



Environmental risk assessment of neonicotinoid insecticides for bees: a retrospective analysis of the problem formulation

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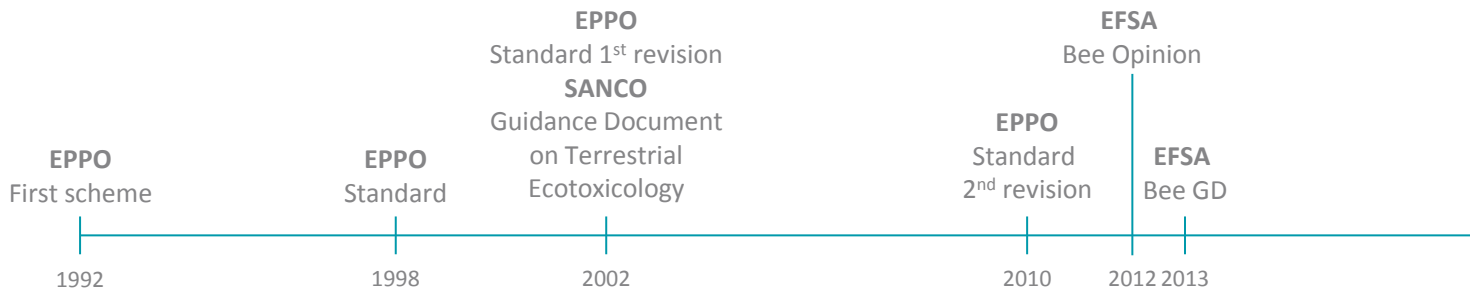


A retrospective analysis

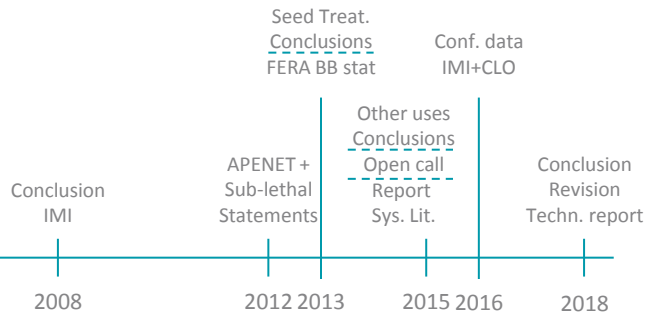
- For the risk assessment of pesticides, the PF is defined once for all in the relevant GDs.
- In mid 2000s, incidents linked to the use of neonicotinoids triggered the revision of the PF in place, paving the way for new RA procedures.
- This presentation performs a retrospective analysis of the PF within the EFSA GD, using the latest assessment of neonicotinoids risk as main touchstone.

A little history

Risk assessment frameworks



Neonicotinoids assessments by EFSA



Overview

Characteristics of a good Problem Formulation¹

- Should provide clearly defined goals
- Should make use of unambiguous endpoints (avoid those that cannot be easily measured)
- Should be able to identify all relevant risks

Aspects considered in this presentation

- Identification of relevant routes of exposure
- Quantification of exposure
- Quantification of effects
- Consideration of spatial and temporal variability



¹US EPA, 1998. Guidelines for ecological risk assessment, EPA/630/R-95-002F

Identification of routes of exposure

Dust drift

- The relevance of this route of exposure, particularly for seed treatments (off-crop), became apparent in the mid 2000s (due to some specific incidents).
- None of the previously available documents proposed any scheme for assessing the risk due to this route of exposure.
- The quantification of the exposure via dust drift is complex as it depends on multiple variables. Current estimations present important uncertainties.
- The current scheme for refining the exposure values (dust deposition) has proven unpractical, as it requires information at EU level on sowing equipment and/or Heubach-AI values.



Identification of routes of exposure

Guttation

- This route of exposure can be important for single honey bees, but its relevance at colony level is debatable for most crops.
- The current mechanistic understanding of guttation is poor, and the screening exposure estimation is very conservative (water solubility).
- The current scheme for refining exposure has proven unpractical, as it requires information at EU level, about the distribution of permanent water source around the area of use of the substance.



Identification of routes of exposure

Other routes of exposure for non-*Apis* bees

- Current routes of exposure are mainly based on experience with honey bees and other bees with similar bio-ecological traits. Bee diversity is significant and little is known on whether the evaluated routes of exposure are protective of other non-considered routes.

