

European Food Safety Authority



Peer Review Report on clothianidin

- Pesticides peer review meeting reports
- Comments on the draft EFSA conclusion

October 2016

TABLE OF CONTENTS

	Document
00	Cover page
01	Pesticides peer review meeting reports
02	Comments on the draft EFSA conclusion

List of all reports from Pesticides Peer Review Meetings

Date		Section
09.06.2016	Pesticides Peer Review expert meeting 145	Ecotoxicology

REPORT OF PESTICIDES PEER REVIEW MEETING 145

CLOTHIANIDIN

Rapporteur Member State: BE

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
xx Month xxxx	Name	

2. Documents submitted for meeting:

Date	Supplier	File Name
24.05.2016	BE	clothianidin updated DAR addendum confirmatory info BCS BE 2016-05-24.docx
24.05.2016	BE	clothianidin updated DAR addendum confirmatory info Sumitomo BE 2016-05-24.docx
January 2016	BE/EFSA	Clothianidin Confirmatory data Technical Report_925e.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
xx Month xxxx	Name	

Appendix 1: Discussion table: CLOTHIANIDIN

Appendix 1: Discussion Table, Clothianidin (In)

5. Ecotoxicology

It was a specific provision of the approval that the applicant was required to submit to the European Commission further ecotoxicological studies on

- a) the risk to pollinators other than honey bees;
- b) the risk to honey bees foraging in nectar or pollen in succeeding crops;
- c) the potential uptake via roots to flowering weeds;
- d) the risk to honey bees foraging on insect honey dew;
- e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
- f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
- g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>General <u>Experts consultation 1:</u> RMS and MSs to clarify the uses to be assessed under the confirmatory data procedure. (This is relevant for both Sumitomo Agro Europe S.A.S and Bayer data)</p> <p>Note: regarding the Sumitomo data, pending on the clarification on the uses</p>	<p>Sumitomo: Granular applications. In the addendum the uses reported were: -potato, 0.07 kg a.s/ha, BBCH00, soil application -maize/sweet maize/sorghum 0.05 kg a.s/ha, BBCH00 (greenhouse and field uses), soil application -Forestry nursery, 1-2 g/plant, BBCH00, soil application</p> <p>Authorisation at national level (EU pesticides database): AT, BE, BG, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SK, UK (In progress SI)</p>	<p>Open points RMS: -to check with PT whether the use authorised in Portugal is considered in the GAP table available in the addendum -to check with FR whether the glasshouse uses in maize/sweet are permanent</p>

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<p>to be considered, the risk assessment for greenhouse (open structures) and on forestry nursery should be further considered.</p>	<p>Bayer: Seed treatment: -winter cereals: 59-100 g a.s./ha -beet: 10-90 g a.s./ha (0.1-0.9 mg a.s./seed)</p> <p>Meeting discussion It was clarified that all the uses currently authorised in MSs should be considered within the data assessment. RMS should liaise with PT to check whether the use that result authorised in PT in the EU pesticide database, is included in the GAP reported in the addendum. Post meeting note: feedback was received by PT to EFSA on this. Uses on clothianidin currently authorised in PT are related to the formulation DANTOP 50 WG, as foliar spray use on apple and pear, peach and nectarine, potato. Therefore, no further actions are required to the RMS.</p> <p>Clarifications were requested for the glasshouse uses in maize/sweet corn authorised in FR. FR should provide more details i.e. in which kind of protected structure the indoor uses are carried out (permanent structure vs open protected structure). RMS should also provide the No data and no tier I risk assessment for the use in forestry was provided with the addendum. Post meeting note: EFSA considered necessary setting a data gap in the absence of any information.</p> <p>For cereals, since the rate per seed (mg a.s./ seed) was not available, it was considered that it can be estimated by assuming a worst case seed weight. One MS also suggested checking the worst case use for RA for B&M within the authorised uses on cereals in order to be consistent in terms of estimation of mg a.s./seed. Some references on the weight of cereals kernels were provided by MSs (an estimated weight range for 1000 seeds considering different cultivars could be 21 to 61 g). As the worst case assumption could lead to high risk, some experts suggested to perform the RA using both the best and</p>	<p>structure vs open protected structure to provide a RA for forestry nursery</p>

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	<p>worst case values.</p> <p>Overall the majority of the experts agreed the RA should be performed with both the best and worst case assumptions for seed weight (21 to 61 g/1000 seeds).</p> <p>Open points were identified for the RMS</p> <ul style="list-style-type: none"> -to check with PT whether the use authorised in Portugal is considered in the GAP table available in the addendum (not needed anymore, see above post-meeting note) -to check with FR whether the glasshouse uses in maize/sweet are permanent structure vs open protected structure -to provide a RA for forestry nursery (not needed anymore, see above post-meeting note) 	
<p>B.9.1. Risk to honeybees and to pollinators other than honey bees Toxicity data <u>Experts consultation 2:</u> MS to agree the endpoints to be used for risk assessment.</p>	<p>The RMS gave background on the issues:</p> <ol style="list-style-type: none"> 1) The long-term RA for bumblebees was originally performed using the toxicity endpoint available for honeybees. During the peer-review the long-term RA for bumblebees was updated by the RMS by assuming an extrapolation factor of 10 (updated DAR addendum 24/05/2016). 2) The chronic endpoint for honeybees (Kling, 2005) was discussed. The calculations performed by the applicant and EFSA to derive the endpoint were evaluated by the RMS. Although both the approaches were considered valid, the LDD50 of 0.00138 (already agreed in an expert meeting) was used in the RA because based on actual concentrations. 3) Only a provisional endpoint was available for larvae (7-day NOEL 0.00528 µg a.s./larva per development period). No data for bumblebees and solitary bees were available. <p>Overall the experts agreed with the endpoints selected by the RMS in the revised addendum.</p>	<p>Point closed</p>
<p>B.9.1. Risk to honeybees and to pollinators other than honey bees Exposure scenarios <u>Experts consultation 3:</u> MS experts to discuss and agree the relevant route of exposure (i.e. scenarios) to be considered for the uses under evaluation according to the</p>	<p>Relevant scenarios to be considered according to EFSA GD 2013</p> <p>For <u>contact</u> exposure (granules pre-emergence and seed treatment): field margin</p> <p>For <u>oral</u> exposure (granules pre-emergence and seed treatment): Treated crop, field margin, adjacent crop, succeeding crop, flowering weeds in the field (only for granule application)</p>	<p>See below</p>

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<p>EFSA GD 2013 (Addendum B.9.1.4, both data from Sumitomo and Bayer)</p>	<p>Meeting discussion and conclusion: The RMS considered the <u>treated crop</u> scenario not relevant for cereals and sugar beet. This was discussed further under the point B.9.7., below. The relevance of the <u>weed</u> scenario for seed treatment was further discussed under the point B.9.3., below</p>	
<p>B.9.2. Risk to honeybees and to pollinators other than honeybees foraging in nectar or pollen in succeeding crops Exposure <u>Experts consultation 4:</u> MS to discuss and agree the exposure characterisation via succeeding crop for honeybees, bumble bees and solitary bees</p>	<p>Exposure in succeeding crops <u>Sumitomo</u> 2 studies are available a) Harrington (2013): one field site in southern France, where maize that had been treated with clothianidin containing granules was grown for three consecutive years prior to the trial ("<i>natural</i>" exposure) b) Lebrun (2015): reports measured residues in nectar and pollen from different succeeding crops at 5 field sites spread over Europe (France, Germany, Spain, Italy and the UK). On each test site, the soil was treated with clothianidin at a rate corresponding to a theoretical long-term plateau concentration (i.e. 121 g a.s./ha), resulting from years of consecutive use of clothianidin at a rate of 80 g a.s./kg ("<i>forced</i>" exposure)</p> <p>Specific issues to be discussed:</p> <ul style="list-style-type: none"> - the soil PEC_{plateau} measured (study a) or estimated (study b) in the 2 studies - the exclusion of the pollen and nectar residues considered as "outliers" in the UK OSR and UK field beans (pollen only) trials in study b) - the limitation of the number (n=1) of the field site investigated in study a) to cover the 90th percentile residue value for use in the risk assessment - the limitation of the number of sampling (N=1) in study b) to cover the 90th percentile residue value for use in the risk assessment - higher tier assessment: the feasibility of extrapolating results from the field effect study (effects of clothianidin residues in pollen for maize on honeybee colonies; 10.4g/01; Thompson 2011) to succeeding crops that produce nectar 	<p>Open points <u>Bayer and Sumitomo uses</u> RMS to update the tier 2 calculation using the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 µg a.s./kg for pollen and nectar respectively). By updating the TIER II calculations the RMS should use the EFSA SHVAL tool instead of the TIER II approach currently followed in the addendum (note that the 90th percentile residue was not accepted). EFSA will support. This calculation should be documented in a revised addendum.</p>

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	<p>Meeting discussion and conclusion:</p> <p>Harrington (2013) it was argued that there are evidences suggesting that a 3 years period is not enough to reach top soil residue comparable to the expected soil PEC_{plateau}: - only 10 µg/kg of clothianidin was measured, which is less than the estimated value; - taking into account the field dissipation data currently available in the dossier and agreed at the EU level, the experts suggest that the PEC_{plateau} will be reached in 10-15 years.</p> <p>Moreover, it was noted that only the first 10cm of soil were sampled for residues measurement, which cannot be considered representative of the root zone uptake (an acceptable depth would be not less than 20 cm).</p> <p>It was noted that it might be more appropriate not to assess the absolute worst case as it would not be realistic (e.g., due to risk management implications it would be unlikely that clothianidin would be used for a period of 15 years). However it was argued that this would not be a GAP procedure (the residue measured in the root zone should be representative of the uses in GAP regardless of the no. of years of product use). Overall, it was agreed that the study conducted as "<i>natural</i>" exposure design, is not suitable for risk assessment.</p> <p>Lebrun (2015) It was further noted that only one sampling was performed in all the trials of this study, which is not compliant with EFSA (2013)¹, which require 3 sampling time during the study. Regarding the exclusion of the pollen and nectar residues considered as "outliers", it was argued that the dataset is not sufficient to verify that the values can be classified as outliers according to the Dixon Q-test. Moreover it was noted that quantifiable levels of metabolites were measured in the samples classified as outliers (e.g., UK oilseed rape pollen samples). It is therefore unlikely that the measured residues in those samples are</p>	

¹ EFSA (European Food Safety Authority), 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295

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	<p>only due to cross-contamination (as suggested by the applicant). It was also considered that the measured "outliers" values are not outside the range of the dataset provided in the appendix F of the EFSA GD (2013). EFSA considered that the study should not be rejected because it is quite well designed and, in general, well conducted. Additionally the results (including the values quoted as outliers) are in line with the existing dataset. The residue values considered as outliers should be included in the exposure characterisation. However, some MSs were reluctant to consider the study suitable for the exposure characterisation due to fundamental issues (cross-contamination and low sampling number) which may indicate that the study is not reliable.</p> <p>Overall the experts agreed that the absolute highest values for pollen and nectar (80 and 16 ug a.s./kg respectively) by considering all the trials from Lebrun (2015) should be considered as the more suitable values. However, the values to be used for risk assessment of succeeding crop are further discussed below.</p> <p><u>Bayer</u></p> <p>The applicant submitted 5 studies (+2 additional studies) in which the concentration of clothianidin in nectar and pollen of bee attractive crops (phacelia, maize or mustard) were measured under conditions of 'contaminated' soil residues (succeeding crops grown on soils with a history of clothianidin use; 3 studies) or 'forced' soil residues (succeeding crops grown on soils treated with clothianidin to obtain a theoretical plateau concentration of clothianidin in the soil; 2 studies). Summary table with the results of the 5 studies: Table B.9.2.2-4 (p. 75).</p> <p>1-3) Jarratt (2014a,b,c): Three field sites in UK to determine residues of clothianidin and its metabolites TZNG and TZMU in bee relevant matrices (pollen, nectar and guttation fluid) collected from flowering rotational crops (Phacelia and maize) cultivated as succeeding crops on fields with a history of clothianidin use and as such with natural aged soil-residues of this active ingredient ("natural residue").</p> <p>4) Ythier (2014): The study has been performed on a field site in France to cover various scenarios</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>(crop rotations) of a consecutive use of clothianidin and to determine the potential residue level of clothianidin and its metabolites TZNG and TZMU in bee-relevant matrices (nectar and pollen) and guttation droplets of succeeding crops (Phacelia, mustard and maize).</p> <p>5) Striffler & Ballhaus (2014): The study has been performed on field site in Germany to simulate various scenarios (crop rotations) of a consecutive use of clothianidin and to determine the potential residue level of clothianidin and its metabolites TZNG and TZMU in bee-relevant matrices (nectar and pollen) and guttation droplets of succeeding crops (Phacelia, mustard and maize).</p> <p>6) Xu & Dyer (2014): Study to investigate the potential accumulation of clothianidin in soil and crop matrices after multiple years of planting clothianidin treated corn and canola seeds (plant bioavailability and soil accumulation).</p> <p>7) Hammel & Vrbka (2014): Calculation of the plateau concentration in soil for clothianidin based on the EFSA Scientific Opinion (2010) on the assessment of exposure of organisms to substances in soil².</p> <p><u>Specific issues to be discussed:</u></p> <ul style="list-style-type: none"> - can the studies be pooled, considering the two different study designs? - can the studies be considered representative for attractiveness vs 90th percentile for establishing the spatial variation of the RUD values? - can the studies be considered representative of the area of use of the active substance, considering that 3 out of 5 were performed in UK? - the soil horizon depth to consider for the PEC_{plateau} - it has not been fully justified why the forced exposure studies on maize, Phacelia and mustard cover the risk to all succeeding crops 	

² EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2010. Scientific Opinion on outline proposals for assessment of exposure of organisms to substances in soil. EFSA Journal 2010; 8(1):1442, 38 pp. doi:10.2903/j.efsa.2010.1442

