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Datum 18 april 2019
Betreft Tijdlijn inzake bijenrichtsnoer

Ons kenmerk
DGA-PAV / **Fout! Onbekende naam voor**
documenteigenschap.

Bijlage(n)
7

Bijlage 1

Guidance Document Bee Risks
NL comments, September 2013 (verzonden per email op 20 september 2013)

General remarks:

The work of EFSA to develop an elaborate guidance document (GD) on the risk assessment of plant protection products on bees and other pollinators, under severe time pressure, is much appreciated. The recent publication of EFSA (July 2013) is intended to provide guidance for notifiers and competent authorities of EU member states (MS) in the context of the evaluation process.

According to the Netherlands' view, this renewed guidance is needed and therefore welcomed as such. However, the Netherlands have the impression that the severe time pressure has led to a number of shortcomings in the guidance with respect to its usefulness for the regulatory process.

After scrutinising the GD, the Netherlands conclude that risk assessments based on the new guidance will take more time and will be more expensive than under the previous guidance, thus effecting the availability of authorised PPP for agriculture and possibly increasing problems for minor uses.

- The GD is very conservative, which means that in many cases higher tier studies are necessary. The guidance for the higher tier is not unequivocal, which will lead to problems with harmonisation 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.
- The need for bumblebee and wild bee risk assessment is not clearly defined, this will lead to problems with harmonisation due to differences in interpretation between MS. Furthermore, the risk assessment for bumblebees and wild bees is more stringent compared to the risk assessment for honeybees (because of data gaps). As a result it is expected that more often a higher tier approach is necessary. Agreement between MS is necessary. Do MS wish to perform the risk assessment on bumblebees and wild bees or not? And if they do, what are the consequences of the outcome of the risk assessment?

- The included list 'Attractiveness of agricultural crops to honey bees and bumble bees for the collection of nectar and/or pollen' is a list of crops visited by bees based on the data available in the literature. Standard agricultural practice is not taken into account and MS still have to consider their national agricultural practices, which may hamper harmonisation of authorisations.
- The guidance document gives two scenarios for the calculation of dust drift of treated seed (option 1: worst case drift in the EU per crop and option 2: take different techniques for seed treatment into account). SCoFCAH needs to take a decision here, otherwise it will be difficult to assess this aspect. (Option 1 is very strict and not realistic for the Netherlands, for example.)
- The guidance on statistical evaluation of (semi-) field trials is complicated. No standard requirements on number of fields or colonies can currently be given. This makes it difficult to evaluate (and perform) a (semi-) field trial. Clear harmonised guidance on this is necessary.
- As indicated in the GD (p. 142), 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. These deposition values should be improved as soon as possible (before adaptation or as soon as possible after adaptation).
- Proposed risk mitigation options are complicated, fragmented (for each of the exposure route a different risk mitigation measure is described); some impractical or even impossible to implement for NL farmers and difficult to enforce by the authorities. Much is left open to the MS: no harmonisation is a risk.
- All trials conducted for the implementation or fine tuning the new guidance should be collated under one umbrella, such as done under CREAM¹.

In the Annex details can be found, which underpin the above mentioned observations.

Appendix: Detailed comments

General remarks

1. The GD is still very conservative, which means that in many cases higher tier is necessary. Experience with the bird and mammal guidance has shown that in higher tier, there are usually many differences in opinion between member states (and also between authorities and industry).

¹ (CREAM is a project on the use of population modelling in ecotoxicology risk assessment / evaluation. The setup is Europe-wide; financed by EU.)

Reaction EFSA: The proposed risk assessment followed the precautionary principle where not enough data were available and uncertainty arose. Therefore the first tier seems to be very conservative. After more data are available it would be possible to work on refinement of the first tier risk assessment in future (precautionary principle).

The GD is still very conservative, which means that in many cases higher tier is necessary. NL proposes a workshop with risk assessors and risk managers to gain practical experience with the GD.

2. Many of the proposed test protocols are not harmonised yet (e.g. by OECD) or even ring-tested. This may lead to problems with evaluation and harmonisation (see appendix O and chapter 8).

Main text of GD

Paragraph 3, 3.2.1 en 3.3.1 Bumble Bee Risk Assessment (same applies to wild bees).

The need for bumblebee risk assessment is defined quite vaguely. This lack of clear guidance can lead to differences in risk assessment between member states, which is not in the interest of harmonisation.

Reaction EFSA: Noted: this has been discussed within the working group and when appropriate changes in the scheme have been made (including the wish of several MS comments to combine the schemes).

NL: The need for bumblebee risk assessment is still not clearly defined, this will lead to problems with harmonisation due to differences in interpretation between MS. Furthermore, the risk assessment for bumblebees and wild bees is more stringent compared to the risk assessment for honeybees (because of data gaps). As a result it is expected is that more often a higher tier approach is necessary. Agreement between MS is necessary. Do MS wish to perform the risk assessment on bumblebees and wild bees or not? And if they do, what are the consequences of the outcome of the risk assessment?

Chapter 11 Mitigation measures

Many different options are possible to mitigate risks by MS. For each exposure route a different mitigation measure should be described. This will be difficult to implement and to enforce. We suggest to develop a select number of robust mitigation measure by which several exposure routes are mitigated.

As in other parts of the GD, much is left to the MS, which will hamper harmonisation.

Some of the proposed mitigation measures are not feasible/realistic to implement and to enforce in the Netherlands' situation. 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 virtual impossible.

Appendices

1. Appendix D 'Attractiveness of agricultural crops to honey bees and bumble bees for the collection of nectar and/or pollen'

It might be useful to add Latin names for the crops. Since only English names may lead to confusion.

