Aan College ter:	**Kennisneming**		**d.d. 28 augustus 2019**
Eerder behandeld:	in MT		**d.d.**
Notitie-opsteller:	5.1.2.e Woo		**Publiceren in Kennisportaal:**
Bijlagen:	2		Nee
Akkoord Secretaris:			**Consultatie:** Nee

C-328.I.03g EFSA consultatie Bee Guidance Document – inbreng Ctgb

Achtergrond
In februari dit jaar heeft de Europese Commissie een mandaat verstrekt aan EFSA om (delen van) het bijenrichtsnoer uit 2013 te herzien. EFSA heeft daarvoor 2 jaar de tijd gekregen.

Onderdeel van de herziening is een consultatie van de risicobeoordelaars van de lidstaten, via het EFSA Pesticides Steering Network. Het Ctgb heeft daartoe bijgevoegd commentaar opgesteld dat uiterlijk 6 september bij EFSA zal worden ingediend. Dit commentaar is gebaseerd op eerder commentaar ingediend in consultaties van de oorspronkelijke Bee GD en het SCoPAFF, aangevuld met nieuw commentaar op basis van onze ervaringen met het GD van de afgelopen jaren.

Ter informatie van het College is toegevoegd welk commentaar al eerder is ingediend en welk commentaar nieuw is. Dit wordt niet opgenomen in het commentaar dat wordt ingediend.

Naast de risicobeoordelaars worden ook stakeholders en (in een latere fase) de risicomanagers van de lidstaten geconsulteerd. Het volledige herzieningsproces is beschreven in bijgevoegd EFSA work plan (bijlage 2).

Bijlage 1: inbreng Ctgb in EFSA consultatie
Bijlage 2: EFSA workplan voor herziening van het Bee GD

Stakeholder and MS consultation on the EFSA Guidance Document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)

Fields marked with * are mandatory.

General considerations

Dear Stakeholders, Dear Member State contact points,

We wish to thank you in advance for your contribution to the review of the guidance document on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees) published in 2013.
In this survey you could provide your comments to specific chapters of the guidance document. Where indicated, you can choose to raise general comments or more focused comment(s) on specific section(s) of the related chapter. For several appendices, there will be dedicated comment boxes. Extensive comments which are rather specific for an appendix may be inserted only in the section for the appendices. Please comment on a specific issue only where it is most relevant to avoid repetition, and please avoid commenting editorial issues.
In the form, you will encounter with abbreviations HB, BB and SB. They translate to honey bee, bumble bee and solitary bee, respectively.

Please note that according to the mandate of the European Commission (M-2019-0100), the review should focus on:
- Evidence on bee background mortality, taking account of realistic beekeeping management and natural background mortality
- Exposure routes, particularly through spray application and seed treatment or granular application
- The list of bee-attractive crops
- The methodology with regard to higher tier testing

Revision of the protection goals will be part of the initiatives of DG SANTE. Therefore, the sections of the guidance document related to the protection goals were not included in this survey.

By accepting the terms, I confirm that I have read and understood the context as described above. I confirm that the comments below originate from me or from the organisation I am representing and I confirm that I did not delegate the commenting to a third person.

Thematic comments on the body text

Chapter 5: Exposure (dietary and contact)

Please select one or both:

a) I have general comment(s) on the exposure

Exposure - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to a specific bee species and or to a specific application method (i.e. honeybees and spray application)

Ctgb: No comments

b) I would like to comment some specific sections (5.1, 5.2, 5.3, 5.4, 5.5)
Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
5.1 pollen/nectar			*Ctgb: No comments*
5.2 contact			*Ctgb: No comments*
5.3 spray			*Ctgb: No comments*
5.4 seed			*Ctgb: No comments*
5.5 granules			*Ctgb: No comments*

