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

EFSA Roundtable with NGOs
26 MAY 2020

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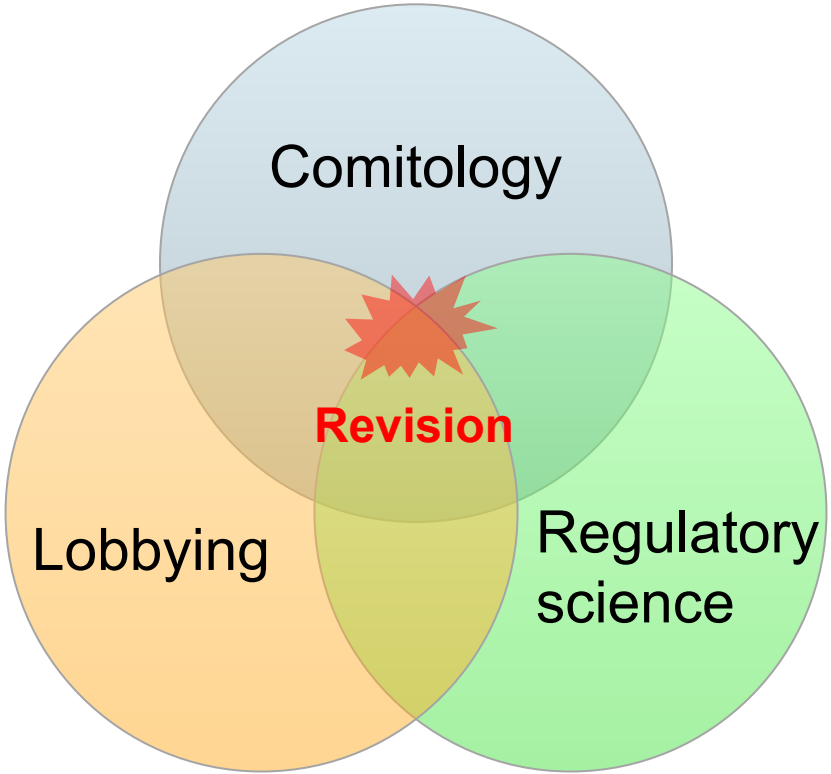

Comitology
Revision
Lobbying
Regulatory science

PART 1

The reasons for the revision of the EFSA BEE GD and the EFSA mandate

The EFSA Bee GD was produced to overcome the very serious weaknesses of the previous scheme to assess the risk of pesticides on bees, which was obsolete and allowed many dangerous pesticides to be authorized on the EU market, like neonicotinoids for instance.

It was published in 2013: civil society organisations and citizens in the EU have been asking for its implementation since then. Its adoption would have tremendously improved the protection of pollinators in the EU, but that was never achieved, because some MSs, behind the closed doors of the SCoPAFF meetings, have been blocking it (for the last 7 years).

Who is behind this blockage and why? This is impossible to know. Despite our efforts, and despite the Ombudsman's recommendations (1), the reasons of this blockage are kept secret, as the EC refused to grant us access to MSs' positions concerning the Bee GD. On December, 2019, the Ombudsman confirmed that the CE's continued refusal to grant us access to the requested documents constituted maladministration (2).

We know, however, that the agrochemical industry has strongly opposed the adoption of this document, asking for « a significant revision » before its implementation. See for instance this excerpt of a letter addressed by ECPA to the EC (2015):

> 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** (...).

In March, 2018, the EC mandated the EFSA to revise the GD. According to the mandate, this was because several MSs were demanding a « scientific updating ».

Interestingly, the main points concerned by this “scientific updating” of the EFSA Bee GD are those which are contested by the industry, while recent scientific developments highlighting the way towards a “holistic risk assessment” are not mentioned. But what is a holistic risk assessment and why it should be the ideal approach of any effective RA?

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:

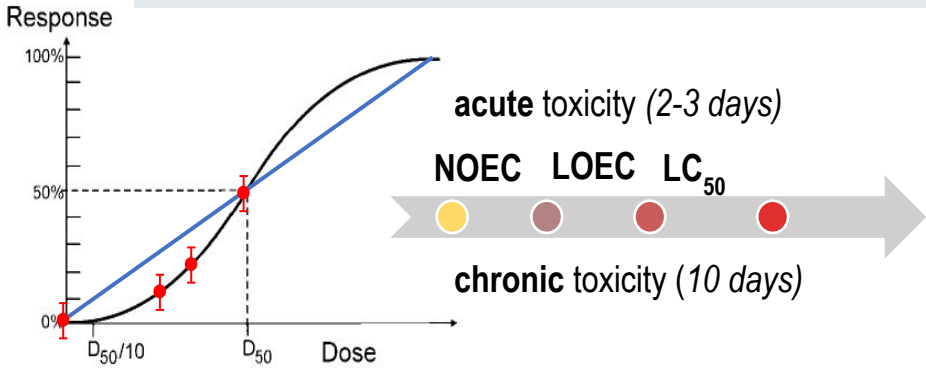
a) select studies to assess natural background mortality;

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 :

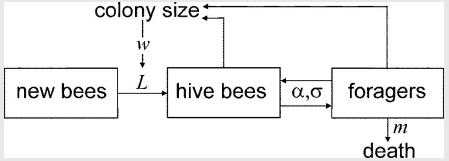
- Variability in measurements (replicates)
- Non asessed synergistic effects and effects of co-formulants and adjuvants
- Non monotonic dose-response relationships
- Non tested sublethal effects

 Linear dose-response could cover some of these uncertainties.

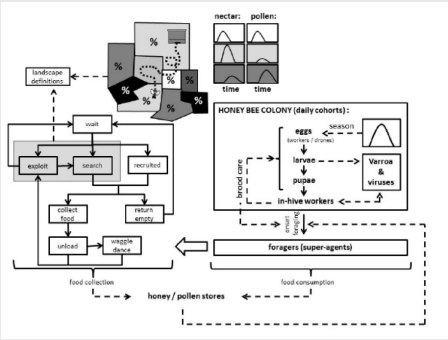
PART 3 : Modelling tool

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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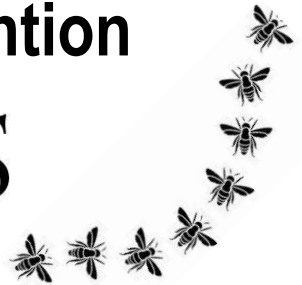

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