# European Food Safety Authority


# Peer Review Report on imidacloprid

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

October 2016

PEER REVIEW REPORT ON **IMIDACLOPRID** OCTOBER 2016

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**REPORT OF PESTICIDES PEER REVIEW MEETING 145**

IMIDACLOPRID

Rapporteur Member State: DE

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:

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|---|---|---|
| xx Month xxxx | Name | |
| | | |

2. Documents submitted for meeting:

| Date | Supplier | File Name |
|---|---|---|
| 27.11.2015 | DE | Imidacloprid_Addendum 10_confirmatory data_2015-11-27.pdf |
| 30.05.2016 | DE/EFSA | Imidacloprid_Technical Report_Confirmatory data |

3. Documents tabled at the meeting:

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|---|---|---|
| xx Month xxxx | Name | |
| | | |

Appendix 1: Discussion table: IMIDACLOPRID

# Appendix 1: Discussion Table, Imidacloprid (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

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| Experts consultation 1<br>**General**<br>RMS and MSs to clarify the uses to be assessed under the confirmatory data procedure, including a consideration of the harvest time of the vegetables, number of seeds to be sown, seed dressing rates and whether hand-spreading of granules is | Open point<br>RMS to contact Portugal and Malta to clarify the authorised uses in these countries.<br>**Post meeting note**: feedback was received from PT to EFSA on this. DE received feedback from MT clarifying that all authorised uses for imidacloprid are foliar applications. EFSA will consider this information in the conclusion (open point originally identified for RMS is now considered obsolete)<br>Seed treatment uses for imidacloprid are winter cereals, beet, leafy vegetables. Granular uses of amenity vegetation. Potato as 'In-planter or in-furrow'<br>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 | Open point<br>RMS to contact-Portugal and Malta to clarify the authorised uses in these countries.<br>**Post meeting note**: Addressed, no further actions for the RMS<br><br>Open point<br>RMS to recalculate the application rate expressed in mg/seed considering TGW of 21-61g for cereals. This will have consequences for tier 1 and tier 2 RA calculations. |

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| considered. | 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 worst case values.<br>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).<br>Open point for the RMS to update the mg a.s./seed based on this discussion.<br>The potato use reported as 'In-planter or in-furrow' was considered as downward spray use for the purpose of the risk assessment. On the basis of this, it was considered to assume that the crop category from the bee tool calculator of EFSA (2013)[1] should be 'potato spray BBCH <10' and all the related scenarios. The 'In-planter or in-furrow' is not covered by EFSA (2013). It was noted that likely the drift can be considered negligible, because the nozzles are directed into the furrow. However, this can be only considered at MS level because no precise information was available about the GAP or spray drift in the addendum (or in the dossier). The 'potato spray BBCH <10' was considered as worst-case.<br>Regarding the leafy vegetable, it was noted that, from the feedback provided by MSs and available to EFSA (no information from Portugal and Malta), no PPP authorised in MS on 'Brassica, flowering, head, leafy' seems to have been granted. EFSA will check further with MSs the status of Brassica, flowering, head, leafy'. For the assessment of the confirmatory data only lettuce and endive will be considered.<br>For the granule application the application rate in g a.s. /ha was not reported in the addendum, but was available in the dossier.<br><br>Open point for the RMS to provide in a revised addendum, the tier 1 calculations for honeybees, bumblebees and solitary bees. This is relevant for all the uses under evaluation. The RMS provided these calculations only for bumblebees and solitary bees (to be updated after the meeting), but at the meeting it was considered necessary to follow a consistent approach for both clothianidin and imidacloprid. It was also noted that the | Open point<br>RMS to provide a revised addendum with the tier I calculations for honeybees, bumblebees and solitary bees. |

[1] EFSA (European Food Safety Authority), 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 268 pp., doi:10.2903/j.efsa.2013.3295

