



Document Title

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

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Bayer CropScience



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 (foliar and 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 imidacloprid 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 on potatoes, cereals, beet and amenity vegetation, the exposure via the 'flowering weeds' was considered as not relevant.
- The exposure via 'honeydew' was considered not relevant for the uses for which confirmatory data on imidacloprid have been presented.
- For the uses under evaluation, 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 indoor use on leafy vegetables (seedling production) and the hand held granular use on amenity turf, a low risk was concluded from exposure to dust drift.
- For all uses (except winter cereals and potatoes), the risk from the exposure of bees in the treated crop was considered as low.

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. Uses (EFSA section 1.1)

BCS has submitted data or argumentation to address the uses where they are the authorisation holder; these include seed treatment, granule and spray applications. The RMS expressed their wish not to receive any information on registered uses where BCS was not the registration holder, hence there may be discrepancies between the registered uses in some member states and the BCS tables of registered uses.

In the confirmatory data BCS also submitted argumentation with regard to the relevant aspects of non-seed treatment or granule uses, the RMS declined to evaluate the data and hence this should not be read as a deficiency of the BCS confirmatory data submission and should be attributed to the many different processes which have been initiated but not yet finalized. For example, the 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 was published in July 2015 and thus 7 months after the submission deadline for confirmatory data on all existing uses in December 2014. Nevertheless, BCS is convinced they have appropriately addressed all topics for which information was requested.

2.2. 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 ^{5.1.2a Woo} 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 (2013b) 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 Addendum 10 to the DAR selective use was made by the RMS of a further guidance document not yet adopted which is the Draft Guidance document for the Authorisation of Plant Protection Products for Seed Treatment (SANCO/10553/2012, January 2014). 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. Additionally the RMS made use of “confidential” data apparently generated by one institute to over-write all other data, this data has not even been submitted for peer review and is again not suitable for the use in risk assessment.

2.3. 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, as well as 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.

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

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

Tier 2 Exposure Characterisation and Tier 2 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. While the risk assessment of the RMS presented in the DAR Addendum of 27 November 2015 considered it appropriate to use the 90th percentile values, which then led to the conclusion that the risk for honeybees was acceptable whereas a risk could not be excluded for bumble bees and solitary bees. The risk assessment has undergone some evolution over time with conflicting views on how to use the data provided resulting in differences between in the initial risk assessment by the RMS (no risk) and by the EFSA (data gap).

The EFSA, in its conclusion states, the following: “The fact that the natural soil experiments were limited to 5 trial locations all in France, resulted in the conclusion that the data were insufficient to justify using 90th percentile pollen and nectar residues values for the risk assessment.”

Thus, in the DAR Addendum Version of 19 July 2016 the RMS presented a tier 2 risk assessment using the absolute worst case residue values selected from the naturally aged soil data set.

However the reason for selecting the sites in France is because they have a clearly demonstrated multi-year continuous use of imidacloprid and therefore are the ideal sites for determination of potential residues in succeeding crops, the intention of all data generated is to provide reliable data representing typical areas of use, BCS is of the opinion that this is exactly what has been done here. Furthermore BCS wants to point out that the use of one individual worst-case value is not representative and appropriate for the risk assessment considering that the majority of samples did not have any quantifiable residues of imidacloprid (21/33 nectar samples were < LOQ and 37/56 pollen samples had no quantifiable residues) hence the risk assessment is not a realistic assessment of potential exposure.



The large number of samples with no quantifiable residues clearly indicates the potential exposure is low.

The risk assessment also fails to take into account additional, already peer reviewed data for imidacloprid which confirms the low expected exposure.

Higher Tier Risk Assessment

Based on evidence from higher tier studies the RMS came to the “Overall conclusion: The risk of imidacloprid to honey bees from consumption of contaminated pollen and nectar in succeeding crops can be considered acceptable; as the level of residues in nectar and pollen detected in the investigated flowering crops were in the range or below levels of primary crops, for which in former assessments (DAR 2005, EFSA 2008 and EFSA 2013a) no clear effects on acute mortality and honey bee colony development were observed.”

In contrast, this view was not shared by the EFSA, who concluded on a data gap for honeybees in succeeding crops ignoring that multiple studies on treated crops are available that show no effects.

In the higher tier risk assessment no account has been taken of the multiple studies on treated crops (that by their nature 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 imidacloprid as a seed treatment in flowering crops such as oilseed rape and sunflower. It must be noticed that this failure is caused by quality and quantity criteria introduced in the EFSA bee GD, which are still under discussion and hence are 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).

For the recommended wild bee or non-*Apis* species laboratory and semi-field and field test methodology are not even yet available. Nevertheless in an attempt to provide evidence under realistic field conditions BCS commissioned the conduct of studies investigating the potential effects on bumble bees, which, however, were destined for the reasons already described above to fail to meet the quality and quantity criteria used by the RMS and the EFSA and that are described in a non-implemented guidance document.

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

For all uses except sugar beet and honey bees and amenity vegetation (hand-held application) and the use as a seed treatment in greenhouse a risk is 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 which is despite the provision of studies which clearly show no adverse effects to honeybee colonies exposed during sowing of winter cereals. Although the EFSA did not, in this case, 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 is somewhat unclear.

