Document Title

Comments by Bayer CropScience on the EFSA conclusion on the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted

EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data. EFSA Journal 2016;14(11):4606, 41 pp. doi:10.2903/j.efsa.2016.4606

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Executive Summary

Many data gaps have been filled which has been recognized by the EFSA and member states.

Data gaps or identified risks still exist only on the basis of the non-existing test guidelines and unclear or unachievable criteria.

Higher tier data is still not considered appropriately and the broad evidence of no harmful effects is ignored.

Based on the totality of the evidence provided in this submission and already available the safety of all the currently registered uses has clearly been established (seed treatment).

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1. Introduction

Bayer CropScience (BCS) has reviewed the peer review of the pesticide risk assessment for the active substance clothianidin in light of confirmatory data submitted by the European Food Safety Authority (EFSA) and wants to comment as follows:

BCS supports the following conclusions made by the EFSA:

- For the uses in potatoes, sorghum, cereals and beets, the exposure via the 'flowering weeds' was considered not relevant, due to the low coverage in field of flowering weeds.
- For the uses in potatoes, sorghum, cereals and beets, the exposure via 'honeydew' was deemed to be as not relevant.
- For the uses in potatoes, cereals and beet, the exposure via 'guttation fluids' was concluded as not the primary route of exposure for bees.
- Risk from exposure via 'dust': For the use in beet, the risk was indicated as low for honeybees.
- For the uses in sugar beets, the 'treated crop scenario' was not considered relevant
- For the uses as granules in maize/sweet corn in permanent glasshouse, all the aspects of the risk assessment within the confirmatory data requirement, could be considered of low relevance due to the low exposure.

However, BCS does not agree with the conclusions that risk assessment could either not be finalized or that the exposure scenario results in a conclusion on high risk for the other evaluated scenarios, the reasons are discussed in more detail below.

2. Comments

2.1. Risk Assessment Methodology (EFSA section 1.2)

Use of the EFSA bee guidance document (2013b): The risk assessment presented in the EFSA conclusion on the confirmatory data is based on the EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, Bombus spp. and solitary bees), 2013b. BCS is of the opinion that this guidance document should not be considered for this process since it has not been adopted by the European Commission and was not in force at the time of the submission or evaluation, which is still the case today. The guidance document has consistently failed to be voted for implementation due to the major short-comings.

BCS agrees with the comments of the [redacted], made in the context of the imidacloprid confirmatory data, with regard to the guidance document (GD):

"*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 purpose in the EU.*"

As the EFSA GD for bees (2013) is not adopted, the data requirements, risk assessment methods and triggers are not part of the uniform principles. For example, the data requirements of the EFSA GD go by far beyond those currently in force (EU Reg. 283/2013) and include the generation of a wide range

of studies, the majority of which do not have any internationally recognised or validated status. Although the EFSA bee GD claims to provide "guidance" on such studies this does not constitute a valid guideline and as such undermines the regulatory process which should be based on ring tested, reliable, reproducible, peer reviewed and validated methodology. The current status, availability and validity of test methods must be described as not available, especially for bumble bees and solitary bees but also for certain guidelines for honeybees. Therefore most of the so called toxicity endpoints extrapolated by the RMS and the EFSA are not suitable for use or consideration. It is virtually impossible to perform a number of lower tier (laboratory) tests and higher tier tests (semi-field and field) required by the EFSA.

Seed treatment guidance document: In the addendum to the DAR selective use was made of the SANCO/10553/2012, January 2014 (Draft Guidance document for the Authorisation of Plant Protection Products for Seed Treatment) by the EFSA. This document is still in the commenting phase and was not adopted at submission date, neither is it today. Data from this draft documents must not be used simply because the content may change over time until it becomes a final guidance document that may eventually be adopted in the future. Any decision making based on draft documents is subject to permanent change.

2.2. Toxicity endpoints (EFSA section 2)

As mentioned and discussed earlier before, the non-meeting of trigger values set by EFSA is in parts driven by the selected toxicity endpoints, i.e. in case that no real endpoints were available then the honeybee endpoint divided by 10 was used, this was the situation for acute toxicity to solitary bees, chronic toxicity to bumble bees and solitary bees. For both species there are even today (2 years after the confirmatory data was submitted and 3 years after the proposed EFSA bee guidance document was published) no validated test methodologies available to derive the toxicity endpoints. Due to the conservativeness of the tier 2 risk assessment prepared by the RMS and the EFSA the need for higher tier risk assessments are triggered. The EFSA evaluation does not take into account the available data which demonstrates that there is no significant difference in toxicity, i.e. that in bumble bees there is no 10-fold higher toxicity observed compared to honeybees.

2.3. Risk Assessment for Succeeding Crops (EFSA section 3)

The comments regarding toxicity endpoints is applicable to the risk assessment performed for succeeding crops.