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| | confirmatory data were identified on the basis of the EFSA conclusion under Article 21 of Regulation (EC) No 1107/2009 (EFSA, 2013)[2].<br>It was agreed by the meeting that professional hand held application of granules should be considered and the dust drift from this type of application can be considered as negligible. | |
| Experts consultation 2<br>**General**<br>MS to consider how to integrate the novel laboratory toxicity endpoints into the RAs noting that the formulations tested included chlotianidin and imidacloprid (HB and BB). | 'New' toxicity endpoints with formulations were available showing in some cases (contact HB) higher toxicity (about a factor of 2) than the toxicity of the technical.<br>It was proposed to still use the data of the technical where the difference of the toxicity between the technical and the formulation is within a factor of 5. It was also considered that the data on formulations provide some indications of a complete different tox profile of products compared to the a.s.<br>Overall, it was agreed to use the endpoints for the technical already agreed in the previous peer review and considered in the addendum for this procedure. | Overall, it was agreed to use the endpoints for the technical already agreed in the previous peer review and considered in the addendum for this procedure. |
| Experts consultation 3<br>**a), f), g) Risk to honeybees and to pollinators other than honey bees 1st tier risk assessment**<br>MS experts to discuss the relevant scenarios for the 1st tier risk assessment for the uses under evaluation and some | For the first consultation bullets see expert consultation 1.<br><br>SANCO/10553/2012, January 2014 (Draft Guidance document for the Authorisation of Plant Protection Products for Seed Treatment) reports updated dust deposition values compared to the ones used in EFSA (2013). Since this is considered as the latest best available scientific and technical knowledge (in line with Art. 21 of Reg. 1107/2009), the majority of the experts considered that SANCO (2014) should be used in the exposure assessment, while the minority considered that EFSA (2013) should be used as it is a final version and published.<br>As a consequence, an open point was identified for the RMS to update/conduct the tier 1 calculations for both oral (acute, chronic, larvae) and contact (acute) exposure for all the bees (HB,BB,SB) where the tox endpoints are available. | Open point<br>The RMS to update/conduct the tier 1 calculations on the basis of the dust drift deposition values reported in the most recent SANCO/10553/2012 rev. 9. The calculations should be provided for honeybees, bumblebees and solitary bees. |

[2] EFSA (European Food Safety Authority), 2012. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid. EFSA Journal 2013;11(1):3068, 55 pp., doi: 10.2903/j.efsa.2013.3068

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| methodological aspects, particularly (weed scenario is considered in a separate point):<br>- MS experts to discuss and agree how to assess the in-furrow use for potato<br>- MS to consider the use of newer data and approach regarding dust drift (i.e. SANCO draft GD on seeds)<br>- MS to consider whether the RMS's conclusion on the use of the granular formulation in areas such as golf-tees and sport fields are agreed<br><br>EFSA to inform and clarify at the meeting that<br>- pending on whether the vegetables are harvested before the flowering (GAP to be clarified), | The granular formulation in areas such as golf-tees and sport fields were considered as not attractive by the RMS i.e. only grass and no considerable flowering weeds present. The risk for hand held applications was considered low for all the scenarios. For machinery application the field margin scenario is considered relevant. Data are not available for granule dust drift. | |