Reaction EFSA: We have included a new list in the final GD and added a sentence to describe the crop.

NL: the included list 'Attractiveness of agricultural crops to honey bees and bumble bees for the collection of nectar and/or pollen' is a list of crops visited by bees based on the data available in the literature. Common agricultural practice is not taken into account and MS still have to consider their national agricultural practices, which may hamper harmonisation of authorisations.

2. Appendix N, and paragraph.2.3. Seed treatment in relation to dust drift.

Two scenario's for dust drift are described. NL favours the second scenario.

Reaction EFSA: We suggest that you inform the SCoFCAH; we see the logic of your argumentation.

NL: The guidance document gives two scenario's for the calculation of dust drift (option one: worst case drift in the EU per crop and option 2: take different techniques for seed treatment into account). SCoFCAH needs to take a decision here, otherwise it will be difficult to assess this aspect. (Option one is very strict and not realistic for the Netherlands.)

3. Appendix K

In the EU assessment of the spray drift deposition onto field margins for non-target terrestrial organisms, the first 1 and 3 m of the off-field area is ignored for field and fruit crops, respectively. This is based on risk management considerations. However in our assessment of the spray and dust drift deposition in the field margin it is not defensible to ignore these first 1 and 3 m because the bees do not know that they should avoid sampling of these plants.

Indeed it seems difficult to defend that bees may be harmed in the first 1 m off-field. But were risk managers asked whether they agree?

Reaction EFSA: EFSA workgroup base risk assessment guidance on their scientific expertise; risk managers are responsible for deciding on the effect and exposure assessment goals, not for developing the risk assessment procedures; so if bees are likely to forage on the first meter of the field margin, there is no need for an EFSA workgroup to ask risk managers for permission to include this in the risk assessment.

NL: What are the protection goals for drift? 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. Question for the risk managers: where do you want to protect the

pollinators for drift (from one metre off-field, three metre off-field or from the field margin etc.?)

4 Appendix N

It is noted that EFSA is currently unable to provide guidance on statistical evaluation of (semi-) field trials, while at the same time demanding that the results are statistically evaluated.

EFSA: Please note that the text has been modified in light of detailed comments.

NL: The guidance on statistical evaluation of (semi-) field trials is complicated. No standard requirements on number of fields or colonies is given. This makes it difficult to evaluate (and perform) a (semi) field trial. Clear harmonised guidance on this is necessary.

Bijlage 2
2016

(verzonden per email op 10 juni 2016)

Dear colleagues,

Please find attached the comments of the Netherlands on **the time-frame proposal of COM for the EFSA 'Bee Guidance Document' and the EC proposal to amend the UP**, as have been made available by COM for the May meeting of the PAFF PPP committee.

On a number of occasions the Netherlands stressed the importance of this guidance to be finalised and have it made available for use in the evaluation of substances and PPP.

In general, the Netherlands truly welcome the proposal for the time-frame that has been prepared by the Commission to implement the EFSA guidance document on the risk assessment for bees. We thank COM for this.

At the same time we would like to express our deep concern about the feasibility of some aspects of the guidance, especially as concerns the wild bees ("Bumble Bees") and the solitary bees. Requirements should be imposed on authorisation holders /applicants that are scientifically sound, up-to-date and feasible. Industry should be able to meet these requirements. If this fails, a regular risk assessment procedure will not be possible.

We listed a number of issues that illustrate our concern in the attached document, together with an overview of general comments, also concerning the amending of the UP. We also pointed to a way forward.

Next to the technical points that are raised, we would urge Commission to provide EFSA as soon as possible with a mandate to review the trigger values on the basis of the BEEHAVE model. In this way revised trigger values should be available before the implementation date of the bee guidance (01 Feb 2017).

Implementation of the guidance will bring to light many unsolved topics and many points that need clarification and perhaps need expert judgement. We emphasise the importance of solving these issues by a harmonised approach amongst MS experts, avoiding different national approaches. That is why we propose to look into the possibilities of installing an expert group (evaluators) working jointly on an existing zonal dossier. By jointly preparing this dossier (a herbicide, a fungicide and / or an insecticide) valuable experience is gained that will motivate risk assessors to make full use of the guidance and harmonise at the same time.

We thank you for considering our comments.

June 2016

NL comments on the proposal for implementation of the EFSA 2013 (revision 2014) Guidance document for RA of bees and the proposal for revision of the Uniform Principles:

General points

- The Uniform Principles contain at several places first-tier trigger values for effect assessments (e.g. for aquatic organisms, birds and also bees). Most of these were already part of the Uniform Principles of 1994. However, the EFSA protection goal opinion² indicated that the specific protection goal of a risk assessment is linked to a 'reference tier' (which is a higher tier) and that lower tiers have to be calibrated against this reference tier (see Figure 7 of protection goal opinion). So, lower tiers may need to be changed in regulatory practice to keep pace with scientific developments. Therefore it is not advisable to describe lower-tier trigger values (like the acute oral toxicity ETR trigger of 0.2) in the Uniform Principles. Instead these principles should be limited to the specific protection goals. This will also give more flexibility in case the first-tier triggers are revised.
- The GD does not contain an adequate 'Tiered approach', as almost all substances fail the first Tier even for honeybees. This can be repaired if the chronic oral trigger is revised before implementation. *See further explanation in comment A.1.*
- The important refinement option of semi-field and field tests for honeybees will become unavailable if the GD is strictly followed. We propose to revise these protocols and to deal with the existing tests in a harmonised (amongst EU experts of Member States) way in the interim period. *See further explanation in comment A.2.*
- We note that many of the topics listed in Annex B need more work before they can be implemented. The intended implementation date is February 2018. This is ambitious, and high priority should be given to this work, especially if these topics are to be assessed among Member States in a harmonised way. We recommend that an expert working group is set up a.s.a.p. where scientists, but also risk assessors, work on the sections of the guidance document that need further development. *See further explanation in comments B2-6).*
- For some of the topics in Annex B (e.g. HPG, homing flight) we seriously doubt that a workable risk assessment will be available per February 2018.
- A timeline should be given for the topics listed in Annex C. To just state that these are 'not to be used' (ever?) is not acceptable to us. Especially the development of a protection goal relevant for other bees than the honeybee is highly important and we recommend that work on this is started as soon as possible. *See further explanation in comment C.4.*