Chapter 6: Effects assessment - Laboratory studies

Please select one or both:

a) I have general comment(s) on laboratory studies

Laboratory studies - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Ctgb: For chronic studies, the recommended endpoint in the EFSA bee guidance is the no-effect level. In other areas of ecotoxicological risk assessment, nowadays the EC10/EC20 is also calculated when possible, and used in the risk assessment in certain cases (see EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673). It would be good to explain why in this guidance document the no-effect level is considered the relevant endpoint. (new comment)

b) I would like to comment some specific sections (6.1, 6.2, 6.3)
Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
6.1 HB	6.1.1.4	79	Ctgb: The shortcut value for honeybee larvae is based on 5 days intake. The harmonised guideline OECD 45 however requires a 4-day exposure to the PPP. Please consider whether the 5-day intake level in the shortcut value should be adapted.
6.2 BB			*Ctgb: No comments*
6.3 SB			*Ctgb: No comments*

Chapter 6: Effects assessment - Higher tier studies

Please select one or both:

a) I have general comment(s) on higher tier studies

Higher tier studies - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Ctgb: No comments

b) I would like to comment some specific sections (6.1, 6.2, 6.3)

Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
6.1 HB	6.1.2	79	Ctgb: Please elaborate on whether the higher tier data on honeybees have to be performed according to the GAP. This seems to be the case, but it is only very briefly mentioned on pages 69 and 102. However, elsewhere it is implied that as long as the residue levels as expected from application according to the GAP are in line with those measured in the higher tier effects studies, there is no need to use multiple applications in the effects studies. Is this indeed the intention? If so, please clarify which is necessary, since this is otherwise expected to be a major discussion point for product assessments. Nevertheless, we question whether the residue level approach is correct, since exposing a colony twice may be more harmful than exposing it only once with a higher dose, taking into account unknown factors of metabolism and recovery. (new comment, linked to a previous comment: How are multiple applications taken into account? (Comment given on the draft EFSA Guidance in October 2012 by NL (Ctgb, RIVM, Plantum, NVWA, WUR, LNV)).)
6.2 BB			Ctgb: Please elaborate on whether the higher tier data have to be performed according to the GAP (see our similar comment for honeybees).
6.3 SB			Ctgb: Please elaborate on whether the higher tier data have to be performed according to the GAP (see our similar comment for honeybees).

Chapter 7: Trigger values

You are invited commenting on the methodology of the derivation of trigger values.

Please select one or both:

a) I have general comment(s) on the trigger values

Trigger values - General comment(s)
4000 character(s) maximum

Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Ctgb: No comments

b) I have species specific comment (HB, BB, SB)

Please comment at least in one row. If you have more comments for a specie (row), you can indicate more paragraph/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
HB			Ctgb: 1) Using the lowest background mortality will lead to a conservative and unrealistic assessment. A realistic background mortality should be used, not the lowest. (Comment given on the draft EFSA Guidance in October 2012 by NL (Ctgb, RIVM, Plantum, NVWA, WUR, LNV)). 2) Appendix M describes the chosen trigger value for the first tier. After qualifying the dataset on background mortality in Appendix K as limited, the lowest available value is chosen. This comment hence also applies to not only the appendices but also the main document: 1. Is the dataset truly limited, or is it just that the spread in the results is so wide that the median value is discarded? The test that resulted in the chosen level of 5.3% background mortality is based on visual inspection of the outlier. Why are medians within tests used for qualitative comparison, while in the end the lowest value is chosen? Why aren't all results used for comparison? 2. This most conservative value is derived using a theoretical time span before foraging, and is thus very uncertain. 3. How much effect can be detected in the semi-field study, when control mortality rate is e.g. at the median of 13%[1]? And: how much effect (e.g. total mortality, or duration of a certain elevated level) is acceptable from a population dynamics point of view (observing both the survival of the colony (also over the winter) and the production of honey)? Wouldn't it be easier if a trigger value was calibrated against a background mortality that accounts for the power of the (semi-)field test, or, if this is less than a certain biologically relevant value, against that biologically relevant value? The justification would be that although there is a theoretical risk that applications that violate the conservative trigger go unnoticed although they already may cause an effect in the field, it is also quite possible that this effect would not be measureable by the (semi-)field test, anyway. (Comment given on the draft EFSA Guidance in March 2013 by 'the Netherlands (NPPO, Ctgb, RIVM, Bijen@wur) and slightly rewritten for the current commenting round by Ctgb).
BB			Ctgb: For bumblebees, an extrapolation factor of 10 on the endpoints is used in case only honeybee toxicity data are

