**Van:** [redacted]
**Aan:** 
**Onderwerp:** Voorzet oplegger voor COM / Bijenguidance
**Datum:** donderdag 9 juni 2016 00:58:00
**Bijlagen:** Comments from the Netherlands_GD Bees.docx

---

Hoi [redacted],

Bij deze de beloofde voorzet voor de oplegger. Kijk maar even wat je ervan vindt.
Ik sprak [redacted] nog hierover en hij is van mening dat we de Commissie dringend moeten voorhouden om toch een impact assessment uit te voeren.
Het Ctgb gaat op een later moment van deze GD last krijgen, op dezelfde manier als dat mbt de GD protected crops is gebeurd. Ik heb deze aanbeveling nog niet in de oplegger opgenomen, ik probeer je morgen hierover nog te spreken.

Groet, tot morgen, [redacted]

**Comments from the Netherlands on the time-frame for the use of EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees (Apis mellifera, Bombus spp. and solitary bees). Point B.04 on the Agenda of SCoPAFF, May 18 – 19 2016.**

The Netherlands truly welcome the proposal for the time-frame that was prepared by the Commission to implement the EFSA guidance document on the risk assessment for bees. On a number of occasions we stressed the importance of this guidance to be finalised and have it available for use.

At the same time though we would like to express our deep concerns about the feasibility of this guidance. Requirements should be imposed 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 illustrates our concerns in the attached appendix, together with an overview of general comments.

Apart from the technical points that were raised here, we would urge upon the Commission to as soon as possible provide EFSA with a mandate to review the tigger values on the basis of the BEEHAVE model. In this way revised trigger values should be available before the implementation date of the guidance (01 Febr 2017).

Implementation of the guidance will bring to light many unsolved topics and many points that need clarification. We emphasize the importance of solving these issues by a harmonised approach, not allowing MS to find national ways of solutions. That is why we propose the Commission to look into the possibilities of installing an expert group that jointly works 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.

**Van:** [redacted]
**Aan:** [redacted]
**Cc:** [redacted]

**Onderwerp:** RE: mei_2016_ctgb_comments_on_com_implementation_
**Datum:** woensdag 8 juni 2016 09:01:33
**Bijlagen:** mei_2016_ctgb_comments_on_com_implementation_NVWA.docx

---

Hoi [redacted],

Nog een paar aanvullingen. Ik miste nog de impact voor het effectief middelenpakket en de onduidelijkheid over de data van ingang. Wellicht had ik niet de laatste versie en staat het in jouw versie anders.

Succes verder.

Met vriendelijke groet,


[redacted]
Nederlandse Voedsel- en Warenautoriteit
Divisie Landbouw en Natuur
tel: [redacted]
e-mail: [redacted]


-----Oorspronkelijk bericht-----
Van: [redacted])
Verzonden: woensdag 8 juni 2016 8:05
Aan: [redacted]
CC: [redacted]
Onderwerp: mei_2016_ctgb_comments_on_com_implementation_

Beste harde werkers,

Enkele kleine revisies van mij.
Als dit verwerkt is, lijkt het mij een prima commentaarstem dat ik graag richting COM doorgeef (en ook de collega's ' to consider' )

Dank voor jullie werk alvast,
Groet, [redacted]

[redacted]

**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 opinion[1] 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 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.*

---

[1] 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. There it is mentioned that for plant protection products submitted after 15 October 2016 part the chapters of the Guidance as listed in Part A should be used. Whereas in Part A of the Annex of the Commission Notice 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. Which will have an enormous impact on the availability of PPP for growers. 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 moment[2], and on model calculations with an unsuitable model[3]. 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 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.

---

[2] governmental project BO-20-002-011

[3] 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

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).

**Van:** [redacted])
**Aan:** [redacted]
**Cc:** [redacted]
**Onderwerp:** mei_2016_ctgb_comments_on_com_implementation_
**Datum:** woensdag 8 juni 2016 08:04:49
**Bijlagen:** mei_2016_ctgb_comments_on_com_implementation_.docx
ATT00001.txt

---

Beste harde werkers,

Enkele kleine revisies van mij.
Als dit verwerkt is, lijkt het mij een prima commentaarstem dat ik graag richting COM doorgeef (en ook de collega's ' to consider' )

Dank voor jullie werk alvast,
Groet, [redacted]

[redacted]

**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 opinion[1] 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 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.*

---

[1] 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).

Regarding Annex 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 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 moment[2], and on model calculations with an unsuitable model[3]. 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 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:

[2] governmental project BO-20-002-011
[3] 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

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).

**Van:** [redacted]
**Aan:** [redacted]
**Cc:** [redacted])
**Onderwerp:** Commentaar NL op roadmap en UP bijen
**Datum:** dinsdag 7 juni 2016 16:13:07
**Bijlagen:** mei 2016 ctgb comments on com implementation .docx

---

Hoi allemaal,

Hier een nieuwe versie van het Ctgb inhoudelijk commentaar, in het nieuwe format, met al input van [redacted] verwerkt.

Roept u maar :-)

Groeten [redacted]
PS Ik ben er deze week dus alleen morgen nog., en [redacted] is er helemaal niet deze week.

---

**Van:** [redacted]
**Verzonden:** dinsdag 7 juni 2016 11:05
**Aan:** [redacted]
**Onderwerp:** Dank! Re: overleg EU Bijen GD Locatie Ede/ Wageningen

Beste mensen,

Bedankt voor jullie flexibiliteit vanochtend met (de vorm van) het overleg. Belangrijker nog bedankt voor alle gewaardeerde inbreng! Uiteraard stel ik jullie input, kennis en kunde zeer op prijs.
Mooi dat we snel het eerste 'commentaar-paper' vanuit het Ctgb kunnen omwerken, conform de afspraken van vanochtend.
Ik zie eea dan woensdag einde dag tegemoet. Graag sturen naar alle deelnemers en ook (cc?) aan [redacted].

Mijn streven is om ons commentaar en de oproepen aan COM en LS vrijdag te versturen.

Groet, [redacted]

[redacted]
Ministry of Economic Affairs
DG Agriculture and Nature
The Netherlands
Verstuurd vanaf mijn iPad

Op 30 mei 2016 om 13:52 heeft [redacted]> het volgende geschreven:

> Geachte genodigden,
>
> Als het goed is heeft u betreffende bovenstaand onderwerp al bericht ontvangen van [redacted]
>
> Op verzoek van [redacted] treft u bijgaand een datumbriefje voor het plannen van een overleg Bijen GD.
>
> Helaas zijn de mogelijkheden zeer beperkt, desondanks hoop ik dat u tijd kunt vrijmaken.

Wilt u zo vriendelijk zijn uw beschikbaarheid in te vullen en deze zo spoedig mogelijk retour te sturen.

Hartelijk dank voor uw medewerking.

Met vriendelijke groet,

[redacted]
Management assistent

Ministerie van Economische Zaken
Directie Plantaardige Agroketens en Voedselkwaliteit
Bezuidenhoutseweg 73 I B-zuid 4e etagel
postbus 20401 I 2500 EK DEN HAAG
Tel.: [redacted]
Mob:+[redacted]

Let op! Bij bezoek aan het ministerie dient u in het bezit te zijn van een geldig legitimatiebewijs!



<2016-05-30 datumbr. Bijen guidance document .docx>

[redacted]

**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 opinion[1] 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 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 be become unavailable if the GD is strictly followed. We propose to revise these protocols and to deal with the existing tests in a harmonized 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 harmonized way. We recommend that an expert working group is set up a.s.a.p. in which 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.*

---

[1] 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 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).

Regarding Annex 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 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 moment[2], and on model calculations with an unsuitable model[3]. 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 expert risk 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 not in use. The Commission is asked to ensure that the environmental Fate sections come to a harmonized agreement on inputs and formats for outputs before Feb 2017.

Regarding Annex B:

---

[2] governmental project BO-20-002-011

[3] 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

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 was ever 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).

**Van:** [redacted]]
**Verzonden:** 07 June 2016 16:09
**Aan:** [redacted]
**Onderwerp:** RE: mei_2016_ctgb_comments_on_com_implementation_.docx

[redacted],

Hier is de publicatie; ik ben het met je eens dat die expert werkgroep zou moeten/kunnen sleutelen aan die 7% maar dat staat voor mijn gevoel los van het aanpassen van de eerste tier; aanpassen van de eerste tier is veel gemakkelijker dan aanpassen van die 7% (want onderdeel van agreed protection goal).

Groeten van [redacted]

**From:** [redacted]
**Sent:** 07 June, 2016 16:00
**To:** [redacted]
**Subject:** RE: mei_2016_ctgb_comments_on_com_implementation_.docx

Bedankt [redacted]! Ik heb nog een zinnetje toegevoegd aan jouw UP stuk, en een voorbeeld zoals gevraagd. Ook nog een paar andere wijzigingen aangebracht.

Zou je me die publicatie over de 7%-20% kunnen sturen?
Ik dacht dat we besproken hadden dat we ook aan die 7% nog wel zouden kunnen sleutelen met een expert werkgroep. Maar dat lijkt jou dus geen goed idee?

Ik stuur het nu rond naar iedereen!

Groeten [redacted]

**Van:** [redacted]
**Verzonden:** dinsdag 7 juni 2016 14:52
**Aan:** [redacted]
**Onderwerp:** RE: mei_2016_ctgb_comments_on_com_implementation_.docx

Hoi [redacted]

Zie attached mijn input; ik kon niet goed aansluiting maken op jouw stuk over de protection goals dus heb jouw tekst doorgestreept :-) Voel je uiteraard vrij om dat terug te veranderen of er een andere draai aan te geven.

De industrie-referentie kon ik niet plaatsen; ik had het over een referentie die aangaf dat de 7% bovengrens voor de effecten vervangen kan worden door een 20% bovengrens; dat houdt echter ingrijpen in in het specific protection goal en dat is voor de trigger discussie voorlopig een brug te ver, lijkt mij.

Groeten van [redacted]

---

**From:** [redacted]
**Sent:** 07 June, 2016 12:23
**To:** [redacted]
**Subject:** mei_2016_ctgb_comments_on_com_implementation_.docx

Hoi [redacted]
Dit heb ik er tot nu toe van gemaakt. Leek me handig om alvast naar jou te sturen. Ik ga het straks zelf ook nog een keer goed lezen. Bij de gele dingen hoop ik dat jij iig input kunt leveren en alle verdere commentaar is ook welkom!
Groeten [redacted]



Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.
De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

This message may contain information that is not intended for you. If you are not the addressee or if this message was sent to you by mistake, you are requested to inform the sender and delete the message.
The State accepts no liability for damage of any kind resulting from the risks inherent in the electronic transmission of messages.

