05 October 2022

Wrap-up of the day

Trusted science for safe food

efsa
European Food Safety Authority

Joint introduction by SANTE and EFSA

- Highlight effort from all actors involved, both in terms of scientific/technical work, but also in terms of collaboration/engagement
- Expressed the wish that everyone co-operates in order to have a swift adoption of a tool that will allow a better consideration of the risk to bees compared to the current one.
- "Do not let 'perfect' to be enemy of 'good'"
- EFSA further presented
  - How ToRs in the mandate have been addressed
  - Elements of novelty in the revised GD
  - Plan for next steps

Southern zone feedback

- Acknowledged the effort of the WG
- Had mainly points on the scope of the GD (microbials?), and its relation to risk mitigation options (indirect effects/interface between RA/RM)
- Further point related to the lack of experience with the equivalence testing (need for calibration/testing)
- Introduction of new parameters for exposure estimation is welcome (particularly by HR)

Central zone feedback

- Document was considered scientifically strong
- CZ organised internally in a structured manner and conveyed feedback on a clear scale of priorities
- Key topics for which improvement is envisaged include (but are not limited to):
  - TRT scheme
  - LF use in the tier-1
  - need for a methodology to address BB risk in greenhouses
  - streamline/tool-aid for mixture toxicity
- For most of these aspects, a proposal for amendment was also made
- Proposal to organised a workshop/training to facilitate a harmonised application of the new methodology
- Inter-species extrapolation: majority of MS are willing to accept a higher level of uncertainty for the time being in order to have an implementation. Other MSs consider the current state of knowledge insufficient for a risk assessment methodology.

Northern zone feedback

- Acknowledged the effort of the WG, but would have liked to have today's presentation before the PC.
- Criticism on the structure of the GD, which they would like to streamline as much as possible, pushing more information to the supporting document and /or appendices.
- Would like to have an executive summary inspired by the one contained in the AGD.
- Would like to have some clear statement in the GD concerning the SPG and the interpretation of data requirements for non-*Apis* bees.
- Consider that the current lower tier assessment for non-*Apis* bees is unclear (no strict high/low risk), nor when higher tier studies should be requested.
- Concerns about the use of LF, PFF, deposition values, Tef used in tier-1.
- Have further concerns about higher tier studies for non-*Apis* bees concerning representativeness/extrapolation, power to detect effects, lack of standardisation, and complexity in their interpretation

Overall take-home from MSs

- The core science underpinning the GD was mostly not challenged
- Most comments relate to the translation into a process that is workable while compliant with the SPG
- Overall feeling is that:
- Risk assessment for HB is OK
- Risk assessment for non-*Apis* is more problematic, both at the lower tier and at the higher tier -> reflects the lack of a clear SPG -> reflects weaker scientific knowledge.

CropLife/SeedEurope/IBMA feedback

- Acknowledged the effort of the WG, also in the reporting of the background information. This posed however a challenge for the commenting.
- Wish to have further space for interaction, in terms of providing more information, and work on case studies; wish to be included in further developments (e.g., workshop envisaged in the morning with MSs)
- Reiterate that more clarity would be needed for understanding what data to provide for non-*Apis* bees. The suggestion is to use a tiered approach of HB and request experimental data for SB and BB only if specific concerns are highlighted.
- Concerns about the need to re-do testing due to the change in the requirement for the parameters that feeds into the risk assessment.
- Concerns about several aspects of the GD concerning realism lower tier; sublethal effects; 1:1 propagation from individual to colony level; high complexity already at the lower tier; higher tier studies interpretation (including Exposure Assessment Goals); use of modelling; statistical and data analysis carried out in several part of the GD;
- Welcome the exclusion of microorganism, but would wish to have some more clarity on semiochemicals and natural substances.

PAN/Apimondia/Pollinis/BeeLife feedback

- Acknowledged the enormous work performed by EFSA: improvement in risk conceptualisation, literature review and calculation
- A prompt implementation is envisaged
- A better use of graphics could help improve the accessibility of the whole text
- Many concerns raised regarding several points:
  - Undefined threshold for BB and SB: proposal is to use 3% for SB/BB in higher tier
  - Lack of drive for generating new data for wild bees
  - Increase reliance on models whose validation status was questioned
  - Challenged the hierarchy of the tiered approach: all tiers should have the same weight, especially field test should not be taken as the reference tier
  - Disproportional effort put on exposure assessment compared to effect
  - Tank mixture consideration is missing, while the methodology used for metabolites is not optimal
  - Several routes of exposure which are currently not accounted must be considered
  - MAF should be considered
  - Risk mitigation should not be considered in the risk assessment process
  - MDR threshold for synergy of 3 should be lowered to 1.5
  - Testing should be strengthened and made mandatory especially for SB and BB, which should also include consideration of sub-lethal effects and prolonged tests.
- Non-standard independent studies should be accounted for

Copa-Cogeca/CIBE feedback

- Support the evidence-based approach taken by EFSA
- Concerns related to no positive impacts being detected across EU after neonics ban. Argue that a risk-benefit analysis should underpin the whole process including measuring the positive impact of the change in the risk assessment.
- Challenged the exposure assumption despite the effort put in place by farmers to minimise contamination and exposure to bees in and off-field.
- Asked the implication of the application of the GD on the availability of PPP, especially for low-risk substances, minor uses, etc.
- Questioned the realism of the 'edge of field' scenario. Assumption used in the exposure assessment are considered too worst-case (weeds, succeeding crop).
- Welcomed the possibility to account for mitigation measures.
- Not fully satisfied with the crop categorisation, lack of clarity in the crops 'usually harvested before flowering'. The same species used for seed production or not should be treated as separate crop.
- Welcomed the introduction of PFF, LF, and Bsf

Overall take-home from stakeholders

- The effort made by EFSA was acknowledged in terms of adopting a data-driven approach and in terms of transparency in the reporting
- Concerns were anyway raised by all stakeholders
- Clear difference in perspective
  - predicted level of exposure/effects is too worst-case vs. should be made more conservative
  - Envisaged testing strategy is potentially too demanding vs. not yet adequate
- Worries that the complexity of the whole scheme would be burdensome
- The implication for the authorisation process from the lack of a defined thresholds for BB and SB raised concerns from all sides, and different proposal were made to overcome this
- There is the need to further see through the implication of the application of the GD on the authorisation process, despite the effort made by the WG to provide an impact assessment on ~7000 uses and ~180 different substances

Main discussion points and clarifications

- TRT
- Landscape factor
- Mixtures
- Calculator
- How to deal with the undefined threshold
- Consideration of higher tier studies
- Build together on the acceptability of the study design for higher tier experiments
- Status of model validation used in the risk assessment and proposal to use it for combining effects at the colony level
- Weeds scenario
- Academic science vs. regulatory science
- Appropriateness of tiered approach