[1] Following the guidance, any additional mortality above the chosen level of background mortality (5.3%) will trigger semi-field testing. This background mortality value is close to the 5th percentile of the total (but stated as limited) set of observations. Assuming that such a distribution of mortality rates is valid for the bees in semi-field studies, the implication is that the first tier will be more conservative than the next tier (as intended). However, as a result in 95% of the triggered semi-field testing, the background mortality will be higher – up to 6 times. This raises doubt that the 'minimal effect' will be detected in the next tier, simply because by chance such effects will be obscured.

			available, based on a review of available data in 2012/2013. This factor is assumed to account for interspecies differences in sensitivity. Since the finalisation of the EFSA bee guidance document in 2013, many new studies have been performed. A recent analysis by industry of acute toxicity data showed that bumblebees are generally equally to or less sensitive than honeybees, which would suggest that the extrapolation factor of 10 from honeybee to bumblebee endpoints is not needed. Of course, there is little to no information on chronic and larval toxicity of bumblebees. Also, a major issue in the bumblebee risk assessment scheme is the fact that it is copied from the honeybee, while especially *exposure factors* are likely very different for bumblebees. These two issues call for caution in removing safety factors. Lastly, we do not have access to the underlying data and have only seen this analysis on a conference poster. Nevertheless, we suggest that the EFSA try to obtain the data from industry and look into the relative sensitivity in laboratory studies of bumblebees compared to honeybees, to better support any extrapolation factor chosen. Reference: Optimizing laboratory testing for bee species: a comparative sensitivity analysis for honey bees and bumblebees. 5.1.2.e Woo , Cheminova Deutschland GmbH & Co. KG, Germany. Poster at Setac Europe 29th Annual Meeting, May 2019. (new comment)
SB			*Ctgb: No comments*

Chapter 3: Risk assessment schemes

Please select one or both:

a) I have general comment(s) on the risk assessment schemes

Risk assessment schemes - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Ctgb:

1) The guidance document does not contain a risk assessment scheme for exposure via honeydew (as indicated on page 11, this was 'because of high uncertainty around this exposure route'. This is considered an important omission, as contaminated honeydew may cause significant exposure and has led to past incidents with honeybees in the Netherlands. Therefore we consider a risk assessment for this exposure route necessary for the protection of bees. In the Netherlands, we do consider this exposure route in the risk assessment for bees, and we have made a list of crops in which honeydew can be present, based on Dutch agricultural practice. For these crops, the exposure route via honeydew is included in the risk assessment. The risk is estimated based on the toxicity of the product and the period of application of the product. In case of a potential risk, the options for refinement include either a restriction on application when bees are actively flying on the crop or the submission of (semi-)field studies in order to demonstrate a low risk in a more realistic situation. For systemic substances, additional information may be submitted on residue levels in honeydew. It is recommended that EFSA includes a risk assessment for exposure via honeydew in the guidance document. Please see the list of crops in which honeydew can occur in Appendix II-3 of Chapter 7

Ecotoxicology; terrestrial; bees; National elements; version 2.3 (file:///H:/Documents/Downloads/G+7+Ecotox+terrestrial+birds+and+mammals+EU+EM2.3.pdf). Please note that recent research has shown that honeydew is also a significant exposure route for other non-target arthropods, which emphasizes the need to include this route in any new guidance (Calvo-Agudo et al. 2019: https://www.pnas.org/content/pnas/early/2019/07/30/1904298116.full.pdf). (new comment)

