BEE POLLINATOR RISK ASSESSMENT
PROPOSAL FOR A PRACTICAL APPROACH

European Crop Protection

Key take-aways:

- **The Bee Guidance Document and its underlying principles are not a realistically feasible way forward for the assessment of risks to bees.**
- **If applied consistently, the Bee Guidance Document approach would result in a denial of registration for most pesticides,** including those used in organic agriculture. It puts at risk the approval of substances with important, even essential benefits, **without making a positive contribution to improved bee health.**
- The European crop protection industry therefore calls for a review of the Bee Guidance Document and **proposes a more workable regulatory European bee risk assessment approach that implements the most recent scientific principles.**

Background

In 2013, the European Food Safety Authority (EFSA) published a Guidance Document on the risk assessment of plant protection products on bees (honey bees, bumble bees and solitary bees), the so-called "Bee Guidance Document".[1] It is based on a risk assessment approach introduced by the "Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees".[2]

To this day, the Bee Guidance Document has not been approved by EU Member States. In fact, in December 2013, the European Commission, EFSA and Member States had acknowledged the need for a revision of certain elements of the document and that it could not be implemented as such. So far however, no progress has been made in several of the identified areas.[3] In 2016, the European Commission proposed a stepwise implementation plan and to amend the underlying base legislation. Neither one of these proposals has been adopted so far either. While the discussions are not progressing, the document is already being used and has provided results that informed policy proposals.

The crop protection industry believes that a significant revision of the document is required to build a practicable and consistent approach.

Critical challenges of the Bee Guidance Document approach:[4]

1. **The document is based on extremely conservative assumptions and linked to unrealistic protection goals.**
   Regarding the protection goals, EFSA requires that for "no risk" to be identified, a compound must not cause more than 7% reduction in colony size. This value was arbitrarily defined on the basis of theoretical considerations rather than biological data. Research shows that natural fluctuations in beehive populations due to weather conditions, diseases or pests such as the *Varroa* mite, are often much higher.[5] It is therefore practically impossible to show that variability of colony strength greater than 7% was not due to pesticide use on a crop.
2. **The document proposes a tiered risk assessment approach. However, this approach loses its value because the trigger values are too conservative and do not differentiate substances that do not target insects.**
   In practice, this would mean that even when looking at honey bees only, 77% of all substances would fail the tier 1 assessment and require higher tier studies, which are very resource-intensive.
3. **The requirements for these higher tier testing studies are not workable.**
   Even recent field studies at unprecedented scale carried out by the industry or academic researchers, would not fulfill the proposed criteria. Example: a single study requires field testing areas exceeding the land size of Malta (see Figure 1).
4. **For a number of studies required by the Bee Guidance Document, internationally validated test guidelines or methodologies are not yet available.** The European crop protection industry is highly committed to broadening the testing scope according to scientific progress, but guideline development and validation are a long process (see Figure 2).
5. **There is not enough testing capacity available in Europe to run the required studies.** Additionally, certain testing is further limited to specific seasons of the year.
   Example: in the Northern hemisphere, honey bee larval testing is currently only possible from May to August.

Seven contract research organizations confirmed several of these challenges.[6]

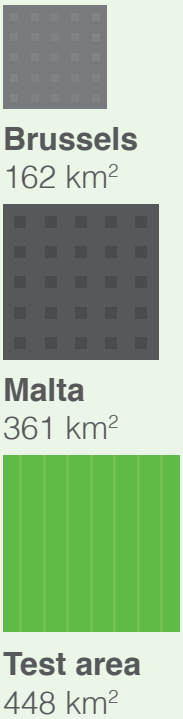

Figure 1: Field Testing Area Requirement under Bee Guidance Document

Moving forward towards a practical approach

The application of the overly conservative Bee Guidance Document approach could impact many plant protection products. For example, in the context of ongoing substance registration renewal processes, 27 active substances with no relevant intrinsic bee toxicity (19 herbicides, 1 plant growth regulator and 7 fungicides) were identified to have data gaps since 2016.[7] The Guidance Document thus puts at risk the approval of substances with important, even essential benefits, without making a positive contribution to improved bee health.

