.9.4.2.3	UK: It is noted that only one of the residue/exposure studies was carried out on the proposed crop, that on pumpkin (i.e. a fruiting vegetable). It is also noted that the studies were conducted under semi-field conditions and not in the field as outlined in the EFSA guidance document. The latter point would imply that any resulting residues are potentially worst case. Whereas the former point needs detailed consideration and has determination as to whether the studies are relevant to the proposed uses.	Co-RMS CZ: To cover the uncertainties including crop extrapolation, the highest DT50 for both pollen and nectar was used. We are of the opinion that semi-field studies can be considered as worse case in comparison to field studies.	See proposal for further discussion in an experts' meeting in comment (3).
(48)	Vol 3 Annex B.9.4.2.3	UK: The UK notes that the RMS proposes to use the worst case DT50 for both	Co-RMS CZ: Further explanation and justification regarding the	See proposal for further discussion in an experts' meeting in comment (3).

Confirmatory Information (bees) Addendum to B.9				
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**
		pollen and nectar in a refined assessment. The data are from a variety of crops and locations and whilst the RMS has considered the latter, there doesn't appear to be any detailed consideration of the former (i.e. the relevance of the range of crops used). It is assumed that the data are being interpreted as a "DT50" in pollen and nectar that is relevant for all crops/plants (inc weeds), is this correct? It would be useful to include some further explanation.	range of crops used in residue tests and crops in GAP will be provided in the addendum. It is correct that the highest DT50 from all pollen and nectar DT50 values (except for apples) was selected and used for all crops in GAP as the worst case to cover all the uncertainties.	
(49)	Vol 3 Annex B.9.4.2.2 Tier 2 chronic risk assessment using residue decline	UK: It would be useful to have a conclusion as to which scenarios/uses were resolved using the residue decline data.	Co-RMS CZ: We are not sure if this is necessary. The current tables seem to be quite transparent.	Addressed
(50)	Vol 3 Annex B.9.4.2.2 Tier 2 Refinement of RUD	UK: It is noted that the RUDs from the submitted data are higher than the default values and hence have not been used in the risk assessment. It would be useful if there was a greater consideration as to why these data aren't considered appropriate and hence aren't used in the risk assessment.	Co-RMS CZ: More consideration as required will be provided in the addendum.	Addressed Further considerations have been added to the addendum. See also comment (70).
(51)	Vol 3 Annex B.9.4.2.2 Tier 2 Effect studies (Szczesaniak (2017))	UK: It is noted that the conclusion of the Szczesaniak (2017) is that there were no treatment related effect at nectar	Co-RMS CZ: The NOEC from larval toxicity study should be 1.30 mg a.s./kg, not mg a.s./L (a	Peer review proposed The use of the study (Szczesniak, 2017) for risk assessment and the

Confirmatory Information (bees) Addendum to B.9

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
		concentration of up to 0.5 mg a.s./kg diet. The reference to nectar is unclear as the test substrate was 50% sucrose. It is also noted that there is no consideration regarding the fact that the bees were free flying, hence the actual exposure in terms of per bee or per larvae is unknown. Whilst the comparison with the adult chronic data is clear, the comparison and associated conclusion regarding the larval endpoint is not so clear, especially as the units are different, i.e. mg a.s./L vs mg a.s./kg. It would be useful if this was clarified.	typo). The use of this study in the risk assessment should be discussed at the expert meeting.	endpoints to be used should be further discussed and agreed in an experts' meeting. Further discussion on some elements of this study was already proposed in earlier comments. See also (6), (7), (30), (32), (53), (55), (84), (85) and (92).
(52)	Vol 3 Annex B.9.4.2.2 Tier 2 Effect studies (Szczesaniak (2017))	UK: It was noted that the bees were free flying, however there was not data regarding the surrounding habitat nor is there any consideration of this issue in the risk assessment. It would be useful if this element of the study was considered further. In addition, it was noted that there were potentially extreme weather events, i.e. no rainfall for two months and temperatures down to -12°C, it would be useful if there was a consideration of these aspects in the risk assessment.	Co-RMS CZ: See comment (30).	Addressed See comment (30).

Confirmatory Information (bees) Addendum to B.9

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
(53)	Vol 3 Annex B.9.4.2.2 Tier 2 Effect studies (Szczesaniak (2017))	UK: The comparison with the residue data from the exposure trials is useful and potentially indicates the variability that can occur under very controlled conditions, it also questions the relevance of taking a mean value given that there is up to over two orders of magnitude difference between the minimum and maximum values. It also indicates that whilst acknowledging the worst case nature of the study, some of the residues are greater than the proposed NOEC. It would be useful to discuss the use of the study by Szczesnick further and in particular whether it can be used to demonstrate whether the risk to bee brood is acceptable.	Co-RMS CZ: More consideration as required will be provided in the addendum. The use of this study in the risk assessment should be discussed at the expert meeting. It would also be useful to discuss the use of colony feeding studies in the risk assessment generally.	See proposal for further discussion in an experts' meeting in comment (51).
(54)	Vol 3 Annex B.9.4.2.2 Tier 2 Effect studies (Renz (2017))	UK: It is noted that the study was conducted after bee flight and hence the use of this study and the associated results are potentially limited to where this risk mitigation measure is practical and used by MS. Despite the application after bee flight, "a significant negative effect on the mortality of adult worker bees" was recorded in both the 24 g a.s./ha and 48 g a.s./ha application	Co-RMS CZ: Since it is clear from the previous studies that sulfoxaflor causes significant negative effects on bees when applied during bee flight it was reasonable to conduct another cage study with application after bee flight. It is stated in the addendum that "the newly submitted OECD 75 tunnel study (Renz, 2017) and	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (56), (57), (74), (77), (83), (92) and (98).