b) I would like to comment some specific sections (3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7)
Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
3.1 intro			*Ctgb: No comments*
3.2 spray	Table 2, 3 and 5	17, 19, 21	Ctgb: Please clarify in this chapter whether the application rate AR that is to be used in the calculations is the single application rate, and if so, why multiple application does not need to be included in the screening and first tier calculations. (new comment)
3.3 solid	Table 6, 7 and 9	26, 31, 23	Ctgb: Although most solid formulations will be applied only once per crop, multiple applications would be possible for granular formulations. Therefore, please clarify in this chapter whether the application rate AR that is to be used in the calculations is the single application rate, and if so, why multiple application does not need to be included in the screening and first tier calculations. (new comment)
3.4 accum.			*Ctgb: No comments*
3.5 water	3.5.1 , Figure 1	45	Ctgb: A step in the risk assessment is to check whether 'guttation occurs in <10% of the location/calendar-year combinations'. This is a generic issue and not substance-specific. Since the finalization of the guidance document, much work has been done on guttation (to our knowledge at least by the JKI in Germany and by industry). This work seems to suggest that guttation is not a relevant exposure route in many cases. To avoid unnecessary work, it would be very helpful if the guidance document would contain a list of crops for which guttation should be considered in the risk assessment. Is this already possible? (new comment)
3.6 met.			
3.7 high.	n.r.	52	The GD leads to many cases where higher tier studies are necessary. The guidance for the higher tier is not unequivocal, which will lead to problems with harmonization due to differences in interpretation between MS. NL proposes a workshop with risk assessors and risk managers to gain practical experience with the GD through selected 'case studies', and is willing to contribute. (NL comment sent to SANCO on 20/09/2013)

Chapter 4: Uncertainty analysis

Please select one or both:

a) I have general comment(s) on the uncertainty analysis

Uncertainty analysis - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Ctgb: No comments

b) I would like to comment some specific sections (4.1, 4.2)
Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	paragraph	page	Comment
4.1 high.			*Ctgb: No comments*
4.2 WoE			*Ctgb: No comments*

Chapter 8: Mixture toxicity

Comments on Mixture toxicity
4000 character(s) maximum

Ctgb: No comments

Chapter 9: Risk mitigation options

a) I have general comment(s) on risk mitigation options

Risk assessment schemes - General comment(s)
4000 character(s) maximum
Pending on the nature of your comment, please consider to indicate whether your comment is restricted to e.g. a specific bee species.

Proposed risk mitigation options are complicated, fragmented (for each of the exposure route a different risk mitigation measure is described), and in some cases impractical or even impossible to implement for NL farmers[2], and difficult to enforce by the authorities. Much is left open to the MS, resulting in the distinct possibility of a lack of harmonization. We suggest development of a select number of robust mitigation measures by which several exposure routes are mitigated. (NL comment to SANCO on 20/09/2013)

b) I would like to comment some specific sections (9.1, 9.1.1, 9.1.2, 9.1.3, 9.1.4, 9.1.5)

[2] Example: 'Only drill seed when the wind speed is less than 12 km/hour'. These weather conditions hardly occur in the Netherlands, so drilling seeds is virtually impossible.

Please comment at least in one row. If you have more comments for one section (row), you can indicate more subsection/appendix and/or more page numbers in the respective columns.

	Sub-section	page	Comment
9.1			
9.1.1	n.r.	90	There is a mistake in the third bullet. The words 'succeeding crops' should be replaced by 'crops grown in nurseries'. If risk mitigation sentences are relevant for bee-attractive plants treated in a nursery and later sold to an end-user, the plants should be accompanied by these sentences.
9.1.2			
9.1.3			
9.1.4			
9.1.5			

Chapter 10: Sublethal effects

Comments on Sublethal effects
4000 character(s) maximum

Ctgb: No comments

Thematic comments on specific Appendixes

You can make here specific comments on one or several appendices. Please ensure that issues already commented earlier are not repeated here.

I have specific comment(s) on the following Appendix/Appendices:

	Comment (4000 character(s) maximum per Appendix)
Appendix A	*Ctgb: No comments*
Appendix D	1) It is recommended to compare this list to the Honey MRL list that will take effect from 01/2020, and to ensure that the two are in line. (new comment) 2) Useful information for honeybees is available in the Dutch Evaluation Manual, which contains a list of the relative attractiveness of various crops to honeybees. While the information in the two lists is generally in line, this is not always the case, and we note, for example, that cereals are considered attractive to honeybees in the EFSA guidance but not according to the literature review done in the Netherlands. We recommend that any updated EFSA list contains a reference for each entry, and that the references used in the Dutch list are considered. Please see Appendix II-1 of Chapter 7 Ecotoxicology; terrestrial; bees; National elements; version 2.3 (https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2019/03/01/7.-terrestrial-ecotox-bees-nl-part-em2.3) and the underlying references as given in Steen, J. van der en Cornelissen, B., Dracht in Nederland (cultuurgewassen en wilde