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>Meeting discussion and conclusion:</p> <p>It was suggested to select the highest available residue measurement for pollen and nectar and to use it in the exposure assessment. It was noted that the natural exposure studies could be considered more realistic (more representative of the accumulation over years). Therefore, they should be considered more suitable for the exposure assessment rather than the "forced" ones. It was discussed whether "forced" and "natural" exposure studies should be considered equally relevant as the results of the forced exposure studies could be considered worst case.</p> <p>Overall, the majority of the experts agreed that the highest residue level in pollen and nectar from the 'natural' exposure studies should be included in the exposure assessment. This was appropriate in this case as the soil residue levels from the 'natural' exposure studies were equal or higher than the expected accumulation of use over successive years (soil PEC_{plateau}). Note this expected accumulation was estimated by EFSA using the current approach for PECsoil accumulation (ESCAPE model, based on the available DegT50 in the field), which resulted, in any case, lower than the value estimated by the applicant in the dossier. The calculation approach used by the applicant using the soil PEARL approach which is still under development is considered not appropriate in regulatory submissions.</p> <p>It was noted additional trials carried out in Germany were available (see Table B.9.2.2-3 in the revised addendum) from a previous evaluation of clothianidin. Those data were considered realistic worst case regarding the soil concentration. Therefore, they might be used together with the three new natural exposure studies to assess the geographical distribution of RUD values. A full assessment according to the principle of the EFSA GD of the studies was not available in the addendum. It was noted that even considering the additional trials the geographical representativeness would be weak (data only from Germany and UK). Therefore, the 90th percentile cannot be used, in line with the EFSA GD.</p> <p>The following specific points were discussed: <i>- can the studies ("natural" and "forced") be pooled, considering the two different study designs?</i> With this dataset the experts concluded not to pool the data</p>	

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	<p>- <i>can the studies be considered representative for attractiveness vs 90th percentile for establishing the spatial variation of the RUD values?</i> It was considered that using the highest residue value from the natural exposure study was considered the most appropriate approach due to the geographical spread.</p> <p>- <i>can the studies be considered representative for the area of use of the active substance, considering that 3 out of 5 were performed in UK?</i> No. The meeting acknowledged that the assessment regarding the area of use of the substance cannot be easily carried out. Anyway, the geographical representativeness of the natural exposure studies in terms of random distribution is considered not addressed (studies only in Germany and UK). The selection of the highest value might account for these uncertainties.</p> <p>- <i>the soil horizon depth to consider for the $PEC_{plateau}$</i> For annual crops an acceptable depth would be not less than 20 cm for PEC calculation.</p> <p>- <i>it has not been fully justified why the forced exposure studies on maize, Phacelia and mustard cover the risk to all succeeding crops</i> With the available dataset, the absolute worst case was agreed and it might cover this uncertainty.</p> <p>It was discussed whether the most suitable residue values from the entire dataset (Sumitomo and Bayer data) should be considered to address the succeeding crop scenarios (except forestry nursery) for all the uses under evaluation. The experts concluded that it is scientifically sound to use the most realistic data available in the dataset of Bayer. This means that only the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 ug a.s./kg for pollen (Jarratt, 2014b) and nectar (Jarratt, 204c) respectively) could be used. It was highlighted that this approach may not fully address the attractiveness of the crop as foreseen in the EFSA GD as well as the different potential uptake from succeeding crops other than those investigated. However, even if the uncertainty with respect to the recommendation of the EFSA GD cannot be addressed with the available data, the experts</p>	

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	<p>agreed that this was the best way to make use of the available data. The experts agreed that the succeeding crop scenario should be developed to implement the EFSA GD recommendations.</p> <p>Open point RMS to update the tier II calculations using the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 ug a.s./kg for pollen and nectar respectively). These values should be used for the succeeding crop scenarios of all (Sumitomo and Bayer) uses under evaluation (except forestry nursery). By updating the TIER II calculations the RMS should use the EFSA SHVAL tool instead of the TIER II approach (note that the 90th percentile residue was not accepted) currently followed. EFSA will support. This calculation should be documented in a revised addendum.</p>	
<p>B.9.2. Risk to honeybees and to pollinators other than honeybees foraging in nectar or pollen in succeeding crops Risk assessment <u>Experts' consultation 5</u> -Sumitomo data: MS to discuss the review of the 3 year study performed in France (10.4g/01 study from Thompson 2011), provided in the addendum (10.4g/03, Lewis 2015). Pending on the outcome of the above discussion, MS to reconsider if the 3 year study, may be suitable to address the risk to honeybees for maize, as</p>	<p>Higher tier risk assessment for succeeding crop scenario data (Sumitomo), available for honeybees Only maize was consider as succeeding crop. The RMS concluded a low risk on the basis of the use of 10.4g/01 study from Thompson 2011. The study was evaluated by EFSA in EFSA 2013³. In the Addendum the RMS has summarised it again and a review from the applicant was also presented (10.4g/03, Lewis 2015). Reported under B.9.7.</p> <p>Meeting discussion and conclusion: During the previous peer-review, several concerns were raised regarding the field study on maize by Thompson, 2011b and the study analysis by Lewis, 2014. The statistical power was discussed in relation to the high inter-colony variability observed. It was argued that the study has a low statistical power (assuming that the observed variability is a suitable estimation of the real natural variability). It was noted</p>	<p>Open point RMS to update the addendum, by taking into consideration the conclusion of the experts' meeting.</p>

³ EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin. EFSA Journal 2013;11(1):3066, 58 pp. doi:10.2903/j.efsa.2013.3066

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>succeeding crop. - Sumitomo data: MS to discuss how the data gap identified for the succeeding crop can be further address (e.g. are further data on oilseed rape sufficient?). -Bayer data: MS to discuss and agree if the 3 studies on honeybees, bumblebees and solitary bees are suitable and may be used to address the risk via succeeding crop.</p>	<p>that most of the variability (c. 90%) was due to the inter-colony factor rather than inter-site and temporal factors. This may mean that the number of hives per site is more relevant in terms of statistical power than the number of sites. However, it was argued that the analysis was performed on a limited numbers of hives and sites and that therefore the variability partitioning observed in this study may not represent the real natural variability. Further, it was noted that the RMS pointed out the relevance of the biological interpretation of field trials.</p> <p>It was concluded that, generally, when the results are highly variable it is difficult to draw any conclusion on a cause – effect relationship (i.e. treatment or non-treatment related effects). Generally it was acknowledged that the availability of several pieces of evidence (e.g., several comparable field studies) can be useful to make a trend analysis to be used as a weight of evidence for RA.</p> <p>Overall, it was agreed that the re-analysis provided for the study is not sufficient to address the concerns already identified in the conclusion of EFSA 2013 (i.e., the Thompson study cannot be considered sufficient to draw a firm conclusion on the cause-effect relationship).</p> <p>In addition, it was argued that the study may be considered of weak representativeness for succeeding crops that produce nectar.</p> <p>Overall, it was agreed that the higher tier risk assessment for honeybees provided for succeeding crop scenario is not acceptable.</p> <p>Higher tier data (Bayer), available for honeybees, bumble bees and solitary bees</p> <p><u>Field effect studies</u> with treated crops (used as a surrogate for succeeding crops) were used to refine the RA at higher tier level. i.e.:</p> <p>The 3 effects studies on maize performed in France, which have been already evaluated in EFSA 2013.</p> <p>A large-scale monitoring project on the effects of seed treatment of Oilseed Rape with clothianidin on honeybees (Rolke et al., 2014), bumblebees and solitary bees was</p>	

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	<p>submitted (overview of the entire monitoring project is provided under Study 1.8/1 Heimback & Russ, 2014). Within this project:</p> <ul style="list-style-type: none"> - the project area with a complete characterisation of the study fields is reported in Study 1.8/2; Schimmer & Russ, 2014 - the site similarity certification of study sites and its relevance for other rape cultivation sites in Europe is reported in Study 1.8/3; Born, 2014 - measurements of residues of clothianidin in soil before drilling and soil characterisation (Study 1.8/4; Benito et al., M.; 2014) - a comprehensive description of all aspects relevant for the development of the OSR plants at the study fields together with the analysis of the amounts of clothianidin loadings on OSR seeds are reported in Study 1.8/5; Russ et al.; 2014. - residues in nectar and pollen from the treated oilseed rape fields were measured (Persigehl, 2014; Study 1.8/6) - The report from Rolke at al 2014, B.9.7.1 study 1.8/7, page 191) was considered for honeybees. - This study the report from Peters at al 2015, B.9.7.1 study 1.8/8, page 195) was considered for solitary bees. - This study the report from Sterk at al 2014, B.9.7.1 study 1.8/9, page 201) was considered for bumblebees. <p>Meeting discussion and conclusion:</p> <p>The 3 effects studies on maize performed in France were not further discussed (see evaluation note of the EFSA conclusion 2013 on clothianidin for further details). Regarding the <u>OSR large monitoring study</u>, the experts discussed the possible extrapolation of the results from this study to other situation like succeeding crop scenarios and filed margin.</p> <p>For solitary bee, <i>Osmia</i>, the experts noted that the pollen composition indicated that OSR is not a relevant source of pollen. For Bumblebees, the range of pollen composition was very high (2-100%) with an average of 50%. It was argued that in this case, results from hives with a large proportion of OSR pollen could be useful, but this would further reduce</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>the power of the study. Therefore, extrapolation to other scenarios was considered not fully reliable because not worst-case.</p> <p>The study was performed in Germany. The similarity analysis between the study area and the OSR area in EU seems that does not cover the landscape composition i.e. field margin composition in OSR areas other than DE may influence proportion of pollen from different plant species entering into the hive, for example when more attractive plants are available in the field margin. An in depth evaluation of the similarity analysis provided with the study would be appropriate to confirm this.</p> <p>It was noted that the complexity of the study design and the number of analyses and observations performed and reported would require a peer review of all the original study reports. A full consideration of this study within the confirmatory data procedure was not feasible. The study will be evaluated more deeply under the review on the neonicotinoids (Ref. EFSA question number: EFSA-Q-2015-00771).</p> <p>Overall, the experts considered that this study, for the time being, cannot be used to draw firm conclusions on possible extrapolation of the results to other scenarios (i.e. succeeding crops, field margin and treated crop other than OSR) for honeybees. Further consideration for bumblebees would be needed. However, for solitary bees the experts considered that the extrapolation to other crops or scenarios could not be reliably performed because likely the conditions in the study were not worst case for these species</p>	
<p>B.9.3. Potential uptake via roots to flowering weeds Exposure and risk assessment</p> <p>Experts consultation 6: MS to discuss at the meeting if the information on weeds is sufficient to addressed the risk from this scenario</p>	<p>Exposure (flowering weeds)</p> <p><u>Sumitomo</u> data: Study 10.4c/01, Negrini (2014): a large scale (53 locations in FR, IT and HU for maize and 55 locations in FR, ES, DE, UK, HU and PL for potato) monitoring study to determine the presence of weeds and honey dew in potato and maize during the growing season. This was to allow the estimation of the potential uptake via roots to flowering weeds and the risk to honeybees foraging on insect honey dew. From this study it was concluded that the occurrence of flowering weed in potato and maize is low (where weed control following standard agricultural practices is applied) and therefore the exposure to clothianidin residues through flowering weeds in the treated field is negligible.</p> <p>Specific issues to be discussed:</p>	<p>Open point RMS to provide the following clarifications on the Garside et al 2014 study:</p> <ul style="list-style-type: none"> -n. of plots analysed (trials, replicates, observations) -observation timing date and BBCH stage for the crop -n. of species per plot -clarification with regard to the ground cover %