Confirmatory Information (bees) Addendum to B.9				
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**
		rate. It would be useful to include a consideration of the relevance and hence acceptability of this finding.	previously evaluated tunnel studies (Schmitzer 2011a, 2011b) demonstrated that evening application is not sufficient mitigation to ensure the low risk to honeybees in case of application of sulfoxaflor on attractive crop in flower. Therefore, pre-flowering application should be considered.	
(55)	Vol 3 Annex B.9.4.2.2 Overall conclusion on the risk to honey bees via the nectar and pollen route of exposure	UK: The RMS concludes that on the basis of Szczesnick (2017) that the risk to honey bee brood is acceptable. It would be useful if there was more detail regarding how the RMS reached this conclusion especially considering that the residues studies indicated that residues could be greater and that the actual effects study used free flying bees, hence there is uncertainty regarding the actual exposure. Furthermore, there is uncertainty regarding what the exposure was in terms of dosage.	Co-RMS CZ: The use of this study in the risk assessment should be discussed at the expert meeting. See comment (53).	See proposal for further discussion in an experts' meeting in comment (51).
(56)	Overall conclusion on the risk to honey bees via the nectar and pollen route of exposure	UK: Before concluding regarding on the risk to bees, it is considered that the risk to bees foraging flowers that were in bud at the time of application but flower a few days after	Co-RMS CZ: The comment is unclear. It is noted that in the higher tier effect and exposure studies sulfoxaflor was sprayed on open flowers which is	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (77), (83) and

Confirmatory Information (bees) Addendum to B.9

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
		application requires detailed consideration.	considered worse case.	(92).
(57)	Vol 3 Annex B.9.4.2.2 Overall conclusion on the risk to honey bees via the nectar and pollen route of exposure	UK: The RMS concludes on the basis of the previously submitted studies and the newly submitted Renz (2017) study that applying after bee flight is "not sufficient to ensure the low risk to honey bees", the RMS goes on to state that "pre-flowering application should be considered" and more specifically proposes a 5-day pre-flowering restriction. The UK questions the grounds on which this restriction is based as well as the practicality of the restriction. It would be useful to expand the pre-flowering proposal and in particular whether this applies to the crop and weeds present in the crop and whether given the systemic nature of the active substance whether a pre-flowering restriction of 5 days is sufficient and finally whether a pre-flowering restriction is sufficiently robust and practicable given the unpredictability of crops (and flowering weeds) to flower. It is noted that the RMS has proposed a 5 day pre-flowering restriction on the	Co-RMS CZ: The appropriate mitigation measure should be discussed at the expert meeting. More consideration will be provided in the addendum.	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (77), (83) and (92).

Confirmatory Information (bees) Addendum to B.9				
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**
		basis of the previously considered studies and the newly submitted residue studies. The newly submitted studies provide information on the "disappearance" of the a.s. from both pollen and nectar, noting that this can the result of degradation, dissipation, dilution, different levels of contamination in flowers, differential collection by bees etc. These studies do not provide an indication as to the potential levels of the a.s. in pollen and/or nectar in a flower that was treated at bud stage but subsequently blooms. This type of information would be useful to determine whether a pre-flowering restriction is appropriate, i.e. it ensures that exposure will be at an acceptable level and hence justify whether applying up BBCH 59 is sufficient. Finally, it should be noted that there has not been, as yet, any clear definition of an acceptable concentration in pollen and nectar.		
(58)	Vol 3 Annex B.9.4.2.2 Overall conclusion on the risk to honey bees	UK: The UK notes the proposal regarding less attractive crops not needing a pre-flowering restriction and that an	Co-RMS CZ: It is stated in the addendum: "It is noted that the available effect studies	Further considerations on the possible risk mitigation options that can be

Confirmatory Information (bees) Addendum to B.9				
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**
	via the nectar and pollen route of exposure	after bee flight restriction is sufficient. Please can this be justified?	were conducted with highly attractive crop and under worst-case exposure scenarios, under which the bees did not have any access to uncontaminated food to forage, unlike exposure in the natural environment. Therefore, regarding less attractive crop under natural conditions, RMS is of the opinion that evening application would be sufficiently protective mitigation measure. This applies to cereals which are of questionable attractiveness for honeybees and pollen only could be potentially collected by them (nectar is not relevant)." Since there can be different opinions on this issue it should be discussed at the expert meeting.	applied to ensure a low risk to honeybees in case of application of sulfoxaflor should be discussed in an experts' meeting. It is noted that MS and co-RMS had divergent views on the possible risk mitigation options. See also comments (12), (21), (41), (54), (56), (57), (74), (77), (83), (92) and (98). See also comment (63) and (82).
(59)	Vol 3 Annex B.9.4.2.2 Risk to honey bees foraging on guttation fluid	UK: It is noted that the formulation used in the key study is not the representative one; the relevance of this should be considered. (If GF2626 is a representative formulation, then	Co-RMS CZ: GF- 2626 is the other representative formulation. Both formulations were considered comparable during EU review of sulfoxaflor.	Addressed Low abundance of honeybees in an oilseed rape field before it flowers is a common phenomenon (unless

Confirmatory Information (bees) Addendum to B.9

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
		there still needs to be a consideration regarding the relevance of this study to the use of GF2372.) According to Table 9.4.1-60 there was much surrounding flora, could this have led to the low level of foraging in the crop? Is the finding of low foraging/attractiveness in oilseed rape in line with other information, e.g. that from open literature?	More consideration as requested will be provided in the addendum.	attractive weeds are present). According to the study description, the abundance increased when the crop started flowering.
(60)	Vol 3 Annex B.9.4.2.2 Risk to honey bees foraging on guttation fluid	UK: It is noted that this assessment is based on an interim report, when will the final report be available/assessed?	Co-RMS CZ: It was announced by the Notifier that the final report will be issued after the overwintering assessment in spring 2018. The Notifier should be asked to provide it.	Addressed It is noted that since this study had only an interim report, further data could be available at a later stage. See also comments (8), (35), (86) and (96).
(61)	Vol 3 Annex B.9.4.2.2 Risk to honey bees foraging in nectar or pollen in succeeding crops	UK: The conclusion seems appropriate given the available data and previous information on the a.s.	Co-RMS CZ: Noted.	Addressed
(62)	Vol 3 Annex B.9.4.2.2 Risk to honey bees foraging in nectar or pollen in flowering weeds	UK: The UK notes the reference to the EFSA conclusion on imidacloprid and clothianidin – the work that was used appears to focus on early growth stages, i.e. up to BBCH 40 for cereals and therefore, the UK questions the relevance of this precedent and	Co-RMS CZ: This should be confirmed by EFSA.	Indeed the mentioned case for clothianidin and imidacloprid (EFSA, 2016a,b) focused on early growth stages. More considerations might be added to the addendum at later stage (if required by a mandate), before concluding on the relevance of the