Environmental
Toxicology and Chemistry

Hazard/Risk Assessment

# USING BEEHAVE TO EXPLORE PESTICIDE PROTECTION GOALS FOR EUROPEAN HONEYBEE (*APIS MELIFERA* L.) WORKER LOSSES AT DIFFERENT FORAGE QUALITIES

PERNILLE THORBEK, PETER J. CAMPBELL, PAUL J. SWEENEY, and HELEN M. THOMPSON

*Environ Toxicol Chem.*, **Accepted Article** • DOI: 10.1002/etc.3504

Hazard/Risk Assessment

Environmental Toxicology and Chemistry
DOI 10.1002/etc.3504

# USING BEEHAVE TO EXPLORE PESTICIDE PROTECTION GOALS FOR EUROPEAN HONEYBEE (*APIS MELIFERA* L.) WORKER LOSSES AT DIFFERENT FORAGE QUALITIES

Running title: Using BEEHAVE to set honeybee pesticide protection goals

PERNILLE THORBEK,* PETER J. CAMPBELL, PAUL J. SWEENEY, and HELEN M. THOMPSON

Environmental Safety, Syngenta, Jealott's Hill International Research Centre, Bracknell, Berkshire, United Kingdom

* Address correspondence to [redacted]

This article contains online-only Supplemental Data



Submitted 1 December 2015; Returned for Revision 1 February 2016; Accepted 19 May 2016

**Abstract:** Losses of honeybee colonies are intensely debated and while honeybees suffer multiple stressors the main focus has been on pesticides. As a result the European Food Safety Agency (EFSA) revised the guidance for pesticide risk assessment for honeybees. EFSA reports the protection goal of negligible effect at 7% of colony size and then used the Khoury honeybee colony model to set trigger values for forager losses. However, the Khoury model is very simplistic and simulates colonies in an idealised state. Here the authors demonstrate how a more realistic published honeybee model, BEEHAVE, with a few simple changes, can be used to explore pesticides risks. The results showed that forage availability interacted with pesticide induced worker losses and colony resilience increased with forage quality. Adding alternative unexposed forage to the landscape also substantially mitigated the effects of pesticide exposure. The results indicated that EFSA's reported protection goal of 7% of colony size and triggers for daily worker losses are overly conservative. The authors conclude that forage availability is critical for colony resilience and with adequate forage the colonies are resilient to even high levels of worker losses. However, the authors recommend setting protection goals using suboptimal forage conditions to ensure conservatism and for such suboptimal forage a total of 20% reduction in colony size was safe. 

**Keywords:** Pesticide risk assessment, Population modelling, Landscape ecology, Population-level effects, Mechanistic effect model, Pollinator

## INTRODUCTION

Reports of overwintering losses of European honeybee (*Apis melifera* L.) colonies have increased over the last decades and the search for the causes has been intensive [1-3]. Honeybees are exposed to multiple stressors e.g. Varroa mites (*Varroa destructor*) and the viruses they vector[4], lack of forage [5], Nosema and other pathogens and this has been compounded by changes to beekeeping practices and the profitability of beekeeping [1, 6-11]. While most agree that this cumulative load of multiple stressors underlies problems in honeybee colonies, much of the public and scientific debate has centred on the role of a single factor, namely pesticides and in particular neonicotinoids [7, 12], and the debate has been heated and at times emotional [13]. While several laboratory and semi-field studies have indeed shown that high doses of neonicotinoids may affect survival or cause sublethal effects in honeybees (restated in [12]) there is disagreement about the realism of the exposure levels used in these studies [12, 14]. Neither widespread worker mortality nor colony losses have been confirmed in field experiments studying the effects of neonicotinoids [12, 15-17]. However, exposure of honeybees following use of pesticides in the field is difficult to quantify because honeybees are social insects, where the colony acts as a super-organism whose different castes, and individuals within the castes, may experience very different exposures [18]. Honeybee colonies exploit numerous foraging sources over large spatial scales and respond rapidly to changing nectar and pollen availability [19, 20], in-hive workers mix pollen and nectar from different sources [21] and residues dissipate through metabolism and decline during storage and handling [22]. Moreover, the colony has several sophisticated mechanisms that enable it to deal with changing forage availability and other stressors, such as changes to age of first foraging, cannibalism of brood during pollen shortages and flexible egg laying rate by the queen, making it difficult to predict how effects on individuals will impact colony dynamics [23-26]. While it has not been explicitly stated, it appears that an underlying concern is that the complex colony dynamics of honeybees may result in the effects of exposure to systemic pesticides building up without being noticed with colony loss occurring seemingly without warning. For instance, in a study on disorientation of foragers following exposure to a neonicotinoid Henry et al. [27] used a simplistic honeybee colony model developed by Khoury et al. [28] and predicted widespread colony losses as a consequence of forager losses. As a result of the conflicting evidence and these uncertainties about true levels of exposure, effects on individual bees and the resulting colony level impact the European Food Safety Agency ( EFSA ) changed the Guidance Document for regulatory bee risk assessment of pesticides [29]. Of particular relevance to our paper are the changes to protection goals, trigger values for forager losses and the updated exposure calculation methods [29]. For higher tier risk assessments and field studies, EFSA reports a protection goal of negligible effect on the colony as a 7% reduction in colony size [29], but the evidence was behind this figure is unclear. Subsequently, EFSA used the same colony model as Henry et al. [27], i.e. the Khoury et al. model [28], to deduce what level and duration of forager losses would cause less than the protection goal of 7% overall decline in colony size and these values are then used to define trigger values [29]. However, the Khoury et al. [28] model excludes many of the mechanisms and feedback loops that allow honeybee colonies to exploit changing forage availability and cope with stressors, for instance neither honey stores nor seasonality are included [25, 28].

Since then, a new realistic honeybee colony model, BEEHAVE, has been published by Becher et al. [30]. BEEHAVE combines what happens inside and outside the hive by simulating honey bee colony dynamics and agent-based foraging of nectar and pollen in a seasonal landscape. EFSA has reviewed BEEHAVE and concludes that overall BEEHAVE performs well in modelling honeybee colony dynamics, but that BEEHAVE is not yet usable in a regulatory context mainly because it lacks pesticide module and representative scenarios [31]. Here we demonstrate how BEEHAVE with a few simple changes can be used to explore protection goals and how scenarios for different weather patterns and landscape structures can be developed. We use BEEHAVE to explore the following questions: (i) What are the forage requirements of colonies and do these boundaries for survival have implications for pesticide exposure estimation? (ii) How does forage quality affect colony resilience to worker losses? For (ii), the worker losses were simulated in two different ways to mimic two types of studies namely (iia) colony assessment [32, 33] and (iib) Radio Frequency Identification (RFID) transponders study which measures marked foragers return to hive [34]. Subsequently we asked (iii) can alternative unexposed forage mitigate the effects of pesticide exposure, and (iv) what level of worker losses is safe and could be used as protection goal under realistic worst-case conditions?

## MATERIALS AND METHODS

BEEHAVE was used in all simulations. BEEHAVE is a honeybee model developed by Becher et al. [30] that integrates processes inside the hive with landscape dynamics via a forager module. BEEHAVE was developed to study the impact of multiple stressors and is based on a review of existing models and existing knowledge of honeybees [25]. BEEHAVE is extensively documented and comes with a user manual [30], so here we only describe the overall principles and the changes we made.

The colony module is cohort-based and uses difference equations to simulate the colony dynamics. The foraging module is agent-based and simulates the foragers' behaviour and nectar and pollen collection. The landscape is flexible and describes spatio-temporal nectar and pollen availably with foraging activity dependent on both landscape structure and weather patterns (for landscape settings in this paper see below). BEEHAVE is implemented in NetLogo [35] and is extensively documented; for full model description see [30] and www.beehave-model.net.

"Control" here denotes scenarios without pesticide exposure and all pesticide scenarios were paired with control scenarios that had identical settings apart from the pesticide effects unless otherwise stated.

*Changes to BEEHAVE*

All scenarios assessed here were based on the scenario used for pesticide exposure ("JPEbecherSA7_modBhave-Pesticide.nlogo") in supplementary materials of [30]. In Becher et al.'s scenario the landscape consists of a single forage patch with constant nectar and pollen flow located 1000 m from the colony. The weather in Becher et al. is from Rothamsted, Harpenden, UK, year 2009 and mortality is implemented as a multiple of the control per foraging trip (MORTALITY_FACTOR) and only affects active foragers. The changes to this scenario and BEEHAVE are outlined below. Most changes to the [30] scenarios could be carried out with changes to parameter values and input files. However the following changes to the code were necessary:

Two new parameters were introduced to allow BEEHAVE to run control setting for some years before exposure commenced (i.e. a spin-up phase) and again for some years after exposure to study recovery. Additionally, code was added to allow the removal of a fixed daily proportion of foragers and in-hive bees during exposure periods with the introduction of new parameters to set this proportion. Finally, code was added so MORTALITY_FACTOR could be inputted via the landscape input file (INPUT_FILE), where an extra column was added to facilitate this. Full description of all changes to the BEEHAVE version published in [30] can be found in supplementary materials. The altered version of BEEHAVE is also available in the supplementary materials under GNU (GNU General Public License vs 3 http://www.gnu.org/licenses/gpl-3.0.en.html).

*Scenarios*

*Control scenarios*. The purpose of the control scenarios was to explore how colonies in BEEHAVE respond to different settings regarding forage quality. Subsequently these findings were used to explore how forage quality affected colony resilience to pesticide-induced workers losses.

Weather is important for colony dynamics as it controls when foraging can take place, so we aimed to standardise weather to avoid results being driven by weather conditions in a particular year. Becher et al. [30] used weather from Rothamsted 2009, whereas we downloaded average weather for Rothamsted (1981-2010) from the Met Office online database [1] (monthly averages of daily maximum

[1] URL http://www.metoffice.gov.uk/public/weather/climate/gcpwzc5tx ; downloaded 6 October 2015

temperature [˚C], sunshine [hours]), which we interpolated linearly to obtain daily values. We used the same rules as [30] to calculate foraging hours per day (i.e. sunshine hours per day when daily max temperature was above 15˚C). However, inspecting the graphs it was clear that average weather is not the same as standard weather; thus the threshold of 15˚C led to a very abrupt onset of foraging (Figure 1) and colonies struggled to survive. In reality, in most years colonies will experience a few good early foraging days with increasing foraging as the weather warms up and there are also a few good days towards the end of the season. We therefore devised a window function (Weatherwax) to smooth the weather. An Excel spreadsheet with the weather data as downloaded, the interpolation and Weatherwax function can be found in supplementary materials.

*Weatherwax Function.* We used a modified Vorbis window function [36] to estimate the number of hours that bees forage throughout a season. To maintain consistency with the original nomenclature we define a Weatherwax Foraging Function as

$$F_r = 0 \quad \text{for day} < D_{start} \qquad \text{(Equation 1)}$$

$$= \quad \text{for day} > D_{start} \text{ and day} < D_{start} + D_{period} \qquad \text{(Equation 2 )}$$

$$F_r = 0 \quad \text{for day} > D_{start} + D_{period} \qquad \text{(Equation 3)}$$

Where

$F_r$ = the number of hours that bees forage in a day

$F_{max}$ = maximum number of hours that bees can forage

$D_{start}$ = the day number that bees start foraging

$D_{period}$ = total number of days that bees forage

Day = daynumber

The Weatherwax Function was smooth and symmetric about the middle of the foraging period calculated according to [30] and fitted it sufficiently well (Figure 1).

*Forage availability*. Becher et al. set food flow to be constant across the year, but we used the more realistic HoMoPo setting for seasonal food flow [30, 37]. The first day of foraging was calibrated to achieve overlap between foraging season and forage availability (Figure 1) (SHIFT_G that controls the HoMoPo food flow was set to -30). The single forage patch in the landscape (two patches for Landscape Mitigation Scenario see below) did not represent a particular crop or habitat but was a representation of general forage availability and distance in the landscape with the implicit assumptions that during exposure all foragers would forage exclusively on the exposed crop.

*Control Boundaries for Survival Scenarios*

In BEEHAVE the colony requires a minimum quantity of energy (nectar) and protein (pollen) to survive. However, the actual quantities needed depend on sugar concentration of the nectar, the distance between colony and forage, handling time and total hours available to forage in the year. Here we use the term 'boundaries for survival' to denote the combinations of parameter values for nectar sugar concentration, amounts of nectar and pollen, handling time for pollen and nectar and distance between colony and forage patch for which colonies can survive in BEEHAVE.