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<ul style="list-style-type: none"> - how the percentage of occurrence of weeds and the average density (number per m²) could be used to assess the weed coverage of the area of use of the substance (i.e. can the percentage of sites with flowering weeds present in the area and/or the average density be directly compared to the 10% trigger?) - consideration of the representative uses other than maize and potato (i.e. sorghum and forestry nursery) <p><u>Bayer</u> data: Study 1.4/1 Garside et al 2014 (statement on the occurrence of flowering weeds in cereals, sugar beet and potatoes based on data from (herbicide) efficacy trials) Specific issues to be discussed:</p> <ul style="list-style-type: none"> - is it true that exposure via flowering weeds is negligible (taking into consideration that neonicotinoids show a high potential of bioavailability)? <p>Meeting discussion and conclusion: The majority of experts agreed to consider the weeds scenario to be relevant for both the uses of seed treatment and granules, although not specified as being necessary in the EFSA GD (for seed treatment). This is because of the combination of soil persistence, systemicity and high toxicity of certain neonicotinoids. The soil persistence and systemicity were also indicated in the succeeding crops experiments. The study by Garside et al 2014 was discussed during the meeting. The study was considered useful to address the relevance of the weeds scenario for the specific case. However, some clarification would be needed: -n. of plots analysed (trials, replicates, observations) -observation timing date and BBCH stage for the crop -n. of species per plot -clarification with regard to the ground cover % reported in the study (average or total ground cover) Therefore an open point was identified for the RMS to provide these clarifications in a revised RAR (also relevant for imidacloprid). Addressing this point the RMS may request the applicant to provide the data in the study Garside et al 2014 in a tabular format (.xls).</p>	<p>reported in the study (average or total ground cover). RMS to provide a rough estimation of the area occupied by weeds in the study by Negrini (2014), based on the data available in the study report. A revised addendum should be provided.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>Pending on these clarifications a final conclusion can be drawn by EFSA.</p> <p>The study from Negrini (2014) was discussed during the meeting. In this study the presence of weed at different crop growth stages (which was considered essential for the relevance of the weed scenario for clothianidin) was investigated. The information available in the report was i) the number of weed species and ii) the total area of plots. The weed ground cover was not available i.e. no data available regarding the area occupied for each species. However, a rough estimation could be performed by using the weed density and the plot area reported in the study. It was also noted that the number of weeds (i.e. density) and their attractiveness might be more relevant in this case than the 10% weed coverage. However, the experts agreed that the 10% coverage could still be considered a good 'trigger' for this assessment.</p> <p>The RMS should provide this estimation in a revised addendum (this is an open point).</p> <p>Overall, if, pending on the clarifications to be provided in the revised addendum, all the available data (Sumitomo and Bayer) will demonstrate that the flowering weed coverage is below the 10% trigger, the weed scenario for potato, maize, cereals and sugar beet can be considered of low relevance as exposure route. Other uses were not covered by these data i.e. sweet corn/sorghum and forestry nursery. The experts concluded that for sweet corn/sorghum the data on cereals and maize can be used while for forestry nursery it was considered necessary to identify a data gap.</p>	
<p>B.9.4. Risk to honeybees foraging on insect honeydew Exposure Experts consultation 7: MS to discuss at the meeting if the information from the study Negrini 2014 is sufficient to address the exposure to honeydew.</p>	<p>Exposure (honey dew)</p> <p><u>Sumitomo</u> data: Study 10.4c/01, Negrini 2014 (see discussion below)</p> <p><u>Bayer</u> data: Statement 1.5/1 Nauen, 2013 (this statement provides information of the mode of action, known mechanisms of resistance and resistance risk of the three active substances</p>	<p>Point closed</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>present in the product Janus Forte (the pyrethroid beta-cyfluthrin and the neonicotinoids imidacloprid and clothianidin), used as seed treatment in sugar beet).</p> <p>Meeting discussion and conclusion:</p> <p>The study Negrini 2014 investigated the occurrence of honeydew in the potato and maize at different crop growth stages. The conclusion of the study authors and RMS was that, considering the overall limited occurrence of honeydew in potato and maize, it may be considered as a not relevant route of exposure for treated crops. The experts agreed with this conclusion for all the granular uses of clothianidin under evaluation, including sweet corn/sorghum and forestry nursery.</p> <p>The statement paper by Nauen, 2013 was also discussed. Generally the argumentation provided was agreed since clothianidin is intended to control sap sucking insects, at least during the first weeks of growth the exposure of honeybees is likely to be low.</p> <p>It was noted that the ED50 in the study by Foster 2008 was not consistent among the tested clones (varying about 2 orders of magnitude). It was agreed that neonicotinoids resistance to aphids could not be excluded (there are several reported cases of neonicotinoids resistant strains of aphids in literature, including <i>M. persicae</i>, which is an highly polyphagous species), (Bass, Chris, et al. "The global status of insect resistance to neonicotinoid insecticides." <i>Pesticide biochemistry and physiology</i> 121 (2015): 78-87). Moreover it was noted that at later crop growth stages (i.e., after the 8th week) the efficacy of the aphids control will be lower, therefore a certain exposure of honeybees through honeydew might occur.</p> <p>Overall, the experts agreed on the basis of the available data that honeydew can be considered as a low relevance route of exposure for the treated crop and for clothianidin and (relevant for all the uses under evaluation)</p> <p>The experts agreed that this line of evidence is also relevant for imidacloprid. However, from the Foster 2008 study, the variability in the effects concentration on <i>M. persicae</i> was lower than the one for clothianidin. (move to the imidacloprid meeting report)</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>B.9.5. Potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure</p> <p>Experts consultation 8: MS to discuss if the available data may be considered sufficient to conclude that the exposure to guttation fluids is not relevant. This</p>	<p>Sumitomo data 4 studies are available i.e.: <u>Maize</u> 10.4e/01 Thompson 2011a. The study was already considered in EFSA 2013. Since no new data were submitted triggering the re-assessment of this study, the previous conclusion on the risk from guttation is still valid (i.e. data gap due to difficult to extrapolate to situation other than the experimental ones, acute risk not excluded) <u>Potatoes</u> 10.4e/02 and 10.4e/03 Thompson 2013a, b. These studies were already considered in EFSA 2015⁴ on foliar spray uses. The first one was considered not suitable for risk assessment. The second was considered not representative for residue in guttation fluids for the uses as granular applications. 10.4e/04 Ansaloni 2015. This is a new study: to investigate the effects on honeybee colonies of clothianidin applied in-furrows at sowing of potato seeds as a result of exposure to the guttation fluid used as a source of water. The interaction between flight and foraging activity of the bees and the presence of guttation on potato plants, the mortality of the bees, and the condition of the colonies (adult worker population, brood population, presence of healthy queen and areas with pollen and nectar storages) were studied.</p> <p>Meeting discussion and conclusion: <u>Exposure:</u> It was noted that it might be speculated that a different behaviour in a.s. translocation in guttation for seed treatment and granules occurs. It was discussed whether the selection of maximum/mean residue values, as done by the RMS in the addendum to the confirmatory data, may be considered worst case, due to the fact that the dataset is not sufficient for selecting the 90th percentile of exposure as suggested by the EFSA, 2013. It was noted that for the guttation it might be more relevant to have a study in worst case environmental conditions that may maximise this phenomenon. The available study seems to satisfy this condition.</p>	<p>Open point The RMS should update the TIER II calculations for winter cereals reported in the Addendum related to the Bayer dataset.</p>

⁴ EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering all uses other than seed treatments and granules . EFSA Journal 2015;13(8):4210, 77 pp. doi:10.2903/j.efsa.2015.4210