	planten) (deel II) Rapport 606 (https://edepot.wur.nl/343688). If needed, we are happy to help with translations from Dutch into English. (new comment) 3) Comment on footnotes 1, 2 and 3: It would be useful to recommend what kind of data is sufficient to exclude pollen/nectar collection. (new comment)
Appendix E	*Ctgb: No comments*
Appendix F	We assume that this appendix will be updated with the new residue data collected by EFSA and published recently (EFSA Supporting publication 2017; EN-1303). (new comment)
Appendix G	*Ctgb: No comments*
Appendix H	As indicated in the GD (p. 139), the scientific basis of the proposed spray drift deposition values for the field margin for the lower exposure tiers is weak and it is uncertain whether these deposition values are conservative enough. Drift deposition values in the field margin are set on the first metre off-field. Bees that forage closer to the field are not protected. In addition, the drift percentages relevant for this first metre off-field are diluted to account for the effect of the wind angle. These deposition values should be improved as soon as possible. (NL comment sent to SANCO on 20/09/2013, slightly rewritten, and comment on wind angle added)
Appendix I	*Ctgb: No comments*
Appendix J	Appendix J describes how the shortcut values for exposure to nectar and pollen are calculated. Several conservative assumptions are made in the screening step and first tier, which is logical. It is stated that refinements can be made. It is expected that e.g. the RUD value and the sugar content of nectar can be refined. To make such calculations easier, it would be greatly appreciated if EFSA provides a calculation tool in which the input values for the shortcut values can be changed. In the current tool (which is not available online anymore), this is not the case, making it impossible to use the tool for refinements. Also, having the input values for the shortcut values visible in a calculation tool makes it easier to understand the calculations. There are a large number of calculations to be made, with input values from many different places in the guidance document, and providing a detailed calculation tool would greatly help the performance and understanding of this task. (new comment)
Appendix K	Please consider the research done in the Netherlands on background mortality. Chronic trigger values for honey bees should be updated to reflect the most recent data on background mortality, more complex modelling options, and the conservativeness of the linear extrapolation. The NL is able to contribute with the results of two research projects whose results are expected to be published in 2019. Reference: Conservatism in first tier trigger values in pollinator risk assessment. 5.1.2.e Woo Wageningen Environmental Research, Netherlands. Poster at Setac Europe 29th Annual Meeting, May 2019. (Comment made to COM on 21/11/2018, reference added and timing changed (earlier, a publication date 'in the first half of 2019' was foreseen).
Appendix L	*Ctgb: No comments*

Appendix M	1) Please consider the research done in the Netherlands on the dose-response relationship. Chronic trigger values for honey bees should be updated to reflect the most recent data on background mortality, more complex modelling options, and the conservativeness of the linear extrapolation. The NL is able to contribute with the results of two research projects whose results are expected to be published in 2019. Reference: Conservatism in first tier trigger values in pollinator risk assessment. Ivo Roessink, Wageningen Environmental Research, Netherlands. Poster at Setac Europe 29th Annual Meeting, May 2019. (Comment made to COM on 21/11/2018, reference added and timing changed (earlier, a publication date 'in the first half of 2019' was foreseen). 2) A small matter of confusion may be fixed: On page 167 it is stated that Khoury et al. used 15.3% background mortality, while on page 98 this is said to be 15.4%. Could you bring these two in line with each other? (new comment)
Appendix N - 1. Introduction	*Ctgb: No comments*
Appendix N - 2. Spray	*Ctgb: No comments*
Appendix N – 3. Solids	1) Section 3.2.3 describes a choice to be made by the ScoFCAH. Is this text still relevant? (new comment) 2) The dust drift values and the general exposure assessment should be in line with the Sanco seed treatment guidance which is in development. (new comment)
Appendix N – 4. Recommendations	*Ctgb: No comments*
Appendix O – Laboratory studies	1) Several new harmonized guidelines have become available since the finalization of the guidance document (e.g. OECD guidelines on chronic toxicity to adult honeybees and on acute toxicity to bumblebees) and therefore this section should be updated. (new comment) 2) It is assumed that a formulation is more toxic than expected based on the active substance data when there is a factor of five difference between the endpoints (page 203, note b). A recent EFSA report states that in such a comparison, a factor of three should be used (see EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673). Please update the GD to be in line with these more recent developments. (new comment)
Appendix O – Higher tier studies	This section should be adjusted to reflect any changes made based on revisions to Appendix K and M. Please also see 'Other comments'.(new comment)
Appendix P	In the description of the field-to-laboratory studies and field tests for bumblebees, a protection goal is mentioned: "the effects should not be more than 7% on total reproductive output, queen versus male production and queen survival and capacity to nest'.

