The Revision of the EFSA BEE Guidance Document: A Perspective from Civil Society

EFSA Roundtable with NGOs
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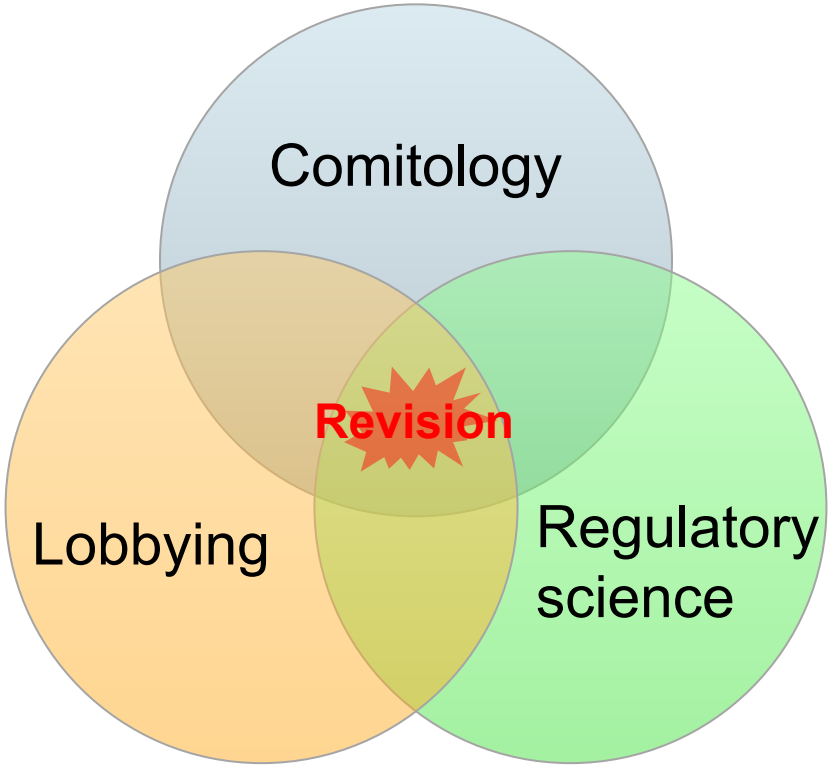

Comitology
Revision
Lobbying
Regulatory science

PART 1
The reasons for the revision of the EFSA Bee GD and the EFSA mandate

From 2013: Blockage by a number of MSs, whose reasons are unknown to civil society and citizens in general, as the positions of MSs expressed in the SCoPAFF meetings are secret, despite the Ombudsman's recommendations. On December, 2019, the Ombudsman confirmed that the CE's continued refusal to grant access to the requested documents constituted maladministration.

Strong opposition from the agrochemical industry, which asks for "a significant revision" before its implementation:

> We believe that new scientific developments and recent data on honey **bee mortality** in Europe need to be considered to define relevant protection goals and considerably revise the document. In particular industry has been working on the topic (...) and data analysis indicate that several aspect deserve a revision, as for example the differences between acute and **chronic thresholds** and **extrapolation factors** between bees. (...) **We would therefore request a thorough review of the guidance document and its protection goals** (...).

Excerpt of a letter addressed by the industry to the EC (2015)

PART 1
The reasons for the revision of the EFSA Bee GD and the EFSA mandate

2018: the CE mandates the EFSA to revise the GD, in order, according to the mandate, to update the EFSA Bee GD with the most recent scientific developments.

The “scientific updating” emerging from the mandate coincides with the main points of the EFSA Bee GD contested by the industry, while recent scientific developments highlighting the way towards a “holistic risk assessment” are not properly taken into account.

PART 2
The way towards a more « holistic risk assessment approach»

Following recent scientific publications on the issue (*infra*), a “holistic” risk assessment should take into account:

a) temporal and spatial dimensions of pesticide exposure;

b) co-exposure to multiple compounds;

c) differences among bee species with different life histories in levels of exposure and sensitivity; and

d) sublethal effects.

PART 2 : The way towards a more « holistic risk assessment approach»
Effects assessment

❖ Lethal (Acute contact/oral, chronic)

Test	HB	BB	SB
Acute toxicity – contact (adult)	● (214)	● (246)	●
Acute toxicity – oral (adult)	● (213)	● (247)	●
Chronic toxicity (adult)	● (245)	●	●
Acute toxicity (larvae)	● (239)	●	●

● Available and validated (OECD laboratory tests) ● Unavailable

❖ Sublethal effects on:

- **Behaviour:** waggle dance (HB), harvest and transport of nectar, homing flight, orientation/navigation, feeding behaviour, odour discrimination, recognition, learning ability
- **Development:** colony growth (HB)
- **Physiology:** neurophysiology, thermoregulation, mobility
- **Reproduction:** production of the queen (HB), fertility of drones (HB), egg-laying capacity, ovary development (SB)
- **Immune system:** immune response, microbial gut
- **Longevity**
- **Social activities** of the colony (HB, BB)

❖ **Co-exposure to multiple compounds** (cumulative & synergistic)

+ combined exposure to sub-lethal concentrations of different AS.

 An efficient risk assessment should ideally include tests on all types of effects (acute, chronic, sublethal, co-exposure). For the time being, no sublethal or co-exposure tests are included.