- **Honeybees**

With regard to the major higher tier study where the potential impact of dust exposure was evaluated the EFSA makes the following statement:

“No Heubach active substance values were provided for these studies; only some values on the dustiness of the used seed batches.”

The Heubach active substance values are not a requirement in the EFSA evaluation scheme, rather they form part of the un-validated and unapproved DRAFT seed treatment guidance document which the EFSA themselves did not use due to the lack of validation. The statement is additionally factually incorrect as Heubach values and indeed Heubach active substance data for the seeds was included in the main higher tier study report (report M-504522-02-1, page 22) and although the RMS was informed of the availability of the data they have not included the data in the DAR Amendment 10.

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 imidacloprid 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 ^{5.1.2} , 5.1.2.e Woo ^{5.1.2} ; 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} , 5.1.2.e Woo ^{5.1.2} ; 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} , 5.1.2.e Woo ^{5.1.2} ; 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 ^{5.1.2} , 5.1.2.e Woo ^{5.1.2} ; 2014a	Assessment of potential impacts on honey bee colony development, their hibernation performance and concurrent monitoring of aerial dust drift during the sowing operation of imidacloprid FS 350A G – Treated winter barley with typical commercial vacuum-pneumatic sowing technology, directly adjacent to full-flowering <i>Phacelia tanacetifolia</i> in United Kingdom	M-504522-02-1

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

Hence in a total of four 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 Wool, 5.1.2.; 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 Wool, 5.1.2.; 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 Wool, 5.1.2.; 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 the need for a 90th percentile exposure data from of all seed treatment facilities and sowers of winter cereals in Europe. There is no definition of what this actually 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 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 imidacloprid 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 of imidacloprid as a seed treatment in cereals 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 pollinators including bees other than honeybees is unlikely during sowing of winter cereals. 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), see citation below.

“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.”

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).

- **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 seed treatment quality and the impossibility of defining (let alone satisfying) the 90th percentile when conducting dust drift risk assessments have already been made as regards to winter cereals and apply in general. For sugar beets there is also the fact that the seed treatment is such that it is generally acknowledged to result in a very low possibility of dust formation. This is due to the specific process by which the seeds are coated and also because the sugar beet pills are usually sown by mechanical planters. This has clearly been ignored by the EFSA in their risk assessment.

Outdoor uses on leafy vegetables

For assessing the potential exposure of bees from dust during sowing of vegetables it is not at all clear what values the EFSA has used in the risk assessment. According to the EFSA 2013b guidance document this exposure route is “Not relevant for insecticides due to high quality coating”; hence it would be reasonable to expect the conclusion of the risk assessment to be the same as for sugar beet. However this is not the case and no explanation is given for why this should not be the case.

2.6. 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, bumble bees or solitary bees. The EFSA chose to ignore a recently completed review of the attractiveness of crops, the following is given as the explanation.

“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....”

This is an interesting comment as the RMS has been happy to use non-peer reviewed data for other aspects of the risk assessment; additionally the information related to the attractiveness of crops is available in English on the Ctgb website and on the report tables as well. The recently published US-EPA comprehensive survey of attractiveness of crops was also not considered (USDA, 2015).

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.

Potatoes

At the time BCS was developing the confirmatory data it was stated that potatoes are not attractive to honeybees (EFSA 2013 original version, USDA 2015) however based on a single source in Denmark (note it would appear that this published data is only available in Danish and seems not to be published in a peer review article). Furthermore, even in the case that individual visits of honey bees to fields of potato could be reported in literature, the assumptions of exposure to pollen from potatoes used in the



EFSA risk assessment ignores all the available peer reviewed literature on the pollination ecology of the crop family Solanaceae, which confirms non-attractiveness to honeybees.

In the case of the exposure of bumblebee to potato pollen, BCS recognizes the published lists of attractiveness of crops (USDA 2015 and EFSA 2013b) and submitted a field study to evaluate the potential risk of the in-furrow use in potatoes and the exposure to field relevant concentration in pollen. The out-come of this study confirms again that the conclusion of the EFSA risk assessment is over conservative. Yet again the higher tier field study with bumble bees was rejected despite being performed to the best available design and using the species regarded as being most appropriate for the testing due to the commercial availability.

Finally the RMS (and EFSA) appears to not understand the application technique for an in-furrow application in potatoes. A detailed description of the equipment and technique was provided, however the evaluation still assumes that the application is equivalent to a downwards spray ignoring the fact that this application technique will result in negligible spray as the tubers are either sprayed within the equipment (with no air outlet) or in the base of the furrow and then immediately covered with soil. It was noted this technique is recognised as being of low exposure e.g. by Ctgb and UK-CRD and hence the unrealistic approach taken by the RMS and the EFSA are not appropriate. This was noted in the expert discussion i.e. *“It was noted that likely the drift can be considered negligible, because the nozzles are directed into the furrow.”* However this is not taken into account in the risk assessment or even discussed in the EFSA conclusion or the amendment to the DAR.

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.

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