	This protection goal is not included in chapter 2 of the guidance document, which only seems to list the protection goal for honeybees. Please ensure that the Appendix and the protection goal chapter are in line. (new comment)
Appendix Q	In the description of the field-to-laboratory studies and field tests for solitary bees, a protection goal is mentioned: "not more than 7% difference compared to controls in cell production rate, off-spring production and sex ratio, progeny survival and vigour (the vigour can be assessed measuring the adult longevity after emergence) until next spring". This protection goal is not included in chapter 2 of the guidance document, which only seems to list the protection goal for honeybees. Please ensure that the Appendix and the protection goal chapter are in line. (new comment)
Appendix R	*Ctgb: No comments*
Appendix S	*Ctgb: No comments*
Appendix T	*Ctgb: No comments*
Appendix U	*Ctgb: No comments*
Appendix X	Table X2 (page 255) uses an outdated FOCUS document. FOCUS goundwater (May 2014) and FOCUS surface water (May 2015) came into force in May 2015 and December 2015 respectively and refer to new interception values published in EFSA guidance on DegT50 values (2014) which came into force in May 2015. The updated values should be used in the bee risk assessment. For your convenience, you can use the Dutch evaluation manual, in which we have already adapted the table from the 2014 birds and mammals guidance to the newest interception data. See section 1.3.2 of Chapter 7 Ecotoxicology; terrestrial; birds and mammals; EU-part; version 2.3 (https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2018/05/01/7.-terrestrial-ecotox-birds-and-mammals-eu-part-em2.3) (new comment)

Other comments

If You have any general comment (suggestion/recommendation) regarding the revision exercise, please insert here: *1000 character(s) maximum*

Ctgb

Our specific comments, as well our general technical comments below, are made in light of our desire for a practically feasible guidance document, based on the latest scientific insights, that can be adequately implemented as soon as possible.

General technical comments:(1) It is unclear if and when a (semi-)field study result could or should replace a first tier result, or merely provide relevant information to better qualify (or recalculate) the first tier result. This should be further elaborated on in the guidance, especially in view of the shortcomings that were noticed in EFSA (2012) on the design and possibilities of the current field tests. In the event that (semi-)field testing does directly address all relevant protection goals through an appropriate test design and with sufficient power, it should provide enough information to analyse and explain any differences in the results compared to the lower tier assessment.

As we noted in our comment above, (semi-)field data was used to set the trigger value in the first tier, but using a very worst-case value based on one study. In principle, this is appropriate for the lower tiers, however, by using this lowest value as a requirement for effect detection in higher tier (semi-)field studies as well, it is almost ensured they will not be able to detect such a low effect level (i.e. the quality for future field studies is required to be higher than those used to set the trigger value), considering the spread of the total data considered in Appendix K. In general, the tiered assessment is more conservative in the lower than in the higher tiers, so by requiring that future higher tier tests be able to meet the conservative value used in the lower tier, the entire “tiered approach” of the guidance seems to be undermined. (Comment given on the draft EFSA Guidance in March 2013 by 'the Netherlands (NPPO, Ctgb, RIVM, Bijen@wur) and slightly rewritten for the current commenting round by Ctgb).

(2) At no point does the guidance clarify whether the Term of Reference "assessment of the acute and chronic effects of Plant Protection Products on bees" requires that the effects on bees of cumulative and aggregate exposure to all Plant Protection Products within a crop system over time should be assessed. Likewise, the guidance refrains from asserting that it suffices to only consider the risk of a single Plant Protection Product, or only one component of this product at a time. Nevertheless, the guidance is based on an edge-of-field assessment and considers implicitly the risk of a single product for a healthy, unstressed, colony(i.e.an unrealistic situation).