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>It was pointed out that according to EFSA GD 2013, unless it can be proven that it is scientifically justified, the maximum PEC value should be used for chronic assessment. Otherwise the TWA PEC could be considered acceptable.</p> <p>It was noted that there is a decline of the a.s. Moreover, it was pointed out that decline of the a.s. in guttation fluids is also assumed to occur according to the EFSA GD. Therefore, it could be justified to use the TWA a.s. concentration in guttation for the chronic assessment (over 5 days for larvae and 10 days for adults) in this case.</p> <p>Overall, the experts concluded that the approach followed by BE in the addendum of clothianidin can be considered acceptable. In particular, the highest residue value was considered acceptable for the acute exposure assessment. For the assessment to larvae it was agreed that the most appropriate value to be used is the TWA concentration over 5 days. For the chronic assessment to adults it was agreed that the most appropriate value to be used is the TWA concentration over 10 days.</p> <p>The meeting agreed to consider this conclusion relevant for both the Sumitomo and Bayer data (see open point below, under the discussion of Bayer data).</p> <p>Since the Bayer dataset on guttation for winter cereals covers both clothianidin and imidacloprid (i.e. a formulation containing the 2 active substances was investigated), this conclusion was also agreed for imidacloprid.</p> <p><u>Effects:</u></p> <p>For potatoes the RMS concluded low risk. However, it was noted that some of the studies available were previously considered not suitable for the RA.</p> <p>The only new study (10.4e/04 Ansaloni 2015) was taken into account for the higher tier RA.</p> <p>However it was argued that one single study might be not sufficiently informative and representative of the worst-case. The geographical representativeness of the study was also considered low (only one study location in Spain cannot be considered sufficiently representative for both S- and N-EU). Furthermore it was noted that the environmental conditions in the study location (Spain) were not likely to represent the worst case (water</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>saturation in soil and high humidity did not occur).However, it was noted that the study conditions might be a worst case for other water sources (the water demand for the honeybee colony is likely to be higher in S-EU).</p> <p>The statistical power of the study was also questioned.</p> <p>Regarding the extrapolation of the data to maize it was argued that there are substantial difference in potato and maize with regard to the guttation. For maize and sorghum no new data were provided. Therefore the RMS concluded that further data are needed to make this extrapolation.</p> <p>See overall conclusion below.</p> <p>Bayer data: 5 new effect studies were presented and reported from page 106 to 147: 3 on winter cereals (1 on wheat and 2 on barley), 2 for sugar beet. In the studies on winter cereals a PPP with clothianidin and imidacloprid was investigated. In the studies with sugar beet, a PPP with clothianidin, imidacloprid and beta-cyfluthrin was investigated. In these studies, the guttation frequency of the crop, the honeybee activity in the guttation crop and the <u>residues present in guttation fluid</u> were assessed.</p> <p>Specific issues to be discussed:</p> <ul style="list-style-type: none"> - in the 2 studies performed on winter cereals it is not ideal that hives were overwintered on the test site, in the absence of specific information regarding the availability of nearby food sources (additional information regarding the surrounding vegetation and on the colony assessments has been provided and included in the revised Addendum) - the studies submitted were all conducted in Germany. It is stated that the data are worst case, however, this statement is not well documented <p>Meeting discussion and conclusion: <u>Exposure:</u> It was pointed out that the dataset is not sufficient for selecting the 90th percentile of exposure as suggested by the EFSA, 2013.</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>As currently the 90th percentile residue level was used, an open point for the RMS to use the maximum residue level from the Bayer data for the acute exposure assessment was identified (see the discussion above, under Sumitomo data).</p> <p><u>Effects:</u></p> <p>A detailed discussion on each single study available investigating occurrence of guttation and effects on honeybees was not performed, but the available dataset was considered for drawing a conclusion.</p> <p>The experts agreed that the available data set is generally not sufficient to draw a firm conclusion on the non-relevance of guttation as route of exposure. Concerns were expressed as to whether the available data are sufficient to address the SPG. The extrapolation to other crops would need a larger dataset. In general even is for some crops a good dataset is available further data are needed to draw a firm conclusion.</p> <p>Some experts noted that there is evidence that bees are not primary collecting water from guttation fluids. The most relevant guttation plant (worst case) is maize, in which the residues are high. However, generally this route of exposure should be further investigated, because the current evidences are not sufficiently informative.</p> <p>Generally, the experts considered guttation as not the primary route of exposure for bees, even if cannot fully excluded (i.e. evidence from cereals and maize data). Even if acute effects could not be excluded, the long term risk is likely to be low.</p> <p>Overall conclusion on the risk from guttation for the uses under evaluation of clothianidin and imidacloprid</p> <p>As a general line of evidence the experts noted that bees using guttation are only rarely observed. This consideration is based not only on the available data in the confirmatory data package (imidacloprid and clothianidin) but also on other data available at the MS level for other dossiers or literature.</p> <p>It was noted that the results from the studies on cereals and sugar beet are generally in line with the results of the above reported study. It was noted that guttation occurred but no clear effect was reported in the studies. However the statistical power was not assessed. It was noted that, for cereals, if the three available studies would be pooled</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>together, the statistical power might be higher.</p> <p>Taking into account all the evidences discussed during the meeting, the experts identified uncertainties driven by the lack of clear pieces of evidence (i.e., the adequacy of the dataset to address the SPG, lack of evidence demonstrating the low relevance of this route of exposure across Europe). Overall the majority of the experts considered that the risk for just the uses under evaluation can be considered low on the basis of the available data. The minority of the experts considered that more information is needed to draw a firm conclusion (i.e., on whether the power of the available effects assessment is sufficient to conclude no effect and there is uncertainty around the exposure assessment).</p> <p>The experts agreed that the guttation assessment for honeybee also covers the bumblebees and solitary bees as specified in the EFSA GD.</p>	
<p>B.9.6. Potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure (Field margin and adjacent crop) Exposure and risk assessment Experts consultation 9: -MS to discuss and agree if the exposure via dust drift for seed treatment of winter cereals and sugar beet is adequately addressed -MSs to the risk assessment to honeybees, bumblebees and solitary bees via exposure to dust.</p>	<p>Sumitomo: no new data were provided. In the conclusion EFSA 2013 a low risk was concluded for dust exposure for granular applications, based on dustiness studies and assuming that there is no air-flow in the application machinery when the granule are applied in furrow. No tier I or TierII risk assessment was provided.</p> <p>Meeting discussion and conclusion: It was noted that there is evidence from some MSs showing that some drift may occur for some granular products. Therefore, it was suggested that until clear information is provided with regard to the transplanting/sowing machinery to be used it should not be speculated that the exposure through dust drift cannot be relevant for granules. It was noted that this was not the conclusion drawn in EFSA, 2013 where a low risk was concluded, provided that no airflow sowing machinery are used. It was noted that the occurrence of dust drift may be substance-specific and that the Heubach value alone was not necessarily sufficient to exclude the occurrence of dust drift. However, those data have not been peer-reviewed because not available to the meeting and not submitted within the confirmatory dataset. However, the issue will be reflected in</p>	<p>Open points The RMSs (BE) for clothianidin and (DE) for imidacloprid to perform tier I calculation on the basis of the dust drift deposition values in SANCO/10553/2012, January 2014. The calculations should be provided for honeybees, bumblebees and solitary bees.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>the EFSA conclusion.</p> <p>Bayer (exposure): dust drift was measured in 4 studies for winter cereals, 3 in Germany.</p> <p>The applicant submitted studies measuring dust drift residues in the field margin in winter barley (2 sites in DE) and winter wheat (2 sites in DE), in winter barely after sowing with pneumatic sowing machinery (3 sites in DE), 1 study to assess potential effects on honeybee colonies during and after air sowing operation of winter barley seeds and 1 study to assess potential effects on honeybee colonies during and after vacuum-pneumatic sowing operation of coated sugar beet pills (4 sites in UK).</p> <p>Specific issues raised during the peer review:</p> <ul style="list-style-type: none"> - for the winter cereals studies: the draft Guidance Document on Seed treatment (SANCO/10553/2012, January 2014) gives 0.38 g/ha as a worst-case dust deposition for cereals which is 8 times higher than the maximum of measured in these studies - for the winter cereals studies: the two studies give only limited information for evaluation of dust deposition: do they reflect a best-case situation as no Heubach value (% dust) and no Heubach-as values (considering the concentration of as in dust) are available? - whether 3-D-dust deposition exposure (which can be expected to be about 13 times higher) should be further considered. - the EFSA Guidance Document for bees suggest to select the sowing machine at EU level that deliver the 90th percentile based on ranking of dust emission and area of use in order to ensure that the machine used for experimental measurement cover the 90th percentile. This exercise would be needed to conclude that the measured value of 0.61 g a.s./ha is worst-case for EU - to discuss the Heubach values and the Heubach a.s. values from the study Lueckmann (2014) study in the light of the data given in the draft Guidance Document on seed treatment (SANCO/10553/2014, January 2014), in order to ensure that these seed parameters from the study represent the agricultural practice in Europe 	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<ul style="list-style-type: none"> - less sites were used in the dust drift field study than specified in the guidance document - the extrapolation of the results from the large scale field study on oilseed rape to demonstrate an acceptable risk to bumblebees following exposure to dust drift (RA based on higher tier) <p>Bayer (risk assessment): tier I and tier II were available. The tier II is based on measured dust deposits. A high risk was identified. The Tier II should be discussed, pending also on the discussion on the relevance of the exposure.</p> <p>A higher tier risk assessment to honeybees was based on a honeybee effect study in UK on winter barley (Lueckmann&Stafeel 2015, 1.7/4) and on sugar beet in Germany (Lueckmann&Stafeel 2014, 1.7/5). The relevance of these studies and the higher tier risk assessment should be discussed.</p> <p>The RMS concluded a low risk to honeybees for winter cereals and sugar beet. No higher tier data were available for bumblebees and solitary bees. The higher tier data on honeybees on winter barley (Lueckmann&Stafeel 2015) and the study on OSR on bumblebees and solitary bees were used to conclude a low risk. This should be discussed at the meeting.</p> <p>Meeting discussion and conclusion: <u>Exposure</u> -SANCO/10553/2012, January 2014</p> <p>The most recent version of the SANCO/10553/2012, November 2015 rev.9 on seed treatment reports updated dust deposition values compared to the ones used in the EFSA GD. Since this is considered as the latest best available knowledge (in line with the art. 21 of Reg. 1107/2009), the majority of the experts considered that SANCO 2015 should be used in the exposure assessment, while the minority considered that EFSA GD should be used as it is a final version and published.</p> <p>As a consequence open points were identified for the RMSs (BE for clothianidin, DE for</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>imidacloprid) to update the tier I calculations for both oral (acute, chronic, larvae) and contact (acute) exposure for all the bees (honeybees, bumblebees and solitary bees) where the tox endpoints are available.</p> <p>- <u>winter wheat</u> (studies 1.7/1 and 1.7/2) and <u>winter barley</u> studies with clothianidin and imidacloprid (study 1.7/3 - Lueckmann, 2014, R11129) and <u>winter barley</u> study on clothianidin (study 1.7/4 – Lueckmann & Staffel, 2015):</p> <p>It was further noted that there is no information as to whether the machinery used in all the studies covers the 90th % of exposure.</p> <p>For <u>winter wheat</u> (studies 1.7/1 and 1.7/2) Heubach value (% dust) and Heubach-as values are not available. This information is considered by SANCO 2014 as essential to properly address dust drift deposition assessment.</p> <p>For <u>winter barley</u> (studies 1.7/3 and 1.7/4), it was noted that, Heubach value was available.</p> <p>However, it was argued that individual studies with few varieties might be not sufficiently representative (and sufficient to overrule the dust deposits in SANCO 2015 based on a larger dataset) as the amount of dust drift is very much dependent on the quality of the seed dressing rather than the properties of the a.s.</p> <p>Therefore according to the SANCO 2015 these studies alone are not sufficient for estimating the exposure from dust deposition.</p> <p>Overall, for both imidacloprid and clothianidin, it was agreed to use only the exposure values in the SANCO 2015 in the tier I. No value from the available data was considered suitable for tier II calculations.</p> <p><u>Effects</u></p> <p>In the study 1.7/4 – Lueckmann & Staffel, 2015 effects were also investigated.</p> <p>The RMS concluded a low risk on the basis of the observations from this study, showing no acute and long-term effects. The biological observations were done on <i>phacelia</i> as adjacent crop. The statistical power of the study was not assessed but it is likely to be low (i.e. 2 control and 2 treated fields each filed with 8 hives). The study was conducted in UK and it was considered not representative of other EU conditions. The meteorological conditions and the bee activity in the study should be compared with other EU situations</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>for ensuring that it represents a worst-case. The RMS noted the use of <i>phacelia</i>, being a highly attractive crop, was supposed to cover uncertainties regarding other factor influencing the exposure. One study with 2 sites was considered not sufficient to address the exposure and effect SPG.</p> <p>The quality of seeds used in the study was not representative of the standard treated cereals seeds on the market, therefore the exposure could not be considered as worst-case.</p> <p>The majority of the experts considered that the study alone, without further data cannot be considered sufficient to draw a conclusion regarding the effects on bees. It was noted that with respect to the winter cereal uses, the study may represent a worst-case situation (sowing in the study done when flowering field margin were present). Overall, the experts considered that the risk to honeybees from dust exposure for winter cereals should be further addressed. The same conclusion is for bumblebees and solitary bees.</p> <p>For bumblebees and solitary bees and also honeybees the large monitoring study on OSR on clothianidin was used as line of evidence in the higher tier risk assessment by the RMS (see general discussion on this study, below).</p> <p>Study 1.7/5 – Lueckmann & Staffel, 2014</p> <p>For sugar beets the studies available for imidacloprid and clothianidin were similar as study design as for the UK study in winter cereals. Therefore the above argumentation is agreed to be relevant also in this case. However, it was noted that the concentration of the active substances and the dust deposition is very low. The experts considered as line of evidence the low exposure is sufficient to conclude a low risk to bees (HB, BB, SB) for sugar beet for both clothianidin and imidacloprid.</p> <p>It is considered however necessary to have the Tier I calculations based on the SANCO values as agreed above (see open point for the RMSs)</p>	
<p>B.9.7. Acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of</p>	<p>Sumitomo:</p> <p>For <u>maize</u> the 3 year study by Thompson 2011b, evaluated in EFSA 2013 was presented. A review of the statistical power was also provided. Only the latter has to be</p>	<p>See open point below.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>contaminated nectar and pollen (Treated crop) Exposure Experts consultation 10: MSs to discuss if the available data are sufficient to address the exposure for the use in potato. Risk assessment</p>	<p>considered (see experts' consultation under B.9.2.) For <u>potato</u> only measured residue levels in pollen was provided (Bousquet 2014). Since the 90th percentile was used by the RMS in the addendum, in line with the discussion above, the highest value should be used (see open point for Tier II under experts' consultation 11)</p> <p>Meeting discussion and conclusion</p> <p>Bayer: the large monitoring study on OSR mentioned above was presented (see Experts consultation 4).</p>	
<p>B.9.7. Acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen (Treated crop) Risk assessment Experts consultation 11: -MSs to discuss the risk assessment to honeybees, bumblebees, solitary bees (tier II and higher tier)</p> <p>-Bayer data: the new higher tier studies on honeybees, bumblebees and solitary bees on OSR, under discussion point 4 can be considered for the treated scenario. This point is also linked to the discussion point 3, on the scenarios for the uses under evaluation)</p>	<p>Sumitomo Tier I was calculated for maize/sweet maize/sorghum and potato. The TierII took into account the residue levels in pollen of potato and maize from 3 years study in France for maize. High risk was identified to honeybees, bumblebees and solitary bees. Higher tier: RMS concluded a low risk to honeybees on the basis of the 3 years study in France for maize The RMS also concluded that the results can be extrapolated to potato. The RMS considered the risk to bumblebees and solitary bees as an issue that could not be finalised. Meeting discussion and conclusion: See experts' consultation under B.9.2. succeeding crop. For the TIER, RMS should update the calculations with the highest residue levels available (open point).</p> <p>Bayer The RMS did not present any risk assessment to honeybees, bumblebees and solitary bees, assuming that the treated crop scenario is not relevant for the uses under evaluation.</p> <p>Meeting discussion and conclusion</p>	<p>Open point RMS to provide the TIER II calculations by considering the highest residue values for maize/sweet maize/sorghum and potato to be consistent with the approach agreed under experts' consultation B.9.2, succeeding crop. For cereal, TIER I calculation should be provided.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p><u>Sugar beet</u> The experts considered the treated crop could be considered as not relevant, when the crop is not a seed bearing crops. Sugar beet flowers the second year (is a biannual crop), therefore it was noted the treated crop is in any case not relevant but rather might be considered as succeeding crop. It was noted that sugarbeet when are not growth for seed production they are harvested and planted in other areas. Overall, the experts considered that a specific treated crop scenario should be developed for bi-annual crop. For the use under evaluation, it was concluded that this scenario is not relevant if beet are not grown for seed production. However, in the GAP table available in the addendum this information was not reported. At MS level, where uses on beet are authorised this issue should be further considered.</p> <p><u>Cereals</u> The applicant provided some argumentations e.g. wind pollinated, not attractive. No data where provided to support this argumentation. The EFSA GD 2013, due to diverging data from literature, considered that further data should be provided to exclude collection of pollen by honeybees, bumblebees and solitary bees. The palynological analysis available in the large monitoring study does not allow to fully exclude wheat pollen collection e.g. from the photos available in the study report, wheat was not flowering. The attractiveness of agricultural horticultural crops was further analysed by van der Steen, et. Al., 2015 report n. 606, Wageningen Univerisity. This analysis is based on a literature review and experts judgment. Cereals are reported as not attractive. However, the paper is in Dutch and not available to other MSs e.g. not peer reviewed. By quickly looking at the references of the report, it seems that only one paper, published after 2013, is cited. Overall, the experts concluded that the EFSA GD is still the reference point for attractiveness of cereals. Therefore an open point was identified for the RMS to provide the TIER I risk assessment.</p> <p>The large monitoring on OSR</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>For solitary bee, <i>Osmia</i>, the experts noted that the pollen composition indicated that OSR is not a relevant source of pollen. For Bumblebees, the range of pollen composition was very high (2-100%) with an average of 50%. It was argue that in this case, results from hives with a large proportion of OSR pollen could be useful, but this would further reduce the power of the study. Therefore, extrapolation to other scenarios was considered not fully reliable because not worst-case.</p> <p>The study was performed in Germany. The similarity analysis between the study area and the OSR area in EU seems that does not cover the landscape composition i.e. filed margin composition in OSR areas other than DE may influence proportion of pollen from different plant species entering into the hive, for example when more attractive plants are available in the filed margin. An in depth evaluation of the similarity analysis provided with the study would be appropriate to confirm this.</p> <p>It was noted that the complexity of the study design and the number of analyses and observations performed and reported would require a peer review of all the original study reports. A full consideration of this study within the confirmatory data procedure was not feasible. The study will be evaluated more deeply under the review on the neonicotinoids (Ref. EFSA question number: EFSA-Q-2015-00771).</p> <p>Overall, the experts considered that this study, for the time being, cannot be used to draw firm conclusions on possible extrapolation of the results to other scenarios (i.e. succeeding crops, field margin and treated crop other than OSR) for honeybees. Further consideration for bumblebees would be needed. However, for solitary bees the experts considered that the extrapolation to other crops or scenarios could not be reliably performed because likely the conditions in the study were not worst case for these species</p>	

TABLE OF CONTENTS

	Document
00	Cover page
01	Pesticides peer review meeting reports
02	Comments on the draft EFSA conclusion

List of all reports from Pesticides Peer Review Meetings

Date		Section
09.06.2016	Pesticides Peer Review expert meeting 145	Ecotoxicology

REPORT OF PESTICIDES PEER REVIEW MEETING 145

CLOTHIANIDIN

Rapporteur Member State: BE

Specific comments on the active substance in the section

5. Ecotoxicology

are already listed in the relevant reporting table. Comments submitted for this meeting are listed below.

1. Comments submitted for this meeting:

Date	Supplier	File Name
xx Month xxxx	Name	

2. Documents submitted for meeting:

Date	Supplier	File Name
24.05.2016	BE	clothianidin updated DAR addendum confirmatory info BCS BE 2016-05-24.docx
24.05.2016	BE	clothianidin updated DAR addendum confirmatory info Sumitomo BE 2016-05-24.docx
January 2016	BE/EFSA	Clothianidin Confirmatory data Technical Report_925e.pdf

3. Documents tabled at the meeting:

Date	Supplier	File Name
xx Month xxxx	Name	

Appendix 1: Discussion table: CLOTHIANIDIN

Appendix 1: Discussion Table, Clothianidin (In)

5. Ecotoxicology

It was a specific provision of the approval that the applicant was required to submit to the European Commission further ecotoxicological studies on

