# Feedback to the open consultation EFSA Bee Guidance Document

[redacted] (BeeLife)
On behalf of PAN-Europe, Apimondia, Pollinis and BeeLife

Pesticide Action Network Europe

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POLLINIS

BeeLife
European Beekeeping Coordination

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# Objective of Regulation EU 1107/2009

Authorise pesticides as far as **human, animal health and the environment are protected**

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# Objective of (Environmental) Risk Assessment

Evaluate the data generated by industry (and independent science) in view of protecting the environment

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# General comments

Acknowledge the hard work performed by EFSA staff and related scientists -> Improvement in risk conceptualisation, literature review and calculations.

**CONCERNS** (reduction in bee protection):

1. RISK MANAGEMENT: Undefined threshold (BB, SB):
   - allows space for different interpretation of tests results.
   - does not meet the precautionary principle concept and the fact that BB and SB need higher protection than HB

   CONSEQUENCES FOR RA: BB and SB can be used in higher numbers. EFSA to ensure **statistical power to detect at least 3% significant difference between control and tested group**.

2. LACK OF COHERENCE: Despite the lack of data recurrently argued by EFSA, interpretation of Regulation not to **increase data availability to calibrate the models proposed**.

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CONCERNS:

3. **INCREASE RELIANCE ON MODELS**, based on assumptions -> Validation of models? Models screened by modelling experts? Experience shows that models are not able to properly predict reality. E.g. FOCUS models keep being used despite the fact pesticide residues found in the environment exceed what FOCUS models predicted.

4. Despite a general increase in scientific knowledge on bee tests, **EFSA 2022 proposal is a step back with regards to EFSA 2013 for a series of aspects**, e.g. sublethal tests (homing flight, HPG…), BB and SB testing

5. The draft guidance **keeps basing itself on LD50**. This is much less precautionary than NOAEL or LD10.

6. **FIELD TEST AS REFERENCE TIER IS AN ERROR**. It is not supported by science as being a better option, neither by facts (on the contrary, the neonicotinoid story has shown that it is not, on its own, a reliable way to decide if a pesticide is safe): **lab tests should be given at least equal weight. EFSA should not suggest to disregard lab sublethal effects!**

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# General comments

## In essence and simplifying, **what CHANGED with regards to SANCO/10329/2002**?

EXPOSURE

- We included pollen and dust as exposure routes (incl. Seed treatments)
- Calculations and models to establish exposure

EFFECT

- We included a 10 day chronic toxicity test (HB)
- We added a field test for BB and SB
- Calculation of combined effect at colony/population

So we think, solving some issues, a prompt implementation can be done shortly

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# General comments

| Concern | Proposal |
|---|---|
| Disproportionate **effort in methodological development** for refining the exposure assessment, involving plenty of factors that **effectively reduce exposure**, while not integrating refining toxicological observations arguing that methodology is unavailable | BASE ON WORST-CASE (NO REFINEMENT). In parallel invest in effect assessment (e.g., sublethal methodology validation) |
| Disproportionate **effort in improving the evaluating** exposure (literature review, EKE, etc), in comparison with toxicity evaluation (sublethal effects) | Perform thorough LITERATURE REVIEW.<br>Consider WORST-CASE INSTEAD OF REFINEMENT |
| Metabolite mixture and tank mixtures risks missing | Metabolites as in EFSA 2013, consider tank mixtures or CONSIDER SAFETY FACTORS |

# Exposure assessment

| Concern | Proposal |
|---|---|
| Exposure through **honeydew** (high priority matrices), **water**, **soil**, propolis, inhalation, wax, extrafloral nectaries not considered in RA[1] | INCLUDE IN RA: e.g., take WORST-CASE from nectar/pollen and apply to HONEYDEW AND WATER |
| Refinement of exposure - risk mitigation measures belong to risk management, not risk assessment | REMOVE FROM RA |
| Multi application factor was not considered, regarded as not reasonable. | INCLUDE INTERVAL APPLICATION TIME ALSO IN FLOWERING |
| The Dilution scenario (Landscape Factor) is possible, but the Additive scenario is not | Either not include or include a MIXTURE FACTOR with potential to MULTI-RESIDUE EXPOSURE or residues of same a.i. coming from other fields |

[1] What is the risk for underestimating exposure?

# Effects assessment

| Concern | Proposal |
|---|---|
| Ratio of 3 is used to investigate if synergistic effects appear in a.s. Vs PPP | REDUCE TO 1.5 or follow Regulation 284/2013 |
| - Specific sublethal evaluation in HB, BB and SB not accepted due to lack of validated tests.<br>- Species richness for solitary bees is not included | INCLUDE IN TIER 1, INVEST IN VALIDATION (reprotoxicity, behavioural description, morphological) |
| Chronic toxicity of 10 days is too short for low toxic active ingredients, and does not show the cumulative toxicity of no–very toxic substances | Duration of at least 20 DAYS or until CONTROL MORTALITY REACHES 50% |

# Bumble bees and solitary bees

**First tier for BB and SB should be mandatory:** even in the absence of a defined effect threshold, first tier studies will provide important data to better characterise risk.

=> **GD should clearly state that tests with BB** (OECD Test Guideline No. 247 and 246) **and SB** (Osmia spp. Roessink I, 2019 and Roessink I, 2017) **are compulsory and must be used as a reference to derive hazard parameters for these bee groups**

=> **Chronic, larval, sublethal and TRT studies must be conducted also for these bee species, by adapting existing OECD protocols for HB and /or utilising robust non-validated protocols.**

**Adopt a proactive approach,** extinction is running faster than protocol validation.

# Thanks for your work and letting us share our concerns

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