² EFSA, 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010 8(10): 1821, 55 pp.

- It should be acknowledged in the document that the guidelines/test protocols mentioned are the ones currently available and that, once new harmonised guidelines become available, these should be used instead (e.g. guidelines for testing acute toxicity to bumblebees are currently being ring-tested, and, once adopted, should be used instead of OECD 213/214).
- For us the time-frame as mentioned in the Commission Notice, page 2, under 1 is not clear. It is mentioned that for plant protection products submitted after 15 October 2016 part of the chapters of the Guidance as listed in Part A should be used. Whereas Part A of the Annex of the Commission Note mentions the date of 31 January/October 2017.

Regarding Annex A:

- 1) Almost all substances (including herbicides and fungicides) fail the first Tier risk assessment. This is expected to have an enormous impact on the availability of PPP. Thus, the Tiered approach of the GD is not adequate. A Tiered approach should filter out part of the substances so that only those substances for which an actual risk is expected go to the higher Tier. The problem is caused by the trigger for the chronic oral risk assessment, which is so low that even when substances show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. New information shows that the chronic oral trigger is set too conservatively. The trigger is based on an assumption of background mortality which is debatable and being tested in the Netherlands at this moment³, and on model calculations with an unsuitable model⁴. We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 01 February 2017).
- 2) If the protocols for higher tier testing of the GD are strictly followed, very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment. In addition, the protocols are so demanding that there is, as of yet, no means to address this in such a way that honeybee field and semi-field tests would be feasible. This means that this refinement option, which is currently very often used, will become unavailable. Two other refinement options are given: risk mitigation and exposure refinement (i.e. residue measurements in nectar and pollen). However, risk mitigation cannot reduce all risks and there is as yet little experience with exposure refinement, making the usefulness of this refinement option uncertain. We recommend that the protocols are revised as soon as possible, taking into account the new information on background mortality (see A.1) and making use of all expertise available in the field. In the meantime, we propose that the usefulness of currently available semi-field and field tests for the risk assessment is assessed by

³ governmental project BO-20-002-011

⁴ EFSA, 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level. EFSA Journal 2015;13(6):4125, 91 pp. doi:10.2903/j.efsa.2015.4125

expert risk assessors. To ensure that this is done in a harmonised way, we propose that a working group of risk assessors from Member States assesses three pilot dossiers (one insecticide, one herbicide and one fungicide). Agreements made in this working group will have to be laid down in such a way that decisions based on those agreements are legally sound.

- 3) Currently the FOCUS run-off scenario is not in use. The Commission is asked to ensure that the environmental Fate sections come to a harmonised agreement on inputs and formats for outputs before Feb 2017.

Regarding Annex B:

- 1) Some of the topics in Annex B are indeed risk assessments that can be implemented per February 2018, in accordance with the title of the Annex, while others seem more like action points for the expert working group that we recommend above (e.g. 'reconsideration of safety factors' and 'a revision of the GD' are hardly things to address in a specific active substance or product dossier). It is recommended that there is a clear separation between these two types of goals in the Annex.
- 2) We are not convinced that a fully-validated and reliable method/model for estimating accumulative toxicity will be possible by Jan 2018, particularly considering that up to this time this "optional" section of the chronic toxicity test has rarely been implemented. Since honeydew is not included in the current (2014) version of the Guidance, it is unclear what to do if a screening step does not pass. Would the next step be risk mitigation? Is there some refinement? If refinements or mitigations are possible/the next step, this would presumably also have to be placed here in Annex B.
- 3) Considering the problems with methodologies for appropriate honey and bumble bee field tests according to Appendix O of the EFSA GD, it seems unlikely that adequate solitary bee (semi) field methodologies (according to Appendix O) will be available by January 2018.
- 4) Sublethal effects – considering how difficult it is to link sublethal effects to colony-level effects this point seems very open. Other than HPG, there is no sublethal effect assessment in the current (2014) version of the Guidance. In addition, even for HPG, January 2018 seems optimistic considering the need for standard tests and adjusted risk assessment schemes considering the protection goal and effect of the sublethal effect(s) on bee populations.
- 5) Effects on homing flight – this is not yet part of the RA scheme in the (2014) Guidance, so it seems optimistic that it will be available as of January 2018.
- 6) Development of landscape modelling – this refinement is quite specific per Member State. It is likely that some Member States (like the NL) will be faster at developing this than others. It is possible that a model from the NL could be used as a basis for other MSs, but this would require a large amount of time to develop. In the meantime, it might be good to specify when extrapolation might be possible.