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| only one or two RAs and most likely two different conclusions would be needed for that scenario<br>- according to the Bee GD, the adjacent crop scenario is relevant for the oral RA. The Ef factor is indeed lower than for the field margin, but the SV is higher. | | |
| Experts consultation 4<br>**c) Weeds**<br>MS experts to discuss the relevance of the weed scenario for the representative uses, in particular:<br>- MS to consider the weed scenario for the seed dressing uses as an exceptional case<br>- MS to discuss at the meeting if the information on weeds is sufficient | 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 for seed treatments in EFSA (2013). This is because of the combination of soil persistence, sistemicity and high toxicity of certain neonicotinoids. The soil persistence and sistemicity were also indicated in the succeeding crops experiments.<br>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:<br>-no. of plots analysed (trials, replicates, observations)<br>-observation timing date and BBCH stage for the crop<br>-no. of species per plot<br>-clarification with regard to the ground cover % reported in the study (average or total ground cover)<br>Therefore an open point was identified for the RMS to provide these clarifications in a revised RAR. Addressing this point the RMS may request the applicant to provide the data in the study Garcide et al 2014 in a tabular format (xls). Pending on these clarifications a | Open point<br>RMS to provide the following clarifications on the Garside et al 2014 study:<br>-no. of plots analysed (trials, replicates, observations)<br>-observation timing date and BBCH stage for the crop<br>-no. of species per plot<br>-clarification with regard to the ground cover % reported in the study (average or total ground cover).<br>A revised addendum should be provided. |

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| to addressed the risk from this scenario | final conclusion can be drawn by EFSA.<br><br>Overall, pending on the clarification to be provided in the revised addendum, if all the available data will demonstrate that the flowering weed coverage is below the 10% trigger, the weed scenario for potato, cereals and sugar beet can be considered of low relevance as exposure route. Other uses were not covered by these data i.e. leafy vegetable and amenity vegetation. As regards amenity vegetation, see experts consultation 3. | |
| Experts consultation 5<br>**f) dust drift**<br>MS to discuss<br>- the relevance of the dust drift exposure for the granular uses<br>- whether the exposure via dust drift for seed treatment uses are adequately addressed<br><br>Note: granules are not necessarily drilled | 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.<br>However, those data have not been peer-reviewed because not available to the meeting and not submitted within the confirmatory dataset. This issue will be reflected in the EFSA conclusion.<br>See also experts consultation 1 and 3.<br><br>As regards seed dressing use on cereals, higher tier studies for dust drift were available for winter wheat (study R09247-2) and winter barley with clothianidin and imidacloprid (R09247-1 and R11129) and winter barley study on imidacloprid (Lueckmann & Staffel, 2014).<br>It was noted that there is no information as to whether the machinery used in all the studies covers the 90$^{th}$ % of exposure.<br>For 2 out of the 4 studies, no Heubach value (% dust) and Heubach-as values are available. This information is considered by SANCO (2014) as essential to properly address dust drift deposition assessment.<br>For 2 studies these measurements (Heubach values) were available. However, it was argued that individual studies with few varieties might be not sufficiently representative (and not sufficient to overrule the default values in SANCO (2014), which are based on a larger dataset) as the amount of dust drift is very much dependent on the quality of the | See open point under experts consultation 3 |

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| | seed dressing rather than the properties of the a.s.<br>Therefore according to SANCO (2014), these studies are not suitable for estimating the exposure from dust deposition.<br>Overall, for both imidacloprid and clothianidin, it was agreed to use only the exposure values in SANCO (2014) in tier 1. No value from the available data was considered suitable for tier 2 calculations.<br><br>Additionally, a study was available for sugar beet resulting in values below LOD. The study was not discussed in details, however similar shortcomings could be noted. EFSA noted that, when using EFSA (2013) with the currently available data, a low risk could be demonstrated at first tier. Nevertheless, according to the discussion, the tier 1 assessment has to be performed considering SANCO (2014).<br>See also experts consultation 3. | |
| Experts consultation 6<br>**d) honey dew**<br>MS to discuss the risk to honeydew resulting from the uses under evaluation. | The statement paper by Nauen et al, 2013 was discussed. Generally the argumentation provided was agreed since imidacloprid is intended to control sap sucking insects, at least during the first weeks of growth the exposure of honeybees is likely to be low.<br>In relation to that, the paper by Foster, 2008 was also considered. It was noted that the $ED_{50}$ in the study by Foster, 2008 was not consistent among the tested clones as there were some apparent variability (although this variability in the effects concentration on M. persicae was lower than the one for clothianidin). It was agreed that neonic resistence to aphids could not be excluded (there are several reported cases of neonics resistant strains of aphids in literature, including M. persicae, which is a highly polyphagous species), (Bass, Chris, et al. "The global status of insect resistance to neonicotinoid insecticides." *Pesticide biochemistry and physiology* 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.<br><br>Overall, the experts agreed on the basis of the available data that honeydew can be considered as a route of exposure of low relevance for the treated crop scenario for the uses under evaluation. | Overall, the experts agreed on the basis of the available data that honeydew can be considered as a route of exposure of low relevance for the treated crop scenario for the uses under evaluation. |