Confirmatory Information (bees) Addendum to B.9

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
		considers that further justification is required.		weed scenario.
(63)	Vol 3 Annex B.9.4.2.2 Risk to honey bees foraging in nectar or pollen in flowering weeds	UK: The UK notes the proposal to include a restriction for vegetables and cotton, whilst on the surface this may seem appropriate, it is considered that the risk to bees foraging weeds that flower post treatment needs further consideration. Please see UK comment related to Vol 3 Annex B.9.4.2.2 Overall conclusion on the risk to honey bees via the nectar and pollen route of exposure	Co-RMS CZ: The appropriate mitigation measure should be discussed at the expert meeting.	See comments (58) and (62)
(64)	Vol 3 Annex B.9.4.2.2 The risk to pollinators other than honey bees	UK: The risk assessment would benefit from a more detailed consideration of the Tanzler (2017) study and in particular how the treatment/exposure regime compares to that expected for fruiting vegetables (other than tomatoes), cotton and cereals. Furthermore, there should be a detailed consideration as to the relevance of this study to the ecological assessment. Tanzler (2017) study is of questionable relevance for an ecotoxicogical assessment, for example the colonies appear to be closed the night before	Co-RMS CZ: The study seems to be focused on effects of sulfoxaflor on bumblebees introduced into greenhouses. More consideration will be provided in the addendum.	The use of the study Tanzler (2017) and on the other available information for the risk assessment for bumble bees should be discussed in an experts' meeting

Confirmatory Information (bees) Addendum to B.9				
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**
		treatment and opened the day after treatment – this severely limits the usefulness of this study as this will not occur in the field. In addition, it is noted that only colony per replicate was used and hence this will limit the sensitivity of the study.		
(65)	Vol. 3 – Annex B.9, B.9.4.1, pollen and nectar residue trials, p16.	UK: Additional comments have been added following consideration by UK environmental fate specialists. We note that all applications in the pollen and nectar residue trials were made at the beginning of flowering. Therefore it cannot be completely excluded that at least some of the residue decline observed is as a result of dilution due to bees collecting pollen and nectar from flowers that opened in the days following application (i.e. flowers that were not directly exposed on the day of application). This may or may not be a relevant route of dissipation to consider in the risk assessment.	Co-RMS CZ: We disagree that all applications in the pollen and nectar residue trials were made at the beginning of flowering. Application in residue trials were made at the following BBCH growth stages: apple 63, 64, 65, 66; strawberry 65, 65, 65, 65; pumpkin 61, 65, 65, 69; OSR 62/63, 63, 65, 65. Thus, only one trial in pumpkin was sprayed at the beginning of crop flowering (BBCH 61). Most of trials were sprayed around full flowering (BBCH 65)	Addressed This issue may be further considered if peer-review is required by a mandate at a later stage.

Confirmatory Information (bees) Addendum to B.9				
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**
		However applications at the beginning of flowering may not necessarily represent the worst case application timing with regards to residue decline because of this effect. Can the RMS comment on the appropriateness of application timing with regards estimation of residue decline?		
(66)	Vol. 3 – Annex B.9, B.9.4.2.3, refinement of residue decline in pollen and nectar, p212.	UK: Thank you for the very clear and thorough presentation of the kinetic assessment of residue decline studies. The inclusion of all graphical fits, goodness of fit statistics and summary table (Table (9.4.2-9) was very helpful. As a general point we think the conduct and kinetic fitting of residue decline studies would benefit from additional specific guidance to supplement the existing general requirements from FOCUS kinetics. This would ensure consistent generation, evaluation and presentation of such studies in the future. We have a small number of specific comments below.	Co-RMS CZ: Thank you for your comment.	See proposal for further discussion in an experts' meeting in comment (3). EFSA acknowledges that some more guidance could be developed.
(67)	Vol. 3 – Annex B.9, B.9.4.2.3, refinement of residue decline in pollen and nectar, p212.	UK: According to Table 9.4.2-9 DT50's from a large number of trials were rejected for a variety of reasons (e.g. 9 out of 15 pollen trials rejected).	Co-RMS CZ: FOMC kinetics has been requested for the trials S16-00596-01 pollen, S16-00596-02 pollen, S16-00596-	See proposal for further discussion in an experts' meeting in comment (3).

Confirmatory Information (bees) Addendum to B.9				
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**
		Where SFO fits were rejected (due to poor visual fit and/or chi2>15%) we note that bi-phasic kinetics were also rejected because they failed statistical tests. For the bi-phasic fits, it is not clear which statistical tests failed (chi2 error %, t-test and/or confidence intervals?). However we suspect that in many cases the limited number of data points (n=3 or 4 maximum) would have invalidated the fitting of data to bi-phasic models. For example, since the DFOP model has 4 parameters, the design of the residue study taking a maximum of 4 sampling points would not have been sufficient to allow this kinetic model to be used (the number of data points must be at least 1 more than the number of model parameters). Since the design of the residue study was insufficient to allow fitting of bi-phasic models, perhaps alternative criteria should have been developed to test the acceptability of SFO fits (e.g. alternative chi2 error % triggers compared to standard FOCUS default of 15%, taking into account these are	03 pollen, S16-00602-03 pollen. DFOP model has not been calculated. Alpha and beta parameters failed the confidence intervals. The statistical data will be added to the revised addendum. Alternative criteria to derive conservative SFO DT50 should be discussed at the expert meeting.	

Confirmatory Information (bees) Addendum to B.9				
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**
		semi-field studies with a biological measure of sampling). Alternatively it may have been possible to use the SFO model to derive at least a conservative DT50 from each trial to maximize the number of trials retained?		
(68)	Vol. 3 – Annex B.9, B.9.4.2.3, refinement of residue decline in pollen and nectar, p212.	UK: We think it would be useful to include some discussion around general data quality, variability of initial residues, number of sampling points and trials, crops tested, validity of analytical method and sampling technique etc. in the summary on the reliability of the residue decline studies.	Co-RMS CZ: More consideration will be provided in the addendum.	See proposal for further discussion in an experts' meeting in comment (3).
(69)	Vol. 3 – Annex B.9, B.9.4.2.3, refinement of residue decline in pollen and nectar, p213.	UK: We note the statement that "Since the worst case DT50 values are selected the RMS is of the opinion that they could be applied to all crops in GAP (cereals, cotton, fruiting vegetable)." We think this statement should be better supported by more detailed consideration of some of the points raised in comment (55) above, as well as a more detailed consideration of the relevance of the tested crops versus the actual GAP crops. It is possible that the worst case DT50 is	Co-RMS CZ: More consideration will be provided in the addendum.	See proposal for further discussion in an experts' meeting in comment (3).

