Bee GD revision

Comments from the Northern Zone

TC 5 Oct 2022

General comments/observations

▶ Throughout the GD there is background information provided that is more suitable/relevant in a Supplementary Document. **Please edit the GD for the sake of clarity and in order to keep the GD as short, useable and streamlined as possible.**

▶ Please explicitly state in the GD that the EU Commission has promised that the SPGs for bumble bees and solitary bees will be revised in the future when enough appropriate data and model(s) exists, this revision should also include all relevant parts of this GD.

▶ Please consider adding a chapter like the chapter 2 in the Aquatic GD (executive summary for everyday use in the risk assessment).

▶ **The Bee GD does nowhere refer to a calculator tool. NZ strongly recommends to have a calculator tool ready and available at the time of implementation (similar to BeeTool3).**

Data requirements Reg. (EC) 283/2013 and 284/2013 (6.1.1)

► NZ propose to clearly state that where Regulation (EU) No. 283/2013 and 284/2013 refers to "bees" without specifying "honeybees", the established interpretation is that studies with *non-apis* bees are also relevant when EU-agreed test guidelines are available e.g. acute studies with bumble bees.

Lower tier risk assessment of bumble bees and solitary bees

It is unclear how to perform lower tier risk assessment for bumble bees and solitary bees.

▶ How are the studies required from the data requirements on bees to be used in a lower tier risk assessment? Acute contact and oral BB test (OECD TG 246 & 247) and more OECD TG for *non-apis* bees are on the way.

▶ In case of no lower tier risk assessment is included in the GD (due to the selection of an undefined SPG), then how can MS justify to request the hazard studies mentioned above

Lower tier risk assessment of bumble bees and solitary bees

Chapter 7.3: *"As mentioned in Section 3.1, the magnitude dimension of the SPG for bumble bees and solitary bees was discussed by risk managers on the basis on the consolidated evidence provided by EFSA (EFSA, 2022). MS risk managers agreed to select the option of 'undefined threshold' of acceptable effect indicated in the EFSA document (EFSA, 2022), and to require more frequently higher tier data allowing a better protection of these bee group, in the current absence of knowledge. Based on an 'undefined threshold', a lower tier risk assessment scheme cannot be implemented since there are no values which would allow to interpret any quantitative lower tier outcome. "*

▶ Does "more frequently higher tier data" in reality mean "higher tier data is required for all product uses where bees are likely to be exposed"?

Higher tier risk assessment bumble bees and solitary bees

- ► Challenging higher tier RA due to lack of validated guidelines for field testing (Annex B, chapter 11).

    - A concern is that higher tier field tests will result in low-risk conclusion when there is a risk, as there are no test guidelines. Will a submitted study be able to detect effects?

    -In section 2.2 it is stated that the concept of risk levels can obtain more harmonized evaluations. However, this comparison is only possible if studies has been performed under similar conditions using comparable test methods. Without agreed test methods, which are to date missing, comparison of studies is difficult.

    -Annex C, chapter 2 gives a good statistical overview of why it would be possible to check if a study can detect effects etc. However, this is very complicated, and both the statistics and the tests themselves will take many resources for applicants, and then also for the evaluators (time and resources).

- ► Annex C chapter 2.3 needs to be complemented with guidance on how to draw conclusions on acceptable risk based on the identified risk levels.

Extrapolation between species (6.5)

- Will the high extrapolation factors (*Tef*) of SB (> 400) prevent the differentiation between high and low risk substances? And how can *Tef*s be implemented if HB use defined SPG and *non-apis* bees have undefined SPGs.

  - **How are the extrapolated values to be used for a lower tier risk assessment with an undefined SPG?**

Pre-flowering factor (PFF) (5.3.3)

- Tier 1: Propose to use the FOCUS GD interception values instead of the proposed overly conservative interception values.

- Practical challenge: The PFF requires that it is known how many days before flowering a pesticide application is made. This is currently not stated on GAP tables as normally only the BBCH is given. The time each crop stays in a given BBCH stage depends on "degree days". Therefore, this cannot be known or generalized to the degree of details that the PFF concept requires in the GD.

- **Table 12: Propose change days to BBCH-stages.**

Landscape factor (5.3.7)

Bees do not forage randomly in the landscape but focus preferentially on a single attractive field depending on abundance of pollen and nectar. It is difficult to cover the range of realistic situations that may occur in the field.

By allowing LF studies, we are likely to underestimate the exposure of bees (risk assessment should be a realistic worst-case assessment), and the extrapolation possibilities for these studies are very limited (geography, climate, season, crops in the area etc.). **Please exclude the possibility to submit LF studies and please consider to take the LF out of the GD.**

Note that the LF may only be considered for honeybee adult chronic and the honeybee larva (all other risk cases LF = 1).

Conclusion

Honeybees

▶ Risk assessment with the defined protection goal is possible

▶ We would welcome an edited version considering all comments and a calculator tool

Bumblebees and solitary bees

▶ No apparent lower tier RA

▶ The GD does not support a RA with undefined SPG for non-apis bees

▶ It is unclear if the tests required according to the data requirements will be used