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| Experts consultation 7<br>**e) guttation**<br>MS to discuss whether the available data may be considered sufficient to conclude that the exposure to guttation fluids is not relevant. | Cereals and beet<br>For imidacloprid 5 new effect studies were available in common with clothianidin: 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 residues present in guttation fluid were assessed.<br>No apparent effects in these higher tier studies were reported (which lead to a low risk conclusion made by the RMS for these 3 crops).<br><br>RMS did not perform tier 1 or tier 2 RA for guttation. It was pointed out that the dataset is not sufficient for selecting the 90$^{th}$ percentile of exposure as suggested by EFSA (2013).<br>An open point for the RMS to use the maximum residue level for the acute exposure assessment was identified. 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.<br><br>Potato<br>It was noted that there was a higher bee mortality in one of the 2 studies by Rexer, H. U.; (i.e. 2014d) in about 10 consecutive days. The relevance of this potential effect was discussed. Some experts argued that the difference was minimal. Others highlighted that this trend seems to be correlated to the highest flight intensity period of the bees. EFSA added that an increased forager mortality that was observed here (factor of 2 and more) would be relevant if it was for pollen/nectar foragers; however the proportion of the water collectors in a hive is normally small. Since the statistical power of the study was low, no firm conclusion could be done on the relevance of these effects with reference to the SPG of the EFSA (2013). It was noted that similar pattern was seen in some other guttation studies.<br><br>**Overall conclusion on the risk from guttation for the uses under evaluation of** | Open point<br>RMS to perform tier 2 calculations and provide these in an updated Addendum. |

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| | **clothianidin and imidacloprid**<br>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.<br><br>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 together, the statistical power might be higher.<br><br>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).<br><br>The experts agreed that the guttation assessment for honeybee also covers the bumblebees and solitary bees as specified in EFSA (2013). | |
| Experts consultation 8<br>**a), b), g) ingestion of contaminated nectar and pollen**<br>**Higher tier risk** | Regarding the knowledge on the <u>attractiveness</u> of the pertinent crops,<br><u>Cereals</u><br>The applicant provided some argumentations e.g. wind pollinated, not attractive. No data where provided to support this argumentation. EFSA (2013), due to diverging data from literature, considered that further data should be provided to exclude collection of pollen | Open point<br>RMS to update the Tier 2 calculations for wild bees and perform the Tier 2 for honeybees by using the highest residue values in pollen and nectar |

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| **assessment**<br>MSs to discuss the tier 2 and the higher tier risk assessments to honeybees, bumblebees, solitary bees.<br>- MS to consider if the available knowledge on the attractiveness of the pertinent crops can be considered somehow in the RAs<br>- MS to consider the available residue studies and 2nd tier assessments<br>- MS to consider the available higher tier effect studies | by honeybees, bumblebees and solitary bees.<br>The attractiveness of agricultural horticultural crops was further analysed by van der Steen, et. Al., 2015 report n. 606, Wageningen University. 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.<br>Overall, the experts concluded that EFSA (2013) 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.<br><br>Sugar beet<br>The experts considered the treated crop could be considered as not relevant, when the crop is not a seed bearing crops.<br>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.<br>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.<br>Potato, lettuce and endive<br>For potato, EFSA (2015)[3], data were available showing pollen collection by honeybees. Therefore, potato crop should be considered as attractive. For lettuce and endive, the experts agreed to refer to the beet discussion in clothianidin report regarding the seed production issue. As regards amenity vegetation, see experts consultation 3. | from the naturally aged residue trials and using the EFSA SHVAL tool. |