PART 2

The way towards a more « holistic risk assessment approach»

Current RA → **Holistic RA**

Critical points

- Short duration tests
- No sublethal effects tests
- Single-pesticide tests
- Covering a limited number of bee species

 Some of its composants can already be integrated in revised Bee GD, namely :

- **Long-term chronic effects :** Time-to-death tests
- **Sub-lethal effects:** Homing flight; HPG tests; PER (Proboscis Extension Reflex)
- **Co-exposure**: synergistic and cumulative effects of the main combinations (intentional mixtures).
- **Assessment factors for BB and SB** taking into consideration their different population dynamics and life histories, and more vulnerable species in order to cover pollinator biodiversity.

PART 3
Concerns arising from the process of revision

From the perspective of civil society, there is a major concern arising from the revision process, namely the potential modification of the levels of protection, as established in the current Bee GD. Although this potential modification lies partly outside the EFSA mandate (i.e. SPGs), it is highly dependent on key scientific approaches that EFSA will adopt in order to:

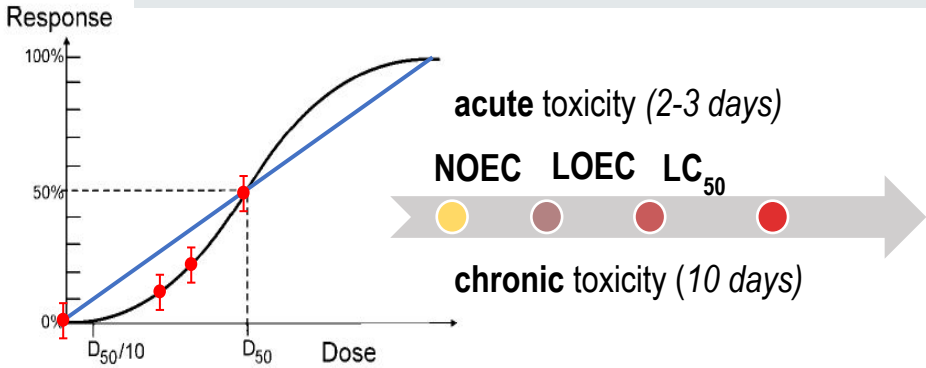
a) select studies to assess natural background mortality;

b) choose modelling tools to determine population dynamics, exposure/stressors; assess SPGs;

c) establish assessment factors and trigger values.

PART 3 : Dose-response relationship

Laboratory tests and endpoints calculations



Effect on individual organism → *Modelling tool* → Effect on colony

Comparison with trigger values

HQ

ET R

Trigg er value

Source of uncertainties :

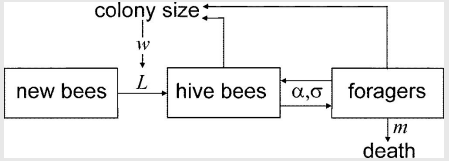
- Variability in measurements (replicates)
- Non asessed synergistic effects and effects of co-formulants and adjuvants
- Non monotonic dose-response relationships
- Non tested sublethal effects

 Linear dose-response could cover some of these uncertainties.

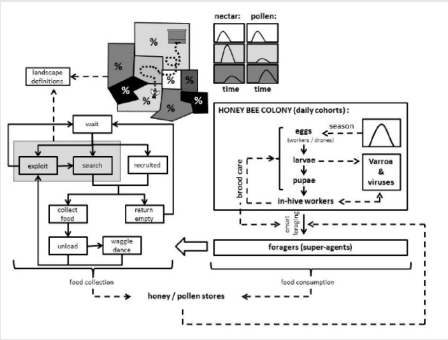
PART 3 : Modelling tool

Use of a model to:

(1) Translate the additional forager mortality into colony mortality
(2) Test complex exposure scenarios (exposure over time / multiple stressors)
(3) Develop worst case realistic exposure scenarios and crop specific scenarios
(4) Higher tier testing (T2-3)



Simple vs. complex model



(1) Set SPG : *How forager loss drives colony decline?*

- Focus on **population dynamic** (intern regulation between castes) = population model?
- Performances of **complex *vs.* simple model** not necessarily better
- **Variability in the determined SPG** :

Khoury model : 7 % vs. **BEEHAVE : 20%** (partially sponsored by the industry)

- high impact and real consequences on RA

(2-4) Consideration of other parameters (landscape, varroa, pesticides..) : Complexified model

What model is going to be used in the revised BGD ?

Conclusions

The revision of the Bee GD seems to be justified less by a scientific than by a political need. The mandate does not address all the potential improvements of the document, but only the points contested by the industry and certain MSs.

The revised Bee GD should integrate all those elements of the holistic risk assessment approach for which tests are (or will soon be) available, namely: **long duration chronic toxicity tests** (time-to-death tests); **sub-lethal effects tests** (homing flight; HPG); **co-exposure tests** (synergistic and cumulative effects of the more common combinations).

To cover all uncertainties which cannot yet be addressed, and all pollinators which cannot yet be included, we ask EFSA to adopt a **conservative approach** and assumptions, in particular with regard to the assessment of **natural background mortality**, **assessment factors** and **trigger values**.

The choice of mathematical and mechanistic models to estimate population dynamics/stressors and to set protection goals should be the object of a transparent and careful process. Civil society actors should be enabled to participate in this choice.

Thank you for your attention

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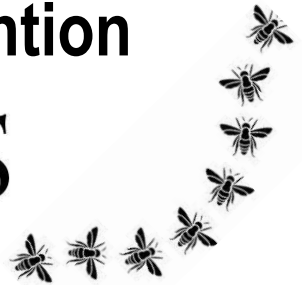

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