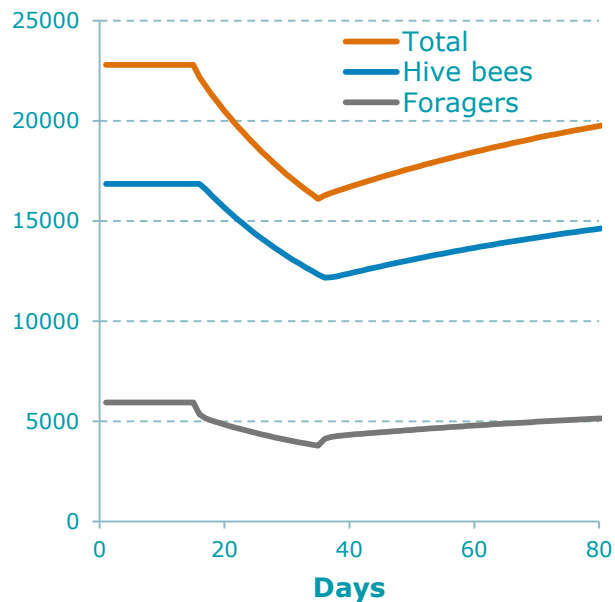


Quantification of exposure

- Unlike in previously available schemes, exposure is quantified using the same dimension (dose per bee) used for quantifying effect thresholds, allowing to reduce uncertain calibration (HQ for oral).
- There is an explicit consideration of multiple factors (residue levels, sugar content in nectar, sugar/pollen consumption, water consumption, contact area of a bee, etc.), most of which can be refined through direct measurement.
- There is a specific assessment exposure target (90th percentile exposure) consistently applied at all tiers → exposure assessment goal.



Quantification of effects



- For the main effect assessed (colony strength/population) clear thresholds of effects are specified and linked to the SPG.
- HB: For lethal effects measured at lower tiers, the link with the SPG has been explicitly addressed (Khoury model) despite being quite oversimplified.
- HB: Forager mortality (part of the SPG) is problematic to measure at higher tiers.

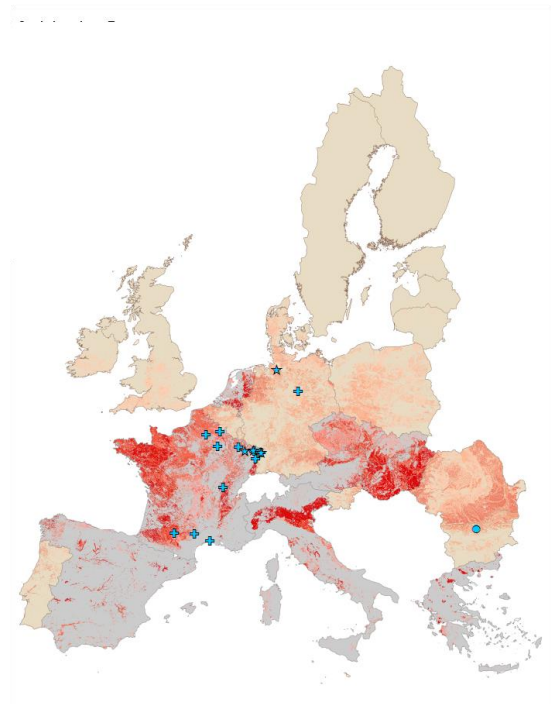


Quantification of effects

- Other bees: the influence of lethal effects measured at lower tiers at higher level of biological organisation (colony/population) is not explicitly addressed.
- All bees: a wide range of sub-lethal effects is explicitly considered in the suggested test protocols (particularly at higher tiers).
- All bees: the link between commonly measured sub-lethal parameters at higher tiers and the SPG is not clear, and their use in the risk assessment is not explicitly addressed. Thresholds of effects are not explicitly mentioned.



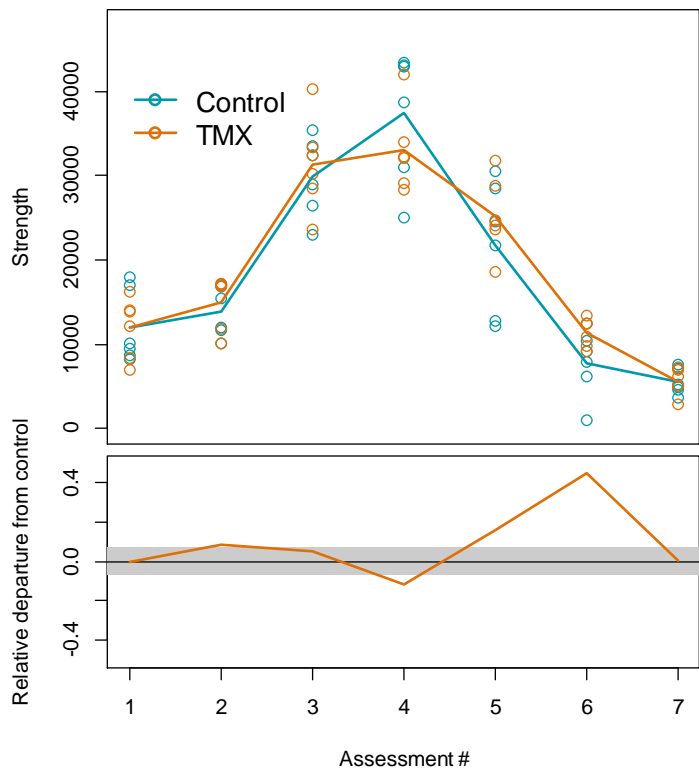
Risk assessment in a variable environment