Regarding Annex C:

- 1) Is the intention of the lines 'chronic oral toxicity test with bumble bees/solitary bees' and 'larval toxicity test with bumble bees/solitary bees' that no such *tests* need to be performed, or that the chronic oral and larval risk assessment to bumble bees and solitary bees does not need to be done? The 2014 Guidance already refers to the honeybee tests for these endpoints, so if the former is meant, it is unclear why this needs to be listed. If the latter is meant, please rephrase.
- 2) No accumulative risk assessment for bumble or solitary bees exists in the 2014 Guidance, so it seems odd to list it here.
- 3) Listing field tests with bumble bees here seems odd, since in Annex A it already says that combined field to laboratory tests should be used. Does this mean that no field tests would ever be used for bumble bees (but would be used for honey and/or solitary bees if a methodology that meets Appendix O would ever be made)?
- 4) Regarding the protection goals for bumblebees and solitary bees, it is surprising that the roadmap states that a final definition of these is not to be used. Or do we misunderstand this and is the intention to revise the protection goals currently included in the GD? The overall level of protection is given by combination of the specific protection goal for the effects on bees and the exposure assessment goal (as described at end of p. 12 of the EFSA bee guidance). This guidance document proposed as the exposure assessment goal for the solitary bees the populations of solitary bees living at the edges of treated fields and indicated that this is a quite conservative exposure assessment goal because only a small proportion of all solitary bees will live at the edges of treated fields (see p. 61). E.g. the least conservative option for this exposure assessment goal could be all populations of solitary bees in a Member State; an intermediate option could be all populations of solitary bees in areas with high use intensity of the pesticide. Thus, it may be advisable to develop a suite of options for the exposure assessment goal that are considered relevant by bee population experts. Thus, it would in principle be possible to develop a road map starting with a non-conservative option for this exposure assessment goal and move stepwise to more conservative options. For the bumble bees a similar approach could be followed. Considering the potential difficulties in developing such new options, we propose that a working group is set up as soon as possible, making use of expertise in the field (e.g. IPBES).

Bijlage 3

(verzonden per mail op 13 januari 2017)

NL comments on the proposal for implementation of the EFSA 2013 (revision 2014) Guidance document for RA of bees and the proposal for revision of the Uniform Principles

January 2017

General points

- 1) It is not advisable to describe lower-tier trigger values (like the acute oral toxicity ETR trigger of 0.2) in the Uniform Principles. Historically, the Uniform Principles have specifically mentioned first tier trigger values, however, more recent science supports deviation from this path: The EFSA protection goal opinion⁵ indicated that the specific protection goal of a risk assessment is linked to a 'reference tier' (which is a higher tier) and that lower tiers have to be calibrated against this reference tier (see Figure 7 of the EFSA protection goal opinion). In practice, this means that lower tiers (trigger values) may need to be updated to keep pace with scientific developments. Referring to the required protection level rather than a specific trigger value will allow the necessary flexibility in updating the risk assessment.
- 2) The Guidance Document(GD) does not contain an adequate Tiered approach, as almost all substances fail the first Tier, even for honeybees. This can be rectified if the chronic oral trigger is revised before implementation. *See further explanation in comment A.1.*
- 3) The important refinement option of semi-field and field tests for honeybees will be become unavailable if the GD is strictly followed. We propose revision of these protocols and dealing with the existing tests in a harmonized way in the interim period. *See further explanation in comment A.2.*
- 4) Many of the actions listed in Annex B are dependent upon the development of "internationally agreed protocols". As a result, adequate implementation of the Guidance will require that this work be given high priority and a concrete planning schedule , especially if these topics are to be assessed among Member States in a harmonized way. We recommend that an expert working group be established as soon as possible, in which scientists and risk assessors work to develop the guidance document further. *See further explanation in comments A.2 and B.2-3.*
- 5) The protection goals for bumble and solitary bees are currently based upon those for honey bees. If risk assessments for bumble and solitary

⁵ EFSA, 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). EFSA Journal 2010 8(10): 1821, 55 pp.

bees proceed under this assumption, as is proposed in the current draft of the implementation timeline, most applications for plant protection products will be rejected. As a result, we consider developing protection goals for bumble and solitary bees to be an extremely important action for which concrete deadlines should be set, rather than being an action set for the "next future". *See further explanation in comment C.2.*

Regarding Annex Part A:

- 1) Almost all substances (including herbicides and fungicides) fail the first Tier risk assessment. Thus, the Tiered approach of the GD is not adequate. A Tiered approach should filter out a number of lower risk substances so that only those substances for which an actual risk is expected go to the higher Tier. The problem is caused by the trigger for the chronic oral risk assessment, which is so low that even when substances show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. New information suggests that the chronic oral trigger is set too conservatively. The trigger is based on an assumption of background mortality which is debatable and being tested in the Netherlands at this moment⁶, and on model calculations with an unsuitable model⁷ (moreover using a background mortality in the model calculations of 15% per day whereas the trigger is based on the assumed background mortality of 5.3% per day, introducing further conservativeness). Furthermore the trigger is based on a linear relationship between the exposure and the mortality which is an unnecessarily conservative assumption. We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 01 February 2017).
- 2) If the protocols for higher tier testing in the GD are strictly followed, very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment, resulting in the possible rejection of many products. In addition, the protocols as outlined in the GD are so demanding that currently it is not feasible to undertake field testing. This means that this refinement option, which is regularly used even under the current assessment framework, will not be possible. Two other refinement options are given: risk mitigation and exposure refinement (i.e. residue measurements in nectar and pollen). However, risk mitigation cannot reduce all potential risks coming from the first Tier, and there is little experience with exposure refinement, making the usefulness of this refinement option uncertain. We recommend that the protocols be revised as soon as possible, taking into account all new information on background mortality (see A.1) and residue measurements (collected by EFSA) and making use of all expertise available in the field. In the meantime, we propose that the usefulness of currently available semi-field and field tests for the risk assessment is assessed by expert risk

⁶ governmental project BO-20-002-011

⁷ EFSA, 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level. EFSA Journal 2015;13(6):4125, 91 pp. doi:10.2903/j.efsa.2015.4125

assessors. To ensure that this is done in a harmonized way, we propose that a working group of risk assessors from Member States assesses three pilot dossiers (one insecticide, one herbicide and one fungicide). Agreements made in this working group will have to be laid down in such a way that decisions based on those agreements are legally sound.