Confirmatory Information (bees) Addendum to B.9				
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**
		protective of all other crops, but we cannot conclude that based on the information currently provided.		
(70)	Vol. 3 – Annex B.9, B.9.4.2.3, refinement of RUDs, p217.	UK: We note that measured RUD values are considerably higher than the values used in the screening and Tier 1 assessment according to EFSA (2013). The measured data is not considered further for refinement of the RUD. Since the residue decline studies have been accepted for the purposes of refining the residue decline DT50, we do not think it is appropriate to completely dismiss the measured residue data from the same studies. Can the RMS provide more justification for not considering these data further? This consideration may take into account the dataset used to derive the RUD values in the original EFSA guidance, as well as any specific issues around the residue decline studies presented here.	Co-RMS CZ: More justification will be provided in the addendum.	Addressed See comment (50).
(71)	Vol. 3, B.9.4.1 Bee toxicity studies, III, Page 16 and Table 9.4.2 1, Summary of reported laboratory bee toxicity studies, Page 193	DE: The NOEC of the 22-days larval study is 1.30 mg a.s./kg diet (nominal concentration). The Co-RMS decided to change the unit of this endpoint from a.s./kg diet to a.s./L diet. However, this is only applicable if the	Co-RMS CZ: It is a typo, it will be corrected.	Addressed The typo had been corrected.

Confirmatory Information (bees) Addendum to B.9				
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**
		density of the larval diet is considered. This would result in a recalculation of the endpoint.		
(72)	Vol. 3, Annex B.9.4.2 Risk assessment for bees	DE: In the first paragraph, the RMS stated that "Given that Sulfoxaflor is not a growth regulating insecticide, a detailed examination of developmental /brood effects is not required." We disagree with this statement. The MoA of sulfoxaflor is closely related to that of the neonicotinoids. For this group of active substances potential sublethal effects on development and reproductive success of bee populations are well described. Thus, in our opinion a detailed examination of developmental, brood and reproductive success of bee populations is requested.	Co-RMS CZ: The sentence will be removed.	Addressed The questioned sentence has been removed from the addendum. Detailed brood assessment was anyway conducted in relation to the respective studies.
(73)	Vol. 3, Annex B.9.4.2 Risk assessment for bumble bees – conclusion Tier 1 level assessment; p. 207 and B.9.4.2.4 conclusions point 5), p.224	DE: Since the publication of the EFSA bee guidance document in 2013 the extrapolation factor of 10 has been subject of many discussions. In addition to the reasoning given in Arena & Sgolastra (2014) further studies have been conducted, e.g. Uhl et al 20161 or Schulz 20162. In between there is evidence that different bee species react highly	Co-RMS CZ: The risk assessment for non-*Apis* bees will be re-considered in the addendum.	The risk assessment for bumbles bees could not be finalised and requires, as for other pending issues, appropriate further discussion in an experts' meeting. Nevertheless, the suggestion of Germany that: "a low risk cannot be demonstrated for bumble bees as a result of the assessment" is noted-

Confirmatory Information (bees) Addendum to B.9				
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**
		variable on different active substances and that the extrapolation factor of ten is not exaggerated. Therefore, we appreciate that the RMS concluded that "When … extrapolation factor of 10 is used for chronic risk to bumblebee adults and larvae, it is clear that nearly all scenarios fail at Tier 1 assessment." Furthermore the RMS highlighted that "ETR values did not meet the relevant triggers at Tier 1 assessment mostly for scenarios treated crop, weeds and succeeding crop." Thus, we would propose to highlight in the conclusion that "a low risk cannot be demonstrated for bumble bees as a result of the assessment". This would be in line with the wording EFSA used for the conclusion of the neonicotinoid review. 1 Uhl, P., Franke, L.A., Rehberg, C., Wollmann, C., Stahlschmidt, P., Jeker, L., et al. (2016): Interspecific sensitivity of bees towards dimethoate and implications for environmental risk assessment. Sci. Rep. 6: 34439. 2 Schulz, R.S. (2016): Potential exposure		

Confirmatory Information (bees) Addendum to B.9				
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**
		and acute effects of frequently used agricultural insecticides on the wild bee species Osmia bicornis. Master thesis. Universität Koblenz-Landau, Landau.		
(74)	Vol. 3, Annex B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies; and B.9.4.2.4 Conclusions - risk assessment to bees, point 4) Risk to honey bees foraging in nectar or pollen in flowering weeds	DE: With regard to the protection of wildlife pollinators the risk mitigation proposal "Do not apply when flowering weeds are present. / Remove weeds before flowering" is questioned, because it contradicts the general aim to protect biodiversity. In particular for the pollinators this is the case because such an RMM would clearly diminish the potential of a landscape to provide nectar and pollen sources. This might lead to higher risks of extinction in locations where alternative flowering habitats are missing or are strongly restricted.	Co-RMS CZ: The appropriate mitigation measure should be discussed at the expert meeting.	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (77), (83), (92) and (98).
(75)	Vol. 3, Annex B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies; point 5) The risk to pollinators other than honey bees and Vol. 3, Annex B.9.4.2.4	DE: The RMS stated that "the risk assessment for honeybees is considered sufficiently protective also for bumblebees". We disagree with this conclusion due to substantial ecological differences to most other species (e.g. Arena & Sgolastra 2014; Rundlöf et al. 2015; Stoner 2016). Arena, M. & Sgolastra, F. (2014): A meta-	Co-RMS CZ: See comment (73).	See comment (73).