Tier 2 Exposure Characterisation and Risk Assessment

As regards to exposure data, BCS does not agree with the use that was made of the data from succeeding crop studies. It is accepted by the RMS and the EFSA that for exposure refinement measured residue data derived from natural exposure scenarios are appropriate to describe a realistic exposure situation, BCS finds the decision on the residue data used not transparent. For preparation of the tier 2 assessment the RMS and the EFSA decided to consider data from all available studies including the use of clothianidin as seed treatment (Bayer Crop Science dossier) and the granular application (Sumitomo dossier) and based on this dataset the highest available residue values from the

'natural exposure' studies were considered. Despite the availability of the multiple data sets EFSA has used maximum measured values instead of the 90th percent values, this approach fails to consider that the majority of the samples showed no quantifiable residues, in the BCS trials 30/53 samples showed no measurable residues in pollen while 24/26 showed no measurable residues in nectar. Additional data which had previously been evaluated was also not taken into account as a "full assessment was not available", again indicating a lack of willingness to consider all available data including that which has been previously peer reviewed. Consequently the failure to correctly consider all available data resulted in a conclusion that the risk assessment could not be finalized.

Higher Tier Risk Assessment

In the higher tier risk assessment no account has been taken of the multiple studies on treated crops (that result in higher exposure than the succeeding crop scenario) are available that showed no effects. Basically all higher tier field effect studies [the majority of these performed to test guidelines that were and still are in place, i.e. EPPO 170 (4)] were judged to be insufficient to demonstrate that the risk to bees was low for the use of clothianidin as a seed treatment in several crops. It must be noticed that this failure is caused by quality and quantity criteria introduced in the EFSA bee GD, which is not adopted nor noted. The EPPO 170 (4) guideline is still referenced as a suitable guideline to be followed in such investigations (see Commission Regulation (EU) No 283/2013 and commission Regulation (EU) No 284/2013).

Higher tier study data for honeybees, bumble bees and solitary bees have been provided by BCS but this data was not evaluated by the RMS and the EFSA. Since apparently data gaps were identified at the lower tier level, it is not appropriate to disregard or exclude evidence from higher tier study data based on statements by the RMS and the EFSA that this data will be evaluated at a later date. If based on this evaluation of the confirmatory data decisions will be taken, then surely all evidence available must be considered beforehand.

The EFSA acknowledges that the large scale monitoring study on oil seed rape, covering 65 km^2, as representative of the typical exposure from succeeding crop, was submitted by BCS but only comments that the study should be carefully evaluated. On the other hand, even without having performed this evaluation, The EFSA states the following: "Overall, the available higher tier risk assessment could not be considered suitable to further address the risk."

BCS was under the impression that submitting studies as confirmatory data would result in their evaluation; however in the comments to the Peer review it is stated:

"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".

Or to put it another way, a study which was designed to try and fulfil the criteria which the EFSA lays down in their 2013 guidance document is too complex to analyze while all other higher tier studies are not sufficiently robust as they do not satisfy the EFSA guidance requirements. Hence under these terms it is impossible to submit any higher tier studies as the reviewers cannot evaluate them.

2.4. Dust drift in field margins and adjacent crops (EFSA section 7)

For all BCS uses except sugar beet and honey bees a risk identified or the risk cannot be concluded. This assessment is not shared by BCS for the following reasons.

Winter cereals:

In evaluating the risk assessment for dust the EFSA concludes a risk in the field margin and the adjacent crop, even though studies have been provided which clearly show no adverse effects to honeybee colonies exposed during sowing of winter cereals. Although the EFSA did not apply the draft guidance document on seed treatment which proposes a "novel" un-validated approach they applied the EFSA 2013b bee Guidance document which is also not adopted and considered relevant for regulatory purposes.

Inevitably the risk assessment fails at Tier 1 and as the higher tier studies were rejected a high risk is concluded. The reasoning for the rejection of the higher tier studies was somewhat unclear.

- **Honeybees**

With regard to the major higher tier study where the potential impact of dust exposure was evaluated the EFSA comments that no Heubach a.s. values were provided but only some values on the dustiness of the seed batches, plus that the individual studies might not be sufficient to overrule the available dust deposition values in EFSA 2013.

The Heubach active substance values are not a requirement in the EFSA evaluation scheme which is based on the dust deposition values. Heubach values (including Heubach a.s. values) were also supplied in some of the studies and hence the comment of the EFSA is not accurate.

To the understanding of BCS Heubach values are the commonly agreed method to measure the "dustiness of treated seeds". It is therefore unclear what additional information the EFSA believes is missing and why this data is described as "only some values on the dustiness of the used seed batches".