- a) the risk to pollinators other than honey bees;
- b) the risk to honey bees foraging in nectar or pollen in succeeding crops;
- c) the potential uptake via roots to flowering weeds;
- d) the risk to honey bees foraging on insect honey dew;
- e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
- f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;
- g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>General <u>Experts consultation 1:</u> RMS and MSs to clarify the uses to be assessed under the confirmatory data procedure. (This is relevant for both Sumitomo Agro Europe S.A.S and Bayer data)</p> <p>Note: regarding the Sumitomo data, pending on the clarification on the uses</p>	<p>Sumitomo: Granular applications. In the addendum the uses reported were: -potato, 0.07 kg a.s/ha, BBCH00, soil application -maize/sweet maize/sorghum 0.05 kg a.s/ha, BBCH00 (greenhouse and field uses), soil application -Forestry nursery, 1-2 g/plant, BBCH00, soil application</p> <p>Authorisation at national level (EU pesticides database): AT, BE, BG, CZ, DE, DK, EL, ES, FI, FR, HR, HU, IE, IT, LU, NL, PL, PT, RO, SK, UK (In progress SI)</p>	<p>Open points RMS: -to check with PT whether the use authorised in Portugal is considered in the GAP table available in the addendum -to check with FR whether the glasshouse uses in maize/sweet are permanent</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>to be considered, the risk assessment for greenhouse (open structures) and on forestry nursery should be further considered.</p>	<p>Bayer: Seed treatment: -winter cereals: 59-100 g a.s./ha -beet: 10-90 g a.s./ha (0.1-0.9 mg a.s./seed)</p> <p>Meeting discussion It was clarified that all the uses currently authorised in MSs should be considered within the data assessment. RMS should liaise with PT to check whether the use that result authorised in PT in the EU pesticide database, is included in the GAP reported in the addendum. Post meeting note: feedback was received by PT to EFSA on this. Uses on clothianidin currently authorised in PT are related to the formulation DANTOP 50 WG, as foliar spray use on apple and pear, peach and nectarine, potato. Therefore, no further actions are required to the RMS.</p> <p>Clarifications were requested for the glasshouse uses in maize/sweet corn authorised in FR. FR should provide more details i.e. in which kind of protected structure the indoor uses are carried out (permanent structure vs open protected structure). RMS should also provide the No data and no tier I risk assessment for the use in forestry was provided with the addendum. Post meeting note: EFSA considered necessary setting a data gap in the absence of any information.</p> <p>For cereals, since the rate per seed (mg a.s./ seed) was not available, it was considered that it can be estimated by assuming a worst case seed weight. One MS also suggested checking the worst case use for RA for B&M within the authorised uses on cereals in order to be consistent in terms of estimation of mg a.s./seed. Some references on the weight of cereals kernels were provided by MSs (an estimated weight range for 1000 seeds considering different cultivars could be 21 to 61 g). As the worst case assumption could lead to high risk, some experts suggested to perform the RA using both the best and</p>	<p>structure vs open protected structure to provide a RA for forestry nursery</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>worst case values.</p> <p>Overall the majority of the experts agreed the RA should be performed with both the best and worst case assumptions for seed weight (21 to 61 g/1000 seeds).</p> <p>Open points were identified for the RMS</p> <ul style="list-style-type: none"> -to check with PT whether the use authorised in Portugal is considered in the GAP table available in the addendum (not needed anymore, see above post-meeting note) -to check with FR whether the glasshouse uses in maize/sweet are permanent structure vs open protected structure -to provide a RA for forestry nursery (not needed anymore, see above post-meeting note) 	
<p>B.9.1. Risk to honeybees and to pollinators other than honey bees Toxicity data <u>Experts consultation 2:</u> MS to agree the endpoints to be used for risk assessment.</p>	<p>The RMS gave background on the issues:</p> <ol style="list-style-type: none"> 1) The long-term RA for bumblebees was originally performed using the toxicity endpoint available for honeybees. During the peer-review the long-term RA for bumblebees was updated by the RMS by assuming an extrapolation factor of 10 (updated DAR addendum 24/05/2016). 2) The chronic endpoint for honeybees (Kling, 2005) was discussed. The calculations performed by the applicant and EFSA to derive the endpoint were evaluated by the RMS. Although both the approaches were considered valid, the LDD50 of 0.00138 (already agreed in an expert meeting) was used in the RA because based on actual concentrations. 3) Only a provisional endpoint was available for larvae (7-day NOEL 0.00528 µg a.s./larva per development period). No data for bumblebees and solitary bees were available. <p>Overall the experts agreed with the endpoints selected by the RMS in the revised addendum.</p>	<p>Point closed</p>
<p>B.9.1. Risk to honeybees and to pollinators other than honey bees Exposure scenarios <u>Experts consultation 3:</u> MS experts to discuss and agree the relevant route of exposure (i.e. scenarios) to be considered for the uses under evaluation according to the</p>	<p>Relevant scenarios to be considered according to EFSA GD 2013</p> <p>For <u>contact</u> exposure (granules pre-emergence and seed treatment): field margin</p> <p>For <u>oral</u> exposure (granules pre-emergence and seed treatment): Treated crop, field margin, adjacent crop, succeeding crop, flowering weeds in the field (only for granule application)</p>	<p>See below</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>EFSA GD 2013 (Addendum B.9.1.4, both data from Sumitomo and Bayer)</p>	<p>Meeting discussion and conclusion: The RMS considered the <u>treated crop</u> scenario not relevant for cereals and sugar beet. This was discussed further under the point B.9.7., below. The relevance of the <u>weed</u> scenario for seed treatment was further discussed under the point B.9.3., below</p>	
<p>B.9.2. Risk to honeybees and to pollinators other than honeybees foraging in nectar or pollen in succeeding crops Exposure <u>Experts consultation 4:</u> MS to discuss and agree the exposure characterisation via succeeding crop for honeybees, bumble bees and solitary bees</p>	<p>Exposure in succeeding crops <u>Sumitomo</u> 2 studies are available a) Harrington (2013): one field site in southern France, where maize that had been treated with clothianidin containing granules was grown for three consecutive years prior to the trial ("<i>natural</i>" exposure) b) Lebrun (2015): reports measured residues in nectar and pollen from different succeeding crops at 5 field sites spread over Europe (France, Germany, Spain, Italy and the UK). On each test site, the soil was treated with clothianidin at a rate corresponding to a theoretical long-term plateau concentration (i.e. 121 g a.s./ha), resulting from years of consecutive use of clothianidin at a rate of 80 g a.s./kg ("<i>forced</i>" exposure)</p> <p>Specific issues to be discussed:</p> <ul style="list-style-type: none"> - the soil PEC_{plateau} measured (study a) or estimated (study b) in the 2 studies - the exclusion of the pollen and nectar residues considered as "outliers" in the UK OSR and UK field beans (pollen only) trials in study b) - the limitation of the number (n=1) of the field site investigated in study a) to cover the 90th percentile residue value for use in the risk assessment - the limitation of the number of sampling (N=1) in study b) to cover the 90th percentile residue value for use in the risk assessment - higher tier assessment: the feasibility of extrapolating results from the field effect study (effects of clothianidin residues in pollen for maize on honeybee colonies; 10.4g/01; Thompson 2011) to succeeding crops that produce nectar 	<p>Open points <u>Bayer and Sumitomo uses</u> RMS to update the tier 2 calculation using the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 µg a.s./kg for pollen and nectar respectively). By updating the TIER II calculations the RMS should use the EFSA SHVAL tool instead of the TIER II approach currently followed in the addendum (note that the 90th percentile residue was not accepted). EFSA will support. This calculation should be documented in a revised addendum.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>Meeting discussion and conclusion:</p> <p>Harrington (2013) it was argued that there are evidences suggesting that a 3 years period is not enough to reach top soil residue comparable to the expected soil PEC_{plateau}: - only 10 µg/kg of clothianidin was measured, which is less than the estimated value; - taking into account the field dissipation data currently available in the dossier and agreed at the EU level, the experts suggest that the PEC_{plateau} will be reached in 10-15 years.</p> <p>Moreover, it was noted that only the first 10cm of soil were sampled for residues measurement, which cannot be considered representative of the root zone uptake (an acceptable depth would be not less than 20 cm).</p> <p>It was noted that it might be more appropriate not to assess the absolute worst case as it would not be realistic (e.g., due to risk management implications it would be unlikely that clothianidin would be used for a period of 15 years). However it was argued that this would not be a GAP procedure (the residue measured in the root zone should be representative of the uses in GAP regardless of the no. of years of product use). Overall, it was agreed that the study conducted as "<i>natural</i>" exposure design, is not suitable for risk assessment.</p> <p>Lebrun (2015) It was further noted that only one sampling was performed in all the trials of this study, which is not compliant with EFSA (2013)¹, which require 3 sampling time during the study. Regarding the exclusion of the pollen and nectar residues considered as "outliers", it was argued that the dataset is not sufficient to verify that the values can be classified as outliers according to the Dixon Q-test. Moreover it was noted that quantifiable levels of metabolites were measured in the samples classified as outliers (e.g., UK oilseed rape pollen samples). It is therefore unlikely that the measured residues in those samples are</p>	

¹ EFSA (European Food Safety Authority), 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>only due to cross-contamination (as suggested by the applicant). It was also considered that the measured "outliers" values are not outside the range of the dataset provided in the appendix F of the EFSA GD (2013). EFSA considered that the study should not be rejected because it is quite well designed and, in general, well conducted. Additionally the results (including the values quoted as outliers) are in line with the existing dataset. The residue values considered as outliers should be included in the exposure characterisation. However, some MSs were reluctant to consider the study suitable for the exposure characterisation due to fundamental issues (cross-contamination and low sampling number) which may indicate that the study is not reliable.</p> <p>Overall the experts agreed that the absolute highest values for pollen and nectar (80 and 16 ug a.s./kg respectively) by considering all the trials from Lebrun (2015) should be considered as the more suitable values. However, the values to be used for risk assessment of succeeding crop are further discussed below.</p> <p><u>Bayer</u> The applicant submitted 5 studies (+2 additional studies) in which the concentration of clothianidin in nectar and pollen of bee attractive crops (phacelia, maize or mustard) were measured under conditions of 'contaminated' soil residues (succeeding crops grown on soils with a history of clothianidin use; 3 studies) or 'forced' soil residues (succeeding crops grown on soils treated with clothianidin to obtain a theoretical plateau concentration of clothianidin in the soil; 2 studies). Summary table with the results of the 5 studies: Table B.9.2.2-4 (p. 75).</p> <p>1-3) Jarratt (2014a,b,c): Three field sites in UK to determine residues of clothianidin and its metabolites TZNG and TZMU in bee relevant matrices (pollen, nectar and guttation fluid) collected from flowering rotational crops (Phacelia and maize) cultivated as succeeding crops on fields with a history of clothianidin use and as such with natural aged soil-residues of this active ingredient ("natural residue").</p> <p>4) Ythier (2014): The study has been performed on a field site in France to cover various scenarios</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>(crop rotations) of a consecutive use of clothianidin and to determine the potential residue level of clothianidin and its metabolites TZNG and TZMU in bee-relevant matrices (nectar and pollen) and guttation droplets of succeeding crops (Phacelia, mustard and maize).</p> <p>5) Striffler & Ballhaus (2014): The study has been performed on field site in Germany to simulate various scenarios (crop rotations) of a consecutive use of clothianidin and to determine the potential residue level of clothianidin and its metabolites TZNG and TZMU in bee-relevant matrices (nectar and pollen) and guttation droplets of succeeding crops (Phacelia, mustard and maize).</p> <p>6) Xu & Dyer (2014): Study to investigate the potential accumulation of clothianidin in soil and crop matrices after multiple years of planting clothianidin treated corn and canola seeds (plant bioavailability and soil accumulation).</p> <p>7) Hammel & Vrbka (2014): Calculation of the plateau concentration in soil for clothianidin based on the EFSA Scientific Opinion (2010) on the assessment of exposure of organisms to substances in soil².</p> <p><u>Specific issues to be discussed:</u></p> <ul style="list-style-type: none"> - can the studies be pooled, considering the two different study designs? - can the studies be considered representative for attractiveness vs 90th percentile for establishing the spatial variation of the RUD values? - can the studies be considered representative of the area of use of the active substance, considering that 3 out of 5 were performed in UK? - the soil horizon depth to consider for the PEC_{plateau} - it has not been fully justified why the forced exposure studies on maize, Phacelia and mustard cover the risk to all succeeding crops 	

² EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2010. Scientific Opinion on outline proposals for assessment of exposure of organisms to substances in soil. EFSA Journal 2010; 8(1):1442, 38 pp. doi:10.2903/j.efsa.2010.1442

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>Meeting discussion and conclusion:</p> <p>It was suggested to select the highest available residue measurement for pollen and nectar and to use it in the exposure assessment. It was noted that the natural exposure studies could be considered more realistic (more representative of the accumulation over years). Therefore, they should be considered more suitable for the exposure assessment rather than the "forced" ones. It was discussed whether "forced" and "natural" exposure studies should be considered equally relevant as the results of the forced exposure studies could be considered worst case.</p> <p>Overall, the majority of the experts agreed that the highest residue level in pollen and nectar from the 'natural' exposure studies should be included in the exposure assessment. This was appropriate in this case as the soil residue levels from the 'natural' exposure studies were equal or higher than the expected accumulation of use over successive years (soil PEC_{plateau}). Note this expected accumulation was estimated by EFSA using the current approach for PECsoil accumulation (ESCAPE model, based on the available DegT50 in the field), which resulted, in any case, lower than the value estimated by the applicant in the dossier. The calculation approach used by the applicant using the soil PEARL approach which is still under development is considered not appropriate in regulatory submissions.</p> <p>It was noted additional trials carried out in Germany were available (see Table B.9.2.2-3 in the revised addendum) from a previous evaluation of clothianidin. Those data were considered realistic worst case regarding the soil concentration. Therefore, they might be used together with the three new natural exposure studies to assess the geographical distribution of RUD values. A full assessment according to the principle of the EFSA GD of the studies was not available in the addendum. It was noted that even considering the additional trials the geographical representativeness would be weak (data only from Germany and UK). Therefore, the 90th percentile cannot be used, in line with the EFSA GD.</p> <p>The following specific points were discussed: <i>- can the studies ("natural" and "forced") be pooled, considering the two different study designs?</i> With this dataset the experts concluded not to pool the data</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>- <i>can the studies be considered representative for attractiveness vs 90th percentile for establishing the spatial variation of the RUD values?</i> It was considered that using the highest residue value from the natural exposure study was considered the most appropriate approach due to the geographical spread.</p> <p>- <i>can the studies be considered representative for the area of use of the active substance, considering that 3 out of 5 were performed in UK?</i> No. The meeting acknowledged that the assessment regarding the area of use of the substance cannot be easily carried out. Anyway, the geographical representativeness of the natural exposure studies in terms of random distribution is considered not addressed (studies only in Germany and UK). The selection of the highest value might account for these uncertainties.</p> <p>- <i>the soil horizon depth to consider for the $PEC_{plateau}$</i> For annual crops an acceptable depth would be not less than 20 cm for PEC calculation.</p> <p>- <i>it has not been fully justified why the forced exposure studies on maize, Phacelia and mustard cover the risk to all succeeding crops</i> With the available dataset, the absolute worst case was agreed and it might cover this uncertainty.</p> <p>It was discussed whether the most suitable residue values from the entire dataset (Sumitomo and Bayer data) should be considered to address the succeeding crop scenarios (except forestry nursery) for all the uses under evaluation. The experts concluded that it is scientifically sound to use the most realistic data available in the dataset of Bayer. This means that only the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 ug a.s./kg for pollen (Jarratt, 2014b) and nectar (Jarratt, 204c) respectively) could be used. It was highlighted that this approach may not fully address the attractiveness of the crop as foreseen in the EFSA GD as well as the different potential uptake from succeeding crops other than those investigated. However, even if the uncertainty with respect to the recommendation of the EFSA GD cannot be addressed with the available data, the experts</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>agreed that this was the best way to make use of the available data. The experts agreed that the succeeding crop scenario should be developed to implement the EFSA GD recommendations.</p> <p>Open point RMS to update the tier II calculations using the highest residue value for pollen and nectar from the "natural" exposure studies (1.5 and 0.6 ug a.s./kg for pollen and nectar respectively). These values should be used for the succeeding crop scenarios of all (Sumitomo and Bayer) uses under evaluation (except forestry nursery). By updating the TIER II calculations the RMS should use the EFSA SHVAL tool instead of the TIER II approach (note that the 90th percentile residue was not accepted) currently followed. EFSA will support. This calculation should be documented in a revised addendum.</p>	
<p>B.9.2. Risk to honeybees and to pollinators other than honeybees foraging in nectar or pollen in succeeding crops Risk assessment <u>Experts' consultation 5</u> -Sumitomo data: MS to discuss the review of the 3 year study performed in France (10.4g/01 study from Thompson 2011), provided in the addendum (10.4g/03, Lewis 2015). Pending on the outcome of the above discussion, MS to reconsider if the 3 year study, may be suitable to address the risk to honeybees for maize, as</p>	<p>Higher tier risk assessment for succeeding crop scenario data (Sumitomo), available for honeybees Only maize was consider as succeeding crop. The RMS concluded a low risk on the basis of the use of 10.4g/01 study from Thompson 2011. The study was evaluated by EFSA in EFSA 2013³. In the Addendum the RMS has summarised it again and a review from the applicant was also presented (10.4g/03, Lewis 2015). Reported under B.9.7.</p> <p>Meeting discussion and conclusion: During the previous peer-review, several concerns were raised regarding the field study on maize by Thompson, 2011b and the study analysis by Lewis, 2014. The statistical power was discussed in relation to the high inter-colony variability observed. It was argued that the study has a low statistical power (assuming that the observed variability is a suitable estimation of the real natural variability). It was noted</p>	<p>Open point RMS to update the addendum, by taking into consideration the conclusion of the experts' meeting.</p>