- Exposure: the spatial variability of exposure is explicitly addressed in the scheme and it is the theoretical basis for the identification of the exposure assessment goal.
- Effects: potential difference in effects due to different environmental/genetic conditions not related to the exposure is not explicitly addressed in the risk assessment scheme. It is assumed that a certain exposure level would always trigger a certain effect.



Risk assessment in time



- Exposure: the temporal variability of residues due to spray applications and dust drift are explicitly addressed through the concept of fTWA. For plant translocation this is not so relevant.
- Effects:
 - the SPG related to forager mortality (HB only) explicitly considers effect over time;
 - the SPG related to colony strength/population abundance does not account for variability in time.



Concluding remarks

Exposure

- The extensive literature review performed by EFSA for the last neonicotinoids assessment confirmed that the relevant exposure routes are considered in the risk assessment scheme. Relevance of guttation still needs to be further investigated.
- The exposure characterisation in conceptual terms made a huge advancement compared to the previously available schemes.
- The refinement strategy for the exposure is logic and consistent. For pollen and nectar it is rather straightforward, but for others (e.g. guttation and dust) it is significantly more problematic.
- Spatial and temporal variability is quite well addressed.

Concluding remarks

Effects

- The problem formulation resulted in a consistent scheme across tiers for endpoints that have a direct link to the effects mentioned in the SPG.
- The use in the risk assessment of all other endpoints considered relevant by the GD is more problematic.
- Spatiotemporal variation of the “effects” (measured endpoints) needs to be better addressed.



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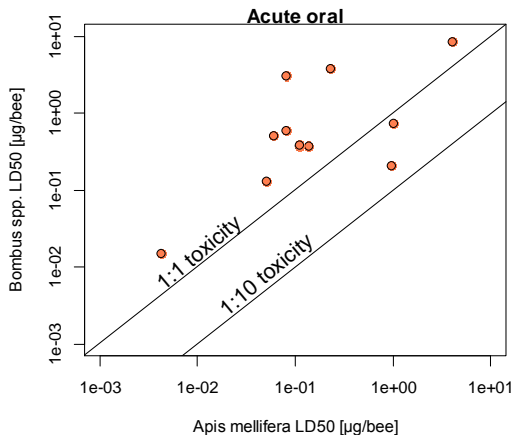
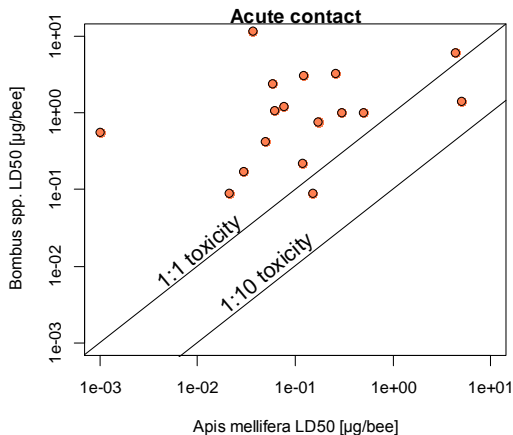
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The tiered approach: tier 1

