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. It is mentioned that for plant protection products submitted after 15 October 2016 part of the chapters of the Guidance as listed in Part A should be used. Whereas Part A of the Annex of the Commission Note mentions the date of 31 January/October 2017.

Regarding Annex A:

1) Almost all substances (including herbicides and fungicides) fail the first Tier risk assessment. This is expected to have an enormous impact on the availability of PPP. Thus, the Tiered approach of the GD is not adequate. A Tiered approach should filter out part of the substances so that only those substances for which an actual risk is expected go to the higher Tier. The problem is caused by the trigger for the chronic oral risk assessment, which is so low that even when substances show no effect at limit doses, they do not usually pass the honeybee chronic oral assessment. New information shows that the chronic oral trigger is set too conservatively. The trigger is based on an assumption of background mortality which is debatable and being tested in the Netherlands at this 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).