The guidance does not comment on how to assess the risk of a single product against the background of potential acute and chronic effects of all the used products on bees. The guidance is very clear on principles of exposure assessment goals, and it is welcomed if these principles were also applied to scenarios that capture the cumulative and aggregate exposure within the cropping season. (Comment given on the draft EFSA Guidance in March 2013 by 'the Netherlands (NPPO, Ctgb, RIVM, Bijen@wur) and slightly rewritten for the current commenting round by Ctgb).

Please insert here the references of publications that support your earlier comments:

	Reference or link
HB	
BB	
SB	
Background mortality	
Landscape	
Guttation	
Attractiveness	
Plant issues / agronomy	
Residues	
Other	

PESTICIDE PEER REVIEW UNIT

Outline of the revision of the Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA, 2013)

European Food Safety Authority
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Tel. +39 0521 036 111 | www.efsa.europa.eu

Table of contents

1. Introduction

EFSA adopted and published in 2013 a guidance document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA,2013), which was republished in 2014 following feedback from Member States collected during a workshop organised by the European Commission (EC).

Although the EFSA 2013 guidance has been used for the assessment of neonicotinoids and its use was recommended by risk assessors in a general ecotoxicology expert meeting (EFSA, 2015), the guidance has not been fully implemented in the process for the approval of the active substances. This is due to insufficient support from Member States represented in the Standing Committee on Plants, Animals, Food and Feed (PAFF). Many Member States have expressed their preference for an update of several aspects of the guidance document. As a follow up, in March 2019, the EC mandated EFSA to revise the guidance (EFSA, 2013).

According to the mandate, EFSA was asked to provide within three months an outline document describing procedural aspects, such as stakeholder consultation, timelines and deliverables. The scope of this document is to describe those aspects and to develop a roadmap for the revision of the guidance.

2. Workplan

The revision of the guidance will be carried out by an EFSA working group (WG) set according to the EFSA rules and standards. EFSA staff and external experts, e.g. from MS organisations and other organisations, will be involved in the WG. The external experts will be selected for their specific experience and expertise relevant to the mandate.

The European Chemicals Agency (ECHA) and EFSA will cooperate to harmonise approaches for assessing risks to bees under the biocides and pesticides regulations. This cooperation includes the possibility for ECHA to comment on documents and be involved in the WG as an observer. This would allow ECHA to follow the work in progress for pesticides and to reflect on commonalities in its activity on the same topic for biocides. Reciprocally, to ensure consistency, EFSA will be consulted on the preparation of the biocides guidance on this topic and may involve the WG.

The time plan for the drafting process, consultations steps and finalisation of the draft for public consultation is presented in **Figure 2**. The time plan takes into consideration the need for EFSA to receive input from risk managers on the definition of specific protection goals in order to review the guidance document. In addition, the revision of parts of the guidance i.e. the exposure via dust drift for seed treatment uses depends on the finalisation of the draft guidance on seed treatment (SANCO/10553/2012, July 2018_rev 16).

A revised guidance document will be published within 24 months from receipt of the mandate, pending the input from the risk managers (RM) needed prior to a public consultation, as explained in section 3.3 and in **Figure 1** and **Figure 2.**

3. Consultation of stakeholders, Member States and other scientific bodies

According to the mandate, during the process of revising the guidance document, EFSA should consult relevant stakeholders, Member State risk assessors and risk managers. EFSA will address this request by organising several consultations as described in the following sections. In brief, the drafting process will include targeted consultations with an *ad-hoc* stakeholder consultation group, with Member States and with the public.

All comments and relevant feedback received will be considered during the revision of the guidance.

3.1. *Ad hoc* Stakeholder Consultation Group

An *ad hoc* Stakeholder Consultation Group has been created to support the drafting of the revision of the guidance document.

EFSA will consult the *ad hoc* Stakeholder Consultation Group on the current guidance (EFSA 2013) to collect feedback to be considered by the WG. Furthermore, the WG will consult the group on initial versions of (or parts of) the revised draft guidance document. No meetings of the *ad hoc* Stakeholder Consultation Group are planned; written comments from group members will be considered by the WG. However, no responses to the individual comments will be made.