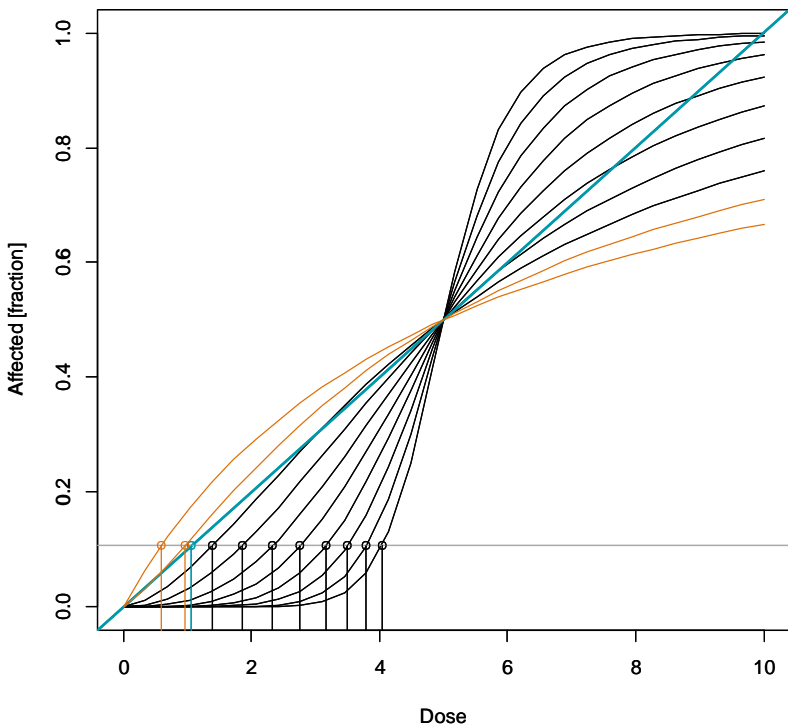


Data from Arena & Sgolatra (2014)

- Very effective for different scenarios (exposure routes, exposure length, application techniques, intake rates).
- Mainly lethality is used, which is easily measurable and unambiguous.
- Relevance of HPG is considerably more ambiguous in relation to the SPGs.
- Highest sensitivity of BB to HB is rare, but it is supported for a screening assessment.



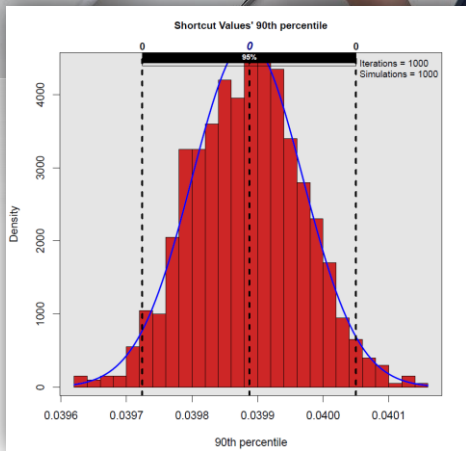
The tiered approach: tier 1



- The interpretation of trigger values is not straightforward, but it is conceptually sound and well linked to the SPG.
- The level of conservativeness depends on the slope of the dose-response (assumed linear).
- Linear dose-response (on a linear scale) might not always represent a worst-case (some curves are sigmoidal only on a log-scale).



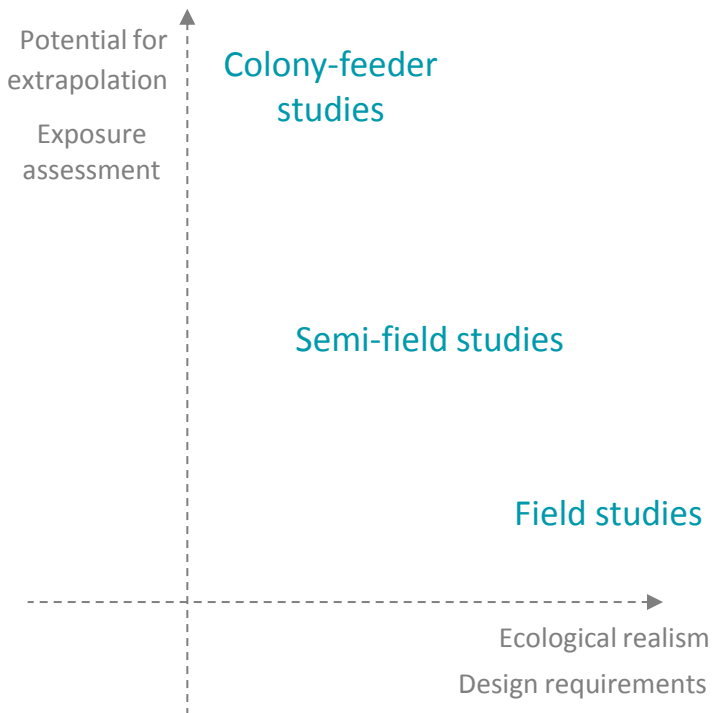
The tiered approach: tier 2 (exposure)



- Refinement of the exposure through direct measurement of residues is straightforward, and allows a better estimation of the exposure assessment goal, accounting for spatial variability.
- The use of the refinement for very toxic substances is limited when the analytical LOQ is close to the relevant toxicological endpoint.



The tiered approach: tier 3



- Different approaches are considered for tier 3.
- More emphasis was given to field studies, but it has been realised that this may not be the best approach.

Dose-response or effect threshold approach?

Lack of detected effect gives less confidence that a certain quantified effect observed under certain exposure conditions.