³ EFSA (European Food Safety Authority), 2013. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin. EFSA Journal 2013;11(1):3066, 58 pp. doi:10.2903/j.efsa.2013.3066

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>succeeding crop. - Sumitomo data: MS to discuss how the data gap identified for the succeeding crop can be further address (e.g. are further data on oilseed rape sufficient?). -Bayer data: MS to discuss and agree if the 3 studies on honeybees, bumblebees and solitary bees are suitable and may be used to address the risk via succeeding crop.</p>	<p>that most of the variability (c. 90%) was due to the inter-colony factor rather than inter-site and temporal factors. This may mean that the number of hives per site is more relevant in terms of statistical power than the number of sites. However, it was argued that the analysis was performed on a limited numbers of hives and sites and that therefore the variability partitioning observed in this study may not represent the real natural variability. Further, it was noted that the RMS pointed out the relevance of the biological interpretation of field trials.</p> <p>It was concluded that, generally, when the results are highly variable it is difficult to draw any conclusion on a cause – effect relationship (i.e. treatment or non-treatment related effects). Generally it was acknowledged that the availability of several pieces of evidence (e.g., several comparable field studies) can be useful to make a trend analysis to be used as a weight of evidence for RA.</p> <p>Overall, it was agreed that the re-analysis provided for the study is not sufficient to address the concerns already identified in the conclusion of EFSA 2013 (i.e., the Thompson study cannot be considered sufficient to draw a firm conclusion on the cause-effect relationship).</p> <p>In addition, it was argued that the study may be considered of weak representativeness for succeeding crops that produce nectar.</p> <p>Overall, it was agreed that the higher tier risk assessment for honeybees provided for succeeding crop scenario is not acceptable.</p> <p>Higher tier data (Bayer), available for honeybees, bumble bees and solitary bees</p> <p><u>Field effect studies</u> with treated crops (used as a surrogate for succeeding crops) were used to refine the RA at higher tier level. i.e.:</p> <p>The 3 effects studies on maize performed in France, which have been already evaluated in EFSA 2013.</p> <p>A large-scale monitoring project on the effects of seed treatment of Oilseed Rape with clothianidin on honeybees (Rolke et al., 2014), bumblebees and solitary bees was</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>submitted (overview of the entire monitoring project is provided under Study 1.8/1 Heimback & Russ, 2014). Within this project:</p> <ul style="list-style-type: none"> - the project area with a complete characterisation of the study fields is reported in Study 1.8/2; Schimmer & Russ, 2014 - the site similarity certification of study sites and its relevance for other rape cultivation sites in Europe is reported in Study 1.8/3; Born, 2014 - measurements of residues of clothianidin in soil before drilling and soil characterisation (Study 1.8/4; Benito et al., M.; 2014) - a comprehensive description of all aspects relevant for the development of the OSR plants at the study fields together with the analysis of the amounts of clothianidin loadings on OSR seeds are reported in Study 1.8/5; Russ et al.; 2014. - residues in nectar and pollen from the treated oilseed rape fields were measured (Persigehl, 2014; Study 1.8/6) - The report from Rolke at al 2014, B.9.7.1 study 1.8/7, page 191) was considered for honeybees. - This study the report from Peters at al 2015, B.9.7.1 study 1.8/8, page 195) was considered for solitary bees. - This study the report from Sterk at al 2014, B.9.7.1 study 1.8/9, page 201) was considered for bumblebees. <p>Meeting discussion and conclusion:</p> <p>The 3 effects studies on maize performed in France were not further discussed (see evaluation note of the EFSA conclusion 2013 on clothianidin for further details). Regarding the <u>OSR large monitoring study</u>, the experts discussed the possible extrapolation of the results from this study to other situation like succeeding crop scenarios and filed margin.</p> <p>For solitary bee, <i>Osmia</i>, the experts noted that the pollen composition indicated that OSR is not a relevant source of pollen. For Bumblebees, the range of pollen composition was very high (2-100%) with an average of 50%. It was argued that in this case, results from hives with a large proportion of OSR pollen could be useful, but this would further reduce</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>the power of the study. Therefore, extrapolation to other scenarios was considered not fully reliable because not worst-case.</p> <p>The study was performed in Germany. The similarity analysis between the study area and the OSR area in EU seems that does not cover the landscape composition i.e. field margin composition in OSR areas other than DE may influence proportion of pollen from different plant species entering into the hive, for example when more attractive plants are available in the field margin. An in depth evaluation of the similarity analysis provided with the study would be appropriate to confirm this.</p> <p>It was noted that the complexity of the study design and the number of analyses and observations performed and reported would require a peer review of all the original study reports. A full consideration of this study within the confirmatory data procedure was not feasible. The study will be evaluated more deeply under the review on the neonicotinoids (Ref. EFSA question number: EFSA-Q-2015-00771).</p> <p>Overall, the experts considered that this study, for the time being, cannot be used to draw firm conclusions on possible extrapolation of the results to other scenarios (i.e. succeeding crops, field margin and treated crop other than OSR) for honeybees. Further consideration for bumblebees would be needed. However, for solitary bees the experts considered that the extrapolation to other crops or scenarios could not be reliably performed because likely the conditions in the study were not worst case for these species</p>	
<p>B.9.3. Potential uptake via roots to flowering weeds Exposure and risk assessment</p> <p>Experts consultation 6: MS to discuss at the meeting if the information on weeds is sufficient to address the risk from this scenario</p>	<p>Exposure (flowering weeds)</p> <p><u>Sumitomo</u> data: Study 10.4c/01, Negrini (2014): a large scale (53 locations in FR, IT and HU for maize and 55 locations in FR, ES, DE, UK, HU and PL for potato) monitoring study to determine the presence of weeds and honey dew in potato and maize during the growing season. This was to allow the estimation of the potential uptake via roots to flowering weeds and the risk to honeybees foraging on insect honey dew. From this study it was concluded that the occurrence of flowering weed in potato and maize is low (where weed control following standard agricultural practices is applied) and therefore the exposure to clothianidin residues through flowering weeds in the treated field is negligible.</p> <p>Specific issues to be discussed:</p>	<p>Open point RMS to provide the following clarifications on the Garside et al 2014 study:</p> <ul style="list-style-type: none"> -n. of plots analysed (trials, replicates, observations) -observation timing date and BBCH stage for the crop -n. of species per plot -clarification with regard to the ground cover %

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<ul style="list-style-type: none"> - how the percentage of occurrence of weeds and the average density (number per m²) could be used to assess the weed coverage of the area of use of the substance (i.e. can the percentage of sites with flowering weeds present in the area and/or the average density be directly compared to the 10% trigger?) - consideration of the representative uses other than maize and potato (i.e. sorghum and forestry nursery) <p><u>Bayer</u> data: Study 1.4/1 Garside et al 2014 (statement on the occurrence of flowering weeds in cereals, sugar beet and potatoes based on data from (herbicide) efficacy trials) Specific issues to be discussed:</p> <ul style="list-style-type: none"> - is it true that exposure via flowering weeds is negligible (taking into consideration that neonicotinoids show a high potential of bioavailability)? <p>Meeting discussion and conclusion: The majority of experts agreed to consider the weeds scenario to be relevant for both the uses of seed treatment and granules, although not specified as being necessary in the EFSA GD (for seed treatment). This is because of the combination of soil persistence, systemicity and high toxicity of certain neonicotinoids. The soil persistence and systemicity were also indicated in the succeeding crops experiments. The study by Garside et al 2014 was discussed during the meeting. The study was considered useful to address the relevance of the weeds scenario for the specific case. However, some clarification would be needed: -n. of plots analysed (trials, replicates, observations) -observation timing date and BBCH stage for the crop -n. of species per plot -clarification with regard to the ground cover % reported in the study (average or total ground cover) Therefore an open point was identified for the RMS to provide these clarifications in a revised RAR (also relevant for imidacloprid). Addressing this point the RMS may request the applicant to provide the data in the study Garside et al 2014 in a tabular format (.xls).</p>	<p>reported in the study (average or total ground cover). RMS to provide a rough estimation of the area occupied by weeds in the study by Negrini (2014), based on the data available in the study report. A revised addendum should be provided.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>Pending on these clarifications a final conclusion can be drawn by EFSA.</p> <p>The study from Negrini (2014) was discussed during the meeting. In this study the presence of weed at different crop growth stages (which was considered essential for the relevance of the weed scenario for clothianidin) was investigated. The information available in the report was i) the number of weed species and ii) the total area of plots. The weed ground cover was not available i.e. no data available regarding the area occupied for each species. However, a rough estimation could be performed by using the weed density and the plot area reported in the study. It was also noted that the number of weeds (i.e. density) and their attractiveness might be more relevant in this case than the 10% weed coverage. However, the experts agreed that the 10% coverage could still be considered a good 'trigger' for this assessment.</p> <p>The RMS should provide this estimation in a revised addendum (this is an open point).</p> <p>Overall, if, pending on the clarifications to be provided in the revised addendum, all the available data (Sumitomo and Bayer) will demonstrate that the flowering weed coverage is below the 10% trigger, the weed scenario for potato, maize, cereals and sugar beet can be considered of low relevance as exposure route. Other uses were not covered by these data i.e. sweet corn/sorghum and forestry nursery. The experts concluded that for sweet corn/sorghum the data on cereals and maize can be used while for forestry nursery it was considered necessary to identify a data gap.</p>	
<p>B.9.4. Risk to honeybees foraging on insect honeydew Exposure Experts consultation 7: MS to discuss at the meeting if the information from the study Negrini 2014 is sufficient to address the exposure to honeydew.</p>	<p>Exposure (honey dew)</p> <p><u>Sumitomo</u> data: Study 10.4c/01, Negrini 2014 (see discussion below)</p> <p><u>Bayer</u> data: Statement 1.5/1 Nauen, 2013 (this statement provides information of the mode of action, known mechanisms of resistance and resistance risk of the three active substances</p>	<p>Point closed</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>present in the product Janus Forte (the pyrethroid beta-cyfluthrin and the neonicotinoids imidacloprid and clothianidin), used as seed treatment in sugar beet).</p> <p>Meeting discussion and conclusion:</p> <p>The study Negrini 2014 investigated the occurrence of honeydew in the potato and maize at different crop growth stages. The conclusion of the study authors and RMS was that, considering the overall limited occurrence of honeydew in potato and maize, it may be considered as a not relevant route of exposure for treated crops. The experts agreed with this conclusion for all the granular uses of clothianidin under evaluation, including sweet corn/sorghum and forestry nursery.</p> <p>The statement paper by Nauen, 2013 was also discussed. Generally the argumentation provided was agreed since clothianidin is intended to control sap sucking insects, at least during the first weeks of growth the exposure of honeybees is likely to be low.</p> <p>It was noted that the ED50 in the study by Foster 2008 was not consistent among the tested clones (varying about 2 orders of magnitude). It was agreed that neonicotinoids resistance to aphids could not be excluded (there are several reported cases of neonicotinoids resistant strains of aphids in literature, including <i>M. persicae</i>, which is an highly polyphagous species), (Bass, Chris, et al. "The global status of insect resistance to neonicotinoid insecticides." <i>Pesticide biochemistry and physiology</i> 121 (2015): 78-87). Moreover it was noted that at later crop growth stages (i.e., after the 8th week) the efficacy of the aphids control will be lower, therefore a certain exposure of honeybees through honeydew might occur.</p> <p>Overall, the experts agreed on the basis of the available data that honeydew can be considered as a low relevance route of exposure for the treated crop and for clothianidin and (relevant for all the uses under evaluation)</p> <p>The experts agreed that this line of evidence is also relevant for imidacloprid. However, from the Foster 2008 study, the variability in the effects concentration on <i>M. persicae</i> was lower than the one for clothianidin. (move to the imidacloprid meeting report)</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>B.9.5. Potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure</p> <p>Experts consultation 8: MS to discuss if the available data may be considered sufficient to conclude that the exposure to guttation fluids is not relevant. This</p>	<p>Sumitomo data 4 studies are available i.e.: <u>Maize</u> 10.4e/01 Thompson 2011a. The study was already considered in EFSA 2013. Since no new data were submitted triggering the re-assessment of this study, the previous conclusion on the risk from guttation is still valid (i.e. data gap due to difficult to extrapolate to situation other than the experimental ones, acute risk not excluded) <u>Potatoes</u> 10.4e/02 and 10.4e/03 Thompson 2013a, b. These studies were already considered in EFSA 2015⁴ on foliar spray uses. The first one was considered not suitable for risk assessment. The second was considered not representative for residue in guttation fluids for the uses as granular applications. 10.4e/04 Ansaloni 2015. This is a new study: to investigate the effects on honeybee colonies of clothianidin applied in-furrows at sowing of potato seeds as a result of exposure to the guttation fluid used as a source of water. The interaction between flight and foraging activity of the bees and the presence of guttation on potato plants, the mortality of the bees, and the condition of the colonies (adult worker population, brood population, presence of healthy queen and areas with pollen and nectar storages) were studied.</p> <p>Meeting discussion and conclusion: <u>Exposure:</u> It was noted that it might be speculated that a different behaviour in a.s. translocation in guttation for seed treatment and granules occurs. It was discussed whether the selection of maximum/mean residue values, as done by the RMS in the addendum to the confirmatory data, may be considered worst case, due to the fact that the dataset is not sufficient for selecting the 90th percentile of exposure as suggested by the EFSA, 2013. It was noted that for the guttation it might be more relevant to have a study in worst case environmental conditions that may maximise this phenomenon. The available study seems to satisfy this condition.</p>	<p>Open point The RMS should update the TIER II calculations for winter cereals reported in the Addendum related to the Bayer dataset.</p>