The changes to the weather scenario and introduction of seasonal food flow resulted in different boundaries for colony survival when compared with Becher et al.[30]. Here we aimed to establish the forage quality required for colony survival in the absence of pesticide exposure by running a series of preliminary scenarios to explore the impact and interaction between distance between forage and hive (hereafter distance), sugar concentration in nectar, handling time and quantity of pollen and nectar. These boundaries for survival have implications for lower tier calculations of exposure in regulatory risk assessments [29] because the lower the nectar sugar concentration that foragers exploit, the more nectar they will need to meet the colonies energetic needs, and hence all else being equal, they will potentially be exposed to a higher pesticide dose per unit energy.

In order to compare the scenarios, we calculated the energetic efficiency (the ratio of energy gained from foraging relative to the energy spent foraging) at the beginning of the day according to the equations from [30]:

Energetic Efficiency = ((nectarConcFlowerPatch * CROPVOLUME * ENERGY_SUCROSE) - flightCostsNectar) / flightCostsNectar (Equation 4)

where nectarConcFlowerPatch is sucrose concentration of nectar [mole sucrose /L], CROPVOLUME is the crop size of foragers [50 µg], ENERGY_SUCROSE is 0.00582 [kJ/micromol] and

flightCostsNectar = (2 * distanceToColony * FLIGHTCOSTS_PER_m) + (FLIGHTCOSTS_PER_m * handlingTimeNectar * FLIGHT_VELOCITY * energyFactor_onFlower) (Equation 5)

where distanceToColony is distance between colony and forage patch [m], FLIGHTCOSTS_PER_m 0.000006 [kJ/m], handlingTimeNectar is the time spent on forage patch [s], FLIGHT_VELOCITY 6.5 [m/s] and energyFactor_onFlower is 0.2 [proportion; no unit] assuming the forager spends 20% of the energy on patch compared to the flight to and from patch.

In BEEHAVE, the handling time increases as nectar and pollen is depleted by the foragers during each day, so the calculated energetic efficiency was the daily maximum (pollen and nectar are replenished once a day in BEEHAVE).

As a result of these preliminary scenarios the following control settings were used in the remaining scenarios: The forage availability followed HoPoMo with SHIFT_G -30, which adjusts the timing of the pollen and nectar flow see [30] for details. Pollen peak availability was set to 1 kg/day, nectar peak availability to 10L/day and sugar concentration in nectar to 2 mol sucrose/L. Weatherwax settings: foraging started on day 55, total number of days foraging 250, peak foraging rate 6.4 h/day. This led to a yearly total of 963.5 hours foraging. In real life most foragers are found within 1 km of the hive if forage is plentiful, but they will go much further if no forage is closer [24]. Colonies have high probability of finding forage within 2000m distance, but little above 3200m [24]. So we chose to run all scenarios with distance between hive and forage at 50m, 500m, and 1000m to cover situations where a flowering crop is likely to provide a large proportion of the forage collected by the colony.

*Fixed Worker Mortality Scenario*

This scenario series matched colony assessment studies where the total number of workers is assessed and was created to predict the colony's resilience to loss for set (fixed) proportions of workers at different times of the year. This scenario was used to explore protection goals for colony size reduction. Mortality was imposed as set proportions of all workers (i.e. in-hive bees and foragers) irrespective of whether they were actively foraging and did not take the mechanism of exposure into account. Fixed worker mortality was initially implemented with a single day duration (10, 25, 50 or 75% of workers removed), which took place once a year, at different times: 1 April, 1 May, 1 June, 1 July or 1 August (flowering crops are rare outside this period) in a fully factorial design. The mortality was not related to background mortality nor intended to represent realistic pesticide mortalities, but to explore the interaction between timing and magnitude of worker losses.

In order to explore the importance of duration of exposure we ran an additional scenario series where total workers losses of 20% and 50% were distributed over 1, 3, 7, 14 and 30 days starting 1 June (which preliminary runs had shown was a sensitive period). This daily mortality was calculated by dividing the total percentage worker lost by duration.

*Forager Mortality per Trip Scenario*

Here, mortality was implemented in the same way as [30], i.e. as a multiple of control mortality per foraging trip and was used for comparison to the trigger values for forager losses in the EFSA guidance document [29]. Mortality was implemented at the foraging patch so it only affected active foragers visiting the patch, thus at each visit the control mortality was multiplied by a set multiplication factor. This type of mortality can represent acute mortality or disorientation where the forager fails to return to hive; in the latter case the forager would in effect be dead to the colony. This type of mortality implementation matches the data that can be gathered from RFID studies, where foraging activity and return to hive is measured [34]. In this scenario series the following factors and effect levels were varied in a fully factorial design: distances between forage patch and hive 50m, 500m, 1000m, the patch was exposed for 1, 3, 7, 14, 30 days, and the mortality level was set at the following multiples of control: 2, 3, 5, 10 with onset of exposure set to start 1$^{st}$ April, 1$^{st}$ May, etc. until 1$^{st}$ August.

As this type of mortality happens at patch the overall mortality was emergent and depended on control mortality, number of visits and proportion of active foragers. The relationship between forager death per trip as a multiple of control and total forager loss is not straightforward to estimate because the total loss is dependent on both the number of active foragers and foraging activity, i.e. the more flights per day an individual bee makes the higher its mortality risk per day and the greater the total number of active foragers the larger the total forager loss. Similarly, even a high mortality risk leads to no mortality of foragers outside the foraging season, because they are not active and therefore not exposed.

*Landscape Mitigation Scenario.* The mitigating effect of alternative unexposed forage was explored by adding an extra foraging patch to the landscape with availability of nectar and pollen set at 10% of control peak abundance (equivalent to a seasonal peak of 1L nectar and 100g pollen per day), and followed the same seasonal variation as the main forage patch. The alternative patch was unexposed and only present during the exposure period which lasted for 30 days starting 1 June. The alternative patch was placed at 50, 500 and 1000m from the hive while the exposed patch was placed 1000m from the hive. The mortality in this scenario series was implemented as in the Forager Mortality per Trip Scenario, but with a MORTALITY_FACTOR of 5 to enforce clear colony level effects.

*Data analysis*

All scenarios were run with 10 replicates. In BEEHAVE the colony overwintering survival is determined on 31 December, so the data analysis mainly focused on colony size at 31 December after 3 years of consecutive exposure events (see figure 4 for an illustration) to account for year on year use of a given pesticide while taking into account queens are unlikely to last longer than 3 years [23]. In order to address protection goal setting, a safe level of forager losses was defined as no risk of colony loss and a maximum of 10% reduction in overwintering colony size after three years of consecutive exposure events.

## RESULTS

*Control Boundaries Scenario*

The peak and minimum size of the colony decreased with increasing distance to forage (Figure 2A). The timing of peak colony size also varied with distance from mid-summer at 50m to late summer at 1000m. Similarly, the minimum colony size was in early spring at 50m but in mid spring at 1000m (Figure 2A). The difference in timing of peak size was more marked for honey stores which was at peak for a several months at 50m distance, but only for a couple of weeks at 1000m (Figure 2B). Thus, at 1000m the colony was at the threshold of starvation and if sugar concentration was lowered or distance to forage or handling time were increased the colony went into decline (supplementary materials Figure S1, Figure S2). The colony only survived within certain boundaries of energetic efficiency (equation 4). With the weather scenario used, a minimum energetic efficiency of 25 was necessary for the colony to survive (Figure 3). Thus, increasing, for example, sugar concentration in nectar could to some extent compensate for greater distance between colony and forage or for longer handling times. In BEEHAVE the control (i.e. without pesticides) mortality of foragers depends on both distance flown and time spent foraging. Therefore, energetic efficiency alone could not fully explain colony survival, because the forager mortality per energy unit brought back to the hive was affected by handling time, distance and nectar sugar concentrations. For instance, with low nectar sugar concentrations the foragers would have to fly more trips to bring back the same amount of energy and therefore flew longer and consequently suffered higher mortality. In contrast, increasing the abundance of nectar and pollen beyond a saturation threshold only had limited potential to compensate for poor energetic efficiency or high forage related mortality (caused by low sugar concentration or high distance or handling time) (supplementary material Figure S2). This was to a certain degree an artefact of BEEHAVE's default threshold for how much honey the bees can store (50kg) and lack of beekeeper interventions (feeding or honey harvest) in the current settings.

*Fixed Worker Mortality Scenario*

The time to recovery after a forager loss depended on forage quality (here implemented as distance). For instance at 50% adult bee mortality the colony recovered before winter at 50m from forage, but failed to fully recover at 1000m from forage (Figure 4). The higher the proportion of workers removed on a single day, the larger the impact on the overwintering size of the colony (Figure 5). Mortality interacted with distance, so at 50m there was hardly any impact on overwintering colony size of even high worker mortalities, whereas at 1000m distance the overwintering size decreased rapidly when worker mortality exceeded 20-30% (Figure 5). The timing of the effect was also important with effects late in the season having larger impact on overwintering size than those early in the season (Figure 5). The colony was more sensitive to worker loss in August because colony size peaked then resulting in a larger total number of workers being removed, egg laying was already declining and there was less time and forage to exploit for the colony to recover before overwintering. It was the total size of the adult worker loss that mattered for overwintering size of the colony, whereas the number of days the mortality was distributed over only had negligible effect (Figure 6).

*Forager Mortality per Trip Scenario*

There was no impact of this type of mortality outside the foraging season, as there was no exposure (see supplementary materials Figure S3). During the foraging season colony size was reduced with increasing mortality factor and increasing duration of exposure (Figure 7) which both led to larger total loss of workers. Again, there was interaction with distance so the colony resilience decreased with increasing distance. Mortality and duration also interacted with timing of exposure (Figure 7), but the worst-case timing of exposure (April and June) was different from that in the Fixed Worker Mortality Scenarios. The reason for this was the way in which mortality was implemented in the two scenarios; in the Forager Mortality per Trip scenarios only foragers were affected, which meant that there was more scope for compensation by lowering the age of first foraging for in-hive bees than in the Fixed Worker Mortality Scenarios, where both in-hive bees and foragers were equally affected.

A safe level of forager losses was defined as no risk of colony loss and a maximum of 10% reduction of overwintering colony size after three years of consecutive exposure events. At 1000m distance from hive to field this resulted in the following trigger values for forager losses: 3 times control mortality per flight for 14 days, 4 times for 7 days, and double for 30 days (Table 1), but at 50m the thresholds were much higher (Figure 7).

*Landscape Mitigation Scenario*

Adding a small amount of alternative forage to the landscape mitigated the effects of exposure to pesticides for settings which would otherwise lead to colony decline and loss (Figure 8). The mitigating effect was larger if the alternative unexposed forage was closer to the colony than the exposed forage. The effects of the landscape mitigation stemmed partly from the presence of additional resource but primarily from fewer bees being exposed. Thus, when the alternative patch was more energetically efficient, because of shorter distance, it was favoured by the foragers. Moreover, when the mortality at the exposed patch was high, fewer foragers were recruited to the exposed patch.

**DISCUSSION**

Our simulations with BEEHAVE indicated that forage quality plays a critical role for the colony's resilience to stressors. From the scenarios to explore the boundaries for control colony survival, it appeared that both energetic efficiency (i.e. the energy gained relative to the energy spent acquiring it) as well as the background foraging mortality per energy unit acquired affected colony resilience. The importance of forage was also reflected in the pesticide scenarios, which in all cases showed that colonies at edge of field had much higher resilience to worker losses than colonies further from the field (when the field was the only source of forage), where energetic efficiency was lower and the background mortality per energy unit acquired were higher. Indeed there was less impact on colonies adjacent to an exposed field with substantial forager losses than far from an untreated field. That bountiful and accessible forage close to the hive is important for honeybees is well known and a fact beekeepers exploit by placing hives next to flowering crops or bee attractive flowers whilst ensuring colony survival by feeding them sugar syrup and fondant at times of nectar and pollen dearth [38]. Similarly, impoverished forage and habitat loss have been implicated in the decline of several bee species [6, 23, 38, 39] and starvation frequently contributes to honeybee colony losses [40, 41].