- 3) Currently the FOCUS run-off scenario is used for the aquatic risk assessment but not for the assessment of the puddle concentrations. It is no problem to perform the scenario calculations and to extract the concentrations but the Commission is asked to ensure that the environmental Fate sections come to a harmonized agreement on formats for outputs before Feb 2017.

Regarding Annex Part B:

- 1) Since no further work is required for the assessment of plant metabolites, we do not see why this topic cannot be implemented per 2017.
- 2) For guttation, scientific studies are needed to assess the probability of occurrence of guttation water in combination with the probability of use of guttation water by the bees (as is correctly pointed out in this annex). To the best of our knowledge nobody is working on these matters so it is very unlikely that these studies are finalized before the proposed implementation deadline of 31 January 2018. We recommend a concrete timeline be established to address the remaining questions surrounding guttation in order to ensure that implementation will be possible in the near future. Since adequate risk assessment is not possible without this information, we recommend to change the implementation date of the guttation risk assessment to 'once the necessary scientific information has been gathered and incorporated into a risk assessment methodology'.
- 3) The extrapolation of residue trials is a topic for which more guidance is needed and we therefore recommend it be moved to Part C.
- 4) Since honeydew is not included in the current (2014) version of the Guidance, it is unclear what to do if a screening step does not pass. Would the next step be risk mitigation? Is there some refinement? If refinements or mitigations are possible/the next step, this would presumably also have to be placed here in Annex B.
- 5) A "re-consideration of the safety factor", as stated in the draft implementation timeline for chronic and larval bumble bee, should be expedited if the implementation deadline of 31 January 2018 is to be met. If the risk assessment is performed using the current safety factors it will fail in most cases and many applications will have to be rejected. The same holds true for the solitary bee risk assessments. This comment goes hand in hand with the development of a protection goal for non-*Apis* bees (see general comment 5 and comment C.2).
- 6) Many of the actions listed in B are dependent upon the development of "internationally agreed protocols". To ensure that the use of protocols is harmonized among Member States, we recommend that an expert working group be established as soon as possible, in which scientists and risk assessors agree on which (draft) protocols can be used from which timepoint on. This can be the same working group as mentioned under comment A.2.

- 7) Since implementation dates mentioned in the third column are either 31st January 2018 or 'one year after availability of internationally agreed protocols' this second implementation date should be also be added to the title of Part B.

Regarding Annex Part C:

- 1) The actions listed in Annex C are vital to the adequate implementation of the GD and should be started as soon as possible. We therefore suggest that Part C be called "Proposed ongoing actions" to better indicate that they should begin as soon as the implementation timeline is adopted.
- 2) As mentioned above, we consider the development of detailed protection goals for bumble and solitary bees to be vitally important. Both the effect and exposure goals in the GD are not considered fully fit for purpose. For example, the GD proposes that the assessment goal for solitary bees be based upon protection of populations of solitary bees living at the edges of treated fields, and indicated that this is quite conservative, because only a small proportion of all solitary bees are expected to be living at the edges of treated fields (see p. 61 of the GD). Less conservative protection goals are also possible: E.g. the least conservative option could be all populations of solitary bees in a Member State; an intermediate option could be all populations of solitary bees in areas with high intensity of pesticide use, etc.. A suite of options could be developed to address the protection goals that are considered relevant by bee population experts. It would, in principle, be possible to develop a tiered scheme starting with a non-conservative option and move stepwise to more conservative options. A similar approach could be followed for bumble bees. Considering the potential difficulties in developing such new options, we propose that a working group be established as soon as possible, making use of existing expertise (e.g. IPBES).

Other comments:

- The timelines mentioned in the Annex should be adjusted to a realistic date after noting of the guidance document in the SCoPAFF.
- It should be acknowledged in the document that the guidelines/test protocols mentioned are the ones currently available and that, once new harmonized guidelines become available, these should be used instead (e.g. guidelines for testing acute toxicity to bumblebees are currently being ring-tested, and, once adopted, should be used instead of OECD 213/214).
- In part B of the Annex an implementation date is needed for risk to larvae of solitary bees. For semi-field and field tests the text in column 'guidance/ test protocol' should be moved to the next column.

Bijlage 4

Ctgb advies uit 2017, bijlage bij kamerbrief over beperkingen neonicotinoiden (Kamerstuk 27858, nr. 396).