Confirmatory Information (bees) Addendum to B.9				
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**
	Conclusions - risk assessment to bees; point 5) The risk to pollinators other than honey bees	analysis comparing the sensitivity of bees to pesticides. Ecotoxicology 23: 324–334 Rundlöf, M., Andersson, Georg K S, Bommarco, R., Fries, I., Hederström, V., Herbertsson, L., et al. (2015): Seed coating with a neonicotinoid insecticide negatively affects wild bees. Nature 521: 77–80. Stoner, K.A. (2016): Current Pesticide Risk Assessment Protocols Do Not Adequately Address Differences between Honey Bees (*Apis mellifera*) and Bumble Bees (*Bombus* spp.). Front. Environ. Sci. 4: 79.		
(76)	Vol. 3, Annex B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies; point 5) The risk to pollinators other than honey bees and Vol. 3, Annex B.9.4.2.4 Conclusions - risk assessment to bees;	DE: In the case of such an effective insecticide we consider it important to conduct at least a screening step risk assessment for solitary bees on the basis of the honey bee surrogate endpoints. Solitary bees are toxicologically and ecologically much more vulnerable than honey bees. Therefore, it is justified to assess the differences and, depending on the outcome of the assessment, it could be stated whether a low risk can or cannot be demonstrated.	Co-RMS CZ: See comment (73).	See comment (46).

Confirmatory Information (bees) Addendum to B.9

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
	point 5) The risk to pollinators other than honey bees			
(77)	Vol. 3, Annex B.9.4.2.4 Conclusions	DE: No low risk for bumble bees and solitary bees has been shown in the risk assessment. Therefore, we disagree with the overall conclusion that "the risk to bees from the proposed uses of sulfoxaflor and its formulated products 'GF-2626' and 'GF-2372' is acceptable when appropriate mitigation measures are applied." We propose to conclude for bumble bees and solitary bees that a low risk could not be demonstrated.	Co-RMS CZ: See comment (73).	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (83), (92) and (98).
(78)	Vol. 3, Annex B.9.4.2.4 viii) Kinetics analysis	DE: Proposed SFO kinetic overestimates degradation rate for S16-00596-01 (pollen), S16-00596-02 (pollen), S16-00596-03 (pollen), S16-00596-04 (both pollen and nectar), S16-00602-01 (nectar), S16-00602-02 (nectar), S16-00602-03 (pollen), S16-00603-02 (both pollen and nectar). Only 3 sampling points are available for S16-00596-01 (nectar), S16-00603-01 (both pollen and nectar), S16-00603-04 (both pollen and nectar), S16-00604-01 (both pollen and nectar), S16-00604-04 (both pollen and nectar) making calculated DT50	Co-RMS CZ: Agrees that SFO kinetic overestimates degradation rate for the trials you mentioned. In case of the trial S16-00596-04 (pollen) and S16-00602-02 (nectar) last two sampling points are underestimated, however, underestimation was observed beyond the measured DT90. Only one data point (5 days) is significantly underestimated for the trial S16-00596-04 (nectar). Therefore, the RMS accepted DT50 from these trials.	See proposal for further discussion in an experts' meeting in comment (3).

Confirmatory Information (bees) Addendum to B.9				
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**
		unreliable. Very high scattering of sampling values for S16-00596-03 (nectar) and S16-00602-04 (nectar) makes corresponding derived DT50 unreliable. Reasons for high scattering should be provided in the summary. The degradation kinetics assessment for the calculation of DT50 values should be generally performed following the appropriate FOCUS degradation kinetics (2014) flowchart (see Figure 7-1 for persistence endpoints) employing proper software (e.g. Cake). Biphasic models should be explored. Values for duplicates should not being averaged, but used in modelling directly. In general, as only 3 or 4 sampling data points were available for every test, where at least 6 points would be expected for deriving robust DT50 according to the FOCUS degradation guidance (2014), consequently one can expect high uncertainty in the corresponding kinetic modelling. It is unclear why higher frequency of sampling was not used during experiments.	The trials with 3 sampling points have already been excluded (trial S16-00603-04 nectar does not exist). DT50 values for trials S16-00596-03 (nectar) and S16-00602-04 (nectar) have been considered unreliable by the RMS. The reasons for high scattering should be provided by the applicant. Biphasic kinetics have been required for some trials, the corresponding graphs and statistical data will be added to the revised addendum.	

Confirmatory Information (bees) Addendum to B.9				
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**
		In the Table 9.4.2-9 it is mentioned briefly that biphasic kinetic was tested for some trials, however no corresponding graphs and statistic values were demonstrated.		
(79)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies i) Acute oral and contact toxicity to bumblebee (Bombus terrestris) – GF-2626	FR: FR agrees with the proposed endpoints.	Co-RMS CZ: Noted.	Noted
(80)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies ii) Chronic oral toxicity to adult honeybees	FR: FR agrees with the proposed endpoint.	Co-RMS CZ: Noted.	Noted
(81)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity	FR: FR agrees with the proposed endpoint.	Co-RMS CZ: Noted.	Noted

Confirmatory Information (bees) Addendum to B.9				
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**
	studies iii) Larval toxicity laboratory test			
(82)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies iv) Apple pollen and nectar residue trial v) Strawberry pollen and nectar residue trial vi) Pumpkin pollen and nectar residue trial vii) Oil seed rape pollen and nectar residue trial	FR: FR agrees with RMS. These 4 studies are considered valid and acceptable. FR considers these data relevant. Indeed the application was made during full flowering and even though only preflowering application is considered acceptable (by FR, see comment below) for the intended uses, these residue levels might then be regarded as worst-case.	Co-RMS CZ: Noted.	See proposal for further discussion in an experts' meeting in comment (58). See also comments (50), (70) and (83).
(83)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies viii) Kinetics analysis of the sulfoxaflor pollen and nectar data	FR: FR notes that the kinetics analysis of the sulfoxaflor pollen and nectar data were provided on the request of RMS to calculate refined ETR values according to the recommendations of the EFSA guidance (for chronic adult oral and larval oral). It is reminded that the EFSA's GD on risk assessment on bees has not been noted by the Commission and the	Co-RMS CZ: Based on the "Outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology", (EFSA, 2015) the risk assessment for bees should be carried out according to EFSA (2013).	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (77), (92) and (98). It is further noted that the Tier 1 risk assessment according to the SANCO

