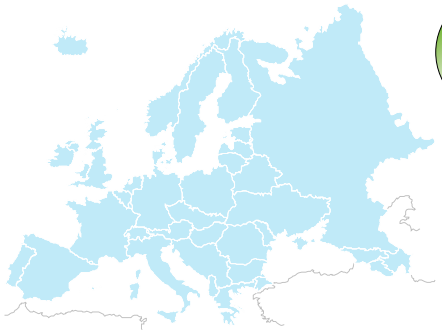
EU REGULATORY UPDATE:
WHY THE BEE GUIDANCE DOCUMENT NEEDS TO BE REVIEWED



Key take-aways:

- **The Bee Guidance Document and its underlying principles should not be used** for any ongoing risk assessment until there is an agreement at EU level.
- **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** based on the science and knowledge gained over the last 3 years.

Background

In 2013, the European Food Safety Authority (EFSA) published a Guidance Document on the risk assessment of plant protection products on 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, this Bee Guidance Document has not been adopted 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, no progress has been made in several of the identified areas.[3] In 2016, the European Commission began to propose a stepwise implementation plan as well as amending the underlying base legislation. Neither one of these proposals has been adopted so far either.

The crop protection industry recognizes the need to review the risk assessment based on scientific progress. However, the Bee Guidance Document approach is not a realistically feasible way forward, for a number of reasons:

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 e.g. weather conditions or Varroa mite infestations, are often much higher.[5] It is therefore practically impossible to show that beehive population variability 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 with unprecedented scales carried out by, e.g. Bayer and a Swedish research group, 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, including Bayer, is highly committed to broadening the testing scope according to scientific progress, but guideline development is 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, honeybee larval testing is currently only possible from May to August.

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

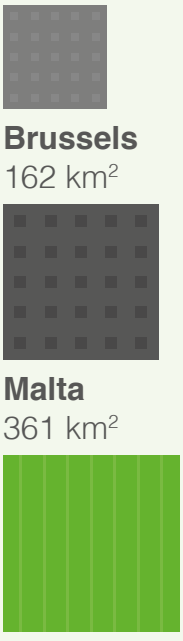


Figure 1: Field Testing Area Requirement under Bee Guidance Document

Potential impact

The European crop protection industry has over the last three years repeatedly pointed out the shortcomings of the Bee Guidance Document. The concern is that as a result of the stringent implementation of the document, registration requirements for almost all insecticides and the majority of herbicides and fungicides would be failed. This concern has been confirmed through several of EFSA's recent conclusions:

A. In the context of the ongoing substance registration renewal process, **21 active substances with no relevant intrinsic bee toxicity** (16 herbicides and 5 fungicides) were identified to have risks to bees or data gaps in 2016.[7]

B. **The recent review of data for the non-restricted uses of neonicotinoids imidacloprid and clothianidin** concluded that "for all the uses for which [data] have been presented, high risks were identified or could not be excluded, or the risk assessment could not be finalized."[8] This is not in line with recent assessments by competent regulatory authorities worldwide such as the Australian APVMA[9], the Canadian PMRA[10] or the US EPA[10].

These examples prove that the impact of the application of the overly conservative Bee Guidance Document approach could go beyond neonicotinoids and affect many other plant protection products. It puts at risk the approval of substances with important, even essential benefits, without making a positive contribution to improved bee health.

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.

Bayer Asks

- **Do not adopt the Bee Guidance Document** as it currently stands, on the basis that it is not fit for purpose.
- **Refrain from using the document** and its underlying principles for any risk assessment until it is officially adopted.
- **Set up a technical expert platform** to revise impractical parts of the guidance considering the progress gained in science over the last three years.
- **Prioritize the revision of the protection goals** before the Bee Guidance document is implemented.
- **Include a transparent impact assessment** of the proposed measures before legislative decisions are taken.

[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] Source: 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] EFSA findings concluded that these 16 herbicides and five fungicide did not pass the bee risk assessment: 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
[8] Confirmatory Data Review (IMD: EFSA Journal 2016;14(11):4607; CTD: EFSA Journal 2016;14(11):4606)
[9] APVMA, Report on bee health and the use of neonicotinoids in Australia, February 2014
[10] Joint PMRA - EPA Update, http://www.hc-sc.gc.ca/cps-spc/pubs/pest/_decisions/rev2016-04/index-eng.php, January 2016