⁴ EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin considering all uses other than seed treatments and granules . EFSA Journal 2015;13(8):4210, 77 pp. doi:10.2903/j.efsa.2015.4210

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>It was pointed out that according to EFSA GD 2013, unless it can be proven that it is scientifically justified, the maximum PEC value should be used for chronic assessment. Otherwise the TWA PEC could be considered acceptable.</p> <p>It was noted that there is a decline of the a.s. Moreover, it was pointed out that decline of the a.s. in guttation fluids is also assumed to occur according to the EFSA GD. Therefore, it could be justified to use the TWA a.s. concentration in guttation for the chronic assessment (over 5 days for larvae and 10 days for adults) in this case.</p> <p>Overall, the experts concluded that the approach followed by BE in the addendum of clothianidin can be considered acceptable. In particular, the highest residue value was considered acceptable for the acute exposure assessment. For the assessment to larvae it was agreed that the most appropriate value to be used is the TWA concentration over 5 days. For the chronic assessment to adults it was agreed that the most appropriate value to be used is the TWA concentration over 10 days.</p> <p>The meeting agreed to consider this conclusion relevant for both the Sumitomo and Bayer data (see open point below, under the discussion of Bayer data).</p> <p>Since the Bayer dataset on guttation for winter cereals covers both clothianidin and imidacloprid (i.e. a formulation containing the 2 active substances was investigated), this conclusion was also agreed for imidacloprid.</p> <p><u>Effects:</u></p> <p>For potatoes the RMS concluded low risk. However, it was noted that some of the studies available were previously considered not suitable for the RA.</p> <p>The only new study (10.4e/04 Ansaloni 2015) was taken into account for the higher tier RA.</p> <p>However it was argued that one single study might be not sufficiently informative and representative of the worst-case. The geographical representativeness of the study was also considered low (only one study location in Spain cannot be considered sufficiently representative for both S- and N-EU). Furthermore it was noted that the environmental conditions in the study location (Spain) were not likely to represent the worst case (water</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>saturation in soil and high humidity did not occur).However, it was noted that the study conditions might be a worst case for other water sources (the water demand for the honeybee colony is likely to be higher in S-EU). The statistical power of the study was also questioned. Regarding the extrapolation of the data to maize it was argued that there are substantial difference in potato and maize with regard to the guttation. For maize and sorghum no new data were provided. Therefore the RMS concluded that further data are needed to make this extrapolation.</p> <p>See overall conclusion below.</p> <p>Bayer data: 5 new effect studies were presented and reported from page 106 to 147: 3 on winter cereals (1 on wheat and 2 on barley), 2 for sugar beet. In the studies on winter cereals a PPP with clothianidin and imidacloprid was investigated. In the studies with sugar beet, a PPP with clothianidin, imidacloprid and beta-cyfluthrin was investigated. In these studies, the guttation frequency of the crop, the honeybee activity in the guttation crop and the <u>residues present in guttation fluid</u> were assessed.</p> <p>Specific issues to be discussed:</p> <ul style="list-style-type: none"> - in the 2 studies performed on winter cereals it is not ideal that hives were overwintered on the test site, in the absence of specific information regarding the availability of nearby food sources (additional information regarding the surrounding vegetation and on the colony assessments has been provided and included in the revised Addendum) - the studies submitted were all conducted in Germany. It is stated that the data are worst case, however, this statement is not well documented <p>Meeting discussion and conclusion: <u>Exposure:</u> It was pointed out that the dataset is not sufficient for selecting the 90th percentile of exposure as suggested by the EFSA, 2013.</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>As currently the 90th percentile residue level was used, an open point for the RMS to use the maximum residue level from the Bayer data for the acute exposure assessment was identified (see the discussion above, under Sumitomo data).</p> <p><u>Effects:</u></p> <p>A detailed discussion on each single study available investigating occurrence of guttation and effects on honeybees was not performed, but the available dataset was considered for drawing a conclusion.</p> <p>The experts agreed that the available data set is generally not sufficient to draw a firm conclusion on the non-relevance of guttation as route of exposure. Concerns were expressed as to whether the available data are sufficient to address the SPG. The extrapolation to other crops would need a larger dataset. In general even is for some crops a good dataset is available further data are needed to draw a firm conclusion.</p> <p>Some experts noted that there is evidence that bees are not primary collecting water from guttation fluids. The most relevant guttation plant (worst case) is maize, in which the residues are high. However, generally this route of exposure should be further investigated, because the current evidences are not sufficiently informative.</p> <p>Generally, the experts considered guttation as not the primary route of exposure for bees, even if cannot fully excluded (i.e. evidence from cereals and maize data). Even if acute effects could not be excluded, the long term risk is likely to be low.</p> <p>Overall conclusion on the risk from guttation for the uses under evaluation of clothianidin and imidacloprid</p> <p>As a general line of evidence the experts noted that bees using guttation are only rarely observed. This consideration is based not only on the available data in the confirmatory data package (imidacloprid and clothianidin) but also on other data available at the MS level for other dossiers or literature.</p> <p>It was noted that the results from the studies on cereals and sugar beet are generally in line with the results of the above reported study. It was noted that guttation occurred but no clear effect was reported in the studies. However the statistical power was not assessed. It was noted that, for cereals, if the three available studies would be pooled</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>together, the statistical power might be higher.</p> <p>Taking into account all the evidences discussed during the meeting, the experts identified uncertainties driven by the lack of clear pieces of evidence (i.e., the adequacy of the dataset to address the SPG, lack of evidence demonstrating the low relevance of this route of exposure across Europe). Overall the majority of the experts considered that the risk for just the uses under evaluation can be considered low on the basis of the available data. The minority of the experts considered that more information is needed to draw a firm conclusion (i.e., on whether the power of the available effects assessment is sufficient to conclude no effect and there is uncertainty around the exposure assessment).</p> <p>The experts agreed that the guttation assessment for honeybee also covers the bumblebees and solitary bees as specified in the EFSA GD.</p>	
<p>B.9.6. Potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure (Field margin and adjacent crop) Exposure and risk assessment Experts consultation 9: -MS to discuss and agree if the exposure via dust drift for seed treatment of winter cereals and sugar beet is adequately addressed -MSs to the risk assessment to honeybees, bumblebees and solitary bees via exposure to dust.</p>	<p>Sumitomo: no new data were provided. In the conclusion EFSA 2013 a low risk was concluded for dust exposure for granular applications, based on dustiness studies and assuming that there is no air-flow in the application machinery when the granule are applied in furrow. No tier I or TierII risk assessment was provided.</p> <p>Meeting discussion and conclusion: It was noted that there is evidence from some MSs showing that some drift may occur for some granular products. Therefore, it was suggested that until clear information is provided with regard to the transplanting/sowing machinery to be used it should not be speculated that the exposure through dust drift cannot be relevant for granules. It was noted that this was not the conclusion drawn in EFSA, 2013 where a low risk was concluded, provided that no airflow sowing machinery are used. It was noted that the occurrence of dust drift may be substance-specific and that the Heubach value alone was not necessarily sufficient to exclude the occurrence of dust drift. However, those data have not been peer-reviewed because not available to the meeting and not submitted within the confirmatory dataset. However, the issue will be reflected in</p>	<p>Open points The RMSs (BE) for clothianidin and (DE) for imidacloprid to perform tier I calculation on the basis of the dust drift deposition values in SANCO/10553/2012, January 2014. The calculations should be provided for honeybees, bumblebees and solitary bees.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>the EFSA conclusion.</p> <p>Bayer (exposure): dust drift was measured in 4 studies for winter cereals, 3 in Germany.</p> <p>The applicant submitted studies measuring dust drift residues in the field margin in winter barley (2 sites in DE) and winter wheat (2 sites in DE), in winter barely after sowing with pneumatic sowing machinery (3 sites in DE), 1 study to assess potential effects on honeybee colonies during and after air sowing operation of winter barley seeds and 1 study to assess potential effects on honeybee colonies during and after vacuum-pneumatic sowing operation of coated sugar beet pills (4 sites in UK).</p> <p>Specific issues raised during the peer review:</p> <ul style="list-style-type: none"> - for the winter cereals studies: the draft Guidance Document on Seed treatment (SANCO/10553/2012, January 2014) gives 0.38 g/ha as a worst-case dust deposition for cereals which is 8 times higher than the maximum of measured in these studies - for the winter cereals studies: the two studies give only limited information for evaluation of dust deposition: do they reflect a best-case situation as no Heubach value (% dust) and no Heubach-as values (considering the concentration of as in dust) are available? - whether 3-D-dust deposition exposure (which can be expected to be about 13 times higher) should be further considered. - the EFSA Guidance Document for bees suggest to select the sowing machine at EU level that deliver the 90th percentile based on ranking of dust emission and area of use in order to ensure that the machine used for experimental measurement cover the 90th percentile. This exercise would be needed to conclude that the measured value of 0.61 g a.s./ha is worst-case for EU - to discuss the Heubach values and the Heubach a.s. values from the study Lueckmann (2014) study in the light of the data given in the draft Guidance Document on seed treatment (SANCO/10553/2014, January 2014), in order to ensure that these seed parameters from the study represent the agricultural practice in Europe 	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<ul style="list-style-type: none"> - less sites were used in the dust drift field study than specified in the guidance document - the extrapolation of the results from the large scale field study on oilseed rape to demonstrate an acceptable risk to bumblebees following exposure to dust drift (RA based on higher tier) <p>Bayer (risk assessment): tier I and tier II were available. The tier II is based on measured dust deposits. A high risk was identified. The Tier II should be discussed, pending also on the discussion on the relevance of the exposure.</p> <p>A higher tier risk assessment to honeybees was based on a honeybee effect study in UK on winter barley (Lueckmann&Stafeel 2015, 1.7/4) and on sugar beet in Germany (Lueckmann&Stafeel 2014, 1.7/5). The relevance of these studies and the higher tier risk assessment should be discussed.</p> <p>The RMS concluded a low risk to honeybees for winter cereals and sugar beet. No higher tier data were available for bumblebees and solitary bees. The higher tier data on honeybees on winter barley (Lueckmann&Stafeel 2015) and the study on OSR on bumblebees and solitary bees were used to conclude a low risk. This should be discussed at the meeting.</p> <p>Meeting discussion and conclusion: <u>Exposure</u> -SANCO/10553/2012, January 2014</p> <p>The most recent version of the SANCO/10553/2012, November 2015 rev.9 on seed treatment reports updated dust deposition values compared to the ones used in the EFSA GD. Since this is considered as the latest best available knowledge (in line with the art. 21 of Reg. 1107/2009), the majority of the experts considered that SANCO 2015 should be used in the exposure assessment, while the minority considered that EFSA GD should be used as it is a final version and published.</p> <p>As a consequence open points were identified for the RMSs (BE for clothianidin, DE for</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>imidacloprid) to update the tier I calculations for both oral (acute, chronic, larvae) and contact (acute) exposure for all the bees (honeybees, bumblebees and solitary bees) where the tox endpoints are available.</p> <p>- <u>winter wheat</u> (studies 1.7/1 and 1.7/2) and <u>winter barley</u> studies with clothianidin and imidacloprid (study 1.7/3 - Lueckmann, 2014, R11129) and <u>winter barley</u> study on clothianidin (study 1.7/4 – Lueckmann & Staffel, 2015):</p> <p>It was further noted that there is no information as to whether the machinery used in all the studies covers the 90th % of exposure.</p> <p>For <u>winter wheat</u> (studies 1.7/1 and 1.7/2) Heubach value (% dust) and Heubach-as values are not available. This information is considered by SANCO 2014 as essential to properly address dust drift deposition assessment.</p> <p>For <u>winter barley</u> (studies 1.7/3 and 1.7/4), it was noted that, Heubach value was available.</p> <p>However, it was argued that individual studies with few varieties might be not sufficiently representative (and sufficient to overrule the dust deposits in SANCO 2015 based on a larger dataset) as the amount of dust drift is very much dependent on the quality of the seed dressing rather than the properties of the a.s.</p> <p>Therefore according to the SANCO 2015 these studies alone are not sufficient for estimating the exposure from dust deposition.</p> <p>Overall, for both imidacloprid and clothianidin, it was agreed to use only the exposure values in the SANCO 2015 in the tier I. No value from the available data was considered suitable for tier II calculations.</p> <p><u>Effects</u></p> <p>In the study 1.7/4 – Lueckmann & Staffel, 2015 effects were also investigated.</p> <p>The RMS concluded a low risk on the basis of the observations from this study, showing no acute and long-term effects. The biological observations were done on <i>phacelia</i> as adjacent crop. The statistical power of the study was not assessed but it is likely to be low (i.e. 2 control and 2 treated fields each filed with 8 hives). The study was conducted in UK and it was considered not representative of other EU conditions. The meteorological conditions and the bee activity in the study should be compared with other EU situations</p>	