Confirmatory Information (bees) Addendum to B.9				
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**
		Member States. Regulatory risk assessment based on the current EPPO 2010 scheme would be appropriate. In addition in order to significantly improve the risk assessment for bees, current EFSA's Guidance would need to be updated using available guidelines (e.g. new OECD guidelines for test on larvae) and state of art on bees made available since its publication. The current EPPO 2010 does not take into account the dissipation of residues in the calculation of toxicity / exposure ratios. FR is of the opinion that DT50 calculations and the residue levels measured at different sampling dates remain relevant to assess the fast dissipation of the residues in pollen and nectar, and to support the relevance of the mitigation measure as proposed by RMS (preflowering application made 5 days before flowering).		guidance (European Commission, 2002) is unchanged compared to the previous conclusions reached during the peer review (EFSA, 2014). The assessment of the higher tier studies makes use of the latest state of the knowledge on the topic (also from EFSA, 2013), but is not diverging from the recommendations of SANCO (2002)

Confirmatory Information (bees) Addendum to B.9				
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**
(84)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies ix) Cage tests/Field tests – GF-2626	FR: FR agrees with the observations of the RMS except for the following: Photographic Evaluation of Brood Development in Individual Cells FR is of the opinion that the results obtained for the first brood cycle are not reliable. Brood indices, compensation indices and termination rates were too variable between replicates and showed abnormal development (no development) of the brood including in control. Besides, the average mortality in control (BTR) is too high (73.62%) and not representative of natural brood mortality. This prevents to detect any effect on brood as no statistical difference may be found in such circumstances. These deficiencies are frequently observed in the OECD 75 tunnel test and is partly due to enclosure of the bee colonies (other factors might also play a role in these deficiencies). This often leads to the necessity to reconduct the test to obtain more reliable results. However, in this case, FR considers that sufficient data was provided in the two tests (Renz, 2017 and Szczesniak, 2017) to conclude on no	Co-RMS CZ: Issue of high termination rate in control should be discussed at the expert meeting. The other comments are noted.	Co-RMS and other MSs proposed further discussion on the study Renz, 2017, therefore it is proposed to further consider the use of this study in an experts' meeting. The potential effects of GF-2626 on the honeybee and honeybee brood should also be further considered in an experts' meeting. See also comments (5), where also a high uncertainty on the validity of the brood assessment was noted and comments (21) and (25). Regarding the study by Szczesniak, 2017, see comments (51) and (7)

Confirmatory Information (bees) Addendum to B.9				
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**
		unacceptable risk for the brood (see below). The results obtained for the second brood cycle are acceptable and normal development of eggs and larvae was observed. FR considers that the observations of individual cells only are not sufficient to conclude on potential effect on brood as the observations made just after the application (first brood cycle) are not reliable. Other data on the estimated amount of brood (see below) and results from other studies are necessary. Amount of brood Other data are available on the total amount of brood (or certain brood stages) estimated in the whole colonies. No effect of T1 and T2 was observed. FR opinion on the brood development: All these data indicate that no significant effect on brood development is expected.		

Confirmatory Information (bees) Addendum to B.9				
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**
		Foraging activity FR considers that effect on foraging activity were significant till 6 and 7 days for the tested doses of 24 and 48 g a.s./ha respectively (7th day being the last day for foraging assessments). Besides, FR notes that effects on behaviour were still observed (cramping bees and locomotion problems) even after the colonies were moved to the monitoring site (8 DAA2 to 40 DAA2). Abnormal behaviour was more important in T1 and T2 than in control.		
(85)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies x) Brood feeding study – GF-2626	FR: FR agrees with the observations of the RMS except for the following: Photographic Evaluation of Brood Development in Individual Cells The results obtained for the first brood cycle are deemed acceptable and normal development of eggs and larvae was observed for T1, T2 and	Co-RMS CZ: Issue of high termination rate in control should be discussed at the expert meeting. The other comments are noted.	See proposal for further discussion in an experts' meeting in comment (51).

Confirmatory Information (bees) Addendum to B.9				
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**
		T3. Effects were observed at T4 and T5. FR notes that the toxic reference fenoxycarb show negative impact, indicating that the application of a volume of 200 mL syrup (applied ten times) was sufficient to detect a potential effect on brood development. However variability was high between the 2 replicates (3 are recommended in the original guideline) of the toxic reference for larvae. Therefore the results on larvae should be considered with caution. Effects on eggs were very significant and the results are fully reliable. FR is of the opinion that the results obtained for the second brood cycle are not reliable. Brood indices, compensation indices and termination rates were too variable between replicates and showed abnormal development of the brood including in control. Besides, the average mortality in control (BTR) is too high (47.35%) and not representative of natural brood mortality. This prevents to detect any effect on brood as no statistical difference can be found in		

Confirmatory Information (bees) Addendum to B.9				
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**
		such circumstances. However, even if these results are not considered reliable for second cycle, they seem to indicate that no or minimal effect on brood development is expected for T1, T2 and T3. FR considers that the observations of individual cells only may not be sufficient to conclude on potential effect on brood. Other data on the estimated amount of brood (see below) and results from other studies could be necessary. Amount of brood Other data are available on the total amount of brood (or certain brood stages) estimated in the whole colonies. No effect of T1, T2 and T3 was observed. FR considers that the effects on total amount of brood in T4 (and T5) are treatment related. FR opinion on the brood development: Taken together these data indicate that no significant effect on brood development is expected.		

Confirmatory Information (bees) Addendum to B.9				
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**
		Parameters other than brood development: FR notes that the toxic reference dimethoate did not show strong effect on adult bees. Then the effects observed in treated colonies might be underestimated and the absence of significant effect in T1, T2 and T3 is doubtful. The absence of strong effect of the toxic reference dimethoate might be explained by the application volume of syrup of 200 mL per day per colony which may be too low to induce lethal effect on adult bees. RMS noted that there was no significant effect of the treatments on the mortality of male adult bees and male pupae. However FR notes there were no (or too few) males in the beehives at the time of observations to allow a reliable comparison. Therefore, no reliable conclusions can be drawn on males. FR notes that effects on behaviour were observed (mainly cramping bees and		