3.2. Member States/risk assessors

EFSA will consult the Member States through the Pesticides Steering Network (PSN) on the current guidance (EFSA 2013) to collect feedback to be considered by the WG. Furthermore, the WG will consult Member States on initial versions of (or parts of) the revised draft guidance document. The consultation will be performed in writing and comments from Member States will be considered by the WG. However, no responses to the individual comments will be made.

3.3. Member States/risk managers

According to the mandate, EFSA is asked to provide as a separate output a review and summary of the evidence as regards bee background mortality, in particular considering realistic beekeeping management and natural background mortality.

EFSA will deliver a technical report, which will be considered in the context of the on-going process for setting specific protection goals (SPGs) led by DG SANTE. Once the risk managers have provided their input on SPGs, EFSA will finalise the revision of the guidance document by setting the lower tier assessment factors (e.g. trigger values) relevant to meet the desired level of protection and by revising the requirements for the higher tier tests. This process is shown in **Figure 1** below while the timelines are presented in **Figure 2**.

In addition to the above consultations, risk managers will be informed on the progress of the drafting at the regular meetings organised by the EC, in particular, the PAFF meetings.

A draft revised guidance will be developed for a public consultation, once the final agreement has been achieved as shown in **Figure 1**.

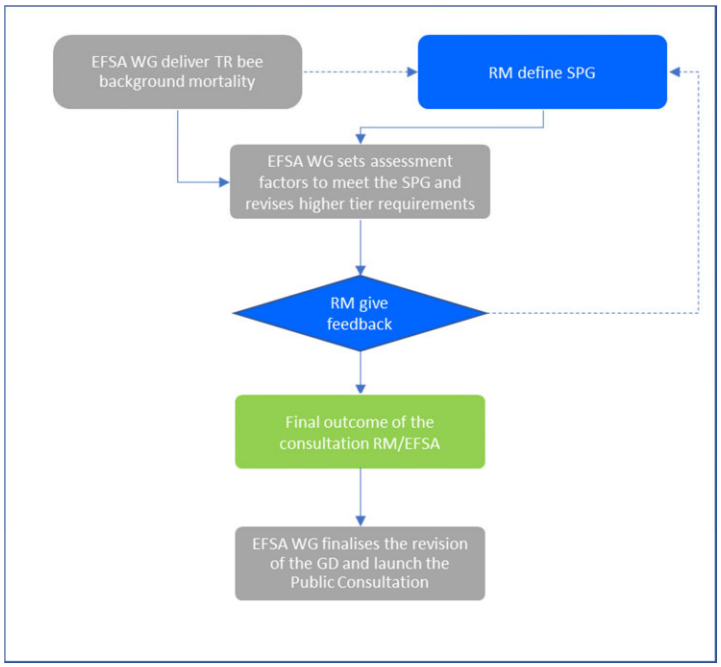

Figure 1: Description on the EFSA deliverable and RM input needed to finalise the guidance document

3.4. Other scientific bodies

The WG may also consult other scientific bodies, such as the EFSA Scientific Committee or the Plant Protection Products and their Residues (PPR) Panel and their working groups (WGs), on specific issues.

3.5. Public consultation

The draft version of the revised guidance will be subject to public consultation, according to EFSA standards.

3.6. Workshop with stakeholders and Member States

A workshop will be organised by EFSA and DG SANTE at the end of the public consultation to give stakeholders (i.e. *ad hoc* Stakeholder Consultation Group) and Member States (risk assessors and risk managers) the opportunity to discuss the comments and provide additional comments. Member States may be invited to present and discuss case studies by using the draft guidance document. Comments and feedback collected during the workshop will be considered to finalise the guidance document.

4. Deliverables

Technical report (TR) on background mortality
According to the mandate, in a technical report will be reported the review and summary of the evidence on bee background mortality, in particular considering realistic beekeeping management and natural background mortality.

Revised guidance document
A revised guidance document will be delivered and published in the EFSA Journal.

Technical report on the various consultations
The comments received via the stakeholders and Member States (risk assessors and risk managers) will be reported in a technical report that will be published on the EFSA web site. This will include also a report of the workshop.

Figure 2: Indicative time plan for the revision process, consultations steps and finalisation of the GD