For the clothianidin confirmatory data the following studies were submitted where honey bee colonies were exposed during the sowing of winter cereals:

Author and year	Report	Document No.
5.1.2.e Woo 2014	Field study to monitor potential effects on honey bees from exposure to guttation fluid of winter wheat (W-WHT), seed-treated either with an imidacloprid or a clothianidin combi-product	M-498939-01-1
5.1.2.e Woo 5.1.2.e Woo 2012	Field study to monitor potential effects on honey bees from exposure to guttation fluid of winter barley (W-BAR), seed-treated either with an imidacloprid or a clothianidin combi-product	M-498922-01-1
5.1.2.e Woo 5.1.2.e Woo 2014	Field study to monitor potential effects on honey bees from exposure to guttation fluid of winter barley (W-BAR), seed-treated with the insecticidal seed-treatment product clothianidin + imidacloprid FS 100 + 175 G in Germany in 2011/2012	M-501261-01-1
5.1.2.e Woo 2015	Final report - Assessment of potential impacts on honeybee colony development, their hibernation performance and concurrent monitoring of aerial dust drift during the sowing operation of Redigo Deter FS 300 G - Treated winter barley with typical commercial pneumatic sowing technology, directly adjacent to full-flowering *Phacelia tanacetifolia* in United Kingdom	M-504538-03-1
5.1.2.e Woo 2015	Final report - Assessment of potential impacts on honeybee colony development, their hibernation performance and concurrent monitoring of aerial dust drift during the sowing operation of Poncho Beta Plus - Treated sugar beet pills with typical commercial vacuum-pneumatic sowing technology, directly adjacent to full-flowering *Phacelia tanacetifolia* in Germany	M-504065-01-1

Although the first three studies were not specifically intended to examine potential effects of exposure during sowing, any effects would also have been observed and in all cases there was no difference in the colony performance between the controls and the treated fields.

The final studies were specifically designed to examine the potential effects of exposure to dust during sowing and also concluded that there were no adverse effects on honeybee colonies.

Hence in a total of five field studies performed at different times, using winter wheat and winter barley and different sowing equipment consistently no effects have adverse effects have been observed on the colonies.

In addition to the studies with exposure of honeybee colonies further studies on the dust exposure during sowing have been performed to compliment studies previously submitted, hence demonstrating that the default values in the guidance documents do not reflect the expected levels of exposure from neonicotinoid seed treatments. They are listed below:

Author and year	Report	Document No.
5.1.2.e Woo 2010a	Monitoring of dust drift deposits during and after sowing of winter barley (W-BAR) treated with Triadimenol & Imidacloprid &Fuberidazol & Imazalil FS 145.2 (60 + 70 + 7.2 + 8 g/L) or Clothianidin & Beta-Cyfluthrin FS 455 (375 + 80 g/L) on fields in Germany	M-366273-01-1
5.1.2.e Woo 2010b	Monitoring of dust drift deposits during and after sowing of winter wheat (W-WHT) treated with Triadimenol & Imidacloprid &Fuberidazol & Imazalil FS 145.2 (60 + 70 + 7.2 + 8 g/L) or Clothianidin & Beta-Cyfluthrin FS 455 (375 + 80 g/L) on fields in Germany	M-366277-01-1
5.1.2.e Woo 2014a	Investigation of dust drift deposits of clothianidin & imidacloprid treated winter barley seeds with pneumatic sowing machinery on fields in Germany in autumn 2011(with first and second amendment to final report)	M-502885-03-1

The EFSA mentions a 90th percentile exposure of all seed treatment facilities and sowers of winter cereals in Europe. There is no definition of what this means and assuming that it intends that the seed treatment quality represents the worst 10% of all winter cereal seed treatment facilities in Europe it is absolutely unclear how this could ever be achieved. BCS has no interest in supporting poor quality seed treatment and it is not clear how BCS could manipulate a the treatment to obtain such a result when extensive effort has been put into improving the quality of the seed treatment in professional, commercial facilities. The effect of this new requirement means that it is impossible to refine a risk assessment by ensuring that a formulation produces low dust by the incorporation of new technological developments (e.g. the development of seed treatment recipes including stickers) as these would not represent the worst-case. Formulation specific values (as described as a means to overcome the conservative default values) are also not possible under this. In any case the legal framework for the use of clothianidin for seed treatment obliges BCS to apply the best available technology (see Commission Directive 2010/21/EU) hence the use of the default values is also not appropriate as it fails to take into account the best technology available. Furthermore, the EFSA does not consider how representative the values used for the risk assessment are, for example the drift values used by EFSA for cereals are based only on a set of data generated by JKI where the seeds are not commercially treated and no details of the treatment "recipe" are given, drift values appear to be based only on 2 studies. From this it can be concluded that the data provided by BCS is at least as representative as that favoured by the EFSA and the RMS in their risk assessments. Hence, it is not understood why the BCS data is not considered appropriate.