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p>for ensuring that it represents a worst-case. The RMS noted the use of <i>phacelia</i>, being a highly attractive crop, was supposed to cover uncertainties regarding other factor influencing the exposure. One study with 2 sites was considered not sufficient to address the exposure and effect SPG.</p> <p>The quality of seeds used in the study was not representative of the standard treated cereals seeds on the market, therefore the exposure could not be considered as worst-case.</p> <p>The majority of the experts considered that the study alone, without further data cannot be considered sufficient to draw a conclusion regarding the effects on bees. It was noted that with respect to the winter cereal uses, the study may represent a worst-case situation (sowing in the study done when flowering field margin were present). Overall, the experts considered that the risk to honeybees from dust exposure for winter cereals should be further addressed. The same conclusion is for bumblebees and solitary bees.</p> <p>For bumblebees and solitary bees and also honeybees the large monitoring study on OSR on clothianidin was used as line of evidence in the higher tier risk assessment by the RMS (see general discussion on this study, below).</p> <p>Study 1.7/5 – Lueckmann & Staffel, 2014</p> <p>For sugar beets the studies available for imidacloprid and clothianidin were similar as study design as for the UK study in winter cereals. Therefore the above argumentation is agreed to be relevant also in this case. However, it was noted that the concentration of the active substances and the dust deposition is very low. The experts considered as line of evidence the low exposure is sufficient to conclude a low risk to bees (HB, BB, SB) for sugar beet for both clothianidin and imidacloprid.</p> <p>It is considered however necessary to have the Tier I calculations based on the SANCO values as agreed above (see open point for the RMSs)</p>	
<p>B.9.7. Acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of</p>	<p>Sumitomo:</p> <p>For <u>maize</u> the 3 year study by Thompson 2011b, evaluated in EFSA 2013 was presented. A review of the statistical power was also provided. Only the latter has to be</p>	<p>See open point below.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
<p>contaminated nectar and pollen (Treated crop) Exposure Experts consultation 10: MSs to discuss if the available data are sufficient to address the exposure for the use in potato. Risk assessment</p>	<p>considered (see experts' consultation under B.9.2.) For <u>potato</u> only measured residue levels in pollen was provided (Bousquet 2014). Since the 90th percentile was used by the RMS in the addendum, in line with the discussion above, the highest value should be used (see open point for Tier II under experts' consultation 11)</p> <p>Meeting discussion and conclusion</p> <p>Bayer: the large monitoring study on OSR mentioned above was presented (see Experts consultation 4).</p>	
<p>B.9.7. Acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen (Treated crop) Risk assessment Experts consultation 11: -MSs to discuss the risk assessment to honeybees, bumblebees, solitary bees (tier II and higher tier)</p> <p>-Bayer data: the new higher tier studies on honeybees, bumblebees and solitary bees on OSR, under discussion point 4 can be considered for the treated scenario. This point is also linked to the discussion point 3, on the scenarios for the uses under evaluation)</p>	<p>Sumitomo Tier I was calculated for maize/sweet maize/sorghum and potato. The TierII took into account the residue levels in pollen of potato and maize from 3 years study in France for maize. High risk was identified to honeybees, bumblebees and solitary bees. Higher tier: RMS concluded a low risk to honeybees on the basis of the 3 years study in France for maize The RMS also concluded that the results can be extrapolated to potato. The RMS considered the risk to bumblebees and solitary bees as an issue that could not be finalised. Meeting discussion and conclusion: See experts' consultation under B.9.2. succeeding crop. For the TIER, RMS should update the calculations with the highest residue levels available (open point).</p> <p>Bayer The RMS did not present any risk assessment to honeybees, bumblebees and solitary bees, assuming that the treated crop scenario is not relevant for the uses under evaluation.</p> <p>Meeting discussion and conclusion</p>	<p>Open point RMS to provide the TIER II calculations by considering the highest residue values for maize/sweet maize/sorghum and potato to be consistent with the approach agreed under experts' consultation B.9.2, succeeding crop. For cereal, TIER I calculation should be provided.</p>

Subject	Discussion Pesticides Peer Review Meeting	Conclusions Pesticides Peer Review Meeting
	<p><u>Sugar beet</u> The experts considered the treated crop could be considered as not relevant, when the crop is not a seed bearing crops. Sugar beet flowers the second year (is a biannual crop), therefore it was noted the treated crop is in any case not relevant but rather might be considered as succeeding crop. It was noted that sugarbeet when are not growth for seed production they are harvested and planted in other areas. Overall, the experts considered that a specific treated crop scenario should be developed for bi-annual crop. For the use under evaluation, it was concluded that this scenario is not relevant if beet are not grown for seed production. However, in the GAP table available in the addendum this information was not reported. At MS level, where uses on beet are authorised this issue should be further considered.</p> <p><u>Cereals</u> The applicant provided some argumentations e.g. wind pollinated, not attractive. No data where provided to support this argumentation. The EFSA GD 2013, due to diverging data from literature, considered that further data should be provided to exclude collection of pollen by honeybees, bumblebees and solitary bees. The palynological analysis available in the large monitoring study does not allow to fully exclude wheat pollen collection e.g. from the photos available in the study report, wheat was not flowering. The attractiveness of agricultural horticultural crops was further analysed by van der Steen, et. Al., 2015 report n. 606, Wageningen Univerisity. This analysis is based on a literature review and experts judgment. Cereals are reported as not attractive. However, the paper is in Dutch and not available to other MSs e.g. not peer reviewed. By quickly looking at the references of the report, it seems that only one paper, published after 2013, is cited. Overall, the experts concluded that the EFSA GD is still the reference point for attractiveness of cereals. Therefore an open point was identified for the RMS to provide the TIER I risk assessment.</p> <p>The large monitoring on OSR</p>	

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	<p>For solitary bee, <i>Osmia</i>, the experts noted that the pollen composition indicated that OSR is not a relevant source of pollen. For Bumblebees, the range of pollen composition was very high (2-100%) with an average of 50%. It was argue that in this case, results from hives with a large proportion of OSR pollen could be useful, but this would further reduce the power of the study. Therefore, extrapolation to other scenarios was considered not fully reliable because not worst-case.</p> <p>The study was performed in Germany. The similarity analysis between the study area and the OSR area in EU seems that does not cover the landscape composition i.e. filed margin composition in OSR areas other than DE may influence proportion of pollen from different plant species entering into the hive, for example when more attractive plants are available in the filed margin. An in depth evaluation of the similarity analysis provided with the study would be appropriate to confirm this.</p> <p>It was noted that the complexity of the study design and the number of analyses and observations performed and reported would require a peer review of all the original study reports. A full consideration of this study within the confirmatory data procedure was not feasible. The study will be evaluated more deeply under the review on the neonicotinoids (Ref. EFSA question number: EFSA-Q-2015-00771).</p> <p>Overall, the experts considered that this study, for the time being, cannot be used to draw firm conclusions on possible extrapolation of the results to other scenarios (i.e. succeeding crops, field margin and treated crop other than OSR) for honeybees. Further consideration for bumblebees would be needed. However, for solitary bees the experts considered that the extrapolation to other crops or scenarios could not be reliably performed because likely the conditions in the study were not worst case for these species</p>	

TABLE OF CONTENTS

	Document
00	Cover page
01	Pesticides peer review meeting reports
02	Comments on the draft EFSA conclusion

Member States' comments on the draft EFSA Conclusion on Clothianidin (RMS: BE)
Pesticides Peer Review Written Procedure: September 2016

(07.09.2016) 2/8

Background			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1		BE (RMS): No comments	Noted
2		CZ: No comment	Noted

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1	1.2. Risk assessment methodology	BE (RMS): Overall, no risk assessment could be performed for the use in forestry nursery (due to the fact that there was insufficient information in the GAP table to determine the application rate in g a.s./ha and thus to perform a Tier 1 risk assessment, and since no higher tier studies are available for this use and no extrapolation from other available studies is possible due to differences in agronomic practices). It is noted that for each exposure route separately this is discussed. However, RMS	Agree. The proposed text was added at the end of the paragraph.

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		considers it useful to also include this as a general remark at the end of the methodology section (where it is also explained why an assessment for maize is not needed).	
2	3. Succeeding crops – Tier 1 risk assessment	<p>BE (RMS): use in forestry nursery: In line with what is mentioned regarding this use in section 4-8, it should be stated here that "No data were available to perform tier 1 risk assessment for forestry nursery use".</p> <p>As no Tier 1 risk assessment was performed for this use, the conclusion that a high risk was indicated is not valid for forestry nursery. The last sentence of the second paragraph should thus say "This conclusion was relevant for the exposure in the succeeding crop scenario for all the field uses under evaluation (<u>except for forestry nursery</u>)"</p>	<p>Agreed</p> <p>The proposed texts were added to the conclusion.</p> <p>This scenario was already identified as 'an issue that could not be finalised in the overview table in section 12 (table 3)</p>
3	4. Flowering weeds in the field – Tier 1 risk assessment	BE (RMS): small typo in the first sentence of the first paragraph: For uses_as granules, ...	Noted and corrected
4	7. Dust drift in field margins and adjacent crops – Tier 1 risk assessment for sugar beets	BE (RMS): The sentence to explain which ETR values indicate a low or high risk is a bit confusing, as it is not very clear which conclusion is related to the field margin and which to the adjacent crops scenario. RMS would suggest to adapt this sentence to:	<p>Agreed</p> <p>The proposed text was added to the conclusion.</p>

Member States' comments on the draft EFSA Conclusion on Clothianidin (RMS: BE)
Pesticides Peer Review Written Procedure: September 2016

(07.09.2016) 4/8

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		"The ETRs, for both the lowest and highest application rate, indicated a low risk from oral exposure for honeybees (acute, chronic and larvae) for both the field margin and adjacent crops. For bumblebees, the ETRs indicated a low acute risk for both the field margin and adjacent crops, but a high chronic risk was not excluded. For solitary bees, the ETRs indicated a low acute and chronic risk for the field margin and a low acute risk for adjacent crops. A high chronic risk was however not excluded for adjacent crops."	
5	7. Dust drift in field margins and adjacent crops – higher tier risk assessment	BE (RMS): The first sentence of the second paragraph seems to be incomplete. RMS assumes it should be corrected to the following: "At the Pesticides Peer Review Meeting 145, it was considered that the EFSA (2013b) <u>suggests selecting suggestion to select</u> the sowing machine at EU level that delivers 90 th percentile (based on ranking of dust emission and area of use), in order to ensure the machine used for experimental measurement covers the 90 th percentile of exposure."	Agreed The text of the Conclusion was revised in order to make it clearer.
6	List of endpoints – Tier 2 ETRs for the succeeding crop scenario	BE (RMS): it is stated in the list of endpoints that these Tier 2 ETRs are relevant for all the uses under evaluation. However, as stated in section 3, they are relevant for all	Agreed The proposed text was added to the conclusion

Member States' comments on the draft EFSA Conclusion on Clothianidin (RMS: BE)
Pesticides Peer Review Written Procedure: September 2016

(07.09.2016) 5/8

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		uses under evaluation, except for forestry nursery.	
7	Conclusions of the evaluation 4. Flowering weeds in the field	Last paragraph: "Therefore, the exposure to bees via this scenario could be considered of low relevance for these uses, particularly when weed control is applied." CZ: It is not clear, if the conclusion on low relevance of the weed scenario is general or if it is related to clothianidin only.	The occurrence of flowering weeds was investigated in potatoes, winter cereals, maize and sugar beet and it was not clothianidin treatment related. Therefore the conclusion drawn is relevant for these crops in general.
8	General comment	UK: The EFSA guidance document on the risk assessment of plant protection products on bees has not been noted in Standing Committee and thus has no formal status for use in risk assessment. It is understood that the Commission has asked EFSA to use it but this does not make it applicable for regulatory purposes in the EU.	Noted
9	Page 13, section 5 (see also table 3 and section 9)	UK: It is stated that the further data would be needed to address the honeydew scenario for the granular use on forest nursery. This is also highlighted as an area that could not be finalised in table 3. However, the peer review meeting report states: <i>'The study Negrini 2014 investigated the occurrence of honeydew in the potato and maize at different crop</i>	Agreed The conclusion was amended accordingly.

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
		<p><i>growth stages. The conclusion of the study authors and RMS was that, considering the overall limited occurrence of honeydew in potato and maize, it may be considered as a not relevant route of exposure for treated crops.</i></p> <p><i>The experts agreed with this conclusion for all the granular uses of clothianidin under evaluation, including sweet corn/sorghum and forestry nursery.'</i></p>	
10	Page 14, section 7 (see also table 3 and section 9)	<p>UK: In table 3 the risk from the guttation scenario is stated as not being finalised for the sorghum and forest nursery uses. This is also reflected in the text of section 7. However, this does not appear consistent with the peer review meeting report, which concludes on guttation: <i>'Overall the majority of the experts considered that the risk for just the uses under evaluation can be considered low on the basis of the available data.'</i></p>	<p>Noted.</p> <p>The discussion and the conclusion of the experts at the meeting was related to the higher tier studies available in the addendum which were on potatoes, winter cereals and sugar beet. It is acknowledged that at the meeting the experts, on the basis of their experience in evaluation the PPP dossiers, pointed out that guttation could be considered generally as not relevant route of exposure. However, for the present Conclusion, EFSA reflected the evidence that no higher tier data and additional information were available for sorghum and forestry nursery allowing to draw a conclusion as for the other representative uses.</p>

Member States' comments on the draft EFSA Conclusion on Clothianidin (RMS: BE)
Pesticides Peer Review Written Procedure: September 2016

(07.09.2016) 7/8

Ecotoxicology			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
11	Page 18, table 3 (see also section 9)	UK: It is unclear why the adjacent crop and dust drift scenarios are stated as areas which cannot be finalised for bumble bees and solitary bees for the sugar beet use in table 3. The peer review meeting report states regarding dust drift: <i>'The experts considered as line of evidence the low exposure is sufficient to conclude a low risk to bees (HB, BB, SB) for sugar beet for both clothianidin and imidacloprid.'</i>	Noted. The Conclusion was revised to better reflect the experts' meeting discussion. No changes in the table 3 were considered necessary (i.e. issues that could not be finalised for bumble bees and solitary bees were identified due to the lack of toxicity data)
12	Page 18, table 3	UK: It is unclear why the adjacent crop and field margins are highlighted as areas that cannot be finalised for the use on forest nursery. This appears inconsistent with the approach for other granule applications.	Agreed The table 3 was amended accordingly.

Other			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
1		BE (RMS): No comments	Noted

Member States' comments on the draft EFSA Conclusion on Clothianidin (RMS: BE)
Pesticides Peer Review Written Procedure: September 2016

(07.09.2016) 8/8

Other			
No.	Reference (e.g. conclusion text, list of endpoints, evaluation table etc)	Member State comment	EFSA response to comment
2		CZ: No comment	Noted