<https://zoek.officielebekendmakingen.nl/blg-813993>

Pagina 3:

Furthermore, we note that the EFSA Guidance (2013) was strictly applied in the assessment of the confirmatory data and re-assessments for the neonicotinoids. While we understand that this was requested by the Commission in their mandate to EFSA, we wonder if this is completely appropriate. The EFSA Guidance (2013) is, for example, very strict when looking at higher tier data, such that field studies as they currently can be performed are not considered adequate (statistical power is too low). While we agree that the (lack of) statistical power of higher tier studies is a problem, we wonder if the application of these strict criteria, from a Guidance which is not yet noted, is procedurally correct, especially because this is only applied for these three substances. Many other insecticides have been placed on Annex I with data from higher tier studies. The statistical power of the residues studies produced by the notifier(s) to address the risks to bees was also very strictly assessed, while there was little information available to the notifiers about how the residues studies would be assessed by the MSs. In addition, it should be noted that in the Netherlands, we utilize national-specific risk mitigation to protect bees off-field (drift reduction), place restrictions on outdoor planting of treated bulbs/seeds, and consider normal agricultural practice regarding the likelihood of flowering weeds in our crops, none of which was considered by EFSA in their assessments. It is likely that other MSs also utilize significant risk mitigations and restrictions on the use of the neonicotinoids and other insecticides.

Pagina 5/6:

In de PraPer-meeting (peer review overleg) zijn opmerkingen gemaakt over het feit dat de herbeoordelingen voor deze drie stoffen zijn uitgevoerd met een GD (de volledige GD, niet slechts een onderdeel) dat niet was goedgekeurd, maar EFSA gaf aan dat dit gebeurde op verzoek van de Commissie. Het GD is volgens EFSA de enige manier om deze herbeoordeling uit te voeren omdat er geen ander GD bestaat met een juist schema voor beoordeling van bijen en andere bestuivers. Dat is (deels) zeker waar. Problematisch in het GD echter is de vraag over de statistische kracht van hogere tierstudies, waar dit GD heel kritisch over oordeelt. Daarnaast kan het GD nog niet volledig worden gebruikt voor andere bestuivers omdat er nog steeds data ontbreken en er op onderdelen van het GD nog steeds heel weinig kennis bestaat over het uitvoeren, evalueren en beoordelen van testen.

Ook de notifiers hebben een aantal hogere tierstudies ingediend, maar deze bleven statistisch onvoldoende overeind. In de PraPer-meeting bleek dat ook de RMS-en zélf niet wisten dat dit GD zou worden gebruikt bij de beoordeling, waardoor de beoordeling van de verschillende stoffen door de RMS-en op verschillende manieren is uitgevoerd: zo heeft Duitsland (RMS voor imidacloprid) voor een deel wél gebruik gemaakt van het GD, en heeft EFSA vervolgens alleen dít deel in hun herbeoordeling meegenomen en alle niet-guidance onderdelen niet.

Gevolg van dit *volledige* gebruik van het GD (EFSA, 2013) is dat deze hogere tier- en residuenstudies veel kritischer bekeken zijn bij de beoordeling van deze drie stoffen dan in de beoordeling van welke andere stof dan ook. Procedureel is dus voor deze stoffen een uitzondering gemaakt. Het is zeer waarschijnlijk dat als andere stoffen op dezelfde manier zouden zijn beoordeeld, er ook risico's en data gaps zouden worden geïdentificeerd. Daar waar EFSA bij deze andere stofbeoordelingen al gebruik maakt van een *deel* van het GD3 worden in de conclusies al veelvuldig data gaps voor bijen geconstateerd.

Ons kenmerk
DGA-PAV / **Fout! Onbekende naam voor documenteigenschap.**

Bijlage 5

NL comments on the proposal for implementation of the EFSA 2013 (revision 2014) Guidance document for RA of bees and the proposal for revision of the Uniform Principles

(verzonden per mail aan de Europese Commissie, 18 september 2018)

The NL supports the adoption of the EFSA Guidance (2013, revision 2014) and a two-step schedule, provided that some adjustments are implemented to make the guidance more workable. Please see our comments on the Commission's proposal below.

Main points:

Commission Notice, Part A:

- 1) The Guidance Document (GD) does not contain an adequate Tiered approach, as almost all substances fail the first Tier, even for honeybees. This can be rectified if the conservative chronic oral trigger is revised based on the latest scientific insights (e.g. background mortality and bee colony modelling). We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 30 June 2019) and can then be included in the revision of the Uniform Principles.
- 2) Because of the strict requirements in the GD very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment. The important refinement option of semi-field and field tests for honeybees will then become unavailable. We propose revision of these protocols before implementation of the guidance (i.e. before 30 June 2019).

Commission Notice, Part B:

- 3) Many of the actions listed in Annex B are dependent upon the development of "internationally agreed protocols". As a result, adequate implementation of the Guidance will require that this work be given high priority and a concrete planning schedule, especially if these topics are to be assessed by Member States in a harmonized way. What is the Commission's view on how to monitor and ascertain progress in this area? Furthermore, a lack of international agreed protocols and guidance on higher tier refinements for bumble bees and honeybees keeps applicants and assessors in the dark on how to perform and assess (semi-)field studies. We therefore recommend that an expert working group be established as soon as possible, in which risk assessors from the member states and EFSA discuss and agree how to interpret and use studies, and which protocols (including drafts) might be used in the event that no "internationally agreed protocol" is available. In view of the conservative first tier risk assessment, these studies will be necessary for many

dossiers. Discussion of and agreement on protocols could prevent many future harmonization issues.

- 4) The implementation date for "Exposure from guttation fluid" should be made dependent on the information needed, as mentioned in the table.

Commission Notice , Part C:

- 5) The protection goals for bumble and solitary bees are currently based upon those for honey bees. If risk assessments for bumble and solitary bees proceed under this assumption, as is proposed in the current draft of the implementation timeline, most applications for plant protection products will be rejected, potentially unnecessarily. As a result, we consider developing protection goals for bumble and solitary bees to be an extremely important action for which concrete deadlines should be set, at the latest before the implementation date of Part B of the Commission Notice.