In their present form, the requirements of the document will virtually make it impossible to register any new or existing insecticides, nor many herbicides and fungicides. The crop protection industry believes that it is time to move forward towards a pragmatic, practicable and consistent document within the regulatory framework, and has invested great effort into the development of a proposal for such a ***practical approach***.[8]

This proposed scheme provides for a level of protection comparable to the EFSA approach and is based on the **current scientific state of the art** for bee pollinator risk assessment. The key features of the approach are outlined in the box below.

ECPA Asks

- To set up a **working group of national experts** to urgently review the Bee Risk Assessment approach in order **to establish a workable and protective solution as soon as possible.**
- **To refrain from using the EFSA Bee Guidance Document** for any risk assessment and decision-making until such a **working group has finished its review** and a way forward has been agreed with Member States.

Figure 2: Overview of status of available testing methods for data requirements in Bee Guidance Document, ECPA compilation.

DATA REQUIREMENTS REG. (EU) 1107/2009	HONEY BEES	BUMBLE BEES	SOLITARY BEES
8.3.1.1.1. Acute oral toxicity	🟢	🟠	🔴
8.3.1.1.2. Acute contact toxicity	🟢	🟢	🔴
8.3.1.2. Chronic toxicity to bees	🟢	🔴	🔴
8.3.1.3. Effects on honeybee development and other honeybee life stages*	🟢 🟠	🔴	🔴
8.3.1.4. Sub-lethal effects	🔴	-	-

🟢 Available and validated to use now
🟢 Method submitted to OECD
🟠 Under development. Ready to use in 2-3 years
🔴 Exploratory work. 5 years or more

* There are two possible tests for honey bees.

Arguments for a practical approach:

More focused:
- focus on honey bees as a representative species for which validated testing methods are available
- focus on main exposure routes
- definition of core data packages

More realistic assumptions
- for food consumption values
- for exposure levels
- for the protection goals

More workable design for field studies
- reflecting use-specific scenarios (e.g. spray applications at flowering)
- or location-independent colony feeding studies

Use of available and validated testing methods
- e.g. OECD guidances for tier 1 testing of active substances and formulations
- e.g. EPPO/OECD tunnel studies for tier 2 testing

In compliance with current regulations
- e.g. trigger value for acute risk assessment to honey bees

[1] EFSA Journal 2013;11(7):3295
[2] EFSA Journal 2012;10(5):2668
[3] Conclusions of Commission Workshop on EFSA Guidance Document on the Risk Assessment of Plant Protection Products on Bees, 11-12 December 2013, Brussels
[4] ECPA Assessment of Bee Guidance Document
[5] See, for example, Apidologie 39 (2008) 694-707, Bee Health in Europe – An Overview Report (2012) or http://onlinelibrary.wiley.com/doi/10.1002/etc.3504/full
[6] Letter to ECPA, from 28 April 2016, signed by eurofins, tier3solutions, SMITHERS, BioChem agrar, ibacon, SynTech, RIFCON
[7] Ethofumesate, Pendimethalin, Imazamox, Iodosulfuron, Flurtamone, 2,4 DB, Isoxaflutole, Mesotrione, Foramsulfuron, Linuron, Propyzamide, Flazasulfuron, Carfentrazone Ethyl, Mesosulfuron Methyl, Propoxycarbazon Sodium, Propineb, Penflufen, Silthiofam, Fenamidone, Cyazofamid, Maleic Acid, Iprodione, Oxasulfuron, Mecoprop P, Bromoxynil, Picoxystrobine, und Imazosulfuron.
[8] Full proposal is available here; the letter to DG Santé, European Commission here (or on the following website: http://www.ecpa.eu/transparency-policy)