Confirmatory Information (bees) Addendum to B.9				
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**
		locomotion problems) even at lower tested rates T1, T2 and T3 (and not only T4 and T5). Even if few bees were affected at T1, T2 and T3, these abnormal behaviours were more important than in control. The raw data available in the study report show that these effects are delayed and were more important between days 16-25. The strong effects observed in T4 and T5 suggest that the lesser effects observed in T1, T2 and T3 at the same period are treatment related. There was no significant effect of the test item treatment T1, T2 and T3 on the colony size until the beginning of overwintering. However FR notes that colony sizes in these treatments increased not as fast as in the control hives (until 37 DAF(Days After Feeding)). This was however not statistically significant. FR also notes that residues were detected in nectar and honey in the hives until 45DAF in T2, T3 and T4 (no data available for T5).		
(86)	Addendum:	FR: FR notes that the study was not yet	Co-RMS CZ: Noted. See also	Addressed

Confirmatory Information (bees) Addendum to B.9

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
	confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies xi) Guttation study – GF-2372	achieved when the study report was prepared and that final report will be issued after the overwintering assessment in spring 2018. FR agrees with the RMS comments.	comment (60).	See also comments (8), (35), (60) and (96).
(87)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies xii) Succeeding crop study – GF-2372	FR: FR agrees with the RMS comments.	Co-RMS CZ: Noted.	Addressed
(88)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.1 Bee toxicity studies xiii) Bumblebee greenhouse study – GF-2626	FR: FR agrees with the RMS comments.	Co-RMS CZ: Noted.	Addressed
(89)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.2 Risk assessment	FR: It is noted in page 192: "An assessment of the acute risk to honey bees was conducted in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO	Co-RMS CZ: It is a typo, it will be corrected.	Addressed The addendum had been corrected considering this comment.

Confirmatory Information (bees) Addendum to B.9

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
	for bees	10329/2002)." FR notes that it is not the case (assessment scheme and triggers are not those of SANCO 10329/2002 but those of the EFSA GD) and this sentence should be removed.		See also comment (83)
(90)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.2 Risk assessment for bees B.9.4.2.2 Screening and Tier1 risk assessment for bees	FR: It is reminded that the EFSA's GD on risk assessment on bees has not been noted by the Commission and the Member States. Regulatory risk assessment based on the current EPPO 2010 scheme would be appropriate. In addition in order to significantly improve the RA for Bees, current EFSA's GD would need to be updated using available guidelines (e.g. new OECD guidelines for test on larvae) and state of art on bees made available since its publication. As higher-tier tests are available and satisfy the requirements of the current EPPO scheme, this part (screening and Tier 1) was not checked in detail by FR.	Co-RMS CZ: Noted. See also comment (83).	Addressed EFSA has noted FR comment. See also comment (83).
(91)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.2 Risk assessment for bees	FR: Kinetics analysis of the sulfoxaflor pollen and nectar data (DT50) were provided on the request of RMS in the purpose to calculate refined ETR values according to the recommendations of the EFSA	Co-RMS CZ: Noted. See also comment (83).	See proposal for further discussion in an experts' meeting in comment (3). See also comments (47), (48), (66), (67), (68), (69), (78) and in addition

Confirmatory Information (bees) Addendum to B.9				
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**
	B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies 1) Risk to honey bees via the nectar and pollen route of exposure Refinement of residue decline in pollen and nectar	guidance (for chronic adult oral and larval oral). The current EPPO 2010 does not take into account the dissipation of residues in the calculation of toxicity / exposure ratios. Then, FR is of the opinion that DT50 calculations are not essential for the risk assessment. The residues measured at Day0 might then be regarded as worst-case. FR considers that these worst-case values can be used in a TER calculation (in a first-tier approach) as it could be done according to the EPPO assessment scheme (even if the scheme recommends this calculation for seed and soil treatments only). This would result in a TER above the trigger of 1 for chronic adult oral (based on the NOEDD of 11.46 ng as/bee/day, highest tested dose) and a TER close to 1 for larval oral toxicity (based on the NOED of 0.200 µg as/larva). In both cases, higher tier tests are necessary to conclude. As the results of the higher-tests available supersede the results of the Tier 1 risk assessment provided by RMS,		comment (83).

Confirmatory Information (bees) Addendum to B.9

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
		this part was not considered essential and was not checked in detail by FR.		
(92)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.2 Risk assessment for bees B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies 1) Risk to honey bees via the nectar and pollen route of exposure - Effect studies Colony feeding study (Szczesniak, 2017) OECD 75 Tunnel study (Renz, 2017)	FR: As it was commented above by FR, the same comments apply to these summaries. Besides: Concerning effects on brood development It is noted in page 220 that high termination rate in control is not the reason for questioning the reliability of brood assessment. FR considers that sufficient data are provided in these two studies to allow a "weight of evidence" approach. Besides the exposure in the test of Renz, 2017 was maximized as bees were forced to forage on freshly treated plants (i.e. without dilution with non-treated matrices) during flowering of a very attractive crop (phacelia). Besides the period of exposure under tunnels of 1 week is sufficient in view of the fast dissipation of the residues in nectar and pollen. The exposure via contaminated syrup in the test of Szczesniak, 2017 might also be considered conservative as syrup was daily administered directly in the hives during 10 days and at	Co-RMS CZ: Issue of high termination rate in control should be discussed at the expert meeting. The other comments are noted.	Some elements are highlighted suggesting the severity of the newly conducted higher tier studies (issued in 2017) and proposing that further testing would be needed ("homing success" study). France view deviates from the view of the co-RMS regarding the proposed risk mitigation options. The studies (Szczesniak, 2017) and (Renz, 2017) should be further discussed in an experts' meeting. See comments (5), (21), (25), (7), (32), (51) and (53). As regards the risk mitigation options, see also comments (12), (21), (41), (54), (56), (57), (58), (74), (77), (83) and (98).