Uniform principles:

- We propose to revise the Uniform Principles only after the chronic oral trigger is revised.

In summary, we propose the following actions to be included in the implementation schedule:

- A Commission mandate to EFSA to set-up an expert group of risk assessors and scientific experts to review the trigger values (especially the chronic oral trigger) for honeybees and to review the protocols for field and semi-field studies taking into account the latest scientific insights, to be finalised before the proposed implementation date of Part A.
- A Commission mandate to EFSA to:
 - review the safety factors for the bumble bee and solitary bee endpoints,
 - develop detailed protection goals for bumble bees and solitary beesto be finalised before the implementation date of Part B.
- The setting-up of a working group of risk assessors from member states and EFSA to discuss and agree how to interpret and use (semi-) field studies, and which protocols (including drafts) might be used in the event that no "internationally agreed protocol" is yet available to foster a harmonized approach in such interim period.

More in-depth comments and explanation of our position can be found below.

Regarding Annex Part A:

- 1) Almost all substances (including herbicides and fungicides) fail the first Tier risk assessment. Thus, the Tiered approach of the GD is not adequate. A Tiered approach should filter out a number of lower risk substances so that only those substances for which an actual risk is expected go to the higher Tier. The problem is caused by the trigger for the chronic oral risk assessment, which is so low that even when substances show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. New information suggests that the chronic oral trigger is set too conservatively. The trigger is based on an assumption of background mortality which is debatable and being tested in the Netherlands at this moment⁸, and on model calculations with an unsuitable model⁹ (moreover using a background mortality in the model calculations of 15% per day whereas the trigger is based on the assumed background mortality of 5.3% per day, introducing further conservativeness). Furthermore the trigger is based on a linear relationship between the exposure and the mortality which is an unnecessarily conservative assumption. We ask the Commission to provide EFSA with a mandate to revise this trigger as soon as possible, so that the revised trigger is available before implementation (i.e. before 30 June 2019).
- 2) If the requirements for higher tier testing in the GD are strictly followed, very few to none of the current field and semi-field tests for honeybees will be acceptable for use in risk assessment, resulting in the possible rejection of many products, potentially unnecessarily. The requirements for (semi) field testing, as outlined in the GD, are so demanding that it is not currently feasible to undertake field testing. This means that this refinement option, which is regularly used under the current assessment framework, will not be possible. Two other refinement options are given: risk mitigation and exposure refinement (i.e. residue measurements in nectar and pollen). However, risk mitigation cannot reduce all potential risks coming from the first Tier, and there is little experience with exposure refinement, making the usefulness of this refinement option uncertain. We recommend that the protocols be revised as soon as possible, taking into account all new information on background mortality (see A.1) and residue measurements (collected by EFSA) and making use of all expertise available in the field.
- 3) Currently the FOCUS run-off scenario is used for the aquatic risk assessment but not for the assessment of the puddle concentrations. It is no problem to perform the scenario calculations and to extract the concentrations but the Commission is asked to ensure that the environmental Fate sections come to a harmonized agreement on formats for outputs before June 2019.

⁸ governmental project BO-20-002-011

⁹ EFSA, 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level. EFSA Journal 2015;13(6):4125, 91 pp. doi:10.2903/j.efsa.2015.4125

Regarding Annex Part B:

- 1) A "re-consideration of the safety factor", as stated in the draft implementation timeline for chronic and larval bumble bee, should be expedited if the implementation deadline of 30 June 2021 is to be met. If the risk assessment is performed using the current safety factors it will fail in most cases and many applications will have to be rejected. The same holds true for the solitary bee risk assessments. This comment goes hand in hand with the development of a protection goal for non-*Apis* bees (see main comment 5 and comment C.1).
- 2) For guttation, scientific studies are needed to assess the probability of occurrence of guttation water in combination with the probability of use of guttation water by the bees (as is correctly pointed out in this annex). To the best of our knowledge no one is working on these matters so it is very unlikely that these studies are finalized before the proposed implementation deadline of 30 June 2021. We recommend a concrete timeline be established to address the remaining questions surrounding guttation in order to ensure that implementation will be possible in the near future. Since adequate risk assessment is not possible without this information, we recommend to change the implementation date of the guttation risk assessment to 'once the necessary scientific information has been gathered and incorporated into a risk assessment methodology'.
- 3) The extrapolation of residue trials is a topic for which more guidance is needed and we therefore recommend it be moved to Part C.
- 4) A screening step for honeydew might not necessarily require "protocols", but would require a risk assessment framework. The potential toxicity is covered by the existing tests and only a framework for estimating exposure should be produced. The text in part B should be updated to reflect this. Also, we note that since honeydew is not included in the current (2014) version of the Guidance, it is unclear what to do if a screening step does not pass. Would the next step be risk mitigation? Is there some refinement? If refinements or mitigations are possible/the next step, this would presumably also have to be placed here in Annex B.
- 5) Many of the actions listed in B are dependent upon the development of "internationally agreed protocols". To ensure that the use of protocols is harmonized among Member States, we recommend that an expert working group be established as soon as possible, in which risk assessors agree on which (draft) protocols can be used from which time point, and what conclusions can be drawn from studies performed according to old protocols. Unless such a working group is made, interpretation of higher tier studies is unlikely to be adequately harmonized, while these studies will be necessary in many cases as the first tier will often fail.
- 6) The statement on the repeated exposure test beyond pupation can be removed from part B, as the OECD GD 239 includes emergence of pupae.