[3] EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering all uses other than seed treatments and granules. EFSA Journal 2015;13(8):4211, 82 pp, doi:10.2903/j.efsa.2015.4211

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| | The available residue studies (for following crop scenario) and the 2nd tier assessments were discussed. RMS gave background on the point of discussion and the available dataset. Several studies were available both with 'natural' and 'forced' exposure. Soil samplings were performed only in the first 10/20 cm. However, it was noted that in the natural aged trials, the measured residues in soil cover the calculated PECplateau (some calculations were available in EFSA (2008)[4]. It was agreed to use the highest residue values from the naturally aged residue trials for the exposure assessments as the number of trials and their representativeness was not sufficient to allow an assessment of the 90$^{th}$ percentile of expected exposure in the area of use. These values are 2.5 ug/kg for pollen and 3.5 ug/kg for nectar.<br>Open point for the RMS to update the Tier 2 calculation for wild bees and perform the Tier 2 for honeybees by using the highest residue value in pollen and nectar.<br>EFSA acknowledged that the use of the *SHVAL* tool could have been the most robust approach for the Tier 2 calculations.<br>Open point for the RMS to update the Tier 2 calculations by using the SHVAL tool. EFSA to support the RMS. This calculation should be documented in a revised addendum if the results will indicate low risk with respect to the Tier 2 approach (note that the 90$^{th}$ percentile residue was not accepted) currently followed by the RMS.<br><br><u>Higher tier</u> effect studies.<br>Two bumblebee effect studies were available. The following shortcomings were highlighted by the RMS in the addendum (assessment of wild pollinators).<br>1-Studies were conducted with B. *terrestris*. However, its representativeness for other bumble bee species has to be questioned.<br>2-Post exposure period at uncontaminated sites.<br>3-Provision of sugar solution as additional food.<br>4-Both studies were carried out with only one control and one treatment plot.<br>5-The residue levels in pollen were rather low.<br>Not all the MSs at the meeting agreed that the shortcomings above would question the | |

[4] EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid, doi:10.2903/j.efsa.2008.148r

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| | suitability of the studies for the RA (shortcomings 1, 2 and 3 were not considered as such by all the MSs). It was noted that the extrapolation to other *Bombus* species is a general risk assessment issue rather than a real shortcoming of the study design.<br>Anyway, it was noted that it would be necessary to rely on other lines of evidence for addressing the risk to wild pollinators.<br>Overall, the majority of experts agreed that, due to the uncertainties (i.e., low statistical power, questionable exposure), the studies are not sufficient to draw any solid conclusion on the effects of imidacloprid on wild bees. | |

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

| **Ecotoxicology** | | | |
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| **No.** | **Reference** (e.g. conclusion text, list of endpoints, evaluation table etc) | **Member State comment** | **EFSA response to comment** |
| 1 | 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. | Member State's opinion is noted. |
| 2 | Page 12, Table 3 | UK: It is unclear why guttation is flagged as a critical area of concern for honeybees for the leafy vegetable scenario. It is assumed that this is a typo and the 'R' should appear in the field margin column instead. The text above states | Indeed this is a typo (swap of columns) and the 'R' should appear in the field margin column instead. Thanks for pointing this out. This was corrected accordingly. |