As colony survival typically depends on overwintering size and effects may accumulate year on year [30, 42] we here propose to set the overall protection goal in simulations as no colony losses and a maximum of 10% reduction in overwintering colony size after 3 years of consecutive exposure events. The Fixed Worker Mortality Scenarios, which matches colony assessments in field studies, showed that when the colony was placed at edge of field the colony made full recovery even after losing 50% of workers. While losses of this magnitude may appear high, they are similar to worker losses caused by swarming, which may happen several times a year in thriving colonies [23]. Similarly, beekeepers employ several techniques to reduce swarming and also make new nucleus colonies by splitting to increase numbers demonstrating that thriving colonies have substantial compensation mechanisms for reduction in size (e.g.[38]). However, in our simulations at 1000m distance the colony was less resilient and the threshold for full recovery within a season was about 20-30 % worker losses. While our results are specific to the forage availability and weather pattern used in the scenarios, which were calibrated to stress the colony, the losses that BEEHAVE predicted a colony could sustain is much more in line with knowledge about bee biology (e.g. swarming), losses associated with movement of hives and beekeeping practices [23, 38] than the protection goal of 7% reported in the EFSA Bee Guidance

Document [29]. Thus, the EFSA reported protection goal of 7% of colony size is overly conservative given the large natural fluctuations found in colony size over the season and between years [16, 17].

The trigger values EFSA calculated for forager losses using the Khoury et al. model [28] were set as a multiple of control [29], however it is not clear whether they mean per trip or per day and as our analysis showed these two are not necessarily the same. Using same protection goals as above (i.e. 10% reduction in overwinter size after three years with consecutive exposure events), our results indicated that forager losses should not be greater than double the control mortality per trip for 30 days, whereas EFSA [29] states that double control mortality is only acceptable for three days [29]. Similarly, we showed that three times control mortality per flight only caused negligible effects if lasting for 14 days whereas EFSA states the limit for negligible effects for three times the control mortality is two days. Similarly, our simulations showed that if the effects were short lived (up to three days) even increasing mortality to 10 times the control mortality per trip had no discernable effects on overwintering colony size. Implementing similar mortalities (i.e. 1.5 to 3 times control) as EFSA [29] and durations (i.e. two to six days) in BEEHAVE had hardly any discernable effects on colony size even at the time of exposure and none on overwintering size. To set their limits for forager losses EFSA used the Khoury honeybee model [28], which excludes honey stores, seasonality of forage and colony dynamics, energy budgets and many of the regulation mechanisms employed by bees to deal with stressors and changing forage availability [25]. This is not meant as a criticism of Khoury et al. [28] as the authors clearly state that: "The aim of this model is simply to provide a basic theoretical understanding of colony dynamics in an idealised state." However, it does highlight the importance of including the factors that are driving a biological system and understanding the limitations and strengths of different modelling approaches [43, 44]. Beekeepers employ a number of management techniques to counteract stressors, for example during years when forage or weather is poor they either reduce honey harvest or feed the colonies or face the consequences through colony loss [38]. We recommend that the control scenario for pesticide risk assessment should be based on a stable colony (i.e. it should not be based on a declining colony that is doomed to fail), but one that is only just stable to ensure conservatism. We here used food stress as means to calibrate BEEHAVE so the control colony was stable but vulnerable. In contrast to pesticide induced stress, parasites and diseases reproduce and multiply and therefore even with unlimited forage and good conditions the colony may not be able to compensate for the bee losses [30]; beekeepers routinely control for Varroa mites and diseases to ensure colony survival [38]. Therefore, vulnerability could also be calibrated in other ways, e.g. by adding other stressors such as Varroa but then the level of foraging stress would have to be reduced to ensure control colony survival. Such calibration should be carried out for representative regions as weather, forage quality, landscape structure and beekeeping practices all will have substantial impact on colony resilience. EFSA state that one of the main obstacles to use BEEHAVE for setting protection goals is the lack of a pesticide module [31]. Here, we demonstrated how some fairly simple changes can overcome the current limitations of BEEHAVE as published, but it also became clear that since the weather, landscape structure and forage quality has such large impact on colony dynamics, work is needed to develop realistic worst-case scenarios. Ideally, a group consisting of experts on diseases, parasites, forage, beekeeping practices, agronomy, landscape ecology and ecotoxicology would define the control scenarios for what constitute realistic worst-case scenarios in terms of landscape structure, beekeeping practices and weather in the different regions.

In our scenarios, the colony needed very good energetic efficiency to survive and it seemed that compared to typical distances flown by foragers and sugar concentrations in nectar this was on the "hungry" side [19, 20, 23]. The reason for the discrepancy between our simulations and natural foraging is probably that we used the same sugar concentration and distance to forage all year, which meant that the colony missed out on some good foraging opportunities which are known to be important for bees, especially if they occur early in the year [38]. However, as long as the food availability for the control scenarios are calibrated so that the colony is on the brink of starvation then the impact of any stressors will be conservative. The sugar concentrations that can sustain a colony depend on the energetic efficiency and background mortality per energy unit acquired, but also on the length of the foraging season and weather. For instance, in Becher et al. [30] where the nectar flow was constant and foraging season longer the colony could survive on lower nectar sugar concentrations than in the simulations presented here, where the foraging was more restricted. However, the sugar concentration of 15% used by EFSA in their calculation of shortcut values used for exposure and risk assessment is probably on the low side for colony survival, unless the handling time is extremely short. Thus, for a handling time of 1200s (typical according to [23]) the energetic efficiency for 15% sugar in nectar is only 12 even at edge of field and thus half of the threshold for colony survival of 25, which we identified in our scenarios. As a consequence, the overall percentile of the exposure implicit in the EFSA shortcut values is likely to be far higher than the 90$^{th}$ percentile exposure value EFSA aimed for.

Although neonicotinoid residues generally are detected in less than 5% of samples [45] there has been much debate over whether the use of neonicotinoids as seed treatments have caused widespread colony failures through exposure via pollen and nectar [12, 13]. Several researchers have found increased forager mortality under laboratory and semi-field studies [12], but the realism of exposure concentrations has been questioned [14] and effects on colony dynamics have not been detected in field studies with naturally foraging honeybees [16, 17]. Moreover, it appears the increase in overwintering colony losses plateaued or was reversed before the neonicotinoid moratorium in Europe came into place [2] and in the USA where neonicotinoids are still used it has also slowed [9]. Our results indicated that if mortalities exceed the recovery potential of the colony the effects build up and the resultant reduced colony size would be clearly visible in colony assessments and honey yield (e.g. Figure 4, 6). Thus, the apparent concern that effects can build up undetected until the colony suddenly collapses seem unfounded especially during targeted regulatory studies where the colonies are frequently monitored and for extended periods post-exposure [32].

Our mitigation scenario indicated that a small amount of alternative forage can reduce the exposure to pesticides on crops if it is of a better quality than the crop, here simulated by a shorter distance. Honeybees choose the most energetically efficient forage and if there is more attractive forage available, sufficient pollination of for example apples, which only have 25% sugar in the nectar, can be challenging e.g. [38]. Together with our findings from the Control Boundaries for Survival scenario and the pesticide scenarios this points to the critical role of increasing the abundance of good quality forage in agricultural landscapes to increase the resilience of honeybees towards the stressors in general. Long term changes to farming practices have led to far fewer flowers in the agricultural landscapes, e.g. over 90% of the flower rich meadows have been lost in the UK since the 1950s [46], clover in pastures has become much less prevalent and more effective weed control has resulted in less and less continuous forage for pollinators [47] (however, the lack of flowering weeds within fields also mean that fields become less attractive to pollinators thus reducing exposure to pesticides outside the flowering period of the crop itself [48]). Beekeepers often feed colonies to increase overwintering survival (e.g. [38]. However, several studies have shown that increased availability of forage on farms, e.g. improved field margin management such as sowing of flower margins and strips, also benefits other wild bee species [49] again highlighting the importance of improving forage availability for pollinators in agricultural landscapes.

We recommend setting protection goals using stressed honeybee colonies at the threshold of decline to ensure conservatism. The results showed that total cumulative loss of workers drives the colony response rather than the number of days the loss is distributed over. We conclude that for such suboptimal conditions a total 20% reduction in colony size is a realistic worst-case protection goal.

*Supplemental Data*—The Supplemental Data are available on the Wiley Online Library at DOI: 10.1002/etc.xxxx.

*Acknowledgment*—We thank M. Becher for help with changes to the code and valuable discussions about the results and mechanisms. We thank V. Grimm for constructive comments on the manuscript.

*Disclaimer*—The authors are employed by Syngenta Ltd.

*Data Availability*—Data are available upon request from the corresponding author at [redacted].

## REFERENCES


1. Neumann P, Carreck N. 2010. Honey bee colony losses. *Journal of Apicultural Research* 49:1.

2. Laurent M, Hendrikx P, Ribiere-Chabert M, Chauzat M-P. 2015. EPILOBEE: Pan-European epidemiological study on honeybee colony losses 2012-2014. EPILOBEE.

3. vanEngelsdorp D, Meixner MD. 2010. A historical review of managed honey bee populations in Europe and the United States and the factors that may affect them. *Journal of Invertebrate Pathology* 103:S80-S95.

4. Wilfert L, Long G, Leggett HC, Schmid-Hempel P, Butlin R, Martin SJM, Boots M. 2016. Deformed wing virus is a recent global epidemic in honeybees driven by Varroa mites. *Science* 351:594-597.

5. Baude M, Kunin WE, Boatman ND, Conyers S, Davies N, Gillespie MAK, Morton RD, Smart SM, Memmott J. 2016. Historical nectar assessment reveals the fall and rise of floral resources in Britain. *Nature* 530:85-88.

6. Potts SG, Biesmeijer JC, Kremen C, Neumann P, Schweiger O, Kunin WE. 2010. Global pollinator declines: trends, impacts and drivers. *Trends in Ecology & Evolution* 25:345-353.

7. Ratnieks FLW, Carreck NL. 2010. Clarity on Honey Bee Collapse? *Science* 327:152-153.

8. Kielmanowicz, Gleit M, Inberg A, Lerner IM, Golani Y, Brown N, Turner CL, Hayes GJR, Ballam JM. 2015. Prospective Large-Scale Field Study Generates Predictive Model Identifying Major Contributors to Colony Losses. *PLOS Pathogens* 11:e1004816.

9. Lee KV, Steinhauer N, Rennich K, Wilson ME, Tarpy DR, Caron DM, Rose R, Delaplane KS, Baylis K, Lengerich EJ, Pettis J, Skinner JA, Wilkes JT, Sagili R, vanEngelsdorp D. 2015. A national survey of managed honey bee 2013–2014 annual colony losses in the USA. *Apidologie* 46:292-305.

10. OPERA. 2013. Bee health in Europe - Facts & figures 2013.

11. Decourtye A, Mader E, Desneux N. 2010. Landscape enhancement of floral resources for honey bees in agro-ecosystems. *Apidologie* 41:264-277.

12. Godfray HCJ, Blacquiere T, Field LM, Hails RS, Petrokofsky G, Potts SG, Raine NE, Vanbergen AJ, McLean AR. 2014. A restatement of the natural science evidence base concerning neonicotinoid insecticides and insect pollinators. *Proceedings of the Royal Society B* 281:20140558-20140558.

13. Eisenstein M. 2015. Seeking answers amid a toxic debate. *Nature* 521:S52-S55.

14. Carreck NL, Ratnieks FLW. 2015. The dose makes the poison: have "field realistic" rates of exposure of bees to neonicotinoid insecticides been overestimated in laboratory studies? *Journal of Apicultural Research* 53:607-614.