Regarding Annex Part C:

- 1) As mentioned above, we consider the development of detailed protection goals for bumble and solitary bees to be vitally important. Both the effect and exposure goals in the GD are not considered fully fit for purpose. For

example, the GD proposes that the assessment goal for solitary bees be based upon protection of populations of solitary bees living at the edges of treated fields, and indicated that this is quite conservative, because only a small proportion of all solitary bees are expected to be living at the edges of treated fields (see p. 61 of the GD). Less conservative protection goals are also possible: E.g. the least conservative option could be all populations of solitary bees in a Member State; an intermediate option could be all populations of solitary bees in areas with high intensity of pesticide use, etc.. A suite of options could be developed to address the protection goals that are considered relevant by bee population experts. It would, in principle, be possible to develop a tiered scheme starting with a non-conservative option and move stepwise to more conservative options. A similar approach could be followed for bumble bees. Considering the potential difficulties in developing such new options, we propose that a working group be established as soon as possible, making use of existing expertise (e.g. IPBES, SETAC).

Directoraat-generaal Agro
Directie Plantaardige Agroketens
en Voedselkwaliteit

Ons kenmerk
DGA-PAV / **Fout! Onbekende**
naam voor
documenteigenschap.

Bijlage 6

NL Comments on Commission's amended proposal on implementation plan Bee Guidance Document

(verzonden per mail aan de Europese Commissie, 21 november 2018)

In the PAFF Committee the Commission tabled a proposal to adopt the EFSA (2014) guidance document on the bee risk assessment together with an amended implementation plan (chronic toxicity parts moved from part A to part B) and a mandate to EFSA for the update of the GD. The proposal would include an amended proposal for revision of the uniform principles, including only the acute toxicity trigger values for honey bees.

The Commission circulated the updated implementation plan. The amended proposal for the uniform principles and a proposal for the EFSA mandate are not yet available, so it is not yet possible for us to fully respond to the Commission's proposal and provide you with a final position. We do however want to communicate our concerns at this stage and propose two essential modifications to strengthen the proposal and a list of items to be included in the EFSA mandate. The NL appreciates that the amended implementation plan now allows for implementation of the less disputed parts of the new GD and an update of problematic parts of the GD based on the latest scientific information, such as honey bee background mortality. However, this does not address all of our previous concerns. We note that the Commission's proposal still includes the implementation of the strict requirements for field and semi-field studies in the current version of the EFSA GD. Since these requirements are dependent on parts of the GD included in the update and thus themselves will be updated, we consider it necessary that these requirements are also moved to part B of the implementation plan. This then follows a clear reasoning: parts of the GD included in the update need to be implemented after the updated GD is adopted and thus included in part B.

To ascertain that the guidance is updated in time for the implementation of Part B, the mandate to EFSA should include a hard deadline. Furthermore, to prevent the implementation of elements of part B in case of delay of completion and adoption of the updated GD, we stress the importance of changing the proposed implementation date of these elements from "30 June 2021" to "one year after adoption of the updated EFSA bee GD". Otherwise we may in two years be faced with the same problems we are trying to avoid by postponing implementation of those elements to allow their update. This also allows applicants sufficient time to ensure their dossiers are in line with the updated GD at the moment of implementation. We note that this is similar to other parts where international protocols still need to be developed.

Our other previously communicated concerns with regard to part B and C of the implementation plan still stand. They can be addressed in the update process of the GD, provided that they are included as specific requirements in the COM mandate to EFSA. See below a list of elements that we feel need to be included in the mandate, based on our previous comments.

List of elements to be included in the COM mandate to EFSA for the update of the bee GD, based on our previous comments:

- 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 the first half of 2019.

- The statistical power requirements for semi- field and field tests should be revisited, considering the data mentioned above.
- Development of detailed protection goals for bumble bees and solitary bees (or provide data to support honey bee assessment/protection goals as sufficiently protective so safety factors can be reconsidered).
- Update of trigger values for bumble bees and solitary bees, considering protection goals.
- Inclusion of scientific information on the occurrence of use of guttation water by honey bees.
- Risk assessment framework for exposure to honey dew. The NL can contribute to this by providing information on the framework currently applied in the NL.

We thank the Commission for taking our comments into consideration.

Bijlage 7
2019

(Verzonden per mail aan de Europese Commissie)

Ons kenmerk
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Please find below our comments on Action Point A.08.01 on the EFSA Bee GD implementation:

In the December SCoPAFF the Commission presented a proposal for the implementation of the EFSA Bee Guidance, including a step-wise implementation plan and a foreseen update of the guidance to bring it in line with the latest scientific insights. The protection of bees is a very important topic for the NL and we therefore wish to take the necessary steps to adopt new risk assessment guidance as soon as possible, provided that the guidance guarantees a sufficient level of protection and is workable for applicants and risk assessors. The NL does not have a formal position on the Commission's proposal yet. However, from a technical perspective the Ctgb is positive about the current proposal, provided that two comments are taken into account:

- the implementation date of Part B should be amended to read "To be used for applications submitted 6 months after adoption by SCoPAFF of the revised EFSA Guidance Document on the risk assessment for bees." This amendment is necessary considering the accustomed responsibility of the SCoPAFF to adopt new revisions of guidance documents before their implementation. It also provides a suitable transition period for applicants to adapt their dossier to the updated guidance when adopted.
- we note that the implementation date of Part A (1 July 2019) is now fast approaching. To allow applicants sufficient time to amend their dossiers after decision making in SCoPAFF we propose to allow for a period of 6 months between SCoPAFF-adoption and the implementation date.

Also, as indicated before, we would also like to review the Commission's mandate to EFSA on the update of the GD before finalising our position.

Many thanks for taking our comments into consideration.