Overall BCS considers that the extensive data set provided within this confirmatory data demonstrates that the risk from exposure during the sowing of winter cereals is very low and will not result in any harmful effects on bee colonies. It should also be noted that no incidents have been reported due to the exposure of bee colonies during sowing of winter cereals during the extensive period of use and the large areas in which seed treatments have been used.

- **Bumble bees and non-Apis bees**

The EFSA performed only a tier 1 risk assessment and does not take into account the biological factors which demonstrate that the exposure of other bees is unlikely during sowing of winter cereals. In the confirmatory data for imidacloprid the RMS stated the following:

"For biological reasons, there is no likelihood of exposure of *Osmia rufa* to dust drift in autumn, also the likelihood of exposure of individuals of *Bombus terrestris* foraging is rather low in autumn. … However the argumentation that the likelihood of exposure of individual bumble bees is low in autumn and no exposure takes places for solitary bees like *Osmia* is shared by the RMS."

The EFSA does not explain why they do not consider the conclusions of the RMS with regard to bumble bees and other non-apis bees as being appropriate but rather simply concludes a high risk (bumble bees) or that the risk assessment cannot be finalised (bumble bees and solitary bees).

Sugar Beet

The EFSA claims to have evaluated the potential exposure from dust according to the EFSA 2013b guidance document; in this document (Appendix C: Relevance of dust for treated seed) sugar beet is regarded as "*not relevant, due to pelleting and filmcoating (and mechanical drilling)*", this conclusion should be applicable to all risk assessments and hence no risk should be concluded for all bee species. The non-relevance of dust for this arable crop as a potential route of exposure has also recently been confirmed by Ctgb in the NL framework (Evaluation Manual, 2016).

In the amended version of the DAR it is also noted that "trials reflecting a bad seed treatment quality of the upper end of what may occur needs to be tested" which is not acceptable considering that legally there is an obligation to use best available technology and indeed no indication has been given as to what a "bad quality" seed treatment could be for sugarbeet.

- **Honeybees:**

For honeybees the EFSA acknowledges that there is no risk from exposure of dust during sowing.

- **Bumble bees and solitary bees:**

The EFSA concluded that the risk cannot be finalised even though they acknowledge the very low drift from sugar beets. The conclusion is purely based on the fact that it is not possible to generate the studies required and ignores the fact that the exposure is negligible.

Comments with regard to the representativeness of the sugar beet quality and the use in the risk assessment with regard to the impossibility of defining (let alone satisfying) the 90th percentile have been made with regard to winter cereals above, for sugar beet, which is recognised as being treated by a specific process which results in seeds with very low possibility of dust exposure, and that are usually sown by mechanical planters. This has clearly been ignored by the EFSA in their risk assessment.

2.5. Treated Crop (EFSA section 8)

Winter Cereals

For winter cereals the EFSA has performed a risk assessment for oral exposure to pollen from the treated crop ignoring the accepted view that winter cereals are not attractive to honeybees, bumblebees or solitary bees. The EFSA chose to ignore a recently completed review of the attractiveness of crops. The attractiveness of agricultural horticultural crops was further analysed by van der Steen, et. Al., 2015 report n. 606, Wageningen University even though this source was known by the EFSA as it was indicated in a parallel confirmatory data of Imidacloprid. Furthermore, the recently published US-EPA comprehensive survey of attractiveness of crops was also not considered (USDA, 2015) was also not considered.

The EFSA also refers to EFSA Bee Guidance Document as the definitive data base for the attractiveness of cereals to honey bees. In the version of this document updated in 2014, the following comment is made with regard to cereals:

"(1) *Generally this crop is considered low attractive to bees for pollen/nectar but their collection cannot be excluded at all due to controversial information found in literature. Data to exclude the pollen/nectar collection by bees need to be provided."*

No reference or source for the "controversial information" is given and hence this cannot be checked, this again shows the inconsistency of the EFSA whereby different standards are applied to data/information as the "controversial" information has presumably also not been made available for peer review. Neither is it clear what data would be acceptable to exclude pollen collection as it has not been identified in any of the BCS studies where the origin of pollen has been investigated.

3. Conclusion

The final conclusion of BCS is that all in all the EFSA conclusion reflects an inconstant way of evaluation, ignoring evidence from studies and data that were generated according to best available procedures including those following the EFSA GD on bees. The approach of the EFSA Bee guidance document is consistently shown to be inappropriate resulting in the conclusion of no safe use for the vast majority of herbicides, fungicides and insecticides including the active substances approved for use in organic farming.

4. References

Commission Regulation (EU) No. 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market; Official Journal of the European Union L 93, 3 April 2013, pp. 1-84.

Commission Regulation (EU) No. 284/2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. Official Journal of the European Union L 93, 3 April 2013, pp. 85-152.

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