15. Cresswell JE. 2010. A meta-analysis of experiments testing the effects of a neonicotinoid insecticide (imidacloprid) on honey bees. *Ecotoxicology* 20:149-157.

16. Pilling E, Campbell P, Coulson M, Ruddle N, Tornier I. 2013. A Four-Year Field Program Investigating Long-Term Effects of Repeated Exposure of Honey Bee Colonies to Flowering Crops treated with Thiamethoxam. *PLoS ONE* 8:e77193.

17. Rundlöf M, Andersson GKS, Bommarco R, Fries I, Hederström V, Herbertsson L, Jonsson O, Klatt BK, Pedersen TR, Yourstone J, Smith HG. 2015. Seed coating with a neonicotinoid insecticide negatively affects wild bees. *Nature* 521:77-80.

18. Rortais A. 2005. Modes of honeybees exposure to systemic insecticides: estimated amounts ofcontaminated pollen and nectar consumed by different categories of bees. *Apidologie* 36 i:1:71 - 83.

19. Beekman M, Ratnieks FLW. 2000. Long-range foraging by the honey-bee, *Apis mellifera* L. *Functional Ecology* 14:490-496.

20. Beekman M, Sumpter DJT, Seraphides N, Ratnieks FLW. 2004. Comparing foraging behaviour of small and large honey-bee colonies by decoding waggle dances made by foragers. *Functional Ecology* 18:829-835.

21. Eyer M, Greco MK, Lang J, Neumann P, Dietemann V. 2015. No spatial patterns for early nectar storage in honey bee colonies. *Insectes Sociaux*.

22. Suchail S, Debrauwer L, Belzunces LP. 2004. Metabolism of imidacloprid inApis mellifera. *Pest Management Science* 60:291-296.

23. Winston ML. 1987. The Biology of the Honey Bee. Harvard University Press, Cambridge, Massachusetts.

24. Seeley TD. 1995. The Wisdom of the Hive - The Social Physiology of Honey Bee Colonies. Harvard University Press, Cambridge, Massachusetts.

25. Becher MA, Osborne JL, Thorbek P, Kennedy PJ, Grimm V. 2013. REVIEW: Towards a systems approach for understanding honeybee decline: a stocktaking and synthesis of existing models. *Journal of Applied Ecology* 50:868-880.

26. Henry M, Cerrutti N, Aupinel P, Decourtye A, Gayrard M, Odoux J-F, Pissard A, Rüger C, Bretagnolle V. 2015. Reconciling laboratory and field assessments of neonicotinoid toxicity to honeybees. *Proceedings of the Royal Society B* 282:20152110.

27. Henry M, Beguin M, Requier F, Rollin O, Odoux J-F, Aupinel P, Aptel J, Tchamitchian S, Decourtye A. 2012. A Common Pesticide Decreases Foraging Success and Survival in Honey Bees. *Science* 336:348-350.

28. Khoury DS, Myerscough MR, Barron AB. 2011. A Quantitative Model of Honey Bee Colony Population Dynamics. *PLoS ONE* 6: e18491.

29. EFSA. 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus spp.* and solitary bees). *EFSA Journal* 11:3295.

30. Becher MA, Grimm V, Thorbek P, Horn J, Kennedy PJ, Osborne JL. 2014. BEEHAVE: a systems model of honeybee colony dynamics and foraging to explore multifactorial causes of colony failure. *Journal of Applied Ecology* 51:470-482.

31. 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* 13:4125.

32. EPPO. 2010. Side-effects on honeybees. *Bulletin OEPP/EPPO Bulletin* 40:313-319.

33. OECD. 2007. Guidance document on the honey bee (*Apis mellifera L.*) brood test under semi-field conditions. *OECD Series on Testing and Assessment* 75:3-27.

34. Thompson H, Coulson M, Ruddle N, Wilkins S, Harkin S. *In press*. Thiamethoxam: Assessing flight activity of honeybees foraging on treated oilseed rape using RFID technology. *Environmental Toxicology and Chemistry*:n/a-n/a.

35. Wilensky. 1999. NetLogo. *http://ccl.northwestern.edu/netlogo/*.

36. Gan W-S, Kuo S. 2007. Embedded Signal Processing with the Micro Signal Architechture. IEEE Press, Wiley and Sons, New Jersey.

37. Schmickl T, Crailsheim K. 2007. HoPoMo: a model of honeybee intracolonial population dynamics and resource management. *Ecological Modelling* 204:219-245.

38. Hooper T. 2010. Guide to Bees & Honey, Fifth Edition ed. Northern Bee Books, Hebden Bridge.

39. Biesmeijer JC, Roberts SPM, Reemer M, Ohlemuller R, Edwards M, Peeters T, Schaffers APP, S. G. , Kleukers R, Thomas CD, Settele J, Kunin WE. 2006. Parallel Declines in Pollinators and Insect-Pollinated Plants in Britain and the Netherlands. *Science* 313:351-354.

40. vanEngelsdorp D, Caron D, Hayes J, Underwood R, Henson M, Rennich K, Spleen A, Andree M, Snyder R, Lee K, Roccasecca K, Wilson M, Wilkes J, Lengerich E, Pettis J. 2012. A national survey of managed honey bee 2010-11 winter colony losses in the USA: results from the Bee Informed Partnership. *Journal of Apicultural Research* 51:115-124.

41. vanEngelsdorp D, Hayes Jr J, Underwood RM, Caron D, Pettis J. 2011. A survey of managed honey bee colony losses in the USA, fall 2009 to winter 2010. *Journal of Apicultural Research* 50:1-10.

42. Horn J, Becher MA, Kennedy PJ, Osborne JL, Grimm V. 2015. Multiple stressors: using the honeybee model BEEHAVE to explore how spatial and temporal forage stress affects colony resilience. *Oikos*:n/a-n/a.

43. Schmolke A, Thorbek P, Chapman P, Grimm V. 2010. Ecological models and pesticide risk assessment: Current modeling practice. *Environmental Toxicology and Chemistry* 29:1006-1012.

44. Schmolke A, Thorbek P, DeAngelis DL, Grimm V. 2010. Ecological models supporting environmental decision making: a strategy for the future. *Trends in Ecology & Evolution* 25:479-486.

45. Collison E, Hird H, Cresswell J, Tyler C. In press. Interactive effects of pesticide exposure and pathogenic infection on bee health – A critical analysis. *Biological Reviews*.

46. Fuller RM. 1987. The Changing Extent and Conservation Interest of Lowland Grasslands in England and Wales: A Review of Grassland Surveys 1930-84. *Biological Conservation* 40:281-300.

47. Goulson D, Lye GC, Darvill B. 2008. Decline and Conservation of Bumble Bees. *Annual Review of Entomology* 53:191-208.

48. Maynard SK, Albuquerque R, Weber C, Mérey Gv, Geiger MF, Becker R, Keppler J, Masche J, Brougham K, Coulson M. 2014. Weeds in the treated field - a realistic scenario for pollinator risk assessment? , Hazards of pesticides to bees - 12th International Symposium of the ICP-PR Bee Protection Group, September 15-17, 2014, Ghent (Belgium).

49. Wood TJ, Holland JM, Hughes WOH, Goulson D. 2015. Targeted agri-environment schemes significantly improve the population size of common farmland bumblebee species. *Molecular Ecology* 24:1668-1680.

Figure 1. Weather and forage availability used in simulations. Rothamsted mean (primary Y-axis): forage hours per day calculated using mean temperature and sunshine hours from 30 years data (1981-2010), with foraging threshold of 15˚C max (total hours foraging: 936). HoPoMo Forage (secondary Y-axis): forage availability as proportion of maximum and SHIFT_G set to -30, which shifts curve to coincide with forage season. Weatherwax (primary Y-axis): foraging hours smoothened to reflect clement days that would occur most years ( total hours foraging: 963).

Figure 2. Seasonal colony dynamics for control hives at different distances from the forage patch. Distance: distance from colony to forage patch [m]. X-axis: day in year. (A): colony size as number of workers, (B) size of honey stores in kg honey.

Figure 3. Overwintering size of colony at different energetic efficiencies (Control Boundaries Scenario).Y-axis: Overwintering colony size (workers on 31 December); X-axis energetic efficiency (energy in nectar brought back divided by energy spent foraging; equation 4); dotted line threshold for colony survival.

Figure 4. Example of colony dynamics over three years with a yearly event where 50% of workers were removed on 1st June (Fixed Worker Mortality Scenario). (A) Colony size; the red vertical line shows the colony size on 31 December after 3 years of consecutive exposure events, which is used as endpoint in other graphs. (B) Honey stores. X-axis time; dotted lines indicate exposure events. Distance: between colony and forage patch [m].

Figure 5. Overwintering size of the colony when different proportions of workers were lost (Fixed Worker Mortality Scenario). Y-axis: overwintering colony size (number of workers on 31 December) after 3 years of consecutive exposure events. X-axis: proportion of foragers and in-hive bees removed. The dotted line shows EFSA's (2013) protection goal of 7% reduction of colony size. Distance: between colony and forage patch [m]. Legend colours indicate the month of exposure (1st day of month)

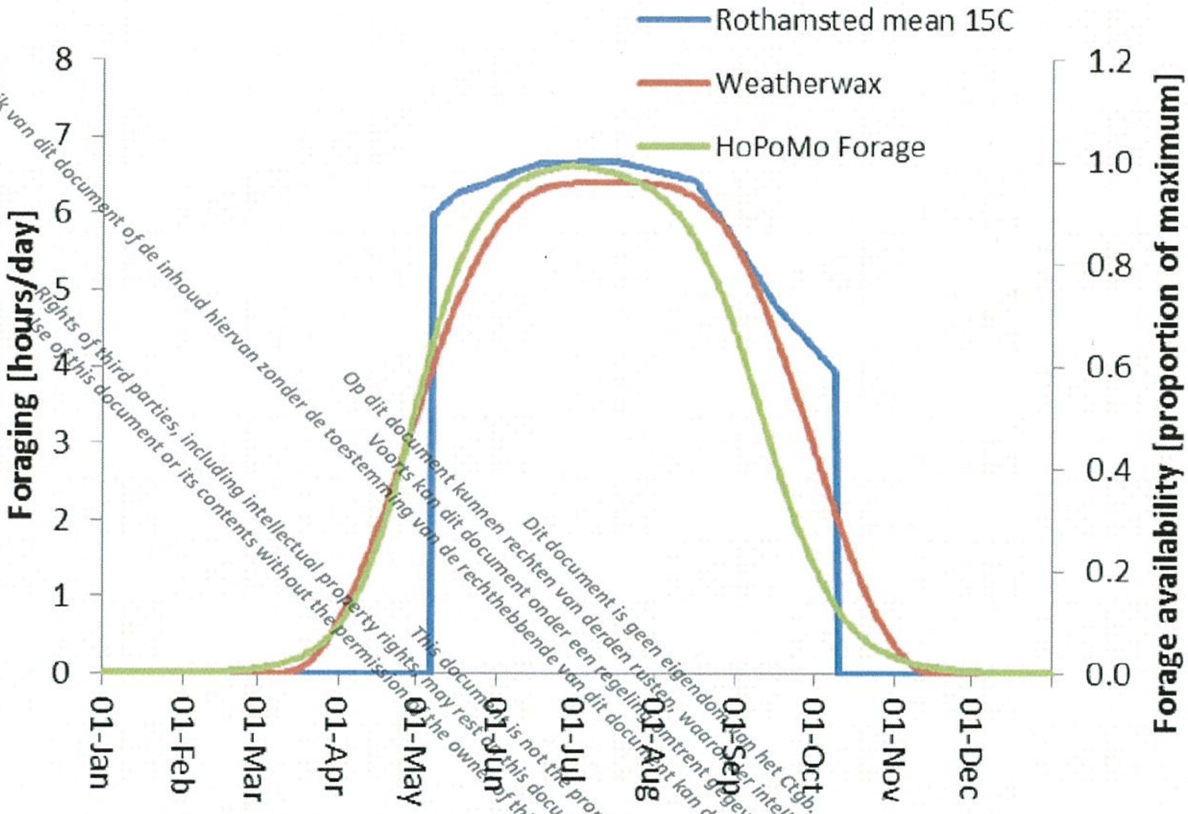
Figure 6. Overwintering size on colony when a given cumulative fixed mortality was distributed over different durations. Exposure started 1 June. Y-axis overwintering colony size (workers on 31 December) after one year with one exposure event. X-Axis: total mortality [proportion of workers removed; no unit], legend: number of days the total mortality was distributed over [days].