| **Ecotoxicology** | | | |
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| **No.** | **Reference** (e.g. conclusion text, list of endpoints, evaluation table etc) | **Member State comment** | **EFSA response to comment** |
| | | that '*the experts agreed that the risk from exposure to residues in guttation fluids, for uses under evaluation can be considered of lower relevance*.' | |
| 3 | Page 12, Table 3 | UK: It is unclear why the risk to solitary bees for the amenity vegetation use and the field margin/adjacent crop scenarios have been flagged as critical areas of concern rather than as areas which cannot be finalised. | This is a typo. Thanks for pointing this out. The two 'R' are removed. |
| 4 | 2. Toxicity endpoints | BE: In line with the (draft) EFSA conclusion for the confirmatory data for clothianidin, a paragraph explaining that extrapolated endpoints were used for bumble bees and solitary bees should be added here. For example, the text below (which is adapted from the clothianidin conclusion) could be used:<br>*According to EFSA (2013b) and in line with the previous conclusion of imidacloprid (EFSA, 2015), to perform a screening risk assessment, surrogate endpoints were agreed for bumble bees (chronic) and solitary bees, assuming that for these species the endpoints for the technical are 10 times lower than those agreed for honeybees. It is noted that for the previous conclusion of imidacloprid (EFSA, 2015), this approach was however not considered appropriate by the experts for bumble bee and solitary bee larvae, because only a provisional honeybee larvae endpoint* | This suggested paragraph is related to the conduct of the risk assessment rather than the toxicity endpoint itself. However, for consistency reasons, this paragraph has been added to the conclusion, Section 2. |

| **Ecotoxicology** | | | |
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| **No.** | **Reference** (e.g. conclusion text, list of endpoints, evaluation table etc) | **Member State comment** | **EFSA response to comment** |
| | | *was available.* | |
| 5 | Conclusions of the evaluation<br>4. Flowering weeds in the field | First paragraph on p. 12: "Therefore, the exposure to bees via this scenario could be considered of low relevance for these uses, particularly when weed control is applied."<br>CZ: It is not clear, if the conclusion on low relevance of the weed scenario is general or if it is related to imidacloprid only. | The occurrence of flowering weeds was investigated in potatoes, winter cereals, maize and sugar beet and it was not active substance related. Therefore the conclusion drawn is relevant for these crops in general. |

| **Other** | | | |
|---|---|---|---|
| **No.** | **Reference** (e.g. conclusion text, list of endpoints, evaluation table etc) | **Member State comment** | **EFSA response to comment** |
| 1 | Appendix A<br>List of the representative uses evaluated | CZ: The following uses in the Czech Republic are missing:<br>Nuprid 600 FS (red) – winter wheat and barley, seed treatment, application rate 126 g a.s./ha ~ 696 g a.s./t seeds. Product dose 1.16 L/t seeds.<br>Nuprid 600 FS (white) – sugar beet, seed treatment, application rate 150 mL product/100000 seed ~ 90 g a.s./ 100000 seed, sowing rate 1.3 unit seeds/ha ~ 117 | Thanks for the information. Appendix A includes the uses supported by the applicant Bayer Cropscience as these uses were assessed by the RMS Germany (and supported by data). Nevertheless, the uses indicated by CZ are covered by the risk assessment presented in the conclusion. The only considerable difference is that EFSA's risk assessments for |

| **Other** | | | |
|---|---|---|---|
| **No.** | **Reference** (e.g. conclusion text, list of endpoints, evaluation table etc) | **Member State comment** | **EFSA response to comment** |
| | | g a.s./ha.<br>Gaucho 70 WS – lettuce, greenhouses only, seed treatment, application rate 117 g a.s./ha ~ 0.728 g a.s./1000 seeds. Product dose 167 g/ha ~ 1.04 g/1000 seeds. | the vegetable uses cover an application rate between 80-150 g a.s./100000 seeds, while the equivalent value as indicated for the use in CZ is only about 73 g a.s./100000 seeds. Since this is relevant only for the treated crop scenario for which a low risk was concluded, this use can also be considered as covered by the conclusion.<br>In section 1.1, on page 7 there is a sentence acknowledging that there are uses authorised in Member States which are not covered by the current risk assessments. This sentence is now slightly reworded. |
| 2 | | BE: No comments | Noted |