Confirmatory Information (bees) Addendum to B.9				
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**
		concentrations above or corresponding to those measured in the nectar of plants freshly treated. Concerning effects on behaviour In both studies effects were observed on behaviour (mainly cramping bees and locomotion problems) even at lower tested rates T1, T2 and T3 (and not only T4 and T5) in the test of Szczesniak, 2017. Even if only few bees were affected at T1, T2 and T3, these abnormal behaviours were more important than in control (in both studies). The raw data available in the study reports show that these effects are delayed and were more important between days 16-25 in the test of Szczesniak, 2017. The strong effects observed in T4 and T5 suggest that the lesser effects observed in T1, T2 and T3 at the same period are treatment related. These effects were also observed late in the test of Renz, 2017 during the monitoring period and not only during the exposure phase under tunnels. In view of the rapid dissipation of the residues measured in pollen and		

Confirmatory Information (bees) Addendum to B.9				
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**
		nectar of plants, such prolonged effects were not expected and remain unexplained. No guidance is currently available to properly assess the magnitude of such effects and their relevance for the protection goals is not yet determined. No link can be made between an effect on behaviour and survival and development of bee colonies. However FR is of the opinion that such effects should be taken into account as they might indicate potential sublethal effects not measurable in the available tests, effects such as "Homing failure". FR also notes the unexplained persistence of residues in nectar and honey until 45 days after beginning of the exposure in the test of Szczesniak, 2017 (even if these levels are low). FR nevertheless notes that the studies were not representative of a preflowering application (preflowering application made 5 days before flowering is proposed by RMS). Actually, in the conditions of the tests, the exposure of the bee colonies is expected to be higher than		

Confirmatory Information (bees) Addendum to B.9				
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**
		the levels of exposure expected following an application 5 days before flowering. Then these observations on behaviour do not represent an alert and do not change the outcome of the risk assessment. They appear to be a sensitive indicator of an exposure to sulfoxaflor (as they can be noticed even when mortality appeared normal). Then FR would recommend to conduct a "homing success" study to verify the absence of effect such as disorientation of forager bees. Such study should be conducted at level of exposure representative of the conditions of use. Then, FR agrees with RMS to recommend pre-flowering application made 5 days before flowering. However, based on available data, FR disagrees with RMS with the recommendation of an evening application (i.e. during flowering) for the less attractive crop (cereals). Besides, FR would also recommend to avoid application during exsudate production periods. This includes the periods when honeydew is secreted by insects and		

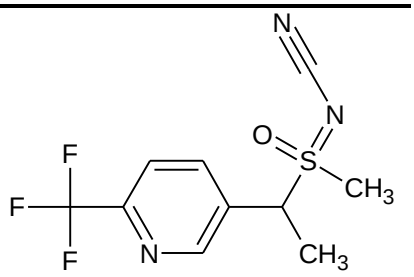
Confirmatory Information (bees) Addendum to B.9				
No.	**Column 1** **Reference to addendum to assessment report**	**Column 2** **Comments from Member States / applicant / EFSA**	**Column 3** **Evaluation by rapporteur Member State**	**Column 4** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the RMS's assessment of confirmatory data**
		the extrafloral nectar produced by plants (this is the case for cotton) as crops may be attractive during these periods. This does not include guttation as exposure of the honeybees via guttation is considered negligible based on available study (Dittbrenner, N. Dr.; 2017) and also on EFSA conclusions on imidacloprid (2015).		
(93)	Addendum: confirmatory Information Volume 3 – Annex B.9 B.9.4.2 Risk assessment for bees B.9.4.2.3 Refinement of the risk assessment through evaluation of higher tier studies 2) Risk to honey bees foraging on guttation fluid 3) Risk to honey bees foraging in nectar or pollen in succeeding crops 4) Risk to honey bees foraging in nectar	FR: Agrees with RMS conclusions.	Co-RMS CZ: Noted.	Addressed

Confirmatory Information (bees) Addendum to B.9

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
	or pollen in flowering weeds 5) The risk to pollinators other than honey bees			
(94)	Vol. 3, B.9, page 4	Applicant: `…ecotoxicological risk assessment are summarised in Table B.9.i.2.` should read `…ecotoxicological risk assessment are summarised in Table B.9.4.1-3.`	Co-RMS CZ: The typo, it will be corrected.	A small correction (typo) on the addendum might be added in a revised addendum, if required by mandate at a later stage.
(95)	Vol. 3, B.9.4.2.1, page 192	Applicant: `…Summary of reported laboratory bee toxicity studies is given in Table B.9.4.4.1. Summary of reported semi-field studies is given in Table B.9.4.4.2.` should read `…Summary of reported laboratory bee toxicity studies is given in Table B.9.4.2-1. Summary of reported semi-field studies is given in Table B.9.4.2-2 and Table B.9.4.2-3.`	Co-RMS CZ: The typo, it will be corrected.	Addressed These typos have been corrected.
(96)	Vol. 3, B.9.4.2.1, page 195	Applicant: In the guttation study, colony size data from the third evaluation is considered to be an artefact of assessment timing as control colonies were assessed first (to avoid residue contamination) early in the morning when foraging activity was low therefore showing a higher number of bees in the colony. The method was adjusted in the remaining 4	Co-RMS CZ: Noted. The final report should be submitted.	Addressed See also comments (8), (35), (60) and (86)

Confirmatory Information (bees) Addendum to B.9				
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**
		assessments in 2017 (data not included in the interim report) to avoid this artefact and showed no effect on colony size from treatments. All assessments including overwintering will be included in the final report available in June 2018.		
(97)	Vol. 3, B.9.4.2.3, page 219	Applicant: There was a small but statistically significant increase in mortality in the morning after the evening application of sulfoxaflor in the tunnel study conducted by Renz (2017). The applicant would like to reiterate that this level of mortality was low, comprising a maximum of 3.5% of the colony size, and had no effect on subsequent colony strength or development.	Co-RMS CZ: Noted.	Noted See also comments (5) and (25).
(98)	Vol. 3, B.9.4.2.3, page 221	Applicant: For cereals, which is not attractive to bees, the mitigation to apply during the evening during the flowering period is not considered to be necessary. As cereal crops do not attract bees, application during the day presents a low risk to bees.	Co-RMS CZ: The appropriate mitigation measure should be discussed at the expert meeting.	See proposal for further discussion in an experts' meeting in comment (58). See also comments (12), (21), (41), (54), (56), (57), (74), (77), (83) and (92).

Appendix B – Used compound codes

Code/trivial name	Chemical name/SMILES notation/InChiKey[(a)]	Structural formula
sulfoxaflor	[methyl(oxo){1-[6-(trifluoromethyl)-3-pyridyl]ethyl}-λ^6-sulfanylidene]cyanamide FC(F)(F)c1ccc(cn1)C(C)S(C)(=O)=NC#N	

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