Figure 7. Colony overwintering size at different exposure durations and mortality levels for foraging trips (Forager Mortality per Trip Scenario). Y-axis: colony overwintering size (workers 31 December) after 3 years of consecutive exposure events. X-axis: Mortality factor, i.e. a multiplication factor that the control background for each trip is multiplied by. Legend colours indicate exposure start (1st day of month_. Distance: between colony and forage patch [m]. Exposure duration the number of days exposure lasted for.

Figure 8. Mitigation effect of adding additional unexposed forage to the landscape (Landscape Mitigation Scenario). The mortality factor per flight was set to 5 times the control for the exposed patch. Y-axis: number of workers. X-axis day in year. Legend colour: control: no exposure and no mitigation patch, No mitigation: exposure but no mitigation patch, 50m-1000m distance between colony and mitigation patch. The mitigation patch had 10% of the nectar and pollen flow of the control. The control and exposed patches were placed 1000m from the colony.

Table 1. Colony size (workers on 31 December after 3 years of consecutive exposure events). Grey shading indicate more than 10% reduction in overwintering colony size. Treatment day: start of exposure. Treatment period: duration of exposure in days. Mortality factor: factor control mortality per flight was multiplied by (1: control). The forage was placed 1000 m from colony.

| Treatment day | Treatment period | Mortality factor | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 | 10 |
| 1st April | 1 | 19845 | 20103 | 19636 | 19680 | 19671 | 19713 |
| | 3 | 19845 | 20787 | 19317 | 19758 | 19453 | 19146 |
| | 7 | 19845 | 19882 | 19752 | 19865 | 19346 | 14230 |
| | 14 | 19845 | 19860 | 19183 | 18731 | 15886 | 3994 |
| | 30 | 19845 | 20124 | 17853 | 14792 | 8507 | 1215 |
| 1st May | 1 | 19730 | 19713 | 19601 | 19787 | 19737 | 19961 |
| | 3 | 19730 | 19849 | 19844 | 19643 | 19896 | 19269 |
| | 7 | 19730 | 19294 | 19410 | 19831 | 18930 | 17580 |
| | 14 | 19730 | 19508 | 19597 | 18388 | 18799 | 16376 |
| | 30 | 19730 | 19289 | 17988 | 11723 | 9330 | 0 |
| 1st June | 1 | 19977 | 19649 | 19994 | 19914 | 19209 | 19966 |
| | 3 | 19977 | 19587 | 19784 | 19544 | 19832 | 19525 |
| | 7 | 19977 | 19423 | 19564 | 19790 | 18926 | 15785 |
| | 14 | 19977 | 19852 | 18985 | 17045 | 16226 | 5726 |
| | 30 | 19977 | 18584 | 11786 | 2511 | 0 | 0 |
| 1st July | 1 | 19651 | 19960 | 19541 | 19907 | 19695 | 19860 |
| | 3 | 19651 | 20322 | 19903 | 19616 | 20004 | 19733 |
| | 7 | 19651 | 19636 | 19541 | 18611 | 19187 | 18422 |
| | 14 | 19651 | 19816 | 18583 | 17631 | 16521 | 13641 |
| | 30 | 19651 | 18297 | 14445 | 6735 | 0 | 0 |



Rothamsted mean 15C
Weatherwax
HoPoMo Forage
Foraging [hours/day]
Forage availability [proportion of maximum]
0
1
2
3
4
5
6
7
8
0.0
0.2
0.4
0.6
0.8
1.0
1.2
01-Jan
01-Feb
01-Mar
01-Apr
01-May
01-Jun
01-Jul
01-Aug
01-Sep
01-Oct
01-Nov
01-Dec


**Figure 1**

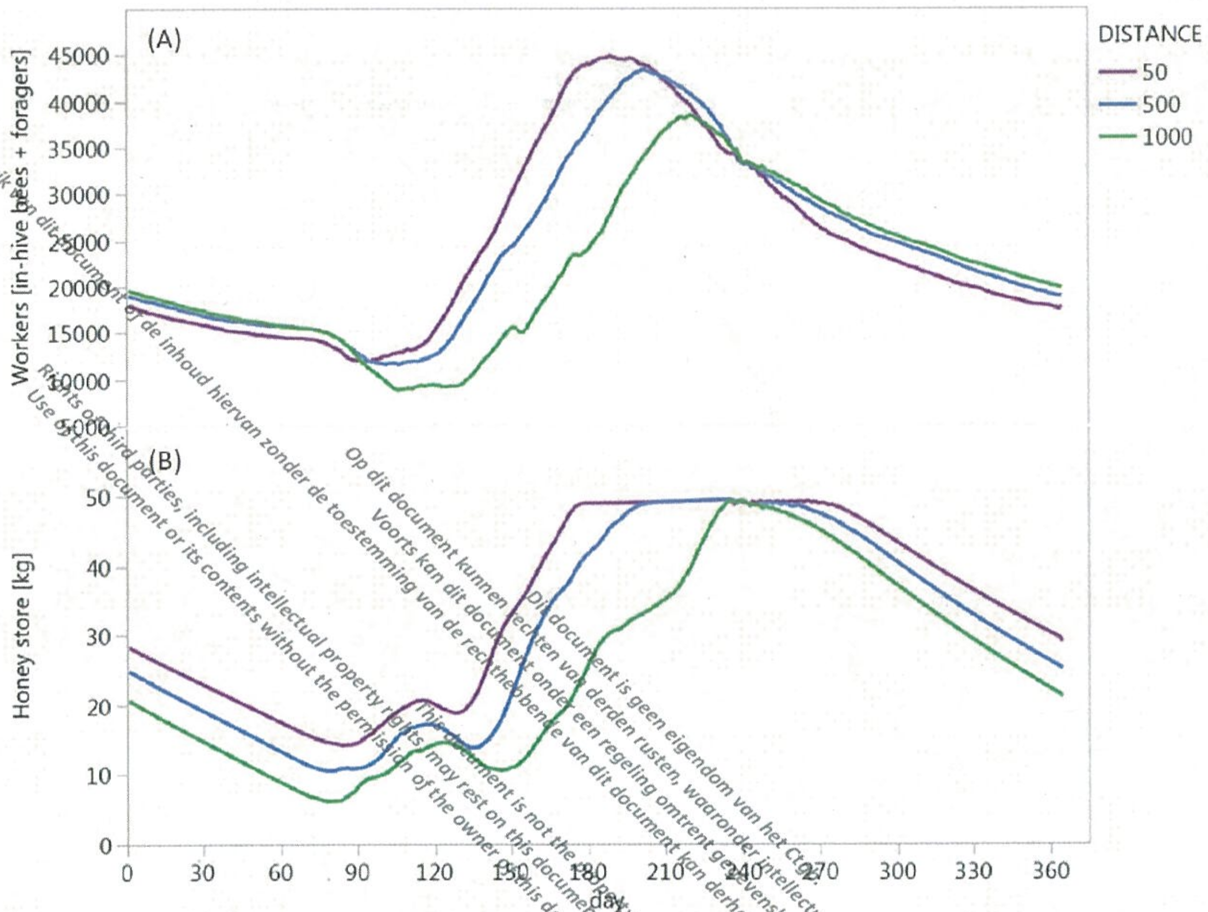
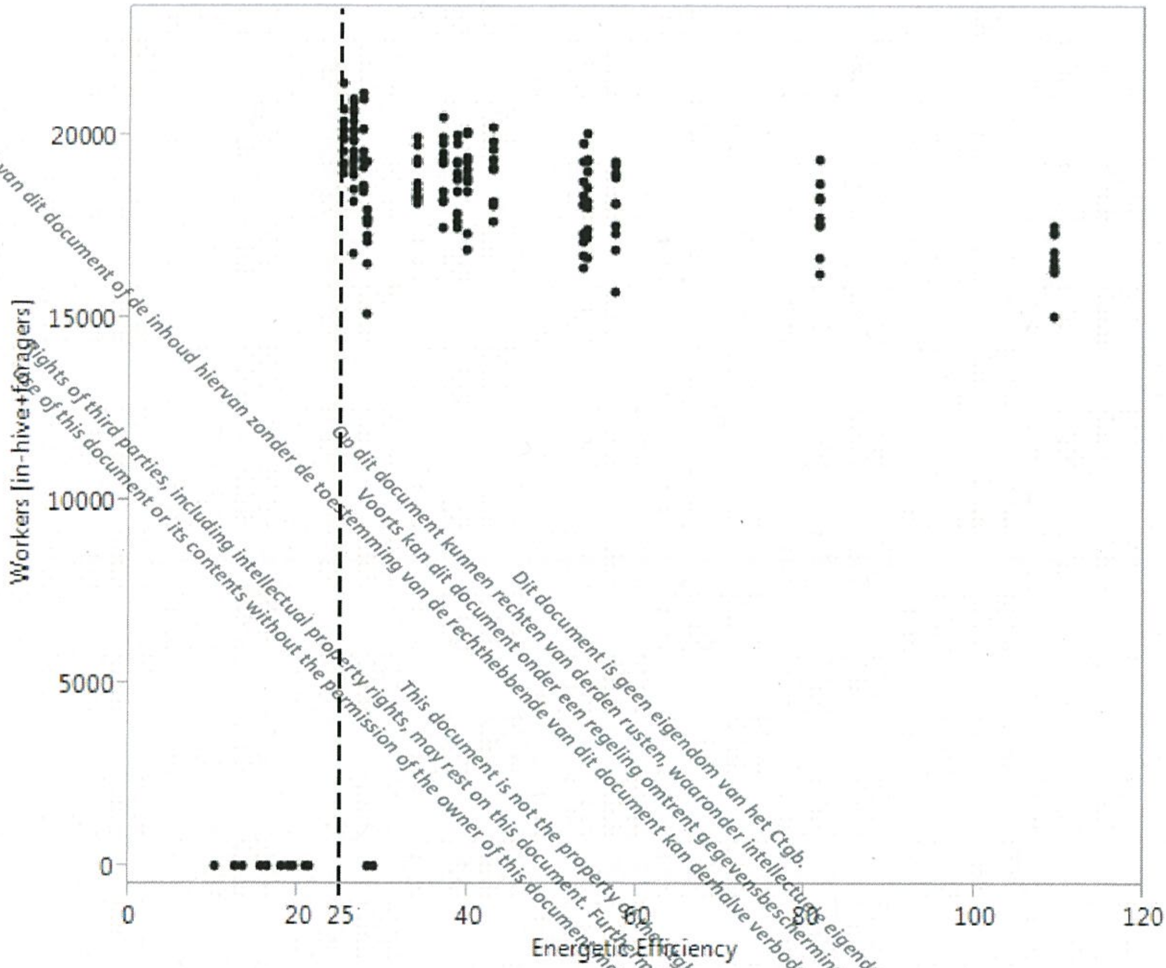

(A)
(B)
Workers [in-hive bees + foragers]
45000
40000
35000
30000
25000
20000
15000
10000
5000
Honey store [kg]
50
40
30
20
10
0
0
30
60
90
120
150
180
210
240
270
300
330
360
day
DISTANCE
50
500
1000

**Figure 2**



20000
15000
10000
5000
0
Workers [in-hive+foragers]
0
20
25
40
60
80
100
120
Energetic Efficiency


**Figure 3**

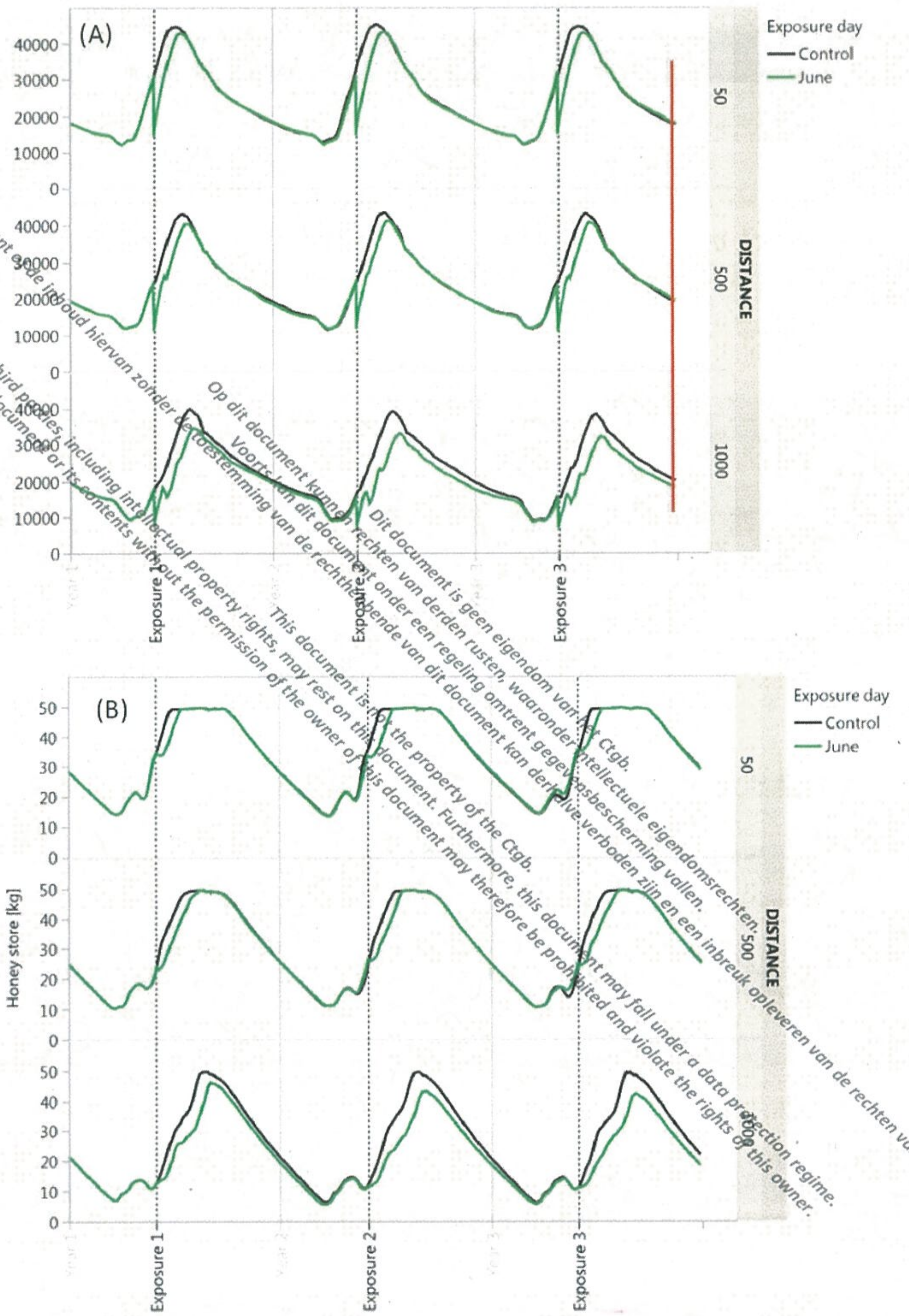

(A)
Exposure day
Control
June
DISTANCE
50
500
1000
Workers [in-hive bees + foragers]
Exposure 1
Exposure 2
Exposure 3
(B)
Exposure day
Control
June
DISTANCE
50
500
1000
Honey store [kg]
Exposure 1
Exposure 2
Exposure 3



**Figure 4**

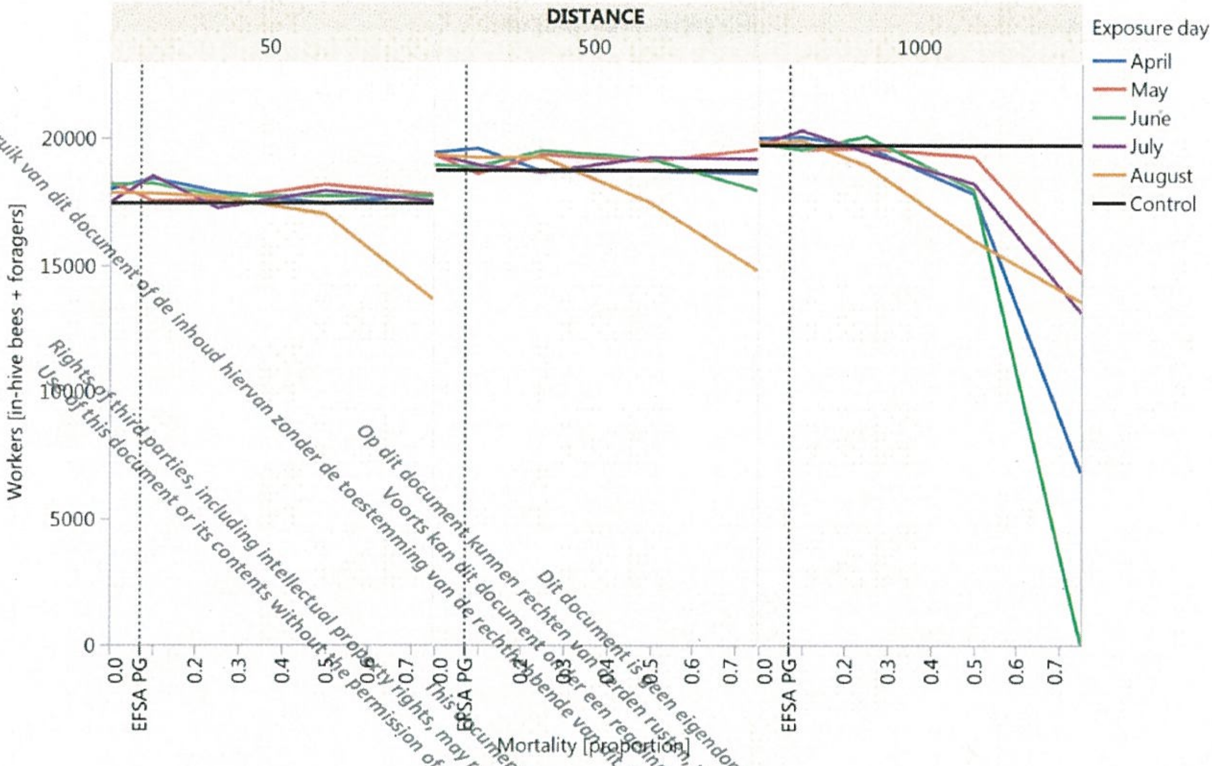

DISTANCE
50
500
1000
Exposure day
April
May
June
July
August
Control
Workers [in-hive bees + foragers]
20000
15000
10000
5000
0
0.0
EFSA PG
0.2
0.3
0.4
0.5
0.6
0.7
Mortality [proportion]

**Figure 5**

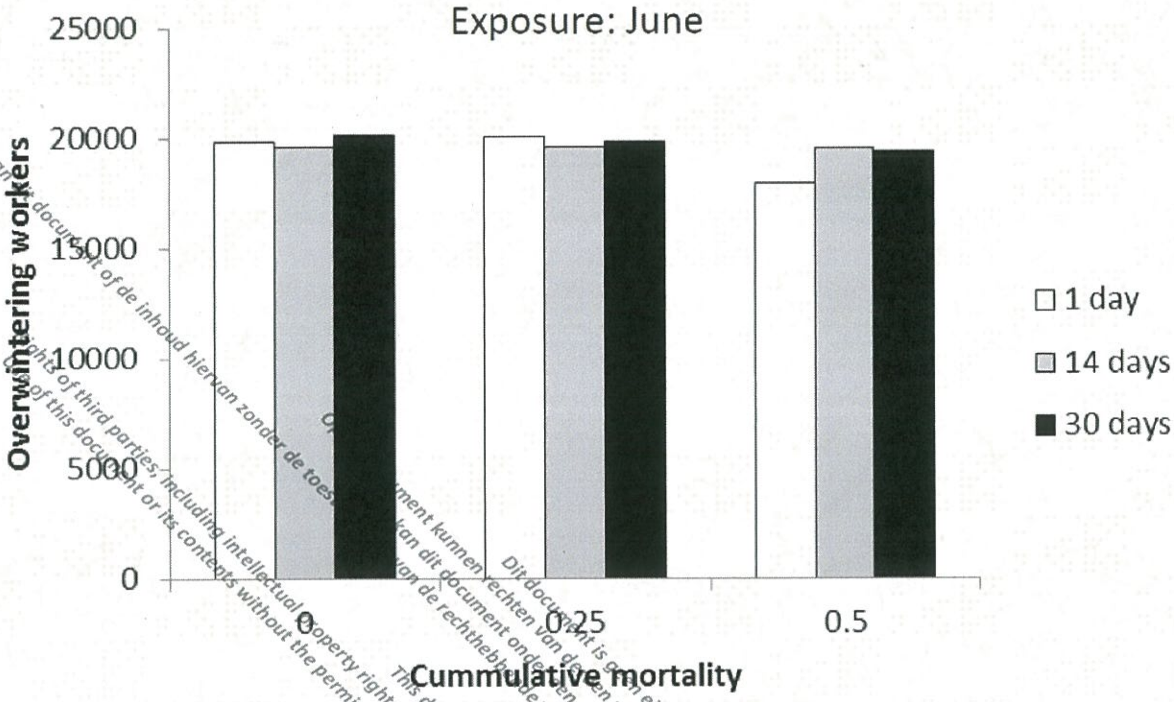
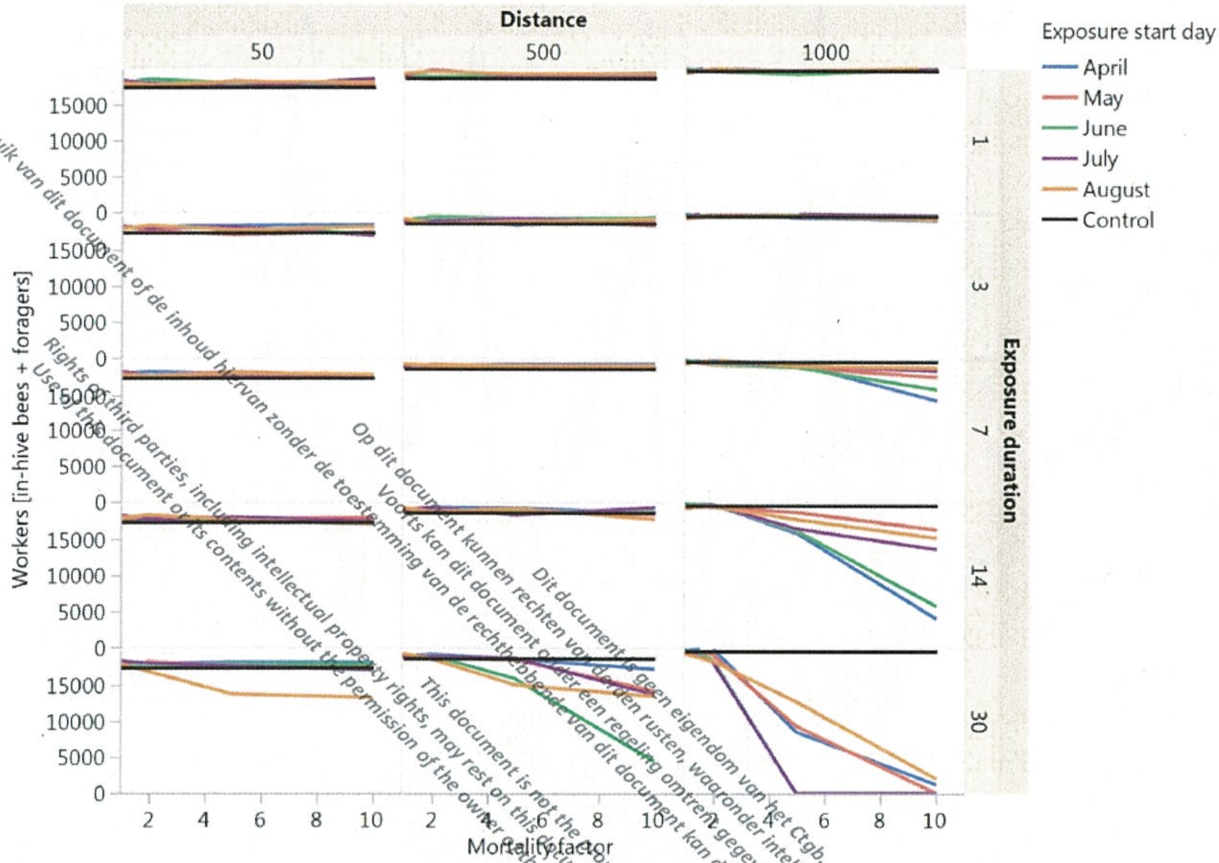
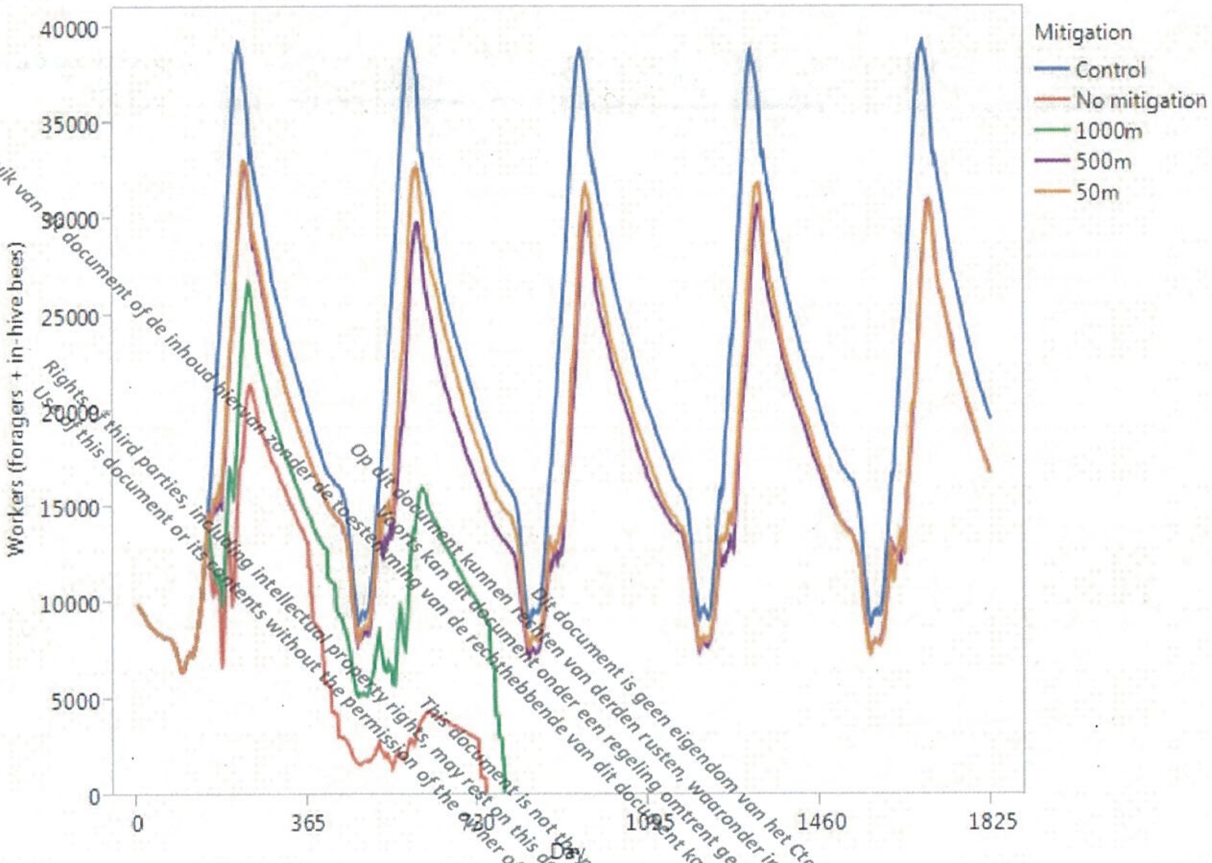

Exposure: June
Overwintering workers
25000
20000
15000
10000
5000
0
0
0.25
0.5
Cummulative mortality
1 day
14 days
30 days

**Figure 6**



Distance
50
500
1000
Exposure start day
April
May
June
July
August
Control
Exposure duration
1
3
7
14
30
Workers [in-hive bees + foragers]
15000
10000
5000
0
Mortality factor
2
4
6
8
10


**Figure 7**



Mitigation
Control
No mitigation
1000m
500m
50m
Workers (foragers + in-hive bees)
40000
35000
30000
25000
20000
15000
10000
5000
0
0
365
730
1095
1460
1825
Day


**Figure 8**

**Van:** [redacted]
**Verzonden:** 07 June 2016 14:52
**Aan:** [redacted]
**Onderwerp:** RE: mei_2016_ctgb_comments_on_com_implementation_.docx

Hoi [redacted]

Zie attached mijn input; ik kon niet goed aansluiting maken op jouw stuk over de protection goals dus heb jouw tekst doorgestreept :-)  Voel je uiteraard vrij om dat terug te veranderen of er een andere draai aan te geven.

De industrie-referentie kon ik niet plaatsen; ik had het over een referentie die aangaf dat de 7% bovengrens voor de effecten vervangen kan worden door een 20% bovengrens; dat houdt echter ingrijpen in in het specific protection goal en dat is voor de trigger discussie voorlopig een brug te ver, lijkt mij.

Groeten van [redacted]

---

**From:** [redacted]
**Sent:** 07 June, 2016 12:23
**To:** [redacted]
**Subject:** mei_2016_ctgb_comments_on_com_implementation_.docx

Hoi [redacted],
Dit heb ik er tot nu toe van gemaakt. Leek me handig om alvast naar jou te sturen. Ik ga het straks zelf ook nog een keer goed lezen. Bij de gele dingen hoop ik dat jij iig input kunt leveren en alle verdere commentaar is ook welkom!
Groeten [redacted]

**Van:** [redacted]
**Aan:** [redacted]
**Cc:** [redacted]
**Onderwerp:** RE: overleg EU Bijen GD Locatie Ede/ Wageningen
**Datum:** maandag 6 juni 2016 17:06:22
**Bijlagen:** [redacted]

---

Beste deelnemers aan dit overleg morgen,

[redacted] hadden voor de vorige SCoPAFF-vergadering, waar de voortgang van dit bijen-guidance op de agenda stond, al bijgevoegd Ctgb-commentaar voorbereid. Inmiddels is dit document nogmaals geupdate.
Ik stuur dit jullie nu toe als handvat en ter voorbereiding op ons overleg morgen. Met excuses voor deze enigszins late actie!
En met dank aan [redacted]

Tot morgen,
groet, [redacted]
[redacted]

*Beleidsmedewerker / Policy officer*
Ctgb
College voor de toelating van gewasbeschermingsmiddelen en biociden
Board for the Authorisation of Plant Protection Products and Biocides
Bezoekadres / visiting address:
Bennekomseweg 41, 6717 LL Ede
Voor navigatie gebruik *Horapark*
Postadres / postal address:
Postbus / P.O. box 8030, NL-6710 AA Ede, The Netherlands
T [redacted]
M [redacted]
E [redacted]
I www.ctgb.nl

---

**Van:** [redacted]
**Verzonden:** maandag 30 mei 2016 13:52
**Aan:** [redacted]
**CC:** [redacted]
**Onderwerp:** overleg EU Bijen GD Locatie Ede/ Wageningen
**Urgentie:** Hoog

Geachte genodigden,

Als het goed is heeft u betreffende bovenstaand onderwerp al bericht ontvangen van [redacted].

Op verzoek van [redacted] treft u bijgaand een datumbriefje voor het plannen van een overleg Bijen GD.

Helaas zijn de mogelijkheden zeer beperkt, desondanks hoop ik dat u tijd kunt vrijmaken.

Wilt u zo vriendelijk zijn uw beschikbaarheid in te vullen en deze zo spoedig mogelijk retour te sturen.

Hartelijk dank voor uw medewerking.

Met vriendelijke groet,

[redacted]
Management assistent

Ministerie van Economische Zaken
Directie Plantaardige Agroketens en Voedselkwaliteit
Bezuidenhoutseweg 73 I B-zuid 4e etage I
postbus 20401 I 2500 EK DEN HAAG
Tel.: [redacted]
Mob.+ [redacted]

Let op! Bij bezoek aan het ministerie dient u in het bezit te zijn van een geldig legitimatiebewijs!

**Mei 2016**
**Ctgb comments on the proposal for implementation of the EFSA 2013 (revision 2014) Guidance document for RA of bees:**

Regarding Annex A:

1) Perhaps it is good to note that if the parameters of Appendix O are taken into account, very few to none of the current field and semi-field tests for bees will be acceptable for use in risk assessment. In addition, there is, as of yet no means to address this in such a way that field and semi-field tests would be feasible.
2) Currently the FOCUS run-off scenario is not in use, thus the environmental Fate sections would have to decide on agreed upon inputs and formats for outputs before Jan 2017. It is possible that coming to a harmonized agreement for these might take longer than that (taking into account the summer holidays).
3) 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).

Regarding Annex B:

1) As a general point, we note that many of the topics listed in Annex B need more work before they can be implemented (see comments below). 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 harmonized way. We recommend that an expert working group is set up a.s.a.p. in which scientists but also risk assessors work on the sections of the guidance document that need further development.
2) Another general point is that 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.
3) 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...
4) Considering the problems with methodologies for appropriate honey and bumble bee field tests according to Appendix O, it seems unlikely that adequate solitary bee (semi) field methodologies (according to Appendix O) will be available by January 2018.
5) 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.

6) 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.
7) 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 was ever made)?
4) It is not clear how a risk assessment can be performed adequately without a protection goal for bumble bees and solitary bees. In that situation the outcome of the risk assessment will always be unclear. We suppose this means that the protection goals for honey bees will be used, however, since these were very specific to honey bees, this seems inadequate.

General:

We note that even when substances are tested/show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. It might be relevant to discuss ways to address this once the Guidance is implemented in January 2017.