Concept

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

August 2018

The NL supports the adoption of the EFSA Guidance (2013, revision 2014). The Guidance can be implemented so long as a harmonized approach is taken to address those areas of the Guidance which are not yet feasible. Therefore, we also support the Commission's proposal on the time-frame for implementation of the Guidance. However, we note that a large amount of work must still be done in order to have a workable Guidance by the envisaged date of implementation. To that end, please see our comments on the planned time-frame, below.

General points

1) It is not advisable to describe lower-tier trigger values (like the acute oral toxicity ETR trigger of 0.2) in the Uniform Principles. Historically, the Uniform Principles have specifically mentioned first tier trigger values, however, more recent science supports deviation from this path: The EFSA protection goal 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 the EFSA protection goal opinion). In practice, this means that lower tiers (trigger values) may need to be updated to keep pace with scientific developments. Referring to the required protection level rather than a specific trigger value will allow the necessary flexibility in updating the risk assessment.

2) The Guidance Document(GD) does not contain an adequate Tiered approach, as **almost all substances fail the first Tier, even for honeybees**. This can be rectified if the chronic oral trigger is revised before implementation. *See further explanation in comment A.1.*

3) The important refinement option of semi-field and field tests for honeybees will be become unavailable if the GD is strictly followed. We propose revision of these protocols and dealing with the existing tests in a harmonized way in the interim period. *See further explanation in comment A.2.*

4) Many of the actions listed in Annex B are dependent upon the development of "internationally agreed protocols". As a result, adequate implementation of the Guidance will require that this work be given high priority and a concrete planning schedule , especially if these topics are to be assessed among Member States in a harmonized way. We recommend that an expert working group be established as soon as possible, in which scientists and risk assessors work to develop the guidance document further. *See further explanation in comments A.2 and B.2-3.*

5) The protection goals for bumble and solitary bees are currently based upon those for honey bees. If risk assessments for bumble and solitary bees proceed under this assumption, as is proposed in the current draft of the implementation timeline, **most applications for plant**

[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.

protection products will be rejected. As a result, we consider developing protection goals for bumble and solitary bees to be an extremely important action for which concrete deadlines should be set, rather than being an action set for the "next future". *See further explanation in comment C.2.*

Regarding Annex Part A:

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

[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

Fate sections come to a harmonized agreement on formats for outputs before June 2019.

Regarding Annex Part B:

1) The statement on the repeated exposure test beyond pupation can be removed from part B, as the OECD GD 239 includes emergence of pupae.
2) For guttation, scientific studies are needed to assess the probability of occurrence of guttation water in combination with the probability of use of guttation water by the bees (as is correctly pointed out in this annex). To the best of our knowledge nobody is working on these matters so it is very unlikely that these studies are finalized before the proposed implementation deadline of 30 June 2021. We recommend a concrete timeline be established to address the remaining questions surrounding guttation in order to ensure that implementation will be possible in the near future. Since adequate risk assessment is not possible without this information, we recommend to change the implementation date of the guttation risk assessment to 'once the necessary scientific information has been gathered and incorporated into a risk assessment methodology'.
3) The extrapolation of residue trials is a topic for which more guidance is needed and we therefore recommend it be moved to Part C.
4) A screening step for honeydew might not necessarily require "protocols", but would require a risk assessment framework. The potential toxicity is covered by the existing tests and only a framework for estimating exposure should be produced. This should be updated. Also, we note that since honeydew is not included in the current (2014) version of the Guidance, it is unclear what to do if a screening step does not pass. Would the next step be risk mitigation? Is there some refinement? If refinements or mitigations are possible/the next step, this would presumably also have to be placed here in Annex B.
5) A "re-consideration of the safety factor", as stated in the draft implementation timeline for chronic and larval bumble bee, should be expedited if the implementation deadline of 30 June 2021 is to be met. **If the risk assessment is performed using the current safety factors it will fail in most cases and many applications will have to be rejected**. The same holds true for the solitary bee risk assessments. This comment goes hand in hand with the development of a protection goal for non-*Apis* bees (see general comment 5 and comment C.2).
6) Many of the actions listed in B are dependent upon the development of "internationally agreed protocols". To ensure that the use of protocols is harmonized among Member States, we recommend that an expert working group be established as soon as possible, in which scientists and risk assessors agree on which (draft) protocols can be used from which timepoint on. This can be the same working group as mentioned under comment A.2.
7) Since implementation dates mentioned in the third column are either 30th June 2021 or 'one year after availability of internationally agreed protocols' this second implementation date should be also be added to the title of Part B.

Regarding Annex Part C:

1) The actions listed in Annex C are vital to the adequate implementation of the GD and should be started as soon as possible. We therefore suggest that Part C be called "Proposed ongoing actions" to better indicate that they should begin as soon as the implementation timeline is adopted.
2) **As mentioned above, we consider the development of detailed protection goals for bumble and solitary bees to be vitally important.** Both the effect